AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2009

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

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NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

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Staff Assistants

PART 7

Printed for the use of the Committee on Appropriations

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2009

WEDNESDAY, APRIL 2, 2008.

CENTER FOR BIOLOGIES EVALUATION AND RESEARCH

WITNESSES

JESSE L. GOODMAN, M.D., M.P.H., DIRECTOR OF THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

MICHAEL A. CHAPPELL, DEPUTY ASSOCIATE COMMISSIONER FOR FIELD OPERATIONS, OFFICE OF REGULATORY AFFAIRS (ORA), U.S. FOOD AND DRUG ADMINISTRATION

MARY A. MALARKEY, DIRECTOR, OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY, U.S. FOOD AND DRUG ADMINISTRATION

INTRODUCTION OF WITNESSES

Ms. DELAURO. The hearing will come to order.

Today we welcome to the subcommittee Dr. Jesse Goodman, who is director of FDA's Center for Biologics Evaluation and Research, which oversees vaccines, blood products, tissues, and related devices, as well as therapeutics, including cellular, tissue engineering, and gene therapies.

And thank you very, very much for joining us, Dr. Goodman and Mr. Chappell, and I'll rely on you, Dr. Goodman, to make a more formal introduction of Mr. Chappell.

Today's hearing on the Center for Biologics Evaluation and Research is the second in a series of oversight hearings that take a closer look at each of the centers at the FDA.

We began this series with a hearing on February 27th examining the Center for Drug Evaluation and Research, and while the Center for Drug Evaluation and Research receives more attention because of its responsibility overseeing the safety of prescription drugs, Center for Biologics Evaluation and Research regulation of biological and related products is equally important, and I believe this is the first time this subcommittee has held a hearing focused exclusively on CBER.

And I also want to say a thank you to my colleague, Sam Farr, who has expressed a great interest in some issues that come before the center, and it was at his prodding and at his initiation that we decided to hold an oversight hearing.

Unfortunately, the importance of the mission of the Center for Biologics Evaluation and Research is not reflected, in my view, in the fiscal year 2009 budget request.

The non-user fee part of CBER's budget request for 2009 is $158 million, an increase of just under $3 million, or a mere 1.9 percent, over fiscal year 2008.

While the budget request document contains a lengthy description that tries to make this tiny increase sound like it will accomplish a lot, I fear that it will not be adequate. If we are to return the FDA to the gold standard for which it was once known, the agency will need additional resources.

The subcommittee is trying to do our part, but we also need the administration to demonstrate their commitment to improving FDA.

Unfortunately, the administration's budget request for the agency and for CBER does not reflect any type of commitment toward making the necessary improvements.

Providing additional resources could help leverage some of the good work being done at CBER. For instance, in your testimony, Dr. Goodman, you talk about CBER's interdisciplinary review teams and how they work together to design and analyze results of post-approval monitoring.

You also note that CBER has established product safety teams for tissue, blood, and vaccines. This sounds like a serious effort, which I would like to know more about.

The good thing about holding an oversight hearing on CBER is that it allows the subcommittee to examine a number of important issues that we normally would not have the chance to discuss in depth. These include tissue safety, recalls of blood and blood products.

In fact, on these issues, some of the responses to questions for the record last year by the FDA were unsatisfactory and require followup discussion. This hearing provides us that opportunity.

Once more we say thank you to you, Dr. Goodman, and I look forward to discussing the issues with you and appreciate your willingness to rearrange your schedule to accommodate the subcommittee.

Ranking Member Kingston will be late. He has another important meeting that he had to be at. I will ask colleague Congresswoman Emerson if she has some opening remarks.

Mrs. EMERSON. Thank you so much for asking, Madam Chair. I don't have any questions. I do want to welcome you and thank you for being here.

Dr. GOODMAN. Thank you.

Ms. DELAURO. Then let me ask you to proceed, Dr. Goodman, with your testimony, and you know the drill. The entire testimony will be made part of the record, so you're free to summarize in any way you care to.

Dr. GOODMAN. Okay. Well, thank you so much for having me here, and Congressman Farr, Chair DeLauro, and Congresswoman Emerson, I really appreciate your interest, and, you know, we are here to really have a good exchange.

I look at some statements that people give, these 30-second statements, with a lot of envy, but I'm not—that's not my style. And

then when I looked at what—how I feel about the importance of what we're doing and some of our accomplishments, I cut it down from the written statement, but I'd still like to share a few things with you.

As you know, I'm Jesse Goodman. I'm director of the CBER, the Center for Biologics Evaluation and Research, and this is Mike Chappell, who is the deputy associate commissioner for field operations from the Office of Regulatory Affairs, and why he's here, as you know, we work very closely together.

In fact, we have a unique relationship in our center, because we have this Team Biologics, which is a joint enterprise of the center to try to bring the scientists and the field investigators together, and we also, in our center, most people don't realize, but we do the pre-licensure inspections from the Center for Biologics. But we've had a really great working relationship with ORA, and we support them.

As you know and have said, we're responsible for regulating biological products that touch the lives of millions of Americans every day, and I think what's equally important and keeps me awake is that these are important for the preparedness of our nation, they're important for confidence in our health care system, so when you talk about vaccines and blood safety, as you know, this is critical.

The safety expectations are very high, so our normal mode is to take those expectations very seriously and approach them innovatively.

The funding, as you mentioned, first of all, in 2008, I want to express appreciation for the $2.2 million additional we got for our safety activities, $4 million more for our pandemic activities, and that was built on top of the pandemic supplemental that you had given us.

And I'll say a little more. I think we've invested that wisely, and we've made some real gains that you really should share the credit for.

In addition, in 2008, we received $1 million for critical path, and we received coverage of the payroll increases for our program.

As you mentioned, the 2009 budget includes a $3 million increase in budget authority, but also an increase in user fees.

An important point about the user fees is that, with the recent agreement, this does allow user fee use for the complete spectrum of product safety activities, and we are applying increases from both 2008 and 2009 to strengthen product safety activities, which we consider important.

Okay. What are the accomplishments in pandemic preparedness?

These really flow from your investments, and I think they're already quite tangible.

We've accelerated America's preparedness. We've improved our ability to support development and evaluation of new vaccines. We've really enhanced our infrastructure in the center to test and deploy vaccines rapidly in our emergency preparedness.

And then we're engaged—this is an area, as I've mentioned in the past, where the science is often 40 or 50 years old, the assays being used to evaluate vaccines are in clinical trials, or to test them prior to their deployment, are very old, and we're investing

in trying to modernize those assays, and we're doing that in a collaborative way with colleagues around the world.

In part of this accomplishment, last April we licensed the first vaccine to be used against avian influenza in the world. That's an accomplishment.

We recognize some of the limitations of that vaccine, and will very actively engage with HHS and partners in next generation vaccines which hopefully will allow lower doses and more immunologic effectiveness.

These are vaccines using new adjuvants, which raise some important potential safety issues, adjuvants are components which will strengthen the immune response, and also using new technologies, such as cell cultures or even recombinant vaccines, to generate synthetic proteins protective against pandemic flu.

We put forth an accelerated approval platform, really, for annual and pandemic flu vaccines, and we've worked expeditiously to evaluate multiple new vaccines.

I think the interrelatedness of the pandemic preparedness and our whole nation's public health preparedness is illustrated by the fact that, as part of this effort, we've actually doubled the number of licensed U.S. vaccine manufacturers and doubled the capacity to produce flu vaccine for annual flu, with over 130 million doses this year, for the first time able to come close to meeting some of the public health targets that CDC has put out there, and this offers the possibility of saving thousands of lives.

And our hope is also that the diversity in flu vaccine supplied, it better prepares us for a pandemic. It also better prepares us for the kind of events we've had in the past, where one manufacturer may have problems and fail.

So I think that's a really good story.

We've also used this as the opportunity—one thing I want to say is, I was very conscious that when we got the pandemic supplemental, this was an opportunity to help prepare for the pandemic, but also to do it in a way that strengthens our infrastructure and deal with other emergencies that might come along, and we've really tried to do that very deliberatively.

And so, for example, we've used the pandemic investment also to help us do post-marketing product safety activities better. We have a collaboration with Harvard to try to access health care data very quickly from flu vaccination.

We did, some of our scientists did an amazing project collaborating with colleagues at CMS, where we were able to, within a month, capture 10 million immunizations in the CMS population, and look for spikes in an adverse event of interest.

So again, these are the kinds of things that will better prepare us to monitor vaccine safety, both in a pandemic and every year, and actually, they're helping provide examples for all of FDA, in terms of how do we do product safety using health care and other data. So that's been very exciting.

Now, as I mentioned, it's not just pandemic we have to worry about. There are many other threats, ranging from West Nile to bioterrorism, et cetera. These are threats which sometimes we need to develop new products to address, or sometimes we need to do

things to enhance the safety of the blood or tissue supply, and we're actively engaged in that.

We work proactively with HHS and WHO, numerous other organizations, and we're developing—we're involved and engaged in developing vaccines to meet these threats.

One of the things that we did, again with your support, is we really put together the first, in a sense, global regulatory team, involving other regulatory agencies from across the globe, including countries affected by the avian flu risk, like Vietnam, Indonesia, Thailand, to get them at the table with us and our WHO colleagues, and develop a set of standards and approaches to pandemic vaccines so that not just the U.S., but the world, will share information and have high quality vaccines for a pandemic.

With your help, we've strengthened our emergency response infrastructure. I won't go into that in details. But again, this will help us in a pandemic or in other emergencies.

Now, I will say people really look to FDA for our safety and for safeguarding the safety of products, and at the end of the day, our most critical and unique responsibility is to give that objective, independent, expert assessment of safety.

As Ms. DeLauro mentioned, we have put in place very interdisciplinary and proactive approaches, and we are trying to modernize how product safety is done, and we view product safety as encompassing everything from how the product is designed, the quality of manufacturing, and the followup on possible adverse events when it's approved.

We have multidisciplinary review teams up front, so in the spirit of the IOM report, we have safety people involved in the review of the product and in designing the post-marketing studies that will be done, and these folks are all together in the room doing these reviews, and part of that, what that accomplishes, is everybody is identifying their concerns and trying to work issues out, both ahead of approval, and then we take a similar approach with the safety teams after approval.

I really didn't want to see a situation where one group of people knows that an inspection of a facility showed X, another group of people is looking at the adverse events, and another group of people understands the benefits or the need of vaccines, but they're not talking with each other.

We have them all talking to each other, and that tends to resolve issues and conflicts at an early stage, or identify problems at an early stage. Okay.

We also put in place a new regulatory framework for tissue, to enhance tissue safety, and I'm happy to talk more about that.

These safety teams meet regularly and consider all ongoing safety issues, and they also meet in emergencies. We convene them when new signals arise or when a product safety or availability issue comes up.

And of course, one thing that's very unique in what we do in blood and vaccine safety and tissues is, we work very closely and leverage the resources of CDC, and that is a highly collaborative and productive relationship.

So that we identify an issue, we may use our colleagues at CDC to go out and engage the states, the state health departments, the

epidemic intelligence service people, who CDC has out in the states, for example, to conduct tissue safety investigations with us, and that's been an excellent relationship.

One of the things we've tried to do, and I think this is in the spirit of what we understand the public wants, and I think it's the right thing that the public wants, is that when we identify potential concerns to, even if we're not clear if it's related to a product, to try to make that information available to people at an early and appropriate time, and be transparent about what we know and what we don't know.

This can be complicated, and it's a challenging kind of risk communication, but, for example, we've used innovative methods to both identify possible safety signals, like we had a safety signal of Guillain-Barre Syndrome, a neurologic problem with the meningitis vaccine, but then to be able to tell people what we did and didn't know about it, so they were aware, and their physicians are aware, in making health care choices. And the public has really appreciated this.

Now, as Congresswoman DeLauro mentioned, we also have a lot of incredibly promising, exciting, innovative products that I think offer the potential to cure diseases, whether these are gene therapies, stem cells, tissue engineered products, where people are starting to make in the laboratory new organs, but these raise a lot of unique concerns in their development and in their evaluations.

So we're really, this is where our science is very, very important, and where we try to work collaboratively with product developers, with NIH, to stay ahead of the curve and say, how can we move such unique, innovative products more quickly from the laboratory to the clinic, but how can we do that in a way that's safe and makes sense and gets us the needed information. And we have numerous partnerships doing that.

For example, we've issued draft guidance on how to use cord stem cells and guidance on how to maintain high quality in those cells.

We've held joint workshops with NIH on how to develop stem cell therapies for neurologic and cardiac disease and how that should be tested—a whole bunch of things like these to try to move new fields forward while fulfilling our responsibilities.

We set up what's FDA's first inter-center review team involving our center and the device center working together to review tissue-engineered products so people don't have to go into two different centers and deal with two different systems, and so the right experts are doing the reviews.

A lot of this requires a strong science base, and you're all aware of the science board report raising concerns about the state of that.

What I do feel very good about is that the science board did recognize that we were managing our program in an effective way and achieving some very substantial outcomes, despite those limited resources, and they specifically recognized this as they reviewed our center's science.

But examples of some of our scientific accomplishments, as I mentioned, using health care databases in new ways, developing new tools to track adverse events, collaborative studies with the

national toxicology program to make gene therapy safer, a bunch of new methods.

The National Institute of Allergy and Infectious Disease came to us and said, "You guys are the experts, can you help us develop new methods for assuring cells that vaccines and other products are safe," and we worked on that project and were able to provide guidance to industry that's actually allowed development of new vaccines and cell lines that previously could not be safely used.

And I think one of the most well-known examples is providing standards and expertise that allowed implementation of West Nile Virus testing in eight months, and probably prevented thousands of disease transmissions.

So these are scientific accomplishments that we're very proud of. We could certainly do more.

And we are, you know, with your support, for example, through the critical path initiative, and of the center, we're making more investments in these areas.

For example, we're interested in improving our ability to use genomic methodologies to assess rare adverse events, for example, in the vaccine area, et cetera.

Now, the one thing that I feel very personally passionate about, I feel passionate about all of this, but one that I feel particularly passionate about, and we've recently seen how important it is on multiple levels, is that we are in a global community.

Public health is a global issue. As you've heard, diseases know no boundaries. But as we've also found out, manufacturing knows no boundaries, and also, quite frankly, the positive knows no boundaries.

There is knowledge and innovation out there in other countries and other places in the world that we need to keep abreast of. And I mentioned our efforts to work with other regulators and scientific bodies to do that.

But we are very committed to dealing with infectious disease threats, like malaria, chikungunya, another mosquito-borne virus, dengue, which is sweeping through parts of South America and Hawaii, new hepatitis viruses, drug-resistant TB, diarrheal diseases.

People tend to think of these as diseases which just affect others elsewhere, but as the recent episode of the traveller with TB, minor variants of which, by the way, are happening all the time, illustrate, these things are threats to the security of the United States, as well, whether they occur naturally or deliberately, as I mentioned, and we would ignore them at our peril.

So I think in global health, we face a win-win situation, where we can help the world solve some of the major health problems that are there, but where we can also protect our country better.

So we place a very high priority on these global efforts, trying to develop products to meet these needs.

We actually were recently recertified, there's an outside evaluation, as a WHO collaborating center, both for biologic products and for influenza, so we play a role in setting global standards in these areas.

And we're out there. Our blood center director is the chair of the global collaboration for blood safety.

So we're out there trying to both protect our country by assuring that global product quality and safety are high, but also trying to help colleagues throughout the world achieve those goals.

We have a program called the global vaccine initiative that seeks to work with other countries, other regulators, WHO, to facilitate development of vaccines that could help face these neglected diseases, like malaria, TB, et cetera.

And I often say, if there were a safe and effective tuberculosis vaccine, I think I would line up to get it, because I think the risks and the toll of that disease are high, even though in our country right now it isn't an issue.

So this is just a little bit about what we do globally, but what I really want to say is that there are unprecedented opportunities to improve global health, and at the same time, protect the health of our people against emerging infectious disease threats, and we're very engaged in that and spend a lot of effort on it.

So to conclude, we really have a dedicated team. We have knowledgeable staff. We collaborate with lots of others. And we're very committed to promoting innovation and quality concerning the products we regulate.

While there are many new threats emerging, our blood supply is safer than ever, our vaccine infrastructure has dramatically improved, not that there aren't still areas that we're really concerned, and we have record influenza vaccine capacity.

This needs continuous vigilance, monitoring, and improvement, but thanks to your support, I think we're a lot better prepared there, and for future pandemics.

And I'm proud of this record, and my staff's accomplishments.

As I said, we face continuing challenges and risks. We continue to remain vigilant against known and emerging health risks, and we do also in that process strive for continuous improvement.

We realize our resources are limited. There are many resource needs. But we aim to face the highest-risk, most serious problems in an effective way, and we're committed to this vision and mission.

And, you know, frankly, I totally welcome your and any outside input and participation in achieving what I think are common goals for U.S. and public health.

So thanks so much.

[The information follows:]

Statement of

Jesse L. Goodman, M.D., M.P.H.

Director of FDA's Center for Biologics Evaluation and Research

Food and Drug Administration

before the

House Agriculture, Rural Development, Food and Drug Administration,

and Related Agencies Appropriations Subcommittee

April 2, 2008

Good morning, Chairwoman DeLauro, Representative Kingston, and members of the Subcommittee. I am Jesse L. Goodman, M.D., M.P.H., Director of the Center for Biologics Evaluation and Research (CBER) at FDA. I am also a practicing infectious diseases physician. Joining me for today's hearing is Michael A. Chappell, Deputy Associate Commissioner for Field Operations in FDA's Office of Regulatory Affairs (ORA).

CBER is responsible for the regulation of most biological products. These products include vaccines, blood and blood products, and cellular, tissue and gene therapies. These products touch people's lives on a daily basis with over 200 million vaccinations, 29 million transfusions of blood and blood components, and 1.6 million musculoskeletal tissue transplants annually. Safety expectations are extremely high, and we approach those expectations intensely and innovatively.

Biological products play a crucial role in the nation's public health and preparedness, where they are critical in addressing emerging infectious disease threats such as pandemic influenza and terrorism. In these efforts, we seek to stay ahead of the curve and work closely and in an integrated manner with colleagues throughout the government, especially with the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Department of Health and Human Services (HHS). As we advance our critical public health portfolio and work with cutting edge biotech innovations, we strive to stay scientifically up-to-date and work closely with product developers and the public. I appreciate this opportunity to be here today to thank

you for your continued support, to discuss our ongoing efforts to help make needed products available, and to assure they meet the highest expectations of safety and effectiveness.

Funding for the FDA Biologics Program

The FY 2008 Omnibus Appropriations Act contains increases for the Biologics Program of $2.2 million for safety activities, $4.0 million for pandemic influenza, $1.1 million for the Critical Path Initiative, and funding to meet Biologic Program payroll obligations. These amounts are all subject to the FY 2008 across-the-board rescission.

The President's budget for FY 2009 contains a total program level of $245 million for the Biologics Program. This includes a $3 million increase in budget authority and an increase of $6.6 million in user fees to support activities under the Prescription Drug User Fees Act (PDUFA) and the Medical Devices User Fee and Modernization Act (MDUFMA). The PDUFA fee increase supports expanded post-market safety activities, increases to reflect PDUFA workload, an adjustment for rent costs, and increases to support salary and benefit costs. The MDUFMA increase also includes increases for salary and benefit costs. These increases will help FDA meet PDUFA and MDUFMA performance goals. The FY 2009 increase in budget authority also provides resources to help support pay increases and enhancements to the human tissue and blood safety programs that will help support collaborative activities for early detection and response to emerging safety threats.

Pandemic Preparedness

We greatly appreciate your interest in and support for our preparedness efforts. The accomplishments flowing from these investments are already tangible. We accelerated the preparation for a future influenza pandemic, including global and U.S. development and evaluation of new vaccines and the enhanced infrastructure to support rapid vaccine testing, release, and deployment.

I am pleased to note that in April 2007, FDA licensed the first vaccine to immunize individuals against H5N1 avian influenza. We are proactively involved in facilitating the review and development of additional novel products including recombinant and cell based technologies and vaccines that employ adjuvants to stimulate an immune response. We also put forth an accelerated approval pathway for annual flu vaccines based on a biomarker, and we worked expeditiously to evaluate new vaccines and enhance manufacturing quality. As a result, since 2004, we doubled the number of U.S. licensed manufacturers of flu vaccine from three to six and expanded vaccine production to a record of 132 million doses this year. We also recently extended the age indication of live attenuated influenza vaccine to include children two and older.

These successes provide the diversity of current and future vaccine supply and the manufacturing capacity to meet national public health and immunization goals and to save thousands of lives. The improved infrastructure for annual immunization helps make us far better prepared for future pandemics and other emerging infectious disease threats. Additional scientific and support staff, hired in multiple disciplines with

pandemic funds, are now on board. The additional staff is available to review proposed vaccine studies, licensing, and emergency use applications, to analyze product manufacturing and quality, and to establish new approaches to monitoring product safety. These professionals are working with our public health partners and manufacturers to develop globally coordinated and expedited approaches to vaccine production, to develop new molecular tools to evaluate these vaccines, and to initiate collaborative research projects. These projects include developing better, faster assays for vaccine potency and safety and new approaches and systems to use healthcare data to monitor vaccine safety. We also enhanced our critical infrastructure and ability to help sustain safe supplies of blood and tissue products during a pandemic or other emergency.

Emerging science in areas such as bioinformatics, genetics, systems biology, and nanotechnology, as well as the globalization of infectious disease risks, knowledge, and industry make CBER's mission increasingly critical and complex. These factors also present tremendous opportunities to help lead and shape the future of medicine, public health, and product development.

Other Preparedness Activities

Enhancing the nation's preparedness for new or emerging threats is one of our highest priorities. This priority prevails whether the threat is pandemic preparedness, protecting the safety of our blood supply from emerging threats like West Nile Virus, or facilitating the development of vaccines needed to face other natural or deliberate threats such as TB, malaria, resistant bacterial infections, and smallpox or anthrax.

To address these threats, CBER is working proactively within HHS and with the World Health Organization (WHO), other federal agencies, industry, nongovernmental organizations, and regulatory authorities from other nations. We fostered information sharing and rapid development and evaluation of pandemic and other vaccines that will be effective, safe, and high quality for U.S. and global use. We initiated a collaborative effort with regulators from around the world, including regulators from Asia, to establish standards for pandemic vaccines and develop guidances for industry and regulatory agencies, including provisions for accelerated approval, to speed and assist vaccine development. We are also strengthening our emergency response infrastructure, including information technology and communication systems, and our laboratory testing, standards and methods, and quality systems. These steps will provide the tools and capacity that FDA and industry need to help assure vaccine and other critical product availability and quality, should an influenza pandemic or other outbreak occur.

It is essential to do all we can, even when markets for these products are uncertain, to help assure that products needed to face such threats are available, effective, and safe. Therefore, while working closely with many partners to achieve our preparedness goals, our most critical and unique responsibility is to do all that is possible to provide an objective, independent, expert scientific assessment of the safety and efficacy of these and other biologic products.

Safety

CBER emphasizes interdisciplinary, proactive approaches to safety throughout our products' lifetimes. We are using modern methods to prevent, detect, promptly

investigate, communicate and, where needed, take early action on potential safety signals and other problems. These activities begin prior to approval and continue afterwards. CBER's multidisciplinary review teams include clinicians, statisticians, laboratory scientists, and product safety, quality, and manufacturing experts who help identify, evaluate, and, where possible, resolve potential concerns before product approval. They also work together to design and analyze results of post-approval monitoring. Recent innovations include implementing a new regulatory framework for enhanced oversight of tissue safety and creating formal interdisciplinary product safety teams for tissue, blood, and vaccines. These safety teams meet both regularly and during emergencies, with greater frequency if needed. Like our review teams, they bring together diverse disciplines, including product scientists, clinicians, epidemiologists and safety experts, and manufacturing and communications experts to share, analyze, communicate, and act on all available safety information. They also help develop and guide needed strategic and scientific approaches to enhance safety. Our safety teams collaborate closely with other FDA components and other agencies, particularly CDC. In addition, we work with CDC and its Vaccine Safety Datalink, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and academic colleagues, to develop and extend the use of large healthcare databases to detect and investigate potential product safety issues. For example, we responded to recent reports of Guillain-Barré Syndrome cases following meningococcal vaccination and monitored adverse events following rotavirus vaccination. In these and other instances, healthcare data and other new methods helped us to more rapidly and accurately detect, understand, and communicate potential risks and uncertainties. The public has appreciated early recognition and transparency about

potential safety issues and corresponding prompt actions such as changes to product labeling.

We have also used quantitative risk assessment and computer modeling to evaluate complex risks, inform FDA, manufacturers, patients, and health care providers about such risks, and better evaluate potential risk mitigation options. An example is our computer modeled risk assessment, and subsequent risk communications, concerning the potential, but unproven, risk to plasma-derived products from the agent of variant Creutzfeld-Jacob disease, the human counterpart of "Mad Cow" disease. Our team and life cycle approaches to product safety and our use of better bioinformatics and scientific approaches to detecting and mitigating risks are consistent with the Institute of Medicine recommendations concerning drug safety and are being continually strengthened.

Innovation, Critical Path, and Scientific Management

I noted how we work collaboratively to facilitate rapid product development, review, and availability, and to enhance the quality of products needed for our nation's public health preparedness. We also use these approaches to promote efficient science-based development and evaluation of other needed medical products. With your support and support from MDUFMA and PDUFA, we met or exceeded our goals for timely review of product applications and implemented innovations in review quality and efficiency, including increased use of electronic systems to support product evaluation and safety. Many innovative products, for example stem cells and gene therapies, present great promise to help cure or treat serious diseases. Yet, there is great uncertainty about their development, evaluation, and safety. In these areas, we worked collaboratively to help

establish new and better development pathways and tools to evaluate product effectiveness and safety. CBER recently issued draft guidance to industry providing new approaches to licensing cord blood stem cells. We held workshops with NIH and product innovators to help define how best to safely advance products such as gene therapies, cancer vaccines, and stem cells for treating heart and nervous system disorders. We set up FDA's first cross-Center review team and held workshops to provide expert scientific advice, review, and interactions with innovators developing engineered tissue products. These efforts, which are part of our Critical Path initiative, are helping define better, faster approaches to bringing needed innovations to patients, while assuring safety and quality.

To meet public health challenges and to modernize product evaluation for safety, quality, and effectiveness, CBER also conducts highly collaborative mission-related research. We implemented a new Managed Research Program to set scientific priorities and to seek and incorporate external input through our Advisory Committees.

Examples of recent or ongoing scientific activities and accomplishments include:

- innovations in the use of Centers for Medicare & Medicaid Services and the Department of Veterans Affairs databases to assess vaccine safety
- collaborative studies with the National Toxicology Program to reduce risks from retroviral gene therapies
- new methods (developed with NIH support) to test the safety of cell culture derived vaccines and other products, which resulted in new draft FDA guidance, with advice for industry and paths forward for cell culture-based flu vaccines

- numerous standards, such as the rapid and successful implementation of West Nile Virus testing to protect the safety of blood and tissues.

These unique scientific activities not only promote availability of safe, high quality products, but also enhance FDA's expertise and help assure that we practice smart regulation. FDA's web site provides additional information for the public on these and other regulatory scientific programs. FDA leverages its resources through our Collaborative Scientific Training Program, the National Cancer Institute / FDA Oncology Joint Fellowship Program, numerous other interactions with NIH, and through Critical Path collaboration.

Protecting and Promoting Global Health

FDA's international activities and the importance of actively playing both leadership and partnership roles in global health have never been more significant. We live in an increasingly global and interdependent environment. Infectious disease threats such as malaria, chikungunya virus, and dengue fever (for which mosquito vectors are present in the U.S.), avian flu, new hepatitis viruses, HIV, TB, and diarrheal diseases not only affect millions around the world, but also directly or indirectly threaten our population. In addition, medical innovation, manufacturing, and regulation are increasingly global – posing challenges and opportunities. We therefore place a high priority on our global efforts, including fostering the development of quality products such as vaccines to address these threats. We are highly engaged in global information sharing, capacity building, and harmonization. We are a recognized WHO Collaborating Center both for influenza and for biological products and standards. We work through WHO and many

other organizations to provide leadership and support to global efforts in blood, vaccine, and tissue safety, and to provide standards and guidance to enhance the development and quality of needed products. Our Global Vaccine Initiative helps to provide technical assistance and enhance regulatory capacity, and supports the work with WHO, with other regulators, and with manufacturers and nongovernmental groups to enhance efforts to control infectious diseases of major importance.

This is just a snapshot of our commitment to protect and promote global and U.S. health and address major global diseases such as tuberculosis, HIV, and malaria. Through these efforts, CBER seeks to help fulfill unprecedented opportunities to improve lives throughout the world while also meeting pressing needs to protect our nation and its people.

Conclusion

With dedication and teamwork from our diverse and knowledgeable staff, and through collaboration with many others inside and outside government, CBER has achieved and is committed to outstanding accomplishments in promoting innovation and the quality, safety and availability of the products we regulate. Despite new threats, our blood supply is safer than ever, and our vaccine infrastructure has dramatically improved, with record influenza vaccine capacity. Efforts to be better prepared for future pandemics are being supported and there is substantial progress.

We are proud of these and other accomplishments. Yet we face continuing challenges, risks, and tremendous opportunities. We must remain vigilant and continue to strive for improvement. Our Vision is of Innovative Technology Promoting Public Health – in the

United States and globally. We are committed to this vision and our mission, and we welcome and appreciate your input, support and participation to achieve our common goals.

Thank you again for the opportunity to meet with you. I very much look forward to continuing to work together to succeed in our challenging but critical mission.

Ms. DELAURO. Thank you very much, Dr. Goodman. Let me start.

And I do, too, again want to compliment the interdisciplinary efforts that you're making, because I think you're more accurate when you bring people together.

You can look at the product safety teams, which I think put everybody at the table, and you can figure out what direction you might take. But listening to people's concerns—et cetera.

TISSUE REGULATION

Let me start with an area that I just want to get your thoughts on.

This is, and it goes back a bit, so I understand that some things have been done, but I want to just get some idea of where efforts are.

The AP did a two-part series on problems with tissue regulation, as you know. Some shocking statements.

Let me just try to see your reaction to them, and if these things are correct.

First, with respect to a healthy 23-year-old who died after elective surgery involving cartilage replacement, the AP story said he died because the cartilage came from a corpse that had sat unrefrigerated for 19 hours, a corpse that had been rejected by two other tissue banks. The cartilage hadn't been adequately treated to kill bacteria. The Georgia-based tissue bank, Cryo Life, Inc., knew that the donor had the germ, and released the tissue anyway. None of this broke a single federal rule.

Is that accurate?

Dr. GOODMAN. No. No. It did—there were a number of things that broke federal rules, and that event in part, and I think my concern and attention about that subsequent to that led us to push forward a new set of rules that tightened things up.

I think that it is a complex issue and there was——

Ms. DELAURO. At the time, though, they didn't break any federal rules——

Dr. GOODMAN. Well, actually, I want to check with Mary Malarkey, but I believe that compliance action was taken against that company, and our view was that they had broken certain rules.

But Mary Malarkey is director of our Office of Compliance and Biologics Quality.

Ms. DELAURO. Why don't you get to a microphone. Can you identify yourself, Mary?

Ms. MALARKEY. Certainly. I'm Mary Malarkey. I'm the director at the Office of Compliance and Biologics Quality at CBER.

Ms. DELAURO. Okay.

Ms. MALARKEY. And at that time, I was actually the director of the Division of Case Management.

Cryo Life did, in fact, violate the tissue regulations at the time.

We first issued them a warning letter, and then subsequent to that, when they did not choose to recall tissue voluntarily, we ordered them to recall, retain, and destroy tissue that had been manufactured since the time that the tissue was processed that resulted in Mr. Liken's death.

Dr. GOODMAN. You know, I also do want to say that we took this event extremely seriously.

I've met with the family in question in the past. We've sought—we looked at that experience both from a scientific and a policy point of view, and from the scientific point of view, it's changed some of how processors approach things, and it's also resulted in our rules and in guidance that makes it, I think, far less likely that that kind of problem occurs.

Ms. DELAURO. Second, let me move in, if I can quickly, because there now appears to be three votes, and I know——

Dr. GOODMAN. Okay. Do I get to vote?

Ms. DELAURO. Well, I tell you what would be interesting.

Later, we're going to do this Tom Lantos, Henry Hodge, United States Global Leadership against HIV/AIDS, Tuberculosis, Malaria Reauthorization Act, so it's an appropriate vote for today.

Dr. GOODMAN. Okay.

TISSUE REGULATION

Ms. DELAURO. A trade group, the American Association of Tissue Banks, requires accredited members to follow high standards, but without the FDA doing the same, hospitals and doctors can buy from unaccredited suppliers that offer tissue quicker or cheaper.

Is that true or false?

Dr. GOODMAN. What is true is that FDA does not require accreditation by that accreditation body.

Ms. DELAURO. This body?

Dr. GOODMAN. Right.

What is incorrect is that we actually look at accreditation, for example, we do risk-based inspections and compliance activities, and for example, accreditation is one of the factors we consider in deciding on risk and where we focus our efforts.

AATB is an organization we've worked with a lot. They are really doing a lot of work to improve quality in tissues, and they've been very cooperative and collaborative with us, but they also don't have enforcement authority.

We have to—whether they're accredited or not, we have oversight on them, and they need to follow our rules.

Ms. DELAURO. Hospitals and doctors do not have to report tissue infections to health officials, and evidence suggests that many are missed.

True?

Dr. GOODMAN. There is a requirement for the sponsors who we regulate to—you know, the people who ship out the tissue—to report infections to us——

Ms. DELAURO. But hospitals and doctors——

Dr. GOODMAN. I don't believe that——

Ms. DELAURO [continuing]. Do not have to report——

Dr. GOODMAN [continuing]. I don't believe there is—that we have jurisdiction or there's a requirement for the hospitals to report.

I will mention, just because of awareness of that issue and that under-reporting probably does occur, that again, we've put together two projects to try to address this and understand what might be going on out there.

One is, through—in collaboration again with the device center, who has a program called MedSun you may have heard of, which involves actively going out in the health care setting and soliciting outcomes in infections, and we have a tissue project with them that covers a large number of health care sites, and also we have a project with CMS that again is going to get to that database to look.

Ms. DELAURO. But in actuality, hospitals and doctors do not now have to report tissue infection to health——

Dr. GOODMAN. I believe that that is correct. They frequently do.

Ms. DELAURO. Well, I know, but——

Dr. GOODMAN. But it's not required.

TISSUE REGULATION

Ms. DELAURO. The FDA requires no medical training to run a tissue bank or procure tissue.

Is that true?

Dr. GOODMAN. I think that what our—I may turn to Mary Malarkey again, but I believe what is required, it's a more general requirement, that they have to be qualified and have suitable personnel.

Our inspectors can look at records and determine whether they think that's——

Ms. DELAURO. But they don't have to have any real medical training in order to run the bank or to procure tissue——

Dr. GOODMAN. That's my understanding.

Ms. DELAURO. Okay.

FDA rules state broad goals and let industry decide how to meet them. They say tissue should be tested for germs, but do not specify the type or level of testing. The same is for how tissue is disinfected. In some instances, some tissue, in fact, is not disinfected at all.

Is that true?

Dr. GOODMAN. In general, those comments are true.

What is done is, we are actually going to be providing guidance that provides much more detail.

One of the issues here, Congresswoman DeLauro, is that this is an industry where the scientific needs of improving—the science where it is, there are many different things going on to reduce infectious risks, and one of the things we're trying to promote is identifying the best practices and then putting those in guidance.

Ms. DELAURO. I understand, Dr. Goodman, and you all know me well enough to know that I'm about up to the top of my head with guidance——

Dr. GOODMAN. Yeah. Okay.

Ms. DELAURO [continuing]. With some very specific—but I understand, I understand——

Dr. GOODMAN. Can I make one other comment?

Ms. DELAURO. Yeah, but my time has run out, and——

Dr. GOODMAN. Okay. Why don't you go ahead. Sure.

Ms. DELAURO [continuing]. And let me—this is a comment from your former FDA colleague, Bill Hubbard:

"When an industry feels like its feet are not held to the fire, it feels emboldened not to care." William Hubbard, long-time FDA associate commissioner for policy and planning.

The tissue industry was an example of a—that needed a firm regulatory hand, and it never got a firm regulatory—true or false?

Dr. GOODMAN. We have put in place a markedly enhanced system of regulation, and we are going out to these facilities, and the major processors have been inspected, and we have taken actions in the last—in 2006 we put two companies out of business. We got the power to actually put a company out of business.

Are there areas in which the regulations could be strengthened? Yes. Are we actively looking at this industry? Yes.

Ms. DELAURO. That's good, because we'd like to work with you on that, and to increase the regulation in this area. We know that you have taken some steps, but it would appear that there are several areas at the moment where there are real gaps in terms of ensuring the public health, which I know you're committed to.

Ms. Emerson.

USER FEES

Ms. EMERSON. Thank you.

Dr. Goodman, thanks for being here, again.

You know, I have this pet peeve about the fact that user fees are such an important part of the way that FDA does business, and the increased reliance on them just bothers me terribly, because I think there's an over-reliance, number one, and number two, I think there's a public perception that FDA is beholden to the industry it regulates.

And, you know, when the salaries of your staff, in essence, could be perceived as being paid by the drug companies, then that is, to me, not in your good long-term interests.

Anyway, with that being said, do you have an opinion on what you think the appropriate balance of user fees and the appropriations Congress gives you to fund your activities is?

Dr. GOODMAN. Well, you raise a very important question. Okay. Frankly, I would be——

Ms. EMERSON. Just don't be political——

Dr. GOODMAN. No, I'm not being political.

Ms. EMERSON. Okay.

Dr. GOODMAN. Let me put it the other way.

Right now, we get money both from user fees and from appropriated money.

Ms. EMERSON. Right, right.

Dr. GOODMAN. Okay. In my center, we probably have a somewhat lower percentage of user fees than in the drug and device center, okay, but we have a lot of user fee activities, so we use a certain amount of base to pay for those user fee activities.

When it comes down to it, it's about 22 percent of our center's budget that goes to activities that are unrelated to user fees, of which we—you know, base authority that is not tied to user fees in one way or another. Okay.

That 22 percent is used for things like tissue safety, blood transfusion, medicine safety, et cetera.

What I do want to say is that to me, the user fees, for example, PDUFA, have enabled us to dramatically increase our number of reviewers and staff to get the job done.

The user fees, for example, particularly with the change in PDUFA 3 to allow their full use in post-marketing safety activities, have really provided added resources that we are putting into improving post-marketing safety activities.

So if I didn't have those user fees right now, it would be very difficult to carry out our mission.

If Congress and the executive branch—well, the administration or any administration said, "We want to fund FDA 100 percent off appropriated funds," that would be fine with me, as well.

One thing I have to say, and I encourage this culture within my center. I don't care that those are the user fees. I care that we get the job done.

I tell people that those deadlines, which can create pressure, if you have concerns, if you have doubts, if you have additional questions, you don't have to approve the product by that deadline. Okay.

So the culture they I'm aiming to have is make the best decisions, whatever the source of funds are, and to me that's absolutely critical.

Also, those are not, those dates, they're not dates for approval, they're dates for decision, and when we have a concern, the decision is to tell a sponsor, we need you to answer these additional questions, or to provide this additional information.

USER FEES

Ms. EMERSON. Okay. So that begs the question, then, and I apologize for not knowing in advance what the answer is going to be, because, you know, there are so many competing priorities, obviously.

Dr. GOODMAN. Right.

Ms. EMERSON. And when user fees are increased, for whatever reason, how do you all determine what the allocation will be of those additional funds?

Dr. GOODMAN. Well, the way that I determine it is, I look at where I think our mission, you know, is most either at risk or our needs are greatest, so if there's a review division which is being overworked or where it's of incredible public health importance, I will move additional positions from the user fees into that area, or as recently, where I think historically, post-marketing safety activities have been underfunded, now that we can use those, I move those into that area.

Ms. EMERSON. So do you have performance goals for each of those programs so that you can measure how the user fees are—I mean, are you meeting your performance goals better because you have extra user fee money, or is it just——

Dr. GOODMAN. Yeah. No, there's——

Ms. EMERSON [continuing]. Just because the pot is bigger?

Dr. GOODMAN. The performance goals are historically very well developed in the pre-market area, so they are review an I&D within 30 days, review a priority application within six months, et cetera, et cetera. Those we meet. Okay.

The area in which the goals are less developed is the post-marketing, but there, right now for me, FDAAA, first of all, sets a bunch of new goals and requirements, and we will certainly comply with those, and use these funds to comply with those, but also, I look at it and say, here's what I want. I want our safety teams to function this way, I want us to look at health care data this way. And I will apply those resources to that.

Ms. EMERSON. I know our time is up, but I just want to—how does OMB account for all these user fees?

In other words, you know, if we increase your user fees, by—let's just say, if you're going to increase user fees by $30 million, hypothetically, then, does OMB then come in and take $30 million off the top of what the president's budget would advocate for you?

Dr. GOODMAN. I'm not aware, really, of what goes on at that level, but I think to not just avoid that, let me put it—reverse it and make it a little hypothetical.

If user fees allow erosion of non-user—of funding of non-user fee activities——

Ms. EMERSON. Right.

Dr. GOODMAN [continuing]. Then we have challenges, so that there are certain areas, such as tissues and transfusion medicine safety, that may not be covered by user fees, and if anybody mistakenly feels those are covered by increases in user fees, then those kinds of programs themselves are——

Ms. EMERSON. And see, that's what I think is kind of happening with you all, but I better leave it at that, because we have a vote, and my time is up.

Dr. GOODMAN. Okay.

Ms. EMERSON. Thank you.

TISSUE RECOVERY

Ms. DELAURO. Let me ask an additional question here.

My understanding is that recovery locations, that most counter-recovery locations, the percentage of recovery establishments that user the locations, hospital operating room, 93 percent, funeral homes, 59 percent.

What is the—is there the restrictions, the regulations around funeral homes, is that of concern to you, where this has been a real problem in the past? As far as I—and that had to do, obviously, with BTS, but as far as I know, this is still a wide open area.

Dr. GOODMAN. It is a concern, but we have acted to both assess, and I hope reduce that concern.

So when Biomedical Tissue Services, and Donor Referral Services, which was another one, a much smaller event, occurred in 2006, those two aspects of those, they were related to recovery in local organizations and funeral homes.

They were the subject both of criminal investigations and ongoing cases, so they are not just an issue where, you know, if you—you know, it's kind of like, if you have activities that are designed to be hidden or circumvent regulations, even the best agent, as we see, the city is full of police, but that doesn't mean there's not crime, but you need the police.

An interesting—what we did in response to that, and I acted, I think, you know, almost immediately, is we did two things.

We put together a task force called the human tissue task force, across the FDA, and again, this was quite unconventional, because it wasn't just us guys. We involved Mike's group, high-ranking people in compliance, our chief counsel's office, because of the issue of authorities, et cetera, et cetera.

And we got everybody together, and I said two things. I want to know—let's assess what's happened in the first year these tissue rules have been implemented. Are there weaknesses, are there things we can strengthen? What have we learned? And also, I'm very concerned. I don't want to find out that there's not just these two funeral homes and renegade practitioners doing this, but that it's a general problem.

And what we did, which is amazing performance from our colleagues in the field, is went out—the number may be not exactly right—but over 150, we went and, within just a few months, to over 150 places that are registered as recovering tissues, and we went to every one of those and looked at those practices, and where there were any concerns, cited them, gave the message that there's going to be oversight.

Ms. DELAURO. I understand that, and I appreciate the speed, but that is reaction rather than prevention, which gets me to the issue of why aren't we licensing, why aren't we accrediting these places to do this?

I mean, I understand that you take that into consideration, but why do we not accredit or license these places which, if we find it out, in addition to which we found out here through a doctor in Colorado, we find out from investigative reporters that this is going on, it's not having to uncover it, as an agency uncover it, and yes, there's no question, the blitz. You went out, you did all of this, and I applaud that.

But to leave such a hole in public health, it just seems to be nonunderstandable, not comprehensible that we would just not say, "You can't do this unless we put a stamp of approval. We are the Food and Drug Administration, we put our stamp of approval on—you have to be trained, you have to be licensed, and you have to be credentialed to engage in this kind of activity."

TISSUE REGULATION

Dr. GOODMAN. Yes.

Ms. DELAURO. I don't understand it, Dr. Goodman.

Dr. GOODMAN. So you would argue and support a system where they might not be able to, you know, sort of like with our licensed manufacturers, where they would not be able to conduct any activities until they received——

Ms. DELAURO. That's right. Absolutely.

Dr. GOODMAN. Well, I think that is an option. It would obviously require a different regulatory approach and resources to do that.

What I will say is that what we were doing, following implementation of the tissue rules, which really ramped up the infectious disease testing they should do, saying they should have good manufacturing practices, et cetera, what we initially did is focused on what we believed were the highest risk parts of this industry, which are these processors that make large amounts of tissue for large amounts of places.

So we went to them, we went in, in many cases, corrected their practices. In many cases, their practices were excellent, as you mentioned, or as somebody mentioned, AATB in many cases said they were meeting standards. But we identified the ones where there were problems, and have cited them, and corrected them.

What was not as high on the priority list, but was rapidly moved up there when we encountered these, you know, frankly, not just they weren't compliant, but frankly, off the—out of bounds practices, we did feel we had to go to those.

But you are right, there is not a pre——

Ms. DELAURO. Risk base is only as good as the data on which it sits.

Dr. GOODMAN. Mm-hmm.

Ms. DELAURO. That's the fact. And if you don't have any information, and you don't know what they're doing, and they don't have anything, any—they don't have any regulation and they don't have to meet any demands, they are free to do what they like, and if you happen to find them, fine, and if there's a crisis, then you find them, well, then we can attack it. It is not——

Dr. GOODMAN. Yeah. Well, that's—I understand your concern, and I think, you know, it's a legitimate point.

TISSUE RECIPIENT TRACKING

Ms. DELAURO. Go. Go vote. Go vote.

Well, I would really—look, I can't account for my other colleagues, I can't see why they wouldn't feel the same way that I do about licensing these kinds of places and making them accredited, and to work with you on doing that and putting together an effort that really closes the—you know, just closes this gap. It's not a loophole. It's just not—it's not there. And not only that, it's been reviewed, and they said we're not going to accredit or license them.

Let me—okay. Let me just—the timing on this. I know we're looking to track the tissue replacement to the recipient.

Dr. GOODMAN. Right.

Ms. DELAURO. You are going to look at legality on that tracking system. What's the status of all that?

Dr. GOODMAN. That's ongoing, and I am concerned that I want to enhance our ability to rapidly track to the recipient.

Ms. DELAURO. Ongoing. Dr. Goodman, when are we going to find out whether or not we have the legality, and if we don't, how do we get it, and if we do, how do we use it?

Dr. GOODMAN. Well, I will get back to you with the timetable, but when I say ongoing, I mean it is ongoing, not that it's sitting somewhere. We're having that—we're engaged in that process. I'm an active advocate of it.

Ms. DELAURO. Great. Thank you.

Dr. GOODMAN. Sure.

[The information follows:]

FDA intends to make a determination on tracking of human tissue to the recipient in the next several months. We must consider the circumstances under which a tissue establishment should have access to information in a patient's medical file. The legal questions concern whether existing authorities related to the prevention of transmission of communicable disease authorize us to require health care professionals to disclose or permit access to such information. CBER has been examining recall data and data from industry to determine where the problem areas in track-

ing appear to be. CBER is currently in the process of assessing whether regulatory changes are warranted.

INSPECTION OF FOREIGN BIOLOGICS FIRMS

Ms. DELAURO. Thank you. I appreciate that.

Let me just say, and I don't want to go through the whole litany here, but it's my understanding that, with regard to foreign inspections——

Dr. GOODMAN. Right.

Ms. DELAURO [continuing]. That I was troubled to learn that the average rate of inspection for foreign biologics firms is once every 18.3 years. This is not as bad as CRH's rate, but it is still bad.

What kinds of CBER regulated products tend to be made overseas, and in what countries?

Dr. GOODMAN. Okay. Well, first of all, I have some good news for you. That calculation is essentially not correct.

Ms. DELAURO. Okay.

Dr. GOODMAN. Okay.

Ms. DELAURO. But what is it?

Dr. GOODMAN. So of the facilities of most importance to us, okay, which are the blood establishments, plasma manufacturers, other biologics manufacturers, which would include vaccine manufacturers, so basically our major portfolio, other than tissues——

Ms. DELAURO. Blood, plasma——

Dr. GOODMAN. Okay, blood, plasma——

Ms. DELAURO [continuing]. Vaccines——

Dr. GOODMAN [continuing]. Biologics——

Ms. DELAURO [continuing]. Coming from——

Dr. GOODMAN. Yeah, these are the ones that are more comparable to drugs in terms of some of the kinds of concerns that have come up, in those, I have the numbers here, but basically—basically, what I can tell you is, we are getting to them on an average of every 2.1 years, so we are close to meeting our statutory requirement. I can give you more details on——

Ms. DELAURO. I would appreciate, because I'll tell you, the answer I got from Dr. Von Eschenbach last year——

Dr. GOODMAN. Yeah.

Ms. DELAURO [continuing]. The average inspection frequency for all foreign biologics firms is once every 18.3 years.

Dr. GOODMAN. Yeah.

Ms. DELAURO. I just didn't pull the number out of a hat.

Dr. GOODMAN. That was an error. And actually, also, and I think we've been ahead of the curve there, from 2006 to 2007, we pretty much doubled the number of inspections. We went from 22 to 37.

Ms. DELAURO. If you can get us the list of the countries, what the products are, and——

Dr. GOODMAN. We'll be happy to. No, I want to give you total truth in advertising——

[The information follows:]

Foreign CBER Statutory Firms

Firm Name - Biologics	Country	Products
Alba BioScience (Div. of Scottish National Blood Transfusion)	United Kingdom	Blood Grouping Reagents
ALK-Abello	Denmark	Allergenics (Animal, Insect, Venoms)
Baxter AG	Austria	Plasma Derivatives
Baxter Healthcare	Switzerland	Recombinant Plasma Derivative
Baxter S.A.	Belgium	Plasma Derivatives and Recombinant Plasma Derivatives
Berna Biotech	Switzerland	Vaccines
BioLife Plasma Services	Austria	Viral Marker Test Kits
Biomatech SAS	France	Contract Testing Laboratory
Biotest, AG	Germany	Blood Grouping Reagents
Biovitrum	Sweden	Bulk drug substance: Recombinant Plasma Derivative
Cangene Corporation	Canada	Plasma Derivatives
CSL Behring AG	Switzerland	Plasma Derivatives
CSL Behring GMBH	Germany	Plasma Derivatives and contract filling of Influenza Virus Vaccine
CSL Limited	Australia	Influenza Virus Vaccine
Diagast	France	Blood Grouping Reagents
Genzyme Ireland, Ltd.	Ireland	Contract filling of Plasma Derivative
Genzyme Polyclonals, SAS	France	Plasma Derivative
Glaxo SmithKline	Belgium	Vaccines
Glaxo SmithKline	United Kingdom	Antitoxin
Glaxo SmithKline Biologicals S.A.	Belgium	Filling of vaccines
Glaxo SmithKline Pharma	Italy	Filling of vaccines
GSK / ID Biomedical	Canada	Influenza Virus Vaccine
GSK / ID Biomedical	Canada	Influenza Virus Vaccine
Instituto Grifols, SA	Spain	Plasma Derivatives
Mayne Pharma	Australia	Filling of Antivenin and Antitoxin
MedImmune Vaccines, Inc.	United Kingdom	Influenza Virus Vaccine
Medion Diagnostics GMBH	Switzerland	Reagent Red Blood Cells
Mekos Laboratories AS	Denmark	Allergenic
Millipore (UK) Ltd.	United Kingdom	Blood Grouping Reagents
Novartis	Germany	Vaccines
Novartis	United Kingdom	Flu Vaccine
Novo Nordisk A/S	Denmark	Recombinant Plasma Derivative
Novo Nordisk A/S	Denmark	Recombinant Plasma Derivative
Octapharma AB	Sweden	Plasma Derivatives
Octapharma Pharmazeutika Produktionsges.m.b.H	Austria	Plasma Derivatives
OMRIX Biopharmaceuticals, LTD	Israel	Plasma Derivative
Pharmacia & Upjohn Allergon AB	Sweden	Allergenic
Protherics UK Limited	United Kingdom	Antivenin and Antitoxin
Research Foundation for Microbial for Diseases (Biken)	Japan	Vaccines
Sachisisches Serumwerk (GSK)	Germany	Influenza Virus Vaccine

Foreign CBER Statutory Firms

Firm Name - Biologics	Country	Products
Sanochemia Pharmazeutika	Austria	Viral Marker Test Kits
Sanofi Pasteur	Canada	Vaccines and Antitoxin
Sanofi Pasteur	France	Vaccines and Plasma Derivatives
Sifin Institut	Germany	Blood Grouping Reagents
Vetter Pharma Fertigung GMBH & Co KG	Germany	Filling of Plasma Derivatives
Wyeth Farma SA	Spain	Recombinant Plasma Derivative
Firm Name - Blood	**Country**	**Product(s)**
Department of the Air Force -35th Medical Group	Japan	Blood and Blood Components
Department of the Air Force – 48th Medical Group	United Kingdom	Blood and Blood Components
Department of the Air Force – 31st Medical	Italy	Blood and Blood Components
Department of the Air Force – 51st Medical Group	Republic of Korea	Blood and Blood Components
Department of the Air Force – 39th Medical Group	Turkey	Blood and Blood Components
Department of the Air Force – 374th Medical Group	Italy	Blood and Blood Components
Department of the Air Force – Thule Air Force Base	Greenland	Blood and Blood Components
Department of the Army – Landstuhl Medical Center	Germany	Blood and Blood Components
Department of the Army - Armed Services Blood Bank Center	Germany	Blood and Blood Components
Department of the Army – US Army Health Clinic	Italy	Blood and Blood Components
Department of the Army – US Army MEDDAC	Germany	Blood and Blood Components
Department of the Army – General Hospital	Republic of Korea	Blood and Blood Components
Department of the Army – USFK Blood Center	Republic of Korea	Blood and Blood Components
Kwajalein Range Services – Kwajalein Hospital (Army)	Marshall Islands	Blood and Blood Components
Department of the Navy – US Naval Hospital	Spain	Blood and Blood Components
Department of the Navy – US Naval Hospital	Italy (Sigonella)	Blood and Blood Components
Department of the Navy – US Naval Hospital	Cuba	Blood and Blood Components
Department of the Navy – US Naval Hospital	Japan (Yokosuka)	Blood and Blood Components
Department of the Navy – US Naval Hospital	Japan (Okinawa)	Blood and Blood Components
Department of the Navy – US Naval Hospital	Italy (Naples)	Blood and Blood Components
Healthbanks Cord Blood Center Lab*	Taiwan	Blood and Blood Components
*Doing business with Thermogenesis.		

Unlicensed Medical Devices

Firm	Country	Product
5D Information Management	Canada	Blood Bank Software
MedMira Laboratories	Canada	Diagnostic HIV
Trinity Biotech plc	Ireland	Diagnostic HIV
MAK Systems	France	Blood Bank Software
Dynal Biotech	UK	Testing Instrument

Ms. DELAURO. I have to vote.
Dr. GOODMAN [continuing]. The tissue firms are a different issue.
Ms. DELAURO. Okay. I need to know that.
We're in recess.
[Recess.]
Ms. DELAURO. The hearing will come to order.
Mr. Farr.

BLOOD DONOR RESTRICTIONS

Mr. FARR. Well, Madam Chair, I want to thank you very much for having this hearing.

I have sort of a couple of issues that I really wanted to get at, and I think that's the role of this committee, to do oversight.

I appreciate all the parties coming together and appreciate your testimony.

I have to say, Dr. Goodman, that I just read your background, and you edited the "Tick-Borne Diseases of Humans."

Having spent last week in Big Sur and pulling three ticks out of my body, I thought, now everything is going to start—I should probably talk to you a little about that. But anyway——

Dr. GOODMAN. Absolutely. Luckily, there's not too much Lyme Disease there.

Mr. FARR. The reason I talked to the chair about having this hearing is that it was brought to my attention by members of the gay community in my district that there's a discriminatory policy by FDA in providing blanket deferral to any male blood donor who admits any homosexual activity. And let me just make some points here.

Heterosexuals who are judged to be at risk of exposure to sexually transmitted diseases that could result in transfusion transmitted infections are deferred from blood donations for one year.

Any man who has had sex with another man even once, since 1997, is banned forever from giving blood.

The difference in treatment of homosexual and heterosexual blood donors is inconsistent, at the best, and outright discriminatory, at the worst.

By banning all men who have had sex with other men without regard to how recently the man engaged in sex, or any other circumstances, the current policy screens are based on sexual orientation rather than an established risk behavior. I mean, that's the point.

Why do you seem to establish risk behavior as a criteria for a 12-month ban, but a sexual orientation as a lifetime ban?

And that's where I think it's—also, given that NAT, nuclear acid amplification testing, and other methods, allow detection of HIV-infected donors between 10 and 21 days after exposure, a lifetime donation deferral for men who have had sex with men is over-responsive, punitive, and potentially harmful to the ability of blood banks to maintain adequate blood supplies.

I have a letter from the American Blood Centers, the American Association of Blood Banks, and the American Red Cross, all in support of the 12-month deferral for persons who engage in risk behavior, rather than a lifetime ban.

So my question to you is, in light of the medical and scientific advances since 1983, and given improved blood donation screening improvements, including, I understand, that blood products are quarantined until the products have been thoroughly tested and donation records have been verified, that in light of that, what is preventing FDA from updating your blood donation policy so it does not discriminate against gay men?

Dr. GOODMAN. Okay. Well, thank you, Congressman Farr, for your question, and I know this is a concern to you and many people who have raised it to us.

Mr. FARR. The blood banks are also concerned, because they see a population that could be donors.

Dr. GOODMAN. Well, they're concerned for a number of reasons. They're kind of on the front line, also, of this.

This is simply a scientific decision. The issue here is that our scientists, as best as they can, dealing with data with some uncertainties, have concluded that relaxing this policy at this point would result in a real risk of additional transmission of transfusion transmitted diseases.

Can I finish?

Mr. FARR. Yeah.

Dr. GOODMAN. I mean, that there would be cases, additional cases of HIV transmission in the blood supply, and also Hepatitis B virus transmission. This is a safety issue. It is not discriminatory.

We, for example, defer people who have lived in the United Kingdom during certain years from donating because of the risk that they could transmit Mad Cow Disease.

We defer people for periods of time after travel to malarious areas, and those are based on behaviors, not my judgment of a behavior, no one's judgment of the behavior.

And I also want to say that I am very sympathetic and appreciative of the human rights issues and of the fact that you're talking about a population which is very sensitive to this issue.

BLOOD DONOR RESTRICTIONS

Mr. FARR. The safety issues. The other thing pointed out is that the highest at-risk group now is women, and if that is true, then, and they're deferred if the sexual activity is disclosed, they're deferred for a year. Men aren't.

Dr. GOODMAN. It is still a fact, and you know, here we rely on statistics from our colleagues in the CDC and also from the blood community, that there's two issues about the population of men who have had sex with men, and I also want to say it doesn't matter if they identify themselves as gay or not. You could be a heterosexual and have had sex with men, and it still raises this risk concern.

The issue is that the population——

Mr. FARR. Women who have had sex with men?

Dr. GOODMAN. Hmm? A heterosexual—a person who identifies themselves as heterosexual male who has had sex. Okay.

Mr. FARR. It's the sex with men that is——

Dr. GOODMAN. It's the sex with men that's the risk factor and the issue.

Mr. FARR. Have we told women that?

Dr. GOODMAN. Men who have sex, because it's the male-male sex that results in increased transmission and identifies a group, and it identifies a group that has, as I think you know, a 60-fold increase in HIV compared to the rest of the population, an 800-fold increase in HIV compared to first-time blood donors, and a 1,000-fold increase in HIV compared to repeat blood donors.

This becomes important, I think you raised an important question, and one of the reasons people look at this, and have difficulty understanding the point of view, is that there are essentially around 25 million transfusions in the United States annually.

This is an extraordinary amount of blood that is tested, goes through numerous processes prior to transfusion.

The tests are wonderful. They've helped us get the safest blood supply in history, and the safest in the world right now.

But they are not perfect. They don't identify some early cases. Errors are made in testing. Errors are made in transfusion. Errors are made in which unit goes to which people.

And even rare errors in a system that is that large and where you then have in that system blood with those markedly increased rates of carriage of these infectious diseases, poses a risk.

So that's how, when people look at all these numbers, they find that there would be additional transmission, and I think as long as we see that there would be additional transmission, you know, really, our responsibility, first and foremost, as much as I totally appreciate the desire of people to donate, we do want to increase supply, but our key responsibility is to not lose any of those gains that we've made in blood safety.

Mr. FARR. I don't think that's what I'm disputing. I think that we're all very appreciative of that.

It just seems the policy is not logical if, indeed, the high risk population is now falling on the female side of it.

Dr. GOODMAN. Yeah. So your point is that we're starting to see, if I understand it, increasing infections in other groups, as well, and that we may treat them not the same way.

But again, the issue is, they haven't had this degree of risk in those populations——

Mr. FARR. When was the last time that the FDA reviewed——

Dr. GOODMAN. Well, we are reviewing it right now, and we had a public workshop in 2006, and since that workshop, we've been interacting with others who could bring—including industry—to bring—who could bring additional data into this.

Mr. FARR. And how do you square this with the blood banks' position, that yours is different from theirs?

Dr. GOODMAN. Well, they were at those meetings. We heard their scientific points. And, you know, I'd like to make a couple of comments about that.

One is that we work day in, day out with the scientists in the blood community. We have a very positive interaction. They've helped us solve and face a lot of important blood problems, like West Nile Virus.

But at the end of the day, they have their job to do. They run blood organizations. And we have our job to do, which is to protect the safety of the blood supply.

Usually, we agree, but sometimes we don't agree, and in this case, at this point, based on the current evidence, we don't agree.

And I've heard a lot about how important it is for FDA to make its decisions independently, and to not rely on regulated industry for its decisions, and in this case, this is a regulated industry.

So I think we just need to, you know, keep this based on the science.

Now, that said, we are not—we welcome difference, not just scientific difference from inside the agency, like I said, but we welcome difference from the outside. We welcome a continuing discussion and debate.

If I could have—if I could say, gee, we could remove this deferral and I could have confidence that it wouldn't affect—that people wouldn't get infections transmitted to them, that would be a very happy day for me. Okay.

So I would like to see that happen, but I just don't think we're there yet.

BLOOD DONATIONS

Now, we are working on——

Mr. FARR. You can't determine by questions—I mean, I think the question goes here, is you're banning a whole class of people rather than sexual activity, which is the judgment you use for everyone else.

Dr. GOODMAN. Well, it's a good question. I would just point out it's not the judgment we use for everyone else.

For example, people who have used intravenous drugs, people who have been commercial sex workers who have similar kinds of increased risk, they also are, as a group, based on those behaviors, deferred from donating blood. But that——

Mr. FARR. Deferred or banned?

Dr. GOODMAN. Well, we call it all deferred. Banned, in terms of there is a ban on it.

Mr. FARR. In lifetime, they can't——

Dr. GOODMAN. That's my understanding.

But I do want to, still, I think you're asking a good question, so I don't want to just—because it could be a good question for those groups, too.

Mr. FARR. Well, it's a question of whether, you know, you're using good——

Dr. GOODMAN. No, it's——

Mr. FARR. It seems it's a bifurcated issue.

Dr. GOODMAN. Yeah, you're asking——

Mr. FARR. If you're a gay man, you can't give blood.

Dr. GOODMAN. Yeah.

Mr. FARR. If you're a sexually active woman, maybe high-risk HIV, you're deferred for a year.

Dr. GOODMAN. Mm-hmm. It's not a perfect system, but it's built on the risk rates in those groups.

One of the questions I think you are getting at, that I do want to address, is could we identify a group of men who identify themselves as gay, or have had sex with men—it's really, again, about men who have had sex with men—could we identify a, quote, "safe" group?

For instance, there's people who have had very limited numbers of partners, and inherently, and in my thinking about it, or any of us thinking about it, we would think we could identify a group with an HIV rate very similar to the rest of the population. The problem is, CDC and others have been unable to do that.

So you might suspect you can find groups with somewhat reduced risk compared to the numbers I quoted you, but they are still substantially above the——

Mr. FARR. Well, I just, when you told me about what science and the testing you use, and you use that for deferral, except you make this blanket—science doesn't seem to support that policy decision. That's what I think is discriminatory.

Dr. GOODMAN. Yeah. Well, I beg to differ. Okay. It is our scientists who have looked at the data, including hearing out the blood organizations——

Mr. FARR. How often do you have these reviews?

Dr. GOODMAN. As I said, we had a major workshop in 2006, and based on input from that, we're continuing to look at the data, as we speak.

Mr. FARR. So you haven't decided finally what your future policy will be?

Dr. GOODMAN. Well, the data that I have seen, and what my scientists are telling me, is that we're still at a point where they are concerned that a change in policy to one year would result in transmissions of HIV, and so that's the issue.

I do want to say that, you know, there are some other issues, and potential mitigating approaches, both. There are some other concerns and some potential mitigating approaches.

Potential mitigating approaches, there's future technologies out there that might allow inactivation of pathogens in the blood to provide another, so that if something slipped through, things like the error rate issue may be able to be improved, and therefore much reduce those risks.

But what I'm saying is, based on what our scientists are looking at now, they are seeing this risk of transmission and real cases that would occur.

Now, different people—there are a lot of uncertainties in the data and different people could legitimately view it differently, but our responsibility is to—you know, is really to protect those recipients.

The other case—instance—information I'd like to bring up, because I find it much—do you want me to finish?

The other piece of information that's much more difficult to deal with is the issue of transmission of other potential diseases that could be blood transmitted.

But we are—I will earnestly tell you we're engaged in this issue. We are seeing this as science. We would be delighted if we could change this without a risk to blood recipients, and it is not, in our minds, discriminatory. It's about risk.

And if other populations—you mentioned women getting more HIV—if we saw risk information in other areas and we felt we had to take similar actions, we'd take it.

This is why we have the safest blood supply. The hemophilia groups, other—you know, are very concerned about a change in policy. And most other countries have adopted a similar policy.

Ms. DELAURO. Thank you, Dr. Goodman.

Mr. Boyd.

[No response.]

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chair.

I think I'll submit my questions for the record. I want to apologize to Dr. Goodman. As I mentioned to you earlier, I had a conflict in another meeting, along with Mr. Boyd, on defense. So I apologize.

BLOOD SHELF LIFE

Ms. DELAURO. Thank you.

Let me see if I can ask one more question.

Dr. GOODMAN. Sure.

Ms. DELAURO. Blood shelf life. You're aware of the recent study in the New England Journal of Medicine that indicated heart surgery patients getting transfusions from blood that was stored for longer than two weeks were 64 percent more likely to die in the hospital than those getting blood that had not been stored that long.

I understand FDA said the study was, quote, "narrow and nonrandomized," and that regulatory action would be, quote, "premature."

It's a striking report to a layperson, and surprising.

Could you comment on the study, and are you looking at the issue more closely, even if you're not prepared to take action?

Dr. GOODMAN. Yeah, I'd be delighted to.

There have been conflicting results in similar studies. In other words, there are previous studies that haven't shown worse outcomes, and it sort of depends, you know, what do you call young blood, what do you call old blood, and what patient population you study it in.

So like in a lot of areas in medicine, there's complexities, with different studies showing different results.

I don't question the results of that study. It was well done. But as you noted, it wasn't controlled. In essence, it looked at—it didn't randomize people, it just looked at what blood they received.

Now, what I would like to say is, we are looking at this, and we are working—this is another example where— Mr. Farr mentioned, you know, that our interactions with the blood community.

We, and I think the blood community as well, are concerned about these kind of issues, and we are looking at it.

And in fact, we just decided, actually before that came out, but as a group, to devote some of our scientific resources to try to help that process of evaluating the storage of blood.

Ms. DELAURO. What's the shelf life that you currently work under with regard to blood?

Dr. GOODMAN. The normal shelf life of red blood cells is 42 days, and so if you were to reduce that to 10 days, there would be a huge impact on supply.

Ms. DELAURO. Six weeks versus two weeks is a big difference.

Dr. GOODMAN. It would be a huge impact on supply.

But, you know, that doesn't mean that that issue should be ignored. It needs attention.

For example, is there science that could allow the red cells to be stored for 42 days and not lose any of their capacity?

So part of the reason I'm concerned about that study is that it makes sense, I mean, that older blood is not—you know, is going to have some defects that it gets from storage, and we've known this for a while.

But this may have identified a particularly sensitive population, so it may be that we need to target older cells and younger cells differently.

But what you want to say is this is an area where there's not a lot of investment driving improvements. That's true in something like donor testing and screening, too. It's a small area for the whole pharmaceutical enterprise.

And I can't—I think there's a lot of exciting opportunities through critical path, through NIH, to look at some of these problems, like how do you store, how do you preserve the function of red cells and platelets, that if we applied the kind of modern science we do to that that we do to so many other things in our society, we could really have public health benefits. But the markets are just not large.

TISSUE RETRIEVAL

Ms. DELAURO. How long after death can tissues be taken—can tissue be taken?

Dr. GOODMAN. Is there a specific number in the guidance on how long after death tissue can be taken?

We'll get back to you on the numbers.

[The information follows:]

In the preamble to the final Good Tissue Practice Rule, FDA stated, "Proposed Sec. 1271.180 would require establishments to establish and maintain procedures for all significant steps that it performs in the manufacture of HCT/Ps. We have reorganized Sec. 1271.180 by dividing it into paragraphs for greater clarity and ease of reading. In addition, Sec. 1271.180 now requires you to establish and maintain procedures appropriate to meet core CGTP requirements for all steps that establishments perform in the manufacture of HCT/Ps and further requires that these procedures be designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of HCT/Ps. We note that, depending on the activities that you perform, your procedures may need to cover such issues as the length of time a cadaver may be stored, or the conditions of storage (e.g., temperature). Moreover, to prevent the recovery of contaminated cells or tissues, you need to establish and maintain procedures to prevent the recovery of cells or tissue from a septic donor or from an area of the body where there is a localized infection. The procedures of an establishment that recovers cells and tissue should appropriately address these possible causes of HCT/P contamination to comply with Sec. 1271.180(a)." (69 FR 68611)

FDA finds acceptable the limits that have been established in the American Association of Tissue Banks (AATB) Standards for Tissue Banking, which require that recovery commence within 24 hours of death, providing the body was cooled or refrigerated within 12 hours of death. Tissue recovery might also commence within 15 hours of death if the donor has not been cooled or refrigerated.

What I will just say about that, I believe there are numbers, now, that we put in there, but also that part of the good tissue practice regulations requires them to show that their storage and

preservation practices are sound, so that practice would not be allowed, that you had been concerned about.

Ms. DELAURO. Dr. Goodman, I unfortunately have to leave for another hearing. There are a number of questions, and Mr. Kingston will offer his for the record. He may, if we reschedule, be able to ask those on the record here.

I have additional questions which have to do with the blood recalls in the Red Cross, and inspections, and the flu vaccine, which we understand because of the three new components we may be delayed in getting flu vaccine. There are a whole range of questions.

And I would want to suggest, and it wouldn't be a long hearing, because I think we've had a very good exchange here, that maybe we just try to, we can work with your schedule, just to reschedule and, you know, put a—you know, some absolute time frame on this, so that we don't interfere any longer with your schedule, but allow some of the other questions.

This is a—it's a very—there are hearings around the clock here, and I know you're very busy.

So if we could beg your indulgence on that, I would like to do that, and adjourn this hearing and see if we can then get you back again for a short time.

Dr. GOODMAN. We appreciate your input, oversight, critiques, et cetera, and, you know, we're happy to try to arrange something.

Ms. DELAURO. Thank you. Thank you very, very much for your patience and for your good will.

Dr. GOODMAN. You're welcome.

Ms. DELAURO. The hearing is adjourned.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Subcommittee

Questions for Jesse L. Goodman, M.D., M.P.H.
Director of FDA's Center for Biologics Evaluation and Research
Food and Drug Administration
April 2, 2008

QUESTIONS SUBMITTED BY REPRESENTATIVE FARR

HEREDITARY HEMOCHROMATOSIS

Mr. Farr. Is the FDA directive allowing persons with hereditary hemochromatosis to donate blood fully in place?

Answer. Current regulations permit collection of blood from a person with hereditary hemochromatosis by therapeutic phlebotomy, a treatment similar to a blood donation to treat the disease, for use in transfusions. These collections are subject to restrictions on donation frequency and require conspicuous labeling of the product with the donor's disease that necessitated withdrawal of the blood, as required under 21 CFR 640.3.d.

In August 2001, FDA issued a guidance document entitled "Variances for Blood Collection from Individuals with Hereditary Hemochromatosis" that established an FDA policy on acceptance of alternative procedures under which the current restrictions on frequency of collection and donor disease labeling will not be applied. To obtain approval of such variances, FDA recommends that blood collection centers submit written requests explaining that the individual with hereditary hemochromatosis whose blood will be used for transfusions meets all other allogeneic donor suitability criteria, and the blood collection center should include a copy of the donor form acknowledging that the donor will not be charged a fee for the phlebotomy even if found ineligible as an allogeneic blood donor. A concurrent request can explain that the individual with hereditary hemochromatosis will be allowed to donate more frequently than once every eight weeks based on their physician's prescription.

Additionally, in November 2007, FDA issued a proposed rule entitled "Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use" which, when finalized, would incorporate into the Code of Federal Regulations FDA's current recommendations regarding the conditions for collection by therapeutic phlebotomy of blood for use in transfusion from donors with hereditary hemochromatosis.

Mr. Farr. Is there any reason why a collection site should not be allowing donors with HH to donate?

Answer. If a person with hereditary hemochromatosis does not meet all of the requirements for donor suitability, a collection site should not allow that person to donate blood for transfusion. An otherwise suitable donor with hereditary hemochromatosis can donate blood for use in transfusion provided that the last donation was more than eight weeks prior and that the collection is labeled

conspicuously indicating the donor's disease, such as hereditary hemochromatosis, that necessitated therapeutic phlebotomy. However, if the collection center has obtained approval of variances from the current requirements on donation frequency and donor disease labeling, then units collected by therapeutic phlebotomy from donors with hereditary hemochromatosis can be used to make products for use in transfusion.

Mr. Farr. What can be done to assure that persons with HH can give blood?

Answer. Persons with hereditary hemochromatosis can donate blood by therapeutic phlebotomy for use in transfusion under current regulations that address donation frequency and product labeling. These regulations are in 21 CFR 640.3(d).

The restrictions in these regulations do not apply at collection centers that have obtained variances from FDA based on written requests explaining that the individual with hereditary hemochromatosis whose blood will be used for transfusions meets all other allogeneic donor suitability criteria, and the blood collection center includes a copy of the donor form acknowledging that the donor will not be charged a fee for the phlebotomy even if found ineligible as an allogeneic blood donor. The written request to obtain variances would also explain that the individual with hereditary hemochromatosis is allowed to donate more frequently than every eight weeks based on their physician's prescription. More widespread acceptance by blood collection centers of blood donation by persons with hereditary hemochromatosis likely depends on social and economic factors that go beyond FDA's blood safety standards.

QUESTIONS SUBMITTED BY REPRESENTATIVE BISHOP

PATENT PROTECTION

Mr. Bishop. As you know, there has been considerable debate for several years on drug patent protection, and in particular, when certain drugs should be made available to the public as generic drugs, and at a significantly lower price. What is your view on this issue, particularly given the increasing costs of drugs, particularly for our elderly citizens?

Answer. The generic approval process, created by the Drug Price Competition and Patent Term Restoration Act of 1984, amended by the Medicare Modernization Act, strikes a balance between the need for innovation and the desire to bring generics to the market earlier. The determination of the level and amount of patent protection is a function of the Constitution and patent laws. The only role the Food and Drug Administration has with respect to drug patent protection is to implement the process and policy Congress has legislated. We are always concerned when persons, including senior citizens, are unable to obtain needed medications for any reason. FDA continues to strive to improve and speed-up the generic approval process in order to help ensure that generic drugs do get to market in a more timely fashion.

PATENT PROTECTION – FOLLOW-UP

Mr. Bishop. There have been several proposals introduced aimed at providing brand-name biotech drugs an extra 14 1/2 years of patent protection, which essentially defeats the purpose of establishing a route to market for generic biotech drugs, which have been shown to be effective, particularly in the treatment of certain cancers, which are some of the most expensive drugs in the market. How do we find an effective balance between providing the makers of certain drugs adequate patent protection, versus the needs of millions of patients who find themselves choosing between paying for their medicines and putting food on their tables.

Answer. In June 2007, Secretary Leavitt provided the Administration's position on proposed legislation that would provide a process for follow-on proteins, a generic. The Administration's position includes a paragraph on intellectual property concerns. The letter stated the following:

> "To ensure continued biotechnology innovation, legislation authorizing a follow-on biological pathway should include incentives for sponsors of reference biological products. The Administration believes that sponsors that develop innovative biotechnology products should be eligible for a significant period of market and/or data exclusivity, independent from any patent protections that might be applicable to the product. An additional exclusivity period should also be provided if, during the period of exclusivity, the sponsor of the reference product submits, and FDA approves a biologics license application [BLA] supplement for a new indication for which new clinical studies were required (other than bioavailability studies). Such protections should be robust enough to ensure that a follow-on pathway does not negatively impact innovation. The Administration is pleased that the bill would provide for 12 years of data exclusivity, but is concerned that it does not include an additional period as an incentive to conduct trials supporting the approval of a new label indication, as is currently the case for other drugs."

I am happy to provide a copy of the letter for the record.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 26 2007

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The Administration supports the goal of making safe and effective drugs available and affordable for American consumers. I applaud your commitment to this issue, and appreciate the work done by you and the Committee with respect to proposals to create an abbreviated regulatory pathway related to follow-on biologic products. The Administration supports legislation to create such a pathway to allow for the approval of follow-on biologic products through a robust scientific, regulatory, and legal discussion. Any such legislation must, as a first priority, ensure the safety, purity, and potency of the resulting product, thus protecting patient safety. Furthermore, it should also include adequate intellectual property protections in order to maintain the research enterprise that has generated life-saving medications. However, the Administration has significant concerns with the bill as presently drafted.

Before I address specific provisions, I would lay out some brief background and describe key principles that the Administration believes must be considered in any legislation related to follow-on protein products.

Background

Although some protein products (including human growth hormone and insulin) have been approved under the Federal Food, Drug, and Cosmetic Act (FDCA), the majority of protein products have been licensed as biological products under the Public Health Service Act (PHSA). FDA has approved some follow-on protein products under section 505(b)(2) of the FDCA (an approval pathway that permits reliance upon literature or the agency's finding of safety and effectiveness for a previously approved product), but only with respect to protein products where the innovator products are regulated and were approved as drugs under section 505 of the FDCA. FDA has not rated these follow-on protein products as interchangeable by a pharmacist for the approved innovator product. The section 505(b)(2) pathway is not the same as the abbreviated new drug application approval process in section 505(j) of the FDCA by which generic drugs are approved. There is no approval pathway for biological products licensed under the PHSA that is analogous to section 505(b)(2) or section 505(j) of the FDCA.

It is furthermore clear that biological products are different from other drugs in ways which make a simple extension of the 505(j) abbreviated process to biologics problematic, if one wishes to protect patient safety as a first priority. We note that there is a spectrum of scientific complexity for protein products, from relatively simple peptides to large proteins with highly complex structures. Scientific understanding and technology have advanced sufficiently to permit the agency to approve relatively simple proteins and peptides under some abbreviated pathway. However, the state of scientific understanding and technology (e.g., available analytical techniques) does not currently support the approval of larger and more complex protein products under an abbreviated process such as section 505(j) of the FDCA. As the science evolves, and our ability to make judgments about more complicated protein products advances, FDA may be able to approve abbreviated applications for more complicated proteins. However, a technical and scientific understanding of similarities between two biological products is not enough. We must also understand how health care providers and patients access these products and how they use them in practice, and any legislation must ensure that there are adequate safeguards against the use of these products in a way that compromises patient safety or health. Ultimately, whether a particular biological product or class of biological products is appropriate for follow-on development will depend upon the complexity of the product, the state of the scientific and analytical tools available to industry and the agency, and the analysis of how patients use such products.

Comments on Specific Provisions

Biologics Product Savings Fund
The Administration strongly objects to the provision that directs the Secretary of Treasury to transfer estimated savings to the Federal Government from the Act into a Special Reserve Fund to be made available to the Secretary of Health and Human Services if appropriated. The Administration believes that this provision is unnecessarily complicated and is a fiscally irresponsible way to authorize spending of speculative estimated savings. Actual savings would be impossible to track or audit. Furthermore, this fund would set a bad budget precedent in the face of other pressing priorities such as the long term sustainability of the Medicare program.

Intellectual Property
To ensure continued biotechnology innovation, legislation authorizing a follow-on biological pathway should include incentives for sponsors of reference biological products. The Administration believes that sponsors that develop innovative biotechnology products should be eligible for a significant period of market and/or data exclusivity, independent from any patent protections that might be applicable to the product, to ensure continued innovation. An additional exclusivity period should also be provided if, during the period of exclusivity, the sponsor of the reference product submits, and FDA approves a biologics license application [BLA] supplement for a new indication for which new clinical studies were required (other than bioavailability studies). Such protections should be robust enough to ensure that a follow-on pathway does not negatively impact innovation. The Administration is pleased that the bill would provide for 12 years of data exclusivity, but is concerned that it does not include an additional period as an incentive to conduct trials supporting the approval of a new label indication, as is currently the case for other drugs.

Scope

There are unique scientific issues associated with follow-on biologics (as compared to generic small-molecule drugs), including how to ensure safety and efficacy, how to measure sameness, and immunogenicity of products. There are additional market and public policy implications for specific types of products, such as vaccines and blood products. At present, the science does not exist to adequately protect patient safety and ensure product efficacy through an abbreviated follow-on pathway for all biologic products, and questions exist whether some products, such as vaccines or blood products, would ever lend themselves to such a pathway.

Accordingly, the Administration is concerned that the legislation permits all types of biological products licensed under section 351 of the Public Health Service Act to serve as reference products. The Administration believes that the legislation should be amended to specifically exclude products such as vaccines or blood products, and to require periodic reports to Congress advising on the state of the science and whether science supports expanding the scope of the legislation. A follow-on pathway for these products could be created with a statutory moratorium that could expire or through additional legislative authorization.

The Administration also notes that the draft legislation would transfer certain products now regulated under section 505 of the FDCA to section 351 of the PHSA, and understands that this may be prompted by a desire for uniformity in how proteins are regulated. We believe that such a change should not be undertaken without very careful consideration of the legal and policy implications of such a change on the regulation of these products. For example, insulin products are proteins that have been regulated under the FDCA for more than 60 years. There could be significant regulatory implications if this product class were now to be approved or licensed and regulated under the PHSA. The Administration has not completed this review and looks forward to working with the Committee to carefully consider this issue.

Guidance

The Administration believes that the legislation should be amended to require a predictable and public product-class guidance process prior to acting on any follow-on applications. It should ensure that FDA receives expert and public scientific and technical advice, but should include flexibility for FDA to adjust the process to meet its scientific needs with respect to data requirements and other matters. This guidance process would signal to stakeholders which product classes FDA considers appropriate for follow-on applications and data elements that might allow review and approval of a follow-on product. Such a process will ensure the agency has optimum information regarding safety and efficacy considerations for follow-on products; enhance transparency of decision-making; establish a level-playing field for all follow-on applicants; and encourage follow-on applications by describing Agency expectations for application content.

Clinical Trials
Under section 351 of the PHSA, innovator biologic applicants are generally required to perform one or more clinical studies to establish that a biological product is safe, pure, and potent. The Administration believes that legislation should require that sponsors of follow-on products meet the same high standards for approval as innovator biological products. The data expected to be necessary to meet this standard will depend, among other things, upon the specific biological product at issue.

Therefore, legislation should permit FDA to increase or lower the amount of data needed as dictated by science and done through a transparent and public notification mechanism. The guidance process described above should be used to identify the specific types of data needed to establish safety, purity, and potency for a product class of follow-on biological products. We support the flexibility provided in the bill to adjust the level of needed trials, but believe that the legislation should be amended to require that these determinations be public. However, we believe that, because there are few, if any, circumstances that could be envisioned where assessment of immunogenicity would not be critical, we suggest the bill be amended to exclude this requirement from the waiver authority under proposed 351(k)(2)(A)(ii).

Biosimilarity
Sponsors of applications under section 351(k) should be required to demonstrate biosimilarity for all conditions of use for which the reference product is approved because biosimilars are supposed to perform the same way that the reference product does. If a product proposed for approval in a section 351(k) application behaved differently for the reference product in any indication, it would not be "highly similar."

In addition, the requirements on information regarding mechanisms of action should be changed from "mechanisms of action are known" to "mechanisms of action are known or can be reasonably determined." Because biosimilars may be approved decades after the reference product, and over that time the technology or methods to assess mechanisms of action may have improved, it is reasonable to assess whether the mechanism of action can be determined at the time of the section 351(k) application.

Finally, because there is no definition of what is considered "highly similar" to guide FDA reviews, we suggest that the legislation should require FDA to indicate in product-class guidances what it would consider to be "highly similar" for the purposes of that specific class of products.

Interchangeability
A key aspect of generic drugs is that they are the same as the innovator drugs. Products approved under section 505(j), i.e., generic drugs, may be designated as therapeutically equivalent to the reference product, and thus considered "substitutable" or "interchangeable." Under state law, such products may be substituted for the reference product by a pharmacist, which may provide for significant cost savings.

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However, protein products are more complex and are frequently immunogenic. The impact of immunogenicity can be serious and life threatening. Immunogenicity of proteins is difficult to predict, and therefore, determining interchangeability may be far more complex for protein products than it is for small molecule drugs. In most cases, follow-on products will not be the same as the reference product in the manner that generic drugs approved under section 505(j) are the same as the listed drug. In addition, even if a follow-on protein product is determined to be biosimilar to the reference product, immunogenicity could preclude patients from switching from one product to another.

Because of the variability and complexity of protein molecules, current limitations of analytical methods, and the difficulties in manufacturing a consistent product, it is unlikely that, for most proteins, a manufacturer of a follow-on product could demonstrate that its product is identical to an already approved product. Technology is not yet sufficiently advanced to allow this type of comparison for more complex protein products. Scientific and safety issues of determining interchangeability at present are significant, including for pharmacovigilance (for example, post-market surveillance and withdrawal based on class or a specific product).

For many follow-on protein products, there is a known significant risk in repeatedly switching between products and a resulting negative impact on both patient safety and/or effectiveness. While there may be the possibility of determining interchangeability in the future, pharmacies or patients might substitute biological products determined to be biosimilar, but not determined to be interchangeable for one another, possibly resulting in serious injury or death. Therefore, in light of the current scientific limitations on the ability to make determinations of interchangeability, and because it is critical to protect patient safety, the Administration believes that patients should not be switched from the innovator biological product to a follow-on biological product (or vice versa) without the express consent and advice of the patient's physician, and legislation should not allow for determinations of interchangeability at this time.

The Administration is concerned that the standard established in the bill for interchangeability exacerbates already significant patient safety concerns. The bill language addressing interchangeability is too narrow to assure that products would be interchangeable both when a patient is switched from one product to another, and in the sense that a pharmacist could substitute one product for another without a physician's consent when treatment is initiated for a patient.

In addition, requiring only that the product "can be expected to produce the same clinical result as the reference product" would allow for excessive variability. Products, such as biologics, which already have greater variability than small molecule drugs and immunogenicity issues not posed by other drugs, should not be given a standard that is looser than that of small-molecule drugs. This simply makes a difficult problem worse. If a biological product is to be considered interchangeable, and thus substitutable without the advice or consent of the treating physician, it must be proven to produce the same clinical result in patients so that it can be used in the same manner as therapeutically equivalent, generic drugs approved under section 505(j) of the FDCA.

In addition, if a sponsor seeks a finding of interchangeability, it should be required to do so for all conditions of use for which the reference product is approved for the same reasons as above. The absence of such a requirement in the current bill creates a very real safety hazard – that a patient might be switched to a product for an indication that had never been demonstrated to be either biosimilar or interchangeable.

The bill does not address interchangeability of multiple section 351(k) products that reference the same section 351(a) product. The legislation should be amended to provide that the sponsor of a subsequent section 351(k) application must be required to show interchangeability with both the reference product and with any other previously licensed product that is itself interchangeable with the reference product, again to avoid misleading pharmacists and patients who could make potentially deadly substitutions of medicines. While we in general have no concerns with proposed section 351(k)(5), it should also be amended to allow for this requirement.

Finally, the proposed definition of "interchangeable" as drafted would intrude on the regulation of the practices of medicine and pharmacy – two areas that have traditionally and importantly been left to the States to regulate. Accordingly, the Administration believes this definition should be stricken and redrafted consistent with the Administration's comments on what should be shown to establish a product as interchangeable.

Labeling
The bill does not require that products for which interchangeability has not been demonstrated prominently state this information in labeling. This creates the possibility that a patient will be dispensed a product that has not been demonstrated to be interchangeable. The legislation should expressly require that any product approved under sections 351(a) or (k) bear labeling that describes whether the agency has made a determination regarding the interchangeability of the product with any other licensed product.

Naming
Follow-on biologics also present issues with pharmacovigilance (for example, post-market surveillance and withdrawal based on class or specific product concerns). Currently, all products are assigned an International Non-proprietary Name (INN). This is highly relevant in the context of biosimilars, given that these products would be considered similar, rather than the same. Therefore, the Administration believes that legislation should recognize the potential impact on pharmacovigilance and prescribing and require that these products be assigned a distinguishable, non-proprietary name for safety purposes.

Cost
To review follow-on applications, FDA will need additional resources. We are pleased that the bill appears to explicitly permit the Agency to assess user fees for section 351(k) applications. However, we have not yet had the opportunity to consider the full costs likely associated with the review of follow-on applications under this legislation in order to determine whether this proposal would provide sufficient funding to meet those needs. In addition, it is unclear whether this provision would provide funding for all proposed section

351(k) applications, or only biosimilar applications under proposed section 351(k). We hope to work with the Committee prior to floor consideration to evaluate these issues and ensure that the bill adequately addresses them.

In addition, in light of the importance of ensuring the timely review of safe and effective generic drugs, the Administration believes that the legislation should be amended to authorize the collection of user fees for review of generic drug applications under section 505(j) consistent with the President's FY2008 budget.

Conclusion

The Administration shares the goals of the Committee to make high quality biologic products more affordable for all Americans, and we hope to work with the Committee to address our concerns prior to floor consideration. This letter reflects our major concerns with the legislation at this time, and should not be construed as outlining all of our concerns.

OMB advises that from the standpoint of the Administration's program there is no objection to the transmittal of this letter. We look forward to our collaboration with you on this legislation.

Sincerely,

Michael O. Leavitt

DRUG RECALL PROCESS

Mr. Bishop. On a daily basis, we hear press reports that the Food and Drug Administration has received new information on already approved drugs and/or medical devices, which present unexpected and harmful side effects after use. This often results in side effects which present severe, if not worse medical challenges than the drug's original intended purpose. Whether it's a gel approved to treat diabetic foot and leg ulcers, which we later find may increase the risk of cancer-related deaths, or stents which have been inserted to prevent aneurysms, resulting in more deaths than bi-pass operations. What can be done to get it right the first time, and what can or should the Congress do to aid FDA in providing safer drugs and medical devices to the public?

Answer. It is impossible to learn from a pre-market clinical trial of 10,000 people everything about how a product will perform once it is on the market or in use by millions of people, some of whom may not have the relevant condition, may be taking other medications, or belong to special population groups.

Our goals are twofold. First, ensure that medical products are as safe and effective as they can be. Second, strengthen our postmarket safety monitoring so that we can identify possible adverse events, or other problems, and communicate this important safety information at the earliest possible time to the public.

As part of the Critical Path Initiative, FDA is modernizing the sciences that make medical products safer and more effective, including developing techniques that personalize treatment by identifying those patients who should avoid using a particular medicine, or who need special dosing.

In addition, I will respond to your question. I would like to illustrate how FDA is working in a number of ways to strengthen postmarket monitoring.

First, we seek Congress' continued support in our effort to automate the way we do business, the way we receive, evaluate, and communicate critical safety information. For example, almost 4,000 prescription drug labels are now available electronically on the internet. We will be adding all human and veterinary drug labels to the system soon.

Second, we are also expanding MedWatch to make it more user friendly and efficient and encourage voluntary reporting by healthcare practitioners, patients, and consumers.

Third, we are collaborating with other organizations, such as CMS, health maintenance organizations, and many others to create a distributed electronic network to enable FDA to proactively query huge data sources for specific information about a possible problem with a medical product. This effort and several pilots have been under way for a number of years. Such collaboration was mandated in Section IX of the Food and Drug Administration Modernization Act of 2007, also known Public Law 110-85.

DRUG SAFETY PLANS

Mr. Bishop. The FDA recently named 25 drugs and biologic products, including some well-known and popular medications, whose makers will be required to submit safety plans later this year. The product list as published in the Federal Register and

includes the multiple myeloma medication Thalomid, the anti-psychotic medication Clozaril, and the drug Mifeprex. The plans, called Risk Evaluation and Mitigation Strategy—or REMS, must be submitted to the FDA no later than September 21 or the companies may face "enforcement action," including monetary penalties. How many companies are currently required to submit these REMS, and how does the FDA ensure that their plans are adequate and executed as directed? CDER

Answer. Twenty-four companies were notified that, based on the fact that they were approved with certain elements to assure safe use, they were deemed to have a REMS within the meaning of section 909 of the Food and Drug Administration Amendments Act of 2007, or FDAAA.

The FDA review divisions responsible for the drugs, in consultation with the Center for Drug Evaluation and Research's Office of Surveillance and Epidemiology and the Center for Biologics Evaluation and Research's Office of Biostatistics and Epidemiology, will review the proposed REMS to determine whether they are adequate. If they are adequate, FDA will approve them. Under FDAAA, one requirement for a REMS is a timetable for assessment at least 18 months, 3 years, and 7 years from the date of approving the REMS. At the required timeframes, companies must submit their assessments of how their REMS are working, and FDA will review those assessments and require modifications if necessary.

REMS are enforceable under FDAAA. If the companies do not comply with provisions of a REMS, FDA can take appropriate enforcement action, including imposing civil monetary penalties for non-compliance.

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QUESTIONS SUBMITTED BY REPRESENTATIVE KAPTUR

INTEGRITY OF AMERICAN BLOOD SUPPLY

Ms. Kaptur. During last years hearing I asked about the safety of the American blood supply. By your own estimate, there are 14 million donations of whole blood and 29 million transfusions of blood components in 2006. This number represents the dedication of the American people who give blood and the effectiveness of our system to disseminate this life saver to those who need it. With 2,676 blood establishments, oversight and traceability of this market is particularly important. However, it has come to my attention that when a recall occurs, FDA has no ability to track the actual recovery of material. Is this true? Please provide the committee a snapshot of what types of recoveries you have made.

Answer. The question assumes that FDA typically makes recoveries of recalled product, which is not always the case. FDA assures that voluntary, firm-initiated recalls are conducted appropriately by ensuring that recalling firms communicate clearly and in a timely way with all affected customers or consumers. It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. In addition, the firm has an obligation to conduct effectiveness checks as part of its recall strategy. Effectiveness checks assist in the verification that all known, affected consignees have

received notification about a recall and have taken appropriate action. FDA recognizes that effectiveness checks also serve an audit function, and as part of its audit responsibilities, FDA selectively conducts audit checks separately from the effectiveness checks of the recalling firm.

The Mission Accomplishment and Regulatory Compliance System Recall Enterprise System, also known as the MARCS System or just RES, is the official FDA recall database. MARCS contains specific information on recalled blood products that are returned, retrieved or otherwise recovered FDA receives the information in the MARCS System from monthly update reports received from an FDA-regulated firm. The information is incorporated in the final recall record when the recall is terminated.

The probability of product being retrieved before use depends on a number of factors, most notably the shelf life of the product. Transfusable blood products often have a very short shelf life. Therefore, transfusable blood products often have already been administered at the time of recall. Plasma products for further manufacturing use, due to their longer shelf life, are quarantined for a number of months prior to manufacturing to allow for additional evaluation of donors at subsequent donations. These products can often be retrieved as necessary prior to use in manufacturing.

Ms. Kaptur. Does FDA lack the database and recordkeeping capacity to track the recovery of blood that is recalled?

Answer. MARCS has the recordkeeping capacity to track the recovery of blood that is recalled, including specific information on recalled blood products that are returned, retrieved or otherwise recovered. However, it is the recalling firm's responsibility to submit periodic recall status reports to the FDA so that FDA may assess the progress of the recall. The recall status reports include, but are not limited to, information such as the number of consignees that have responded to the recall communication and the quantity of products on hand at the time the recall communication was received. Recall status reports also include the number of products returned or re-conditioned by each consignee. Information regarding the effectiveness of a recall is incorporated into the MARCS record when the recalling firm terminates the recall.

Ms. Kaptur. As we know, blood does not stay in the market long because it is highly perishable and must be used quickly. This makes the screening and recall of this blood particularly difficult as means for ensuring the integrity of the system. My understanding of FDA's database system is that it is wholly incapable of tracking the effectiveness of recalls since these recalls are conducted by local facilities. Please outline the steps that would be needed to create a system where the recovery data for recalls could used to track recalls' effectiveness?

Answer. FDA currently has a system for capturing the effectiveness of each recall event in a summary format. For example, the system captures information such as the number and type of products involved, how many products were actually retrieved and destroyed, and how many products had been used, and products that are infused or administered prior to the initiation of the recall. The system includes specific disposition information on each recalled blood product that is returned, retrieved or otherwise recovered. At the time when the recalling firm terminates the recall, FDA

receives data on the number of products that were reconditioned or destroyed in routine reports from the recalling firm, FDA updates the MARCS records.

Ms. Kaptur. Since FDA has the statutory authority to mandate a recall, why doesn't FDA track the effectiveness of these recalls once they have occurred?

Answer. FDA has the authority to mandate the recall of licensed blood products when an imminent or substantial hazard to public health exists. However, FDA has not exercised that authority in recent years. Rather, FDA assures that voluntary, firm-initiated recalls are conducted appropriately by ensuring that recalling firms communicate clearly and in a timely way with all affected customers or consumers. In such situations, FDA would track the effectiveness of these recalls very closely and conduct audit checks separately from the effectiveness checks of the recalling firm.

Ms. Kaptur. I am sure this is a story that FDA has been tracking, but in Las Vegas a clinic has been improperly sterilizing syringes and vials of medication for years. This case has prompted Las Vegas to recommend that 40,000 patients who have received treatment at the center get tested for Hepatitis C and HIV. The massive case in Las Vegas underscores the importance for the consequences of improperly regulating human biologics. Now, because of improper oversight and management, 40,000 people might have been exposed to Aids and Hepatitis C. As a regulator, what steps have you take to ensure that this type of problem is not endemic in our system?

Answer. We are aware of several reports of clinics and other healthcare facilities wherein viral infections such as HIV and Hepatitis C have been spread due to improper sterile technique when using needles and syringes, reuse of needles and syringes which are intended for single use only, and improper use of vials of medications meant for single dose use only. The Centers for Disease Control and Prevention—CDC—and FDA are discussing how to work together to develop solutions to this problem. Specifically, to prevent further potential spread of these diseases in the Las Vegas incident, FDA worked with CDC and local blood organizations to assess possible risk from blood donors in the area who had undergone endoscopy at this clinic.

The reusing of needles and syringes which are intended to be used only once and then discarded, and are so labeled, or using medication vials in an inappropriate manner is, first and foremost, unsafe practice on the part of practitioners. In spite of numerous training efforts, including CDC fact sheets that clearly indicate that healthcare providers should never reuse a needle or syringe either from one patient to another, or to withdraw medication several times from a single use vial, such clinical practices still exist. Because the CDC is the federal agency that plays a major role in promoting the practice of proper sterile technique, and in the investigation of the spread of bloodborne diseases, FDA is planning to work with CDC to develop educational measures aimed at improving clinical practice. FDA is planning to post a healthcare practitioner sheet on the FDA website instructing practitioners about the correct use of medication vials, needles and syringes. FDA is considering recommending that healthcare facilities provide more frequent training that demonstrates the correct use of syringes and medication vials and that emphasizes the hazards of reusing needles or syringes. FDA will also suggest that healthcare providers use "safety" syringes that prevent the syringe

and needle from being used again. This safety technology is available from several manufacturers and has been available for many years.

FDA is also considering putting warning statements on multidose vials stating not to reuse syringes or needles when removing medication. Multidose vials are larger containers than single dose vials and can accommodate this additional information on the label. FDA will also recommend that facilities consider prohibiting the use of multidose vials in settings—such as surgical rooms or emergency rooms—that pose a higher risk of accidental contamination of vials.

FDA and CDC are exploring other measures to reduce the transmission of bloodborne pathogens in clinical settings through discussions with stakeholders such as the American Association of Nurse Anesthetists.

Ms. Kaptur. What steps has FDA taken to protect the blood supply from emerging diseases like dengue fever and West Nile virus?

Answer. Following the introduction of West Nile Virus, or WNV, into the United States in September 1999, WNV has become endemic and recurs yearly. WNV has infected between 1.7 and 3.9 million people in the United States, causing nearly 28,000 human cases of disease serious enough to be reported to the CDC and at least 1,086 human deaths. While 80 percent of the infections are asymptomatic, 20 percent cause a flu-like syndrome and less than 1 percent cause neurological symptoms that can be severe and sometimes fatal.

In the fall of 2002, it was demonstrated that WNV could be transmitted by blood components and organs transplants. This led the Department of Health and Human Services to call for the development of a donor screening test. In October 2002, FDA issued guidance to blood establishments on donor and unit management and has periodically updated its guidance. Nation-wide studies of investigational tests began in July 2003, and the first test to screen for WNV in donors of blood, organs, cells, and tissues was approved on December 1, 2005, followed by a fully automated system from the same company licensed on March 2, 2007. A second donor screening assay was licensed on August 28, 2007. We estimate that since 2003, these screening tests have identified approximately 2,600 infected donations from the blood supply, preventing between 2,600 to 7,800 potential exposures of blood recipients to WNV.

FDA has worked with CDC to monitor emerging infectious diseases that may pose a threat to the blood supply such as dengue virus which has been reported in Puerto Rico and in certain border areas in Texas. The same testing platforms used to screen blood for WNV may be amenable to screening for dengue virus or other viral agents. Scientific studies are ongoing to determine the risk of transfusion transmission of dengue virus and the utility of donor screening for infection with dengue virus. FDA will work with blood organizations and manufacturers to facilitate the development of dengue assays for use in donor screening based on an assessment of the study results.

Ms. Kaptur. What would it take to install in the American system a pathogen inactivation or sterilization process for all blood?

Answer. Pathogen inactivation holds the potential promise of protecting blood not only from many known agents but also from emerging agents. However, FDA must balance potential ha rm from the pathogen inactivation process with the benefit of

reducing the risk of infectious disease transmission. It is important that the process for inactivating the infectious agent not harm the blood component. Because some infectious agents are very resistant to inactivation, it is unlikely that there will be a single pathogen inactivation method for all infectious agents. Nevertheless, there are currently candidate procedures for pathogen inactivation of certain blood components, such as platelets. FDA discussed some of these products at a public workshop, *SAFETY AND EFFICACY OF METHODS FOR REDUCING PATHOGENS IN CELLULAR BLOOD PRODUCTS USED IN TRANSFUSION,* in 2002, and most recently in the context of bacterial inactivation of platelets at the Advisory Committee on Blood Safety and Availability in 2008. Further research and development may be needed to facilitate development of novel methods of pathogen inactivation. In particular, no promising candidate technology yet exists for pathogen reduction in red blood cells, and advancement in that area would require a significant investment.

QUESTIONS SUBMITTED BY REPRESENTATIVE KINGSTON

CRITICAL PATH

Mr. Kingston. Critical Path is an initiative that FDA has touted as a way of preparing the agency for the review of the treatments of the future. You briefly mention the Critical Path initiative in your written testimony. Would you elaborate on efforts that are ongoing at CBER through Critical Path that will help safely advance biologics in a more timely fashion?

Answer. CBER Critical Path projects funded during FY 2008 are intended to provide advances in all areas regulated by CBER including blood and blood products, vaccines, allergenic products, and cellular and gene therapy products.

In blood and blood products, we are improving techniques for detecting blood-borne pathogens by studying novel sample preparation methods, evaluating assays for detecting variant HIV strains, identifying approaches to minimize the incidence of transfusion-transmission of the tick-borne disease known as Babesiosis in the United States, and developing improved animal models and biomarkers.

In vaccines, we are developing improved methods to predict safety and efficacy of novel adjuvants and vaccine delivery systems. We are also developing improved databases and biostatistical methods to assess relationship between immunogenicity and efficacy of vaccines.

In cellular and gene therapy products, we continue assessing the safety and efficacy of cellular and gene therapy products, developing new animal models to study safety and efficacy of neural stem cell transplants for use in regenerative medicine and facilitate development of more effective gene therapy for cancer, validating rapid sterility tests, developing methods to more rapidly and reliably predict cancer risk associated with certain types of gene therapy products, and developing improved virus detection methods in gene therapy products.

Additionally, we are developing testing standards for assessing biocompatibility of therapeutic nanomaterials, cancer biomarkers to support reproducible diagnostics for cancer, assays to develop better tools for diagnosing and treating asthma and allergies, and more precise tools to assess the quality of cell substrates used for the production of

cell and gene therapies, vaccines against infectious disease, and therapeutic cancer vaccines.

FACILITY INSPECTIONS

Mr. Kingston. How does the frequency of inspections at U.S. biologics facilities in 2007 compare to past years?

Answer. The frequency of inspections of domestic biologics establishments has remained consistent over the past five years, with FDA conducting inspections of such establishments approximately every two years. These establishments include all licensed establishments that manufacture biological products such as blood, plasma, vaccines, and certain biological devices such as IVDs for blood donor screening. I am happy to provide the following information on inspection frequency:

Frequency of Inspections of Domestic Biologics Establishments			
Year	**Statutory Inventory**	**Inspected**	**Frequency (in years)**
FY 2007	2,459	1,260	2.0
FY 2006	2,458	1,259	2.0
FY 2005	2,526	1,389	1.8
FY 2004	2,648	1,247	2.1
FY 2003	2,662	1,206	2.2

For human tissue, the number of inspections has increased each year. However, the number of registered establishments that manufacture or process human tissue has also increased. FDA uses a risk-based approach for annual prioritization of inspections of tissue establishments. The agency gives the highest priority to those tissue establishments that are subject to a compliance action, those for which the agency has received information indicating there is a potential violation, those whose operations are determined to be of the highest risk, and to those establishments which produce new products.

Mr. Kingston. Can you explain the make-up of Team Biologics?

Answer. Team Biologics, which began in 1997, is a partnership between CBER and the Office of Regulatory Affairs or ORA. Team Biologics has been highly successful in using the diverse skills and knowledge of both ORA and CBER staffs by focusing resources on inspectional and compliance issues in the biological drug and device areas. Team Biologics investigators from ORA and compliance officers from ORA and CBER are highly trained specialists in biological products and their regulation. Product specialists from CBER with expertise in specific processes and products often accompany the Team Biologics investigators during inspections and are always available as a resource.

Mr. Kingston. What happens if Team Biologics observes deficiencies when inspecting a foreign facility?

Answer. If during a foreign or domestic inspection, a Team Biologics investigator or product specialist observe deviations from current good manufacturing practice or other applicable regulations, these deviations are listed on a FDA Form 483 and presented to the firm at the conclusion of the inspection. Upon return to the office, the inspection team writes and submits an establishment inspection report to CBER for review.

For FY 2009, the Administration will seek new statutory authority to allow FDA to approve abbreviated applications for certain biologic products licensed under the Public Health Service Act (PHS Act). Currently, no abbreviated pathway for these products, commonly referred to as follow-on protein products, exists in the PHS Act.

The legislative proposal will include necessary provisions to ensure the safety and effectiveness of these biologic products for patients. The proposal will include a predictable and public guidance process for licensing follow-on protein products under the PHS Act. The proposal will prescribe the type of data required for FDA to review applications for follow-on protein products and will require labeling for the safety concerns related to the interchangeability of these products. In addition, the proposal will include adequate intellectual property protections to preserve continued robust research into new and innovative life-saving medications. The Budget proposes a new authority for FDA to approve follow-on protein products through a new regulatory pathway that protects patient safety, promotes innovation, and includes a financing structure to cover the costs of this activity through user fees.

In your question, you ask whether FDA would be sufficiently staffed to carry out the proposal for follow on proteins if the authorization proposed by FDA is signed into law. FDA expects that the proposed legislative proposal will be aligned with the FDA authority to collect fees under the Prescription Drug User Fee—PDUFA—Program. Therefore, FDA will receive PDUFA fees to support work related to applications for follow on proteins.

REGULATION OF BIOTECHNOLOGY PRODUCTS

Mr. Kingston. Biotechnology products frequently cross the conventional boundaries between biologics, drugs, and devices. How is the determination made to provide for the regulation of some products under CBER and some under CDER?

Answer. Two basic facts influence whether a biological product may be in CDER or CBER. First FDA determines if the biological is a single entity or part of a combination product. If the biological product is a single entity, then as of October 1, 2003 the jurisdiction is based on the following principles.

CDER now regulates biological products that are therapeutic proteins and polysaccharides including, ponoclonal antibodies for in vivo use; proteins intended for therapeutic use—including cytokines, enzymes, and other novel proteins—except for those that are specifically assigned to CBER; therapeutic proteins derived from plants, animals, or microorganisms, and recombinant versions of these products; immunomodulators such as proteins or peptides that are not antigen specific that are

intended to treat disease by inhibiting or modifying a pre-existing immune response; and proteins or peptides intended to act in antigen-specific fashion to treat or prevent autoimmune diseases by inhibiting or modifying pre-existing immune responses; and growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of cells in vivo.

CBER retained jurisdiction over biological products related to cells, genes, vaccines, and blood products such as cellular products or from physical parts of those cells such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines; gene therapy products; vaccines and vaccine-associated products; allergenic extracts used for the diagnosis and treatment of allergic diseases and allergen patch tests; antitoxins, antivenins, and venoms; blood, blood components, plasma derived products, including recombinant and transgenic versions of plasma derivatives, blood substitutes, plasma volume expanders, human or animal polyclonal antibody preparations including radio labeled or conjugated forms, and certain fibrinolytics such as plasma-derived plasmin, and red cell reagents; and human cells, tissues and cellular and tissue-based products also known as HCT/Ps.

If a biological product is part of a combination product, then under section 503(g) of the Federal Food, Drug, and Cosmetic Act, and clarified in August 2005 under 21 CFR Part 3, FDA must assign jurisdiction of a combination product based on its primary mode of action. In these instances, if the biological product is primary, then the appropriate center assignment is based on whether the type of biological product would be in CDER or CBER based on the above criteria.

More information can be obtained on the FDA website which address is as follows: http://www.fda.gov/oc/combination/transfer.htm

FDA PROPOSAL REGARDING APPROVAL OF "FOLLOW-ON" BIOLOGICS

Mr. Kingston. The FY 2009 budget for the FDA includes a plan to seek authority to allow the agency to approve abbreviated applications for certain biologic products, or follow-on biologics, also known as biosimilars, or biogenerics, and to finance such approvals through user fees. I understand that the administration is drafting a legislative proposal that will include the necessary provisions to ensure the safety and effectiveness of these biologic products for patients. When do you expect to complete this proposal?

Answer. Completion of a legslative proposal to approve abbreviated applications for certain biologic products, or follow-on biologics, will involve input from a number of interested parties. FDA welcomes the opportunity to ensure that discussions about follow-on biologics are informed by the most accurate and up-to-date science. Through DHHS, FDA stands ready to provide assistance in order to facilitate the legislative proposal.

Mr. Kingston. What is your plan for ensuring the safety and effectiveness of these biologic products?

Answer. FDA expects that any legislation would require manufacturers of follow-on biologics to meet the same high standards of licensure as innovator biological products. FDA plans to assure the safety and effectiveness of follow-on biologics by

including a legislative pathway that would permit FDA to rely, at least to some extent, on FDA's conclusions regarding the safety and effectiveness, or safety, purity, and potency, of an approved product, while also considering whatever additional data are necessary to determine that the follow-on product is safe, pure, and potent.

Mr. Kingston. Under your proposed budget, would FDA be sufficiently staffed to carry out the proposal if the authorizations is signed into law? OBFP ANSWER THAT OL AND OP ARE WORKING ON CLEARING AS OF 7.16.08.

Answer. For FY 2009, the Administration will seek new statutory authority to allow FDA to approve abbreviated applications for certain biologic products licensed under the Public Health Service Act (PHS Act). Currently, no abbreviated pathway for these products, commonly referred to as follow-on protein products, exists in the PHS Act.

The legislative proposal will include necessary provisions to ensure the safety and effectiveness of these biologic products for patients. The proposal will include a predictable and public guidance process for licensing follow-on protein products under the PHS Act. The proposal will prescribe the type of data required for FDA to review applications for follow-on protein products and will require labeling for the safety concerns related to the interchangeability of these products. In addition, the proposal will include adequate intellectual property protections to preserve continued robust research into new and innovative life-saving medications. The Budget proposes a new authority for FDA to approve follow-on protein products through a new regulatory pathway that protects patient safety, promotes innovation, and includes a financing structure to cover the costs of this activity through user fees.

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INSPECTION OF FIRMS THAT RECOVER HUMAN TISSUE

Mr. Kingston. In 2007 FDA conducted a "blitz" of 153 United States companies that recover human tissue. Will you elaborate on the findings of that effort?

Answer. While FDA identified some deviations from the regulations requiring correction, we did not see any major inaccuracies or deficiencies in records that could put tissue recipients at risk for transmission of relevant communicable disease agents or diseases.

The results of the blitz and other initiatives of the Human Tissue Task Force or HTTF are posted at the FDA website on the CBER page under tissues. Additional information specific to the blitz findings have been presented publicly a number of times, including to the Health and Human Services Advisory Committee on Blood Safety and Availability in August 2007.

The Human Tissue Task Force Report Summary is posted on the HHS website, on the Office of Public Health and Science webpage under blood safety presentations.

The presentation to the Health and Human Services Advisory Committee on Blood Safety and Availability provides additional information on practices of the recovery industry.

Mr. Kingston. Do you have any plans to conduct a similar "blitz" in 2008 or at some other point in the future?

Answer. Although FDA does not have immediate plans for a similar blitz, FDA will continue to use a risk-based approach for annual prioritization of inspections of tissue establishments with highest priority given to establishments that are under a compliance action, establishments where we have received information indicating there is a potential violation, establishments whose operations are determined to be highest risk, and establishments with new product types where we must evaluate and stratify product risk. Operations such as recovery and processing are generally seen as high-risk, resulting in more routine inspections of these facilities.

Although no major inaccuracies or deficiencies in records that could put tissue recipients at risk for transmission of relevant communicable disease agents or diseases were found during the inspection blitz, FDA remains vigilant and we have increased our surveillance activities in this area.

EMERGING SCIENCE

You state in your testimony that emerging science in the areas of bioinformatics, genetics, systems biology and nanotechnology make CBER's mission increasingly complex.

Mr. Kingston. How does CBER manage the challenge of employing the proper experts in the face of emerging science?

Answer. Emerging science presents challenges to CBER's ability to evaluate novel methods and products when we do not have adequate scientific expertise to understand the new technology and how it is being applied. CBER addresses these challenges by encouraging and providing resources for training opportunities to update the scientific expertise of existing staff and by obtaining scientific input from outside experts. We also obtain input through public discussions of novel scientific issues at FDA Advisory Committee meetings and workshops that bring together the appropriate scientific, medical, and regulatory expertise to discuss novel scientific issues. Such workshops often precede development of guidance documents to inform and educate both internal FDA review staff and sponsors of new policies and approaches in regulatory science.

Mr. Kingston. How does emerging science present challenges with respect to FDA's ability to evaluate the safety of these methods and the products they are used to develop?

Answer. CBER addresses these challenges through the scientific expertise of existing staff and by obtaining scientific input from outside experts. We also obtain input through a number of mechanisms such as public discussions of novel scientific issues at FDA Advisory Committee meetings that include scientific and medical experts from academia, industry, and patient representatives. Also, we participate in specific workshops that bring together the appropriate scientific, medical, and regulatory

expertise to discuss novel scientific issues; and that often precede development of guidance documents to inform and educate both internal FDA review staff and sponsors of new policies and approaches in regulatory science

EMERGENCY PREPAREDNESS

Mr. Kingston. You state in your testimony that you are strengthening your emergency response infrastructure in order to enhance the nation's preparedness for emerging disease threats. Can you give some examples of how the infrastructure has been strengthened and how you continue to strengthen it?

Answer. One example of the way CBER is working to enhance the nation's preparedness for emerging disease threats relates to its efforts to improve pandemic preparedness in several ways.

CBER is co-chairing an FDA-wide working group to develop a procedure for prioritizing critical activities during a pandemic that facilitate availability of FDA-regulated pandemic medical products. The procedure will likely include an algorithm or decision tree that can be implemented across the Agency, thus enabling a unified approach to ensuring that the products we regulate continue to be of high quality, safe, effective, and available. During this process, we will identify factors that limit our ability to prioritize and respond rapidly to pandemic needs and, to the extent possible, address those issues.

CBER will continue to improve the information technology infrastructure that plays a key role in our pandemic preparedness strategies. For example, all product offices within CBER have identified their essential pandemic influenza activities and personnel up to three tiers of redundancy to mitigate the effects of absenteeism during a pandemic outbreak. In addition, CBER continues to ensure that essential pandemic influenza personnel are equipped with sufficient IT equipment to enable them to work from remote locations. FDA has established a dedicated Pandemic Influenza web client server to accommodate increased teleworking from home for essential pandemic influenza personnel following implementation of social distancing or other non-pharmaceutical interventions as recommended by CDC. CBER continues to develop innovative methods to ensure efficient communications among a dispersed workforce during a pandemic.

CBER continues to collaborate with other government entities and industry to develop methods and infrastructure for assessing both seasonal and pandemic influenza vaccines. Among the programs included in this effort are pilot projects with Center for Disease Control and Prevention to expand the utility of the Vaccine Safety Data link for real-time or near real-time analysis, and ongoing collaborations with Centers for Medicare/Medicaid Services, Veterans Administration, and the Department of Defense to assess near real-time safety analysis.

Mr. Kingston. How does CBER help assure the availability of vaccines and other critical products should a pandemic flu threat arise?

Answer. CBER is proactively involved in facilitating the review and development of additional novel products including recombinant and cell based technologies and vaccines that employ adjuvants to stimulate an immune response. We also issued

guidance on developing seasonal and pandemic influenza vaccines, which included a description of an accelerated approval pathway. We also worked expeditiously to evaluate new vaccines and enhance manufacturing quality.

As a result, since 2004, we doubled the number of U.S. licensed manufacturers of flu vaccine from three to six and expanded vaccine production to a record of 132 million doses this year. We also recently expanded the age group of recipients of live attenuated influenza vaccine down to age two. These successes help provide the diversity of current and future vaccine supply and the manufacturing capacity to meet national public health and immunization goals and to save thousands of lives. Additional scientific and support staff, hired in multiple disciplines with pandemic funds, are now on board. The additional staff is available to review proposed vaccine studies, and licensing, and emergency use applications, to analyze product manufacturing and quality, and to establish new approaches to monitoring product safety. These professionals are working with our public health partners and manufacturers to develop globally coordinated and expedited approaches to vaccine production, to develop new molecular tools to evaluate these vaccines, and to initiate collaborative research projects. These projects include developing better, faster assays for vaccine potency and safety and new approaches and systems to use healthcare data to monitor vaccine safety. We also enhanced our critical infrastructure and ability to help sustain safe supplies of blood and tissue products during a pandemic or other emergency.

Mr. Kingston. In 2007, FDA approved the first vaccine in the United States for humans against the H5N1 avian influenza. Can you tell me the shelf life of this avian flu vaccine?

Answer. Based on the stability information submitted in the Biologic License Agreement, or BLA, the dating period for Influenza Virus Vaccine, H5N1 is 18 months from the date of manufacture of the final container vaccine. The date of manufacture is defined as the date on which this monovalent vaccine is filled. Thus, the 18-month shelf life includes the time that the product is held in filled final containers at 2-8°C prior to packaging.

Mr. Kingston. What does FDA do with vaccine materials after shelf life of the materials has expired?

Answer. Provided that the expiration date has not been extended in accordance with FDA regulations, FDA recommends that the expired vaccine not be used. FDA requires the companies that manufacture the vaccine to provide direction to the healthcare providers on how to appropriately dispose of expired vaccine.

Mr. Kingston. Can you describe for me the FDA's plan for delivering anti-virals were a pandemic outbreak to occur? Does each state currently have a supply at this time?

Answer. The Department of Health and Human Services (HHS) is stockpiling antivirals and allocating them to states based on population. Federal stockpiles of influenza antivirals are stored and maintained by the Centers for Disease Control and Prevention's, or CDC, Strategic National Stockpile. Plans for deployment of these

stockpiles of antivirals reside with CDC. Delivery of stockpiled medical products falls outside of the scope of FDA's mission and FDA would defer to the plan developed by CDC. In addition, states have the option of purchasing federally subsidized antiviral treatment courses. HHS would be able to provide additional information on both federal and state stockpiles of antivirals.

Mr. Kingston. On a regional basis, are there enough trained personnel to administer the vaccine? Is that a part of the infrastructure you reference in your written testimony?

Answer. Ensuring that there are sufficiently trained personnel to administer vaccines in an emergency falls generally under the purview of the Centers for Disease Control and Prevention, not the FDA.

QUESTIONS SUBMITTED BY REPRESENTATIVE LATHAM

PANDEMIC INFLUENZA

Mr. Latham. GAO has criticized both the 'Strategy' AND the 'Plan' that have been put forth to address the potential for a pandemic influenza. The national Strategy was put forth in November of 2005, while the implementation plan was put forth in May of 2006. GAO says that neither addresses resources, investments and risk management associated with a pandemic. What part of the criticism, if any, was aimed at your role in the preparedness efforts? Secondly, what improvements have been made within your Center to improve your role in pandemic preparedness efforts?

Answer. The criticism that may have been aimed at our role in the preparedness efforts stems in part from a need to increase vaccine production capabilities because current capabilities are limited. CBER carries major responsibility for ensuring the United States is prepared for pandemics. CBER is fulfilling this responsibility by encouraging industry to increase production capacity for safe and effective seasonal influenza vaccines through collaborative interactions with industry, supporting Critical Path research activities, and by collaborating with international health agencies, industry, and government and academic research laboratories on pandemic vaccine research and product development strategies.

CBER is enhancing preparedness programs and developing new innovative programs. This includes programs designed to expedite review and approval of biologics aimed at protecting populations from pandemics.

CBER is co-chairing an FDA-wide working group to develop a procedure for prioritizing critical activities during a pandemic that facilitate availability of FDA-regulated pandemic medical products. The procedure will likely include an algorithm-decision tree that can be implemented across FDA, thus enabling a unified approach to ensuring that the products we regulate continue to be of high quality, safe, effective, and available. As part of this process, we will identify factors that could limit our ability to prioritize and respond rapidly to pandemic needs and, to the extent possible, address those issues.

CBER continues to improve the information technology infrastructure that plays a key role in our pandemic preparedness strategies. For example, all product offices within CBER have identified their essential pandemic influenza activities and personnel

for up to three tiers of redundancy in order to mitigate the effects of absenteeism during a pandemic outbreak. In addition, CBER continues to ensure that essential pandemic influenza personnel are equipped with sufficient IT equipment to enable them to work from remote locations. A key element of this strategy has been establishing a dedicated Pandemic Influenza web client server to accommodate increased telecommuting from home for essential pandemic influenza personnel following implementation of social distancing and other non-pharmaceutical interventions.

In the area of biologics evaluation, CBER continues to collaborate with other government entities and industry to develop methods and infrastructure for assessing both seasonal and pandemic influenza vaccines. Among the programs included in this effort are pilot projects with Centers for Disease Control and Prevention to expand the utility of the Vaccine Safety Data link for real-time or near real-time analysis, and ongoing collaborations with Centers for Medicare and Medicaid Services, Veterans Administration, and the Department of Defense to assess near real-time safety analysis.

CBER is also continuing efforts to develop and improve in-house capabilities for expediting vaccine availability. Our capability to generate reverse-genetics derived reassortants of potential pandemic influenza strains that can be used as reference strains in commercial-scale production will facilitate production and, ultimately, timely availability of an adequately matched vaccine during a pandemic. Our efforts to increase capacity to generate various reagents, including the ability to produce purified antigen for generation of potency reagents will also expedite lot release. Additionally, CBER is assessing alternative methods for improving sensitivity, specificity, robustness, and rapidity of various lot release testing, as well as for measuring vaccine immune responses.

CBER is also working to improve FDA's responsiveness to pandemics through collaborations with industry, as well as with the Health and Human Services, the Biomedical Advanced Research and Development Authority, and our sister agencies: the National Institute for Allergies and Infectious Diseases and the CDC.

CBER is encouraging industry to include in their submissions for regulatory review during the pre-pandemic period any clinical data that may support emergency use of unlicensed pandemic products in the United States vaccine stockpile. Such data would improve our response time to an Emergency Use Authorization or EUA request during a declared emergency.

CBER encourages industry to pursue licensure of seasonal influenza vaccines in order to ensure there is an adequate surge capacity for influenza vaccine manufacturing if needed. By doing so, this may also speed the production and availability of pandemic vaccines during a pandemic.

BLOOD SUPPLY

Mr. Latham. Over the years, there have been various scares in the media about tainted blood supplies. From your perspective, what is the biggest threat to the blood supplies throughout the country, and what steps remain to be taken, if any, to ensure a healthy blood supply?

Answer. Although major efforts are ongoing to address recognized, but uncommon risks to blood safety, the biggest threat to blood safety remains the potential for newly

emerging infectious diseases. This threat arises from the increasingly interdependent world in which we live, as well as from man-made and natural environmental changes that have created new opportunities for pathogens and vectors to affect human populations. Infectious disease threats such as West Nile virus, malaria, chikungunya virus, dengue viruses, and globally arising variants of hepatitis viruses and HIV can directly or indirectly threaten our population as people travel abroad and as disease agents become established domestically. We address these threats through collaborations with CDC and with international groups including WHO to scan the horizon for emerging infectious agents that may pose a threat to the blood supply. For many known agents, we have developed donor deferral criteria and approved donor screening tests resulting in a major improvement in blood safety.

Pathogen inactivation holds the potential promise of protecting blood not only from many known agents but also from emerging agents. However, FDA must balance potential harm from the pathogen inactivation process with the benefit of reducing the risk of infectious disease transmission. It is important that the process for inactivating the infectious agent not harm the blood component. Because some infectious agents are very resistant to inactivation, it is unlikely that there will be a single pathogen inactivation method for all infectious agents. Nevertheless, there are currently candidate procedures for pathogen inactivation of certain blood components, such as platelets. In 2002, FDA discussed some of these products at a public workshop called Safety and Efficacy of Methods for Reducing Pathogens in Cellular Blood Products Used in Transfusion and, in 2008, in the context of bacterial inactivation of platelets at the Advisory Committee on Blood Safety and Availability. Further research and development may be needed to facilitate development of novel methods of pathogen inactivation. In particular, no promising candidate technology yet exists for pathogen reduction in red blood cells, and advancement in that area would require a significant investment.

BIOLOGICS

Mr. Latham. From an evaluation perspective, what is the primary concern of your office in reviewing bio-technology products, versus traditional drugs made through chemistry?

Answer. There are a variety of biological products, with both therapeutic and prophylactic indications, manufactured using bio-technology. In contrast to many chemically-synthesized drugs, it is substantially more challenging and more resource intensive to evaluate the available knowledge and identify the benefits and risks of bio-technology products. This challenge results from several factors including: novel technologies, limited product experience, continuall y evolving scientific knowledge base, and the inherent complexity and variability of biologics which lead to multiple issues such as characterizing the product and assuring appropriate manufacturing controls.

Mr. Latham. Do you need additional authorities to help you in making decisions about biologics, particularly with respect to innovations that may come about in the future in this field?

Answer. FDA is constantly evaluating innovative products and technologies. We have no recommendations for additional authorities at this time. We will continue to evaluate whether there is a need for additional authorities to achieve our mission. We will work within the Administration to report to Congress when a need for new authorities arises.

WEDNESDAY, FEBRUARY 27, 2008.

CENTER FOR DRUG EVALUATION AND RESEARCH

WITNESSES

JANET WOODCOCK, M.D., DEPUTY COMMISSIONER FOR SCIENTIFIC AND MEDICAL PROGRAMS, CHIEF MEDICAL OFFICER, AND ACTING DIRECTOR OF FDA'S CENTER FOR DRUG EVALUATION AND RESEARCH

DAVID J. HOROWITZ, ESQ., DEPUTY ASSOCIATE COMMISSIONER FOR COMPLIANCE POLICY, FDA OFFICE OF REGULATORY AFFAIRS

Ms. DELAURO. The committee is called to order.

Good morning, and thank you very, very much, and let me welcome all of you here today.

I will make some more formal introductions in a second, but I particularly want to say thank you to all of our panelists this morning for their participation.

This is an important hearing, the first hearing on drug safety that this committee has convened in 25 years, so I am eager to get started.

A little over 100 years ago, Congress passed the Pure Food and Drug Act with President Theodore Roosevelt.

Congress passed this landmark legislation to protect the American people from adulterated and sham drugs and unsanitary and dangerous drugs.

In the newspapers today, there are daily stories about unsafe food and unsafe prescription drugs. It's easy to wonder if we have gone back in time to 1906.

We recently discovered that the widely used blood thinner Heparin, under investigation after hundreds of allergic reactions and four deaths among the drug's users, includes an ingredient from a Chinese facility that had not been inspected by the FDA.

What is even more startling is that apparently the FDA inspected the wrong Chinese factory and the wrong firm was entered into the FDA's database.

Cases like this, or controversies surrounding Evandia, Vioxx, Trazalone and beyond are embarrassing, but more than that, in my view, they offer a window into the FDA's myriad failures under the current administration, it's work motivated by ideology compounded by incompetence and negligence and a lack of regard for the health and safety of the American public.

To restore the agency's gold standard in that mission and to ensure the fundamental safety of the drugs that it regulates, I'm guided by four principles.

First, we must increase funding to support the FDA's mission.

Second, we must improve the management of the agency and hold it accountable.

Third, we must push back against the influence of big pharma over the agency.

And finally, and perhaps most importantly, we must let the scientists do their work, guided by science and not by political interference.

The FDA has been starved for resources under seven years of this administration. FDA managers point to a lack of resources as a reason for not carrying out their appointed duties.

The administration is taking the bargain basement approach, then using it as an excuse for its poor performance. We can do better.

Since 2006, despite overall spending limitations imposed by the administration, this committee and Congress have increased the FDA's total budget by more than $227,000,000.

Last year, our subcommittee increased funding for drug safety and other important FDA functions. This marks the beginning of an effort to rebuild the agency's capacity to protect the American public.

But increased funding is only part of the challenge. Funds alone cannot fix an agency that routinely fails at its most basic responsibilities, keeping track of clinical trial, preventing conflicts of interest, following up on critical investigations.

Sixty-five percent of post-market studies on new medications have not yet begun. This startling fact makes it clear what a long way that we have to go.

Considering the agency's record when it comes to its own drug databases, schedules, and reform, I am skeptical of the FDA's newly proposed initiatives to turn things around.

I look forward to hearing more about your plans for implementation and specific funding needs going forward.

Ultimately, better management and resources must go toward supporting independent science in the service of the agency's most important regulatory mission, and that is protecting public health.

Yet in recent years, surveys consistently show that FDA scientists overwhelmingly complain about interference from top level FDA appointees on behalf of corporate and political interests. They feel that factors other than good science play a role in important FDA decisions.

And that may be why too many good scientists continue to leave the agency at a time when we should be trying to attract them and support their work.

We can no longer accept federal agencies tasked to protect the public health that seem only interested in protecting business from embarrassment or cost.

My thanks again to our panelists for being here today. I look forward to hearing from you in addressing these tough issues.

Government has an obligation to its citizens to check private abuse and set standards in the public interest.

I said it before and I believe it bears repeating.

Our commitment to reform requires more resources and better management, less influence from the drug companies, and more influence for independent scientists.

With the public health at stake, nothing, nothing could be more fundamental.

Let me welcome my colleague, our ranking member, Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chair. I have no opening statement.

INTRODUCTION OF WITNESSES

Ms. DELAURO. I want to get the appropriate introductions so people know how credentialed our folks are today.

Our first panel would be Dr. Janet Woodcock, deputy commissioner and the chief medical officer at the FDA, the Food and Drug Administration.

She shares responsibility and collaborates with the commissioner in planning, organizing, directing, staffing, coordinating, controlling, and evaluating the agency's scientific and medical regulatory activities in order to achieve that mission of the FDA.

She most recently served as the deputy commissioner for operations and chief operating officer, FDA, where she was responsible for overseeing agency operations and cross-cutting regulatory and scientific processes at the FDA.

Given her history and the many years of service at the FDA, I believe no one is more prepared to answer our questions on the issue of drug safety than Dr. Woodcock.

She's accompanied this morning by David Horowitz, who is deputy associate commissioner for compliance policy in the FDA's Office of Regulatory Affairs, ORA.

Dr. Woodcock, if you would begin, and, you know, your testimony, and obviously, the entire testimony will be included in the record, and you may give the testimony or summarize in any way you care to.

Dr. WOODCOCK. Thank you. Good morning.

Thank you, Chairman DeLauro, Congressman Kingston, and members of the subcommittee.

I'm Janet Woodcock, deputy commissioner and chief medical officer at the FDA.

I'm also currently acting director of the Center for Drug Evaluation and Research.

I'm here to discuss the budget of FDA's human drugs program as it relates to drug safety.

Joining me for today's hearing is David Horowitz, who is deputy associate commissioner for compliance policy in FDA's Office of Regulatory Affairs.

I'd like to start by thanking this committee for the important increases for the drug program in the fiscal year 2008 budget.

The appropriation contained a $21,000,000 increase for drug safety activities. I believe that's the largest increase for drug safety that we have ever seen.

It included a $10,000,000 increase for CDER's officer surveillance in epidemiology, as well as included $4,000,000 for review of direct consumer advertising.

$6,000,000 was also provided to expand the generic drug review program to meet its markedly increased workload.

And, there was increased funding to meet drug payroll obligations.

Finally, there was an increase of $7.5 million for FDA's critical path initiative that was allocated among the medical product centers and central critical path program.

And I would like to explain how this year's funding is being used to improve drug safety in the United States.

CRITICAL PATH

First, the critical path initiative is improving the science of the drug development process.

For example, FDA has reviewed, along with the European Medicines Evaluation Agency, a new set of kidney safety markers.

These markers, which have now been evaluated in animal tests, will now move to human tests.

It is expected that we'll get a much earlier warning system for drug-induced kidney damage emerging from this program.

There is also vigorous work going on in the area of genetic predictors of drug-induced toxicity.

An increasing number of cases, testing for individual differences—what's different between you and me—will help us to predict, and therefore prevent, drug side effects in individuals who are at risk for them.

In another example, center scientists are working on creating a quantitative model of Parkinson's Disease that can be used to design better clinical trials.

As you know, Parkinson's Disease is one of the many diseases that patients in this country have that really doesn't have acceptable effective treatments for the long term.

So the critical path initiative is beginning to make real contributions to better drug development. That's the development side.

SAFETY FIRST

We also need to make major steps to improve the safety of drugs that are already on the market.

Using the new funding provided this year, we've launched a new initiative called Safety First.

This incorporates the recommendations of GAO and the Institute of Medicine, as well as implantation of the new authorities and safety procedures that we received under the FDA Amendments Act.

Under Safety First, safety issues for marketed drugs will be our number one priority.

We are instituting extensive tracking and project management procedures to make sure we stay on top of these problems.

We're appointing senior physicians, whose only job will be to manage these safety issues in each disease area.

We're making sure that the opinions and the voices of all reviewers and scientists are heard, and I'm happy to go into detail about how we're doing that, and we're strengthening the roles and responsibilities of the Office of Surveillance and Epidemiology.

As we put these programs in place, we're also going to be looking externally to form partnerships with parts of the health care system to collaborate on ways to make medication use safer, because medications are used out in the health care system, and we need

to work with those individuals and systems to improve medication use.

We will build a sentinel network, which is a new type of pharmacovigilance system that will link emerging electronic databases that are emerging out in health care in partnership with health care systems in academia to better track adverse events and drug performance.

Despite these advances, drug regulation has many challenges. The foundation of our efforts is drug quality. Without quality of drugs, safety and efficacy cannot be maintained.

Maintaining quality in a globalized environment where drug manufacturing and clinical trials are increasingly done outside the United States is an ongoing and still growing problem for the drug regulatory program.

Without the foundation of quality, drug safety and effectiveness cannot be maintained.

I would be pleased to discuss this challenge in particular with the subcommittee and answer any of your questions.

Thank you.

[The information follows:]

Statement of

Janet Woodcock, M.D.

Deputy Commissioner for Scientific and Medical Programs,

Chief Medical Officer, and

Acting Director of FDA's Center for Drug Evaluation and Research

Food and Drug Administration

before the

House Agriculture, Rural Development, Food and Drug

Administration,

and Related Agencies Appropriations Subcommittee

February 27, 2008

Chairwoman DeLauro, Congressman Kingston, and members of the Subcommittee, I am Janet Woodcock, M.D., Deputy Commissioner of the Food and Drug Administration (FDA). I am here to discuss the mission of FDA's Center for Drug Evaluation and Research (CDER) and FDA's budget for evaluating the safety and effectiveness of drugs. Joining me for today's hearings is David Horowitz, Deputy Associate Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs (ORA).

Funding for the FDA Human Drugs Program

The FY 2008 appropriation contains important increases of $21 million for drug safety (including $10 million for the Office of Surveillance and Epidemiology, or OSE), $7.5 million for the Critical Path program, $6 million for generic drug review, $4 million for the review of direct-to-consumer advertising, and increased funding to meet Drug Program payroll obligations. As you know, these amounts are all subject to the FY 2008 across-the-board rescission. Thank you for your strong support for FDA efforts to achieve its public health mission related to drug safety and development.

The President's budget proposes an FY 2009 total program level of $739 million for the Human Drugs Program. This includes a $5 million increase in budget authority and an increase of $54 million in fees under the Prescription Drug User Fees Act (PDUFA) and the proposed Generic Drug User Fee Program. The PDUFA fee increase supports FDA's ability to achieve the drug review, drug safety, drug development, and related priorities authorized by Congress in the Food and Drug Administration Amendments Act of 2007. The PDUFA fee increase also allows FDA to improve information

technology to support human drug review. The new Generic Drug User Fee Program will allow FDA to improve generic drug review performance and allow Americans to enjoy greater benefits from generic alternatives. The FY 2009 increase in budget authority funds the annual pay increase for Human Drugs Program employees and allows ORA field operations to improve the safety of imported drugs by increasing import investigations related to counterfeit drugs and other areas of criminal drug activity.

The Value of Drug Regulation

Prescription and over-the-counter drugs are an increasingly critical component in improving the health of Americans. New drugs – and new uses for older drugs – save lives, reduce suffering, and improve the quality of life for millions of Americans. While drugs account for an ever-increasing fraction of the rapidly rising cost of healthcare, innovative new medicines play a significant role in increasing life expectancy in the United States and around the world. Medicines also prevent or slow the progress of many diseases and avoid costly invasive treatments, hospitalizations, and nursing home stays. However, the more widespread use of medications also has had negative consequences. Harm from inherent side effects, misuse, overuse, medication mix-ups, and intentional abuse of drugs has increased. These problems must be vigorously monitored and mitigated.

Thus, FDA responsibilities for oversight of the entire life-cycle of drugs – from pre-market drug testing and development through drug approval, post-market surveillance, and risk management – have never been more important. FDA's

mission is to ensure that safe and effective new drugs are available as quickly as possible and that drugs already marketed remain safe and of the highest quality. We at FDA must continuously adapt to provide a pathway for translating new scientific advances into benefits for patients and to take advantage of new ways to monitor the performance of marketed drugs.

Ensuring the safety of drugs from their earliest introduction into humans during clinical trials and throughout the period when an FDA-approved drug is marketed is a cornerstone of FDA's mission. CDER dedicates at least half of its pre-market review activities to evaluating the safety of investigational drugs and overseeing the safety of clinical trial participants. ORA supports the premarket drug review process by inspecting clinical trials. CDER is in the process of improving its ability to evaluate post-market drug safety and to implement risk management steps.

Drug safety relies on a foundation of drug quality. Improperly manufactured drugs and drugs that are contaminated or illegally marketed can cause significant harm to patients. For this reason, FDA devotes considerable effort to reviewing and monitoring drug manufacturing activities. FDA's ORA field operations conduct risk-based domestic and foreign inspections of drug manufacturers, and ORA monitors drug imports.

Globalization

FDA increasingly faces challenges due to globalization of drug development and manufacturing. Not long ago, most drugs were developed, studied, and manufactured in the United States. Today we routinely review and monitor drugs – both innovator and generic – that are studied or manufactured, at least in part, outside the United States. The supply chain for finished drugs and active drug ingredients now frequently links to manufacturing sites in countries such as China and India. With the globalization of the supply chain, FDA faces an ever-growing number of brokers, traders, distributors, repackagers, and other players involved in the import of pharmaceuticals. The changing world – including the fundamental challenges of many different languages and protocols – requires FDA to devise and evaluate more complex risk scenarios and apply more sophisticated technologies to screen and evaluate drugs entering the United States to ensure their quality.

Our generic drug program illustrates the dramatic changes during the last 10-15 years. Since 1992, we witnessed a 400 percent increase in the number of foreign establishments named in generic drug marketing applications. Today, in India alone, there are nearly 25 times as many drug establishments as there were eight years ago (867 compared to 37). Growth in FDA's capacity to inspect generic drug manufacturing facilities has not been commensurate with this global expansion. FDA's FY 2009 budget proposal for Generic Drug User Fees will assist FDA to respond to some of these challenges. Yet FDA must be able to determine that facilities named in drug applications will meet FDA standards for marketed drug safety, effectiveness, and quality, no matter where they are located.

Another trend we face is the geographical dispersion of clinical trials. Traditionally, industry-sponsored clinical trials were conducted in North America and Western Europe. Today, however, clinical trials in foreign countries are much more common. Clinicaltrials.gov contains data on a recent set of 36,000 clinical trial descriptions where studies were conducted (in whole or in part) in more than 140 countries.

Recent Activities in Drug Safety

Increased attention to safety issues within FDA and growing concern from consumer advocates, health professionals, academic researchers, the media, and Congress prompted FDA to reassess its efforts to ensure that its drug safety program is the best possible.

During the past decade, CDER launched a number of important steps to modernize the drug regulatory system. These steps include:

- Drug Quality for the 21st Century, a quality systems approach to assure Current Good Manufacturing Practices (cGMPs) and other aspects of drug quality
- the Unapproved Drugs Initiative, to make sure that marketed prescription and over-the-counter drugs have been shown to be safe and effective
- the Generic Initiative for Value and Efficiency, to help FDA modernize and streamline the generic drug approval process.

Also during the past decade, perhaps the most notable shift in drug regulation resulted from PDUFA, which brought unprecedented accountability to the new drug review.

PDUFA also institutionalized project management, prioritization, and tracking for drug review.

CDER is also transforming its post-market drug safety program. CDER is accomplishing this transformation with extensive input from our many stakeholders and with advice from many drug experts – including the 2006 study on drug safety by the Institute of Medicine (IOM) sponsored by this subcommittee. CDER is also drawing on lessons learned from previous regulatory modernization initiatives to transform drug safety.

In response to the 2006 IOM report, CDER entered into a contract with the Center for Professional Development to foster a truly collaborative, multidisciplinary, team-based approach to drug safety within the center. CDER is committed to improving workplace leadership, empowering staff, and establishing more effective business practices. The goal is to create a sustainable environment of open and transparent communication, collaborative decision-making, and improved morale and staff retention.

I want to highlight other recent FDA initiatives to improve drug safety through new science, product quality, and institutional change.

FDAAA Drug Safety Improvements: The Food and Drug Amendments Act (FDAAA), a sweeping new act of Congress signed by the President in September 2007, acknowledges FDA's critical role in assuring the safe and appropriate use of drugs after

they are marketed. FDAAA gives FDA substantial new resources for medical product safety and new regulatory tools and authorities to ensure the safe and appropriate use of drugs.

FDAAA directs FDA to shift its regulatory paradigm. With the goal of maintaining a systematic and scientific approach to evaluating benefit versus risk throughout the drug life-cycle, FDA must build the scientific and administrative capacity as an active and collaborative player in the delivery of safe and effective drugs to patients.

Strengthening Science: FDA is working to strengthen the science that supports drug safety at every stage of the drug life-cycle, from pre-market drug testing and development through post-market surveillance and risk management. With the evolution of science underpinning drug development, the focus on empiric data derived from randomized clinical trials has expanded to include, for example, biomarkers and pharmacogenomics, which help maximize the safe and effective use of drugs in individual patients. New scientific methods and tools are emerging to target a specific drug to specific patients where the benefits relative to risks are maximized. A primary objective is to prevent adverse events by predicting drug safety problems before they can cause injury. The goal is to combine new understandings of disease and its origins at the molecular level (including adverse events resulting from treatment) with emerging knowledge about the unique genetic and biologic features of an individual patient that determines how the patient will respond to treatment. If successful, these innovative, efficient, and risk-based drug development processes will improve FDA's ability to detect safety-related problems

earlier. In addition, FDA is currently exploring, testing, and developing new methods of signal detection, data mining, and analysis of patient-level electronic health care data. These new methods will complement our existing passive post-market surveillance system by generating hypotheses about and confirming the existence and cause of safety problems. FDA operates strong safeguards to ensure the security of safety data and to protect the privacy of patients.

International Quality: During the past decade, FDA has been keenly aware of the globalization trend. To respond proactively to this global challenge, FDA developed a variety of solutions. FDA requires facilities that manufacture drugs for the U.S. market to meet FDA's current good manufacturing practice (cGMP) requirements. FDA conducted 498 foreign pre-approval, cGMP, and bioresearch monitoring inspections during FY 2007, an increase of 45 percent from the previous year. We will soon begin implementing an electronic system for accepting and processing drug establishment registration and listing. Electronic registration and listing will provide FDA with a more accurate and thorough accounting of drug manufacturing firms and locations. FDA entered into a number of cooperative relationships with foreign regulators, ranging from cooperation under a Free Trade Agreement, to agency-to-agency Memoranda of Understanding, to more informal arrangements to advance drug quality.

Improving Communications: FDA is continuing work to encourage greater transparency and to ensure that patients and healthcare providers have access to emerging new safety information and the most up-to-date and complete information

necessary to inform their treatment decisions. In September, 2007, FDA released the first issue of a new Drug Safety newsletter. The newsletter, to be published online quarterly, provides information for healthcare professionals about the findings of selected post-marketing drug safety reviews, important emerging drug safety issues, and recently approved new drugs.

On November 5, 2007, FDA announced the selection of 15 voting members to serve on its Risk Communication Advisory Committee. The Committee will advise FDA about how best to communicate to the public about the risks and benefits of all FDA-regulated products to promote their optimal use. The first meeting of the Risk Communication Advisory Committee is scheduled for February 28, 2008.

Strengthening Drug Safety Operations and Management: CDER is taking steps to rebalance the Center's efforts and resources devoted to drug development and post-market drug safety. The goal is to recalibrate the focus on pre-market review and post-market safety and align our policies and processes to ensure that the most appropriate and best-qualified experts lead or have a strong voice in regulatory decisions. CDER is establishing positions in each review division in the Office of New Drugs (OND) devoted to managing pre- and post-market drug safety issues, including a Deputy Director for Safety and a Safety Regulatory Project Manager. We are establishing new roles and responsibilities for staff in the OSE, including delegating authority to OSE for certain regulatory actions, such as review of proprietary names, medication errors, and observational epidemiologic studies. In addition, CDER is also taking steps to provide a focus, intensity of tracking,

deadlines, and accountability for post-market safety activities that equals our focus and performance on pre-market safety, efficacy, and quality review.

Conclusion

FDA has a strong safety record and remains the world's gold standard for drug approval and safety. No drug is absolutely safe. FDA approves drugs only after the drug sponsor demonstrates that a drug's benefits outweigh its risks for a specific population and a specific use, and that the drug meets the statutory standard for safety and efficacy.

When we talk about drug safety, we are really talking about working to ensure a favorable benefit-to-risk balance and ensuring that health care providers and patients have access to up-to-date information about the benefits and risks of drugs so that they can make the best individual treatment decisions. Recent FDA initiatives to balance FDA pre-market review and post-market safety efforts and maintain a systematic and scientific approach to a drug's benefit-to-risk balance throughout the drug life-cycle are evidence of our commitment to the health and safety of patients who use FDA-approved drugs.

Thank you for allowing me to testify. I am happy to respond to your questions.

Ms. DELAURO. Thank you very much, Dr. Woodcock.

Let me just note, the first information that we've had about this Safety First initiative arrived, I believe, last night about 8:30 p.m., so we obviously will take a look and see what we have.

But I must be honest. I would have thought Safety First was, you know, a standard that was set all along, and not something that we now are trying to engage in. Above all, it is about public health, public safety.

With that, let me just ask some questions.

CENTER FOR DRUG EVALUATION AND RESEARCH

Since 2001, the Congress provided more than $2.3 billion for CDER under the acting director, not counting user fees.

It has 62 percent more in taxpayer dollars to spend this year than it had in 2001, more than three times the rate of inflation in that period.

Congress also provided more than the president requested for CDER during the period.

We should have a lot to show for the money, but in my estimation, we don't.

There should have been a series of—there have been a series of GAO IG reports that have highlighted fundamental, and I mean really fundamental problems, with basic systems at CDER that are the foundation for its work.

I'll be looking at the FDA followup on its promises to the GAO and the IG to fix things.

But today I want to know how these things got so bad and did not get a fix until someone else pointed them out.

Unless we have an answer to that question, I'll be very honest with you.

I don't have any confidence that giving CDER more money is going to solve the problems that we have.

FOREIGN DRUG ESTABLISHMENTS

So let me ask you, first, foreign drug establishments. GAO said last fall, FDA does not know how many foreign drug establishments are subject to inspections.

Instead, FDA relies on information from several databases that were not designed for this purpose.

The range of FDA's estimate of the number of firms is between 3,000 and 6,700.

Worse yet, these problems were identified by the GAO 10 years ago, and they were not fixed.

Now, I've got the March 1998 improvements needed in the foreign drug inspection program, 10 years ago.

Why did FDA create three different databases that don't talk to each other, that serve different purposes, and that are all flawed?

Somebody should jot the questions down, because I want answers to these questions, but I'm going to go through, because I don't want the time to expire here, and then we can't get the answers.

Second, official list of drugs.

OFFICIAL LIST OF DRUGS

In August 2006, the HHS inspector general found a huge problem in FDA's official list of approved drug products.

There were 123,856 drugs listed. The IG found that 9,100 or almost 9,200 products were missing and 34,000 products were listed erroneously.

IG found exactly the same problems 15 years earlier in a 1991 report, and they are still not fixed.

How can an agency that regulates drugs not have an accurate list of drugs it has approved and how could it go for 15 years without having fixed the problem?

Third, post-marketing study.

POST-MARKETING STUDY

June 2006 IG report, building on problems found in the 1996 report, found that, one, FDA cannot readily identify whether or how timely post-marketing study commitments are progressing toward completion.

About one-third of the annual status reports on the commitments that drug companies are required to submit were missing or incomplete. FDA lacks an effective management information system for monitoring post-marketing study commitments.

This may be why 66 percent of CDER reviewers told the IG in 2003 that they were only somewhat confident or not confident at all that FDA does an adequate job of monitoring the safety of drugs after they go on the market. The nonprofit had the same results.

When you put of safety issues to a post-market study commitment, you better be able to assure that they get done, which obviously, they're not able to be done.

Why did you allow problems with tracking post-market study commitments to fester so long when they are so critical and a growing part of the post-market drug market?

Final point. Clinical trials.

CLINICAL TRIALS

IG reported last September that the FDA has no idea how many clinical drug trials were going on.

IG found that FDA has inspected only about 1 percent of all clinical trial sites between 2000 and 2005.

Some of the same problems were found by the IG in previous reports but have not been corrected.

How can you regulate clinical trials without a complete list of them?

So if we can start from the top, I would appreciate answers about the databases, foreign drug establishments, et cetera.

Dr. WOODCOCK. Right. Certainly.

And I certainly understand your position on all these matters, and your statements reflect my frustration over the years in having to deal with these issues. It is extremely difficult for FDA staff.

Let me just quote the recent report, and I will go through each of your issues, from the Science Board Subcommittee that reviewed the FDA science and IT capacity, what they say.

"The FDA lacks the information science capability and information infrastructure to fulfill its regulatory mandate."

They also said, "FDA's current information supply chains are inefficient, cost-intensive, and prone to promote errors."

And they go on:

"Consequently, the FDA's ability to support regulatory activities is compromised."

This is from a large group of scientists that we invited in——

Ms. DELAURO. I've read the report.

Dr. WOODCOCK. The IT group. We provided them a lot of information about all the challenges that we face.

So let me move to first the databases.

When I was head of CDER a while ago, I was head of it during the 1990s, I made the ES database, which is one of these databases.

Before that, the inspections were ordered up on paper, and paper was shuffled around to different offices, and naturally then we didn't have any real IT record.

That system I built with I think $30,000 that I was able to scrape together, and unfortunately, we're still running on it.

It doesn't talk very well to the other systems, because it requires investment, requires substantial investments to upgrade all the systems into an integrated system.

A year or so ago, I helped with others form the bioinformatics board at the FDA. We have developed a whole plan of how you would create modernized IT systems to support the regulatory processes at FDA.

The bioinformatics board said the number one priority is to get a single inventory of establishments that make drugs and other FDA regulated products for the agency, not multiple inventories.

The data problems you're talking about, is it 3,000, is it 6,000, comes from the fact that the import system that we have, to use an IT term, corrupts the database by adding duplicate entries that have small differences, if you follow me, and we need a system that refers back to a central inventory.

We have lacked certain authorities in these areas. They have partly been corrected by the FDA Amendments Act.

So the reason—but to answer your first question, the reason we don't have—the reason we have three databases is we have not been able to make the investment in building modern information technology platform, not to support the science, we're not even talking about the science here, support our regulatory activities for drugs.

Okay.

Number two. What about electronic—what about listing?

OFFICIAL LIST OF DRUGS

We have an outdated listing—drug registration and listing system. We are in the process of changing that.

The FDA Amendments Act called for electronic registration and listing, and that is a tremendous help for us, because now we don't have to go through regulations to get that done, although we are doing it.

The current system allows the manufacturers to set their own codes.

It gives them a master code and then they can add codes to it. That way, they can add numerous items to our database that are not approved drugs.

The new system that we're building, the regulation we'll put through and so forth, will address this particular problem.

We do have to have a master list of approved drugs in the United States. We have to know who they are. CMS has to know who they are. The public has to know who they are. All right?

Should I keep going?

Ms. DELAURO. Well, I want you to move quickly, because on your first issue, you know, the requests that have come up here, it would appear that what we're doing is continuing to talk about the resources.

We gave you money. We gave you money to deal with these issues.

We gave you what you requested, and more than an administrations have requested.

I don't know what you've been doing with the money. You can't take care of basic functions, and you come up here this morning and talk about the critical path and new science and all this.

You know, I believe in the research. You can't deal at this agency with basic functions with the money that we have provided.

What have you been doing here the last 10 to 15 years, if it's all going to hell in a handbasket?

And you're not saying anything to anyone, you're not crying out loud that you've got these problems, and you as the Congress have got to address them, that this is the first time at 8:30 last night we get a Safety First document that you're going to concentrate on safety first?

I mean, I don't know what you've been doing for all of these years in these positions that you have, and you had to wait for these new amendments to be able to do what your job is necessary to do, and that is extremely frustrating, when you talk about frustration.

Because all this agency ever does is to cry about resources. All it does is cry about resources.

It says nothing about management. It says nothing about the influence of the industry, which is rife.

And it says nothing about the demoralization of the scientists you have there, who are good, hardworking people, and their views, apparently, don't count for very much, often, not all the time, but often.

Now, I don't know how you're planning to address those issues.

You've got—there were two other areas that I mentioned, and if my colleagues will indulge, let's move quickly and get to an answer, about tracking the post-marketing systems——

Dr. WOODCOCK. Yes.

Ms. DELAURO [continuing]. And why you haven't been able to deal with that issue, and why we can't—we don't have a list of approved drugs.

That's a list. That's a list. And let us know why——

Dr. WOODCOCK. There is a list of approved drugs that is in our orange book. All right.

We don't have a very good inventory, though, of where they're manufactured and so forth.

That is——

Ms. DELAURO. Because of resources, as well?

Dr. WOODCOCK. Yes.

Ms. DELAURO. It's because of resources that you can't keep a list of the accurate drugs, for the last 15 years?

Dr. WOODCOCK. As I said, it's a combination of resources and authorities.

Ms. DELAURO. It's not a question of authorities, my friend.

I've sat here month after month, year after year, with an agency that doesn't want any authority lest it would be forced to use it, lest it would be forced to use it.

And I read the Secretary Levitz, and this is his report that came out at the beginning of the year, which was mostly channeled to food safety.

Not once did we talk about additional authority or, for that matter, additional funding.

A few days ago, he talked about maybe what we ought to do is to have some authority with regard to overseas firms.

So this has not been the case.

We've been assured that everything is fine, everything is fine, and we can go back and get the transcripts and lay them out.

Yes, and as my colleague, Mr. Hinchey, points out, most of your funding comes from the drug companies these days.

Final comment, which is that one, and then the tracking of the post-market studies.

POST-MARKET STUDIES

Dr. WOODCOCK. Yes. The post-market studies, we have cleaned up that tracking multiple times.

The studies that have not been started that you referred to, that are delayed, that you referred to, actually are in pending status, which is something regulation requires.

They haven't been started, but they may or may not be delayed.

Ms. DELAURO. All right. That means they haven't been started.

Dr. WOODCOCK. It takes a while to get some studies started. I'm not saying that all of them are on time.

Ms. DELAURO. And you don't have any mandatory authority, which you haven't wanted, to say to the industry that you need a post-market surveillance, when are you going to do it——

Dr. WOODCOCK. Now, we do. That's what the FDA Amendments Act enacted. Within 180 days from enactment of that Act.

Ms. DELAURO. How do you regulate clinical trials without a complete list of them?

Dr. WOODCOCK. We do not have a complete list of clinical trials. That is correct.

Ms. DELAURO. Another resource problem, as well?

Dr. WOODCOCK. Well, when you add together—I know you say that we have received additional resources.

I'm aware of the $26,000,000 additional for drug safety since 2001 post-Vioxx that had been provided to the agency. I can tell you that that is not adequate to fix all these problems.

All right?

Ms. DELAURO. More money than you requested. More money than you requested.

Dr. WOODCOCK. I'm not in charge of requesting money.

Ms. DELAURO. I'm going to—listen, because we've got to move on, I've got——

Ms. EMERSON. Madam Chairman?

Ms. DELAURO. Yes.

Ms. EMERSON. It seems to me that, because we're not satisfied with a lot of the answers here, that perhaps our subcommittee should do a field trip down to the FDA and meet with the offices of all of these who are running each of these programs, to really kind of get a handle on to see if the right hand knows what the left hand is doing.

Ms. DELAURO. You know, a very, very good suggestion, and I appreciate that, Congresswoman Emerson.

I'm going to conclude, to allow my colleague, Mr. Kingston, to ask some questions. I've gone well over my time.

I note only that, keep in mind the four pillars that we are going to look at, and that's resources, management, influence of the drug industry, less not more, and more influence of the scientists.

I don't know if you agree with that framework. At some point, I'd like to hear whether or not you agree with the framework, or are we only going to continue to hear about the lack of resources that you have, but you have not requested, and you continue to tell us you can move with what you have.

Mr. KINGSTON. Thank you.

DRUG APPROVAL TIME

Doctor, in terms of drug approval, there was great criticism on FDA by Congress for many years that your approval was too slow.

And we worked with you to come up with ways of speeding that up.

Do you have a chart on the duration of approval time?

Dr. WOODCOCK. I don't have a chart I can show you right now, but basically, after the enactment of the Prescription Drug User Fee Act, the very prolonged review times were diminished. They were about cut in half.

Right now, many priority drugs, which are drugs for serious or life-threatening illnesses, where there isn't an alternative, get on the market very rapidly, perhaps within six months, if they can be reviewed in the first cycle and they're not sent back to the company for more work.

Mr. KINGSTON. Well, in terms of the data on it, you're going to be criticized, regardless of what you do, either for approving too many too quickly or going too slowly, and your job is to balance that.

Now, in that equation, do you ever look at the number of deaths that are caused by illnesses by you not approving a drug?

And do you have some statistics that you can share with us on that?

Dr. WOODCOCK. Well, that is only available if a drug is shown to save lives.

Mr. KINGSTON. Well——

Dr. WOODCOCK. If a drug is shown to save lives, it's usually gotten on the market quite promptly.

Part of the problem is that many drugs help provide a lesser benefit. They help with pain, terrible pain. They help with people getting their activities of daily living done.

Say someone who has rheumatoid arthritis. They can go back to work. It isn't necessarily saving their lives, at least in the short term couple years of treatment.

So we do always do analysis of the benefits of any drug versus the risk. That is the fundamentals of whether or not a drug gets on the market, is that the benefits are going to pretty substantially outweigh any risk, because all drugs have some risk.

Mr. KINGSTON. Well, do you, you know, do you answer your critics vigorously, or as vigorously as they attack you, in terms of certain drugs not being approved properly or whatever the results are?

Dr. WOODCOCK. We have——

Mr. KINGSTON. I think that's one thing that maybe this committee would like to know.

Dr. WOODCOCK. Yes.

Mr. KINGSTON. You know, there's always a lot of one-sided outside groups who, you know, quote unknown medical providers and medical personnel, but they don't ever really document it.

I mean, it makes for a great editorial, but not necessarily for great science.

Do you, you know, swing back, and say, "Let's engage in it?"

Dr. WOODCOCK. Well, you're talking about actually doing an analysis of whether overall the benefits of drugs outweigh the risks, in general?

Mr. KINGSTON. Well, not particular drugs.

Dr. WOODCOCK. Mm-hmm.

Mr. KINGSTON. For example, I know that this committee, years ago, there was a drug for epilepsy that I think was approved in France and used maybe widely throughout Europe, but the FDA was really going slow on it in America, and finally, FDA approved it.

But in the meantime, there were some documented cases of death that this drug could have helped, if the people were allowed to take it.

Dr. WOODCOCK. That's right.

Well, that kind of information is very hard to find in a scientific way, okay, without doing a study.

So we, when we approve drugs, we have very strong evidence that the benefits, the overall benefits will outweigh the risks of those drugs.

Nevertheless, a lot of folks feel we're not approving enough drugs. We certainly very recently have had a lot of criticism about that in the cancer area, for example.

And other people feel we approve too many drugs, and that they have too many risks.

Mr. KINGSTON. Do you have any specific drugs or stories that you can relate on that topic, any examples?

Dr. WOODCOCK. Well, any drug that we approve is going to provide benefit for a population, but there's going to be some individuals who are at risk.

For example, you've probably heard of the drug Vioxx, right?

I was at the Arthritis Foundation yesterday, addressing the patients who were there, and one of the patients stood up and said, "Why can't I get Vioxx?"

Because for that person, he had tried everything. He had a serious arthritic condition. For him, the benefits of Vioxx well outweighed the risks of Vioxx.

And I have had many people, from both sides of the aisle, come up to me and say that that one drug was better for them.

Now, overall, Vioxx did not benefit the population. More people were put at risk than the benefit. But you need to understand that, for individuals, many—all the drugs we approve provide a benefit for a substantial number of individuals.

GLOBALIZATION

Mr. KINGSTON. Okay. In terms of the globalization that you talk about in your testimony, and the fact that drugs have traditionally been made in the United States, manufactured, packaged, and so forth here, and now there's a whole series of activities outside of the country, how can you address those?

What is in your vision in terms of trying to figure that one out?

Dr. WOODCOCK. Our maintaining quality relies on a number of factors, all right:

Inspection of the plant; review of how the manufacturing is done; making sure the imports that come into the United States are from qualified facilities and should be imported into the United States; and then surveillance of what happens in the United States from our post-marketing surveillance systems.

Mr. KINGSTON. Let me ask you a question, then.

IMPORTS AND RE-IMPORTATION

If you're able to monitor to your comfort level an importation, why is it that we can't monitor to your comfort level a reimportation?

Dr. WOODCOCK. Well, as I just said, in response to Mrs. DeLauro, we are not—I'm not that comfortable with the systems that we use to check imports, to make sure that foreign facilities manufacturing drugs in other countries, that we are there often enough to be comfortable always, and our data systems are not up to what they should be.

So reimportation would add yet another level of challenge onto that whole system, which is under a great deal of stress right now.

Mr. KINGSTON. Have you ever thought about putting in a study of how that actually can be done?

For example, if we put in our bill some language that would instruct you to come up with a model for reimportation, and that seems to be the only way we're going to be able to get it done, but there would be something that would come from that, correct?

Dr. WOODCOCK. For FDA to have reimportation would require a great number of steps that have been discussed by many parties, and we would need to have confidence that the site of manufacturing, the trail, the pedigree of that product as it moved around maybe into different countries and so forth, that we could keep track of that and that we knew when a product was imported into the United States that it was the authentic product that we thought was being imported.

Mr. KINGSTON. So it would make sense to maybe only do it for, say, a Canadian reimportation rather than one from Singapore?

COUNTERFEIT DRUGS

Dr. WOODCOCK. If—well, as you know, there are a large number of counterfeits and improperly manufactured drugs out in the world.

Mr. KINGSTON. Let me interrupt you a minute.

How much of the counterfeit is actually in life savings versus vanity drugs?

Because I've always heard that the vanity drugs have the bigger counterfeiting.

Do you have a breakdown? I don't know the answer. I'm just asking.

Dr. WOODCOCK. David, do you know that?

Mr. HOROWITZ. I don't have an exact figure on that, but it's—you typically see drugs that are large volume drugs being counterfeited, because you can make more money.

So it's not just the Viagras of the world, but it's also Lipitor and things that are life saving drugs, because a lot of money can be made because of the high volume associated with those drugs.

Dr. WOODCOCK. Also, even though perhaps it might be a vanity drug, if it has a wrong ingredient in there that can be harmful to people, it still could be life threatening. So the risks are very high.

We've talked to regulators in other countries where counterfeits are rife, and any importation of unapproved drugs would have to have extremely careful oversight.

Mr. KINGSTON. Okay. Madam Chair, I want to yield back the unremaining time.

But are we going to have another opportunity——

Ms. DELAURO. Yes, we will have another opportunity.

Mr. HINCHEY. Good morning, Dr. Woodcock.

Dr. WOODCOCK. Good morning.

Mr. HINCHEY. It's very nice to see you again.

I know this is the first time, or at least I believe it is the first time that you've actually testified at the table, but I know you've been at these hearings——

Dr. WOODCOCK. That's correct.

Mr. HINCHEY [continuing]. On numerous occasions, sitting in that row back there, most of the time.

So I congratulate you on moving up in your responsibilities, and you and I both know that they're very serious responsibilities.

And I very much appreciated, frankly, what you said in the context of your testimony today, because it was very positive.

And just listening to that testimony, it's inclined to give someone a positive feeling about what the FDA is doing, and that's very good, and I hope that what you are saying will happen.

But at the same time, it's impossible not to be less than optimistic about that, based upon the past experience that we have, and the way in which the FDA is constituted and funded.

FDA FUNDING SOURCES

We know, for example, that somewhere in the neighborhood of roughly about 65 percent of the funding comes from the corporations that the FDA oversees.

That is just an open invitation to corruption. It's an open invitation to the people who are being overseen having an undue influence on what is being overseen, and the fact of the matter is, we see vast amounts of evidence that it's not working effectively.

And I think that the FDA is not working effectively, and there are many people who look at the situation and who come to the conclusion that it has never been worse than it is today in terms of its effectiveness, in terms of its oversight of the drug companies, in terms of its protection of the people of our country, which is what the FDA was set up to do.

And a large part of that failure has to do with the fact that so much of the resources which were mentioned over and over again this morning come from the people who are being overseen.

And then, in the context of the groups that examine the process, we have an undue number of those people who are directly conflicted, and even though they're directly conflicted, they receive waivers, and the amount of waivers that we've seen is roughly about 17 percent of the people who are on those committees are given waivers, even though they have direct contact with the drug companies and are getting very substantial amounts of money, either directly or indirectly.

All of this causes deep concern among the members of this committee, I think on both sides of the aisle, and the reason is not just because of the abstract numbers that I've been mentioning, but the effect of those.

NEURONTIN/GABOPENTIN

Let me give you an example of that. There's a drug called Neurontin, which I believe is—that's the market name for it. The actual drug is called gabopentin, I think it's called. Is that correct?

Dr. WOODCOCK. I believe so.

Mr. HINCHEY. Pardon me?

Dr. WOODCOCK. Yes.

Mr. HINCHEY. Yeah. That's the real drug name. And it's a drug that is supposed to be used for people who have shingles, things of that nature.

And what we have seen is that people taking this drug, in a number of instances, develop adverse effects toward themselves, some of it very deeply. Some of it attempted suicide, and a lot of it actual suicide.

We have, as a result of an examination that I've been engaged in, and that examination was based upon an initiative that came from an attorney who is a constituent of mine, who was rep-

resenting some people who were involved in this kind of situation. He brought it to my attention.

We sent a letter to the then acting commissioner, Lester Crawford, as you know. I know you worked with him back in 2004. We sent that letter to him back in 2004.

And in the context of that letter, we asked for actions to be taken on this particular drug, and nothing has really happened. It's been three-and-a-half years since that letter went out.

We know that, based upon just a fraction of the information, we know that there have been at least 200 completed suicides and there have been at least 2,500 attempted suicides.

Now, that is not the overall picture. That's just a fraction of the picture, of the big picture that has been examined.

So the number of suicides as a result of taking this drug could be 10 times that number. It could be even more than that, much more than that. We don't know that.

We need the FDA to do an examination on this, to come up with the information as to what is happening, and we have not had an adequate response to the questions that we have asked.

So these are the basic issues that we're confronting here, that this Appropriations Committee is trying to confront.

We have provided substantial amounts of increases in revenue to the FDA, but still, most of the money comes from outside, comes from people who are being overseen, and that needs to stop. We've tried to stop that.

We've tried to have legislation passed which would tell the drug companies to send their money directly to the Treasury, and then the Treasury can provide the money to the FDA.

That seems to me to make a whole lot of sense, because then you abolish the financial connection between the drug companies and the FDA which is set up to oversee them, and you would effectively eliminate most if not all of the direct adverse influence that the drug companies have over the FDA because of the money that they provide to run the operation, and the way in which they get away with having people who have conflicts of interest nevertheless sit on the oversight committees and make decisions which determine whether or not a drug gets on the market or whether or not that drug continues to be on the market, even though it is having adverse consequences to the people who take it, including inducing suicide within them.

So these are the points that we have to confront here, representing the people of this country, trying to protect them, trying to get this FDA, which was set up to be in their interest and to protect them, to actually act in the way it was supposed to act.

Let me just ask you what you think the prospects are for change, generally, and specifically, within the context of Neurontin.

Dr. WOODCOCK. We will see change, as we have been changing, as part of our response to the IOM, the FDA Amendments Act, the Safety First and the additional initiatives we're going to do after that will provide real substantive change, as well as being able to build better surveillance systems to look at what's happening out there to people in the real world.

So I believe there is a prospect for substantial change.

As far as the user fee program, as you know, that was set up by Congress because FDA was felt to have inadequate funding to perform its duties.

Mr. HINCHEY. It was set up by Congress, but it was set up back then at the request of an administration which was saying that we needed to save money from the federal budget, and one of the ways in which we could do that was to have the drug companies contribute to the oversight that the FDA engaged in.

Why the Congress, back then, bought into that idea amazes me, frankly. It was a big, fat mistake, and it needs to be corrected.

We have tried to correct it, but we have never gotten support in order to get it corrected.

We're going to keep trying to do it, and we're determined to get that done, because it just doesn't make any sense to have this kind of very close financial contact with the companies that are being overseen and the overseer.

So it was set up by Congress, but it was set up at the request of an administration similar to the one we have in the White House now, who had the same kind of views on the way in which the government should operate in the context of overseeing corporations whose main objective is just making money, which is—you know, I mean, there's nothing wrong with making money, but let's do it in a way that is not going to kill people and cause people to kill themselves.

Dr. WOODCOCK. As far as Neurontin, we certainly will get back to you on that issue.

[The information follows:]

In an effort to provide a more complete understanding of safety issues associated with the drug Neurontin and the information that Rep. Hinchey's constituent provided to the FDA on possible adverse event associated with Neurontin, FDA officials conducted a conference call with Rep. Hinchey's office on February 29, 2008.

It is never surprising that drugs that affect the nervous system, and gabopentin is one of those, would have neuropsychiatric side effects. All right? That's something we've come to expect.

Large numbers of drugs have neurologic and psychiatric side effects.

And so what we need to do is identify those, be alert to those, and make sure people are properly warned.

On the other hand, some of the conditions for which the drug is prescribed are very serious for people's lives, and so we have to keep a balance there about the availability of a drug to treat very debilitating conditions versus its potential for having side effects.

Mr. HINCHEY. Well, thank you.

Just looking at you, and having looked at you before a little bit further away, you know, I'd like to have confidence in you, and I would like to think that you would have the ability to do something, particularly as a physician yourself.

But I know what we're dealing with, and I know that you can't make these decisions by yourself.

So we would like to do everything that we can to try to correct this situation and continue to work on it, and it's going to have to be worked on aggressively in order to get it done.

Thank you very much for your testimony, and I now turn over the time to my colleague.

Dr. WOODCOCK. Thank you.

Ms. EMERSON. Thanks. Thanks for being here today.

Doctor, can you tell me what percent of the dry, the bulk dry substances used by pharmaceutical manufacturers to produce their drugs as manufacturers—hold on just a second. Are we on zero for time?

No, I think we have no time left for our vote.

Shall we recess for just a minute?

I think we probably, if you don't mind, doctor, I'll ask my question again when we get back.

Dr. WOODCOCK. Certainly. If I could just follow up with Mr. Hinchey here, I just got some more information from my colleague about Neurontin. No. Okay.

We will follow up with you, because we have made some announcements about this.

Mr. HINCHEY. Okay. Thanks very much.

[Recess.]

Ms. DELAURO. The hearing will come to order.

Okay, Mr. Farr, I'm going to go directly to you, after you have your slug of water.

Mr. FARR. Thank you, Madam Chairman.

I appreciate you coming and testifying today.

It's—this hearing is to me one of our most important, because the FDA has traditionally been the agency that has enjoyed the greatest public trust, and those of us that are elected to House of Representatives are the ones that I think I have found that in generally talking about the Federal Government, the highest respect that consumers have had, people have had, is in the government's ability to make sure that our food and drugs are safe.

I think it's shocking to sort of get into, to lift the cloak of the departments and just find out how many critical problems there are, and I couldn't help but wonder, why—identifying, there's a lot of testimony here, identifying what these problems are and they've been for a number of years, why there hasn't been an ask for more money.

Dr. WOODCOCK. Well——

ADDITIONAL FUNDING

Mr. FARR. Is it that the department isn't making the ask, or is it OMB is dinging the ask?

Dr. WOODCOCK. As you well know, that's above my pay grade, and——

Mr. FARR. Well, why should it be? You're in control, as I understand, you're—you oversee the ongoing agency operations.

I mean, that shouldn't be above your pay grade.

Dr. WOODCOCK. I'm a career civil servant. As you well know, the agency heads even do not decide what the Federal Government ask will be. That is an administration function. And——

Ms. DELAURO. Will the gentleman yield for a second?

Don't you have, as the head of the CDER, have any responsibility to let people know what it is that you need to be able to do your job, or do you just say, "Hey, look, this is it, I'll take it, and, you know, come what may"?

Dr. WOODCOCK. No. We have prepared—we saw, for example, the importation issue, manufacturing moving overseas, clinical trials now moving overseas.

We have seen this coming for a decade. We have raised red flags. We have raised the alarm. All right?

Mr. FARR. But who is not watching or listening to that?

Dr. WOODCOCK. Well, if various administrations—this has been going on for more than a decade.

If various administrations and various Congresses have had higher priorities, that's not for us to question at that point.

Mr. FARR. I don't think you can bring Congress that question, because in this town, the president asks and the Congress disposes. It's always initiated with and ask.

Dr. WOODCOCK. I think——

Mr. FARR. I don't think Congress has been cutting that ask. I've been here long enough to know that.

Dr. WOODCOCK. I can tell you——

Mr. FARR. I think it's the other way around.

Dr. WOODCOCK. I can tell you that for over a decade—I know you had Ben England here a few weeks ago, right, testifying about foods, is that right?

He and I, I worked with him on various plans about importation and foods many years ago. We've been concerned about these problems——

Mr. FARR. But that's—I mean, I appreciate that. I appreciate where your concerns are in the ranking.

Dr. WOODCOCK. Right.

Mr. FARR. But the testimony here often is that we don't have the resources to do all these things.

This whole line of questioning is about, well who in the hell is responsible for making sure that you do have those resources? It's got to be in—you're an administrative arm of government. It's got to be from the administration.

And my question is, at OMB, is it either the ask isn't being made or is it OMB rejecting it?

Dr. WOODCOCK. Well, as you well know, you're putting me in a very difficult position. I'm a career civil servant, and, you know, these things are not mine to decide.

Mr. FARR. We'll try to get that answer.

CDER BUDGET, USER FEES

The other thing maybe you could tell me is that, of your budget, the CDER budget is $793,000,000 this year, the ask?

Dr. WOODCOCK. Yes.

Mr. FARR. How much of that budget comes from the Prescription Drug User Fee Act?

Dr. WOODCOCK. For 2009, $380,000,000 from user fees and 357 or 8, rounded off, million from budget authority.

Mr. FARR. So taxpayers put in 358 and the private sector puts in more?

Dr. WOODCOCK. That's correct.

Ms. DELAURO. Does that include direct to consumer and the proposed generic drug user fees?

Dr. WOODCOCK. Yes.

Ms. DELAURO. And generic drug user fees, as far as I know, does not have—is not authorized, and——

Dr. WOODCOCK. That's correct. That's correct.

Ms. DELAURO. And the direct to consumer, what we did is we didn't do that in this budget——

Dr. WOODCOCK. So there's some decrements from that, from a practical point of view.

Ms. DELAURO. 50/50?

Dr. WOODCOCK. The PDUFA is about, yeah, it's about 50/50 with the user fee, prescription drug user fee program versus, that's correct.

Ms. DELAURO. Right, so it's about 50/50?

Dr. WOODCOCK. Mm-hmm.

Mr. FARR. Well, as a career professional, and I appreciate that, and appreciate your service to our government, as a career professional, what would you recommend that budget balance be?

Dr. WOODCOCK. Well, that's a very difficult question, again, to ask me.

DRUG SAFETY FUNDS

Let me respond a little bit. Mrs. DeLauro said earlier about the drug safety money you've given us over the past four years, right, and we are very grateful to that. Post 2001, after Vioxx, we got increments each year for drug safety.

But in 2000, I had testified before the Senate, Mr. Kennedy and Mr. Jeffords, about drug safety, and we were able to get a letter out to Mr. Kennedy and Mr. Jeffords telling them what we thought was needed just for drug safety and post-marketing.

Mr. FARR. And that's my question. I mean, what are those figures?

Dr. WOODCOCK. Okay. The figure was—that was in year 2000. Times have changed. It would probably be more. $150,000,000 in additional funding, minimum.

Mr. FARR. So what would be the—I mean, the question——

Dr. WOODCOCK. I can provide this letter for you, if you would like.

Mr. FARR. I wish you'd be a little more frank about it. You're a career civil servant. You're not a political appointee.

Dr. WOODCOCK. Right.

Mr. FARR. And you're protected. It's your bosses that aren't. And obviously, with a change of administration, they're going to be gone.

So we will have, you know, new figures and new approaches, and hopefully a new advocacy for regaining the credibility that the public so much wants this agency to have.

Dr. WOODCOCK. Well, let me just—can I just——

Mr. FARR. It's very difficult to assure the public that they're getting a fair, unbiased treatment, when more than half of the fees to run the department come from people who benefit from the outcome and make a gazillion dollars off of it.

Dr. WOODCOCK. The prescription drug user fee improved the drug development side of drug regulation.

In other words, it provided substantial resources for improving the review process, including, say, preapproval inspection activities,

and so forth, so that part of the program is more robust than the other programs.

The new prescription drug user fee does give substantial resources to drug safety, for the first time. There were just a few resources given before in PDUFA III, right.

The drug safety program, as I just told you, is really vestigial. There was no real appropriations for drug—specifically for drug, postmarketing drug safety during the entire time I think I worked at the Center for Drugs, perhaps except in 2002.

The other program that really needs improvement has already been pointed out by the chairwoman, and that is the quality program, our ability to manage, track, what are the drug establishments, where are they, who is making the drug, when are they inspected, to be able to get there and inspect them——

Mr. FARR. And how much more money do they need for that?

Dr. WOODCOCK. I don't know the answer offhand, but I would say it is substantial.

Mr. FARR. Well, what's substantial?

Dr. WOODCOCK. Again, I can't give you a direct number. I can give you this letter about the drug safety program, however.

Ms. DELAURO. Why don't you get us an answer on that?

Dr. WOODCOCK. We can certainly try to do that.

Ms. DELAURO. Get us an answer on what you believe it is.

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 13 2000

The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Senator Kennedy:

This letter is in response to the request made by you and Chairman James M. Jeffords, during the February 1 hearing, on drug adverse events. Specifically, you and Chairman Jeffords requested that the Food and Drug Administration (FDA or the Agency) provide a description of the scope and costs of a program that would substantially reduce preventable injuries and deaths from the use of FDA-regulated medical products.

The Institute of Medicine (IOM) report, "To Err Is Human," estimated that as many as 98,000 Americans die each year from preventable medical errors. The report also documented the fact that errors with drugs and devices are a significant part of this national problem. Approximately five percent of the 33.6 million hospital admissions annually are caused by adverse drug reactions (ADRs), at least half of which are preventable. About two percent of patients experience preventable ADRs while in the hospital, with an average length of stay of 4.6 days and a cost of $4,700, yielding a preventable cost of $3.6 billion per year.

These figures are hardly surprising given the accelerating numbers of new products and their central role in healthcare. Safe use of these products is a critical priority. New drugs, medical devices and other medical products have extended lives and revolutionized medicine. But comprehensive systems are not in place to identify problems with product use and to help the medical community manage risks in the face of an onslaught of new and complex products. Such systems are urgently needed as our aging population increasingly relies on medicines and medical devices.

Current resources for monitoring safety are dwarfed by the scale of spending on product approvals and product purchases. FDA now expends $500 million annually on premarket review programs for medical products. In contrast, less than five percent of that amount, about $21 million, is available for postmarket clinical safety programs. This level of spending is about one one-hundredth percent of the annual sales volume of marketed products, estimated at $90.6 billion for prescription drugs and $62.2 billion for medical devices and medical diagnostic products. It is imperative a better balance is struck between speeding new products to market and evaluating the impact as products are actually used.

Comprehensive Risk Management for Marketed Medical Products

Current FDA systems could form the framework for building a comprehensive risk management system for medical products. As outlined in FDA's report, "Managing the Risks of Medical Product Use," successful management of medical product risks requires collaboration among all stakeholders in the healthcare system. For successful collaboration to occur, three key elements need to be in place: 1) systems to find and quantify the risks; 2) programs to investigate, analyze, and understand the risks; and 3) response programs to take action, to inform and intervene as needed to prevent harm.

1. **Systems to find and quantify risks.**

FDA currently relies on reporting both mandatory and voluntary to find risk signals. FDA's programs are designed primarily to serve as a "backstop" for the approval process to find rare, unexpected side effects that could not be discovered in the clinical trials. They are not intended to, and cannot, uncover the incidence of adverse events, their prevention, or the overall health and economic impact on Americans. As outlined in the General Accounting Office report that was the subject of the February 1 hearing, the Agency's current approach is most useful for finding rare events. FDA currently receives about 400,000 reports of adverse events associated with medical products; 21,000 of these describe fatalities and another 11,000 life-threatening events. FDA must investigate and analyze these reports to determine if reported events were actually caused by a medical product, whether they were expected outcomes, and if they were

preventable. Due to resource constraints, the Agency currently puts most focus on serious unexpected events (serious unexpected ADRs and device malfunctions). Over 60,000 additional reports describe problems that required hospitalization or prolonged a hospital stay and 32,000 others report medical device malfunctions. Despite the large number of reports, studies indicate that 90 percent of adverse events are not even reported to FDA at all. For additional information on the scope of product use, the size of the risk, and the potential for health and economic return on investments in safety systems, see the Addendum to this letter.

Methods that actively enlist health professionals in seeking out and reporting events are needed, as are other types of data sources (for example, reports from poison control centers). FDA pilot studies indicate that these are high-yield strategies for finding product safety risks. Key steps required include:

- **Full-scale operation of MedWatch (spontaneous reporting)**--the national program initiated to promote reporting by individual health professionals. With only five staff and an operating budget of $84,000, MedWatch clearly does not have the capacity to operate effectively for the nation. Funding is needed to bring this program into the 21st century, with full-scale implementation of interactive, online reporting for health professionals. This capability is critical to increasing problem reporting, the first step toward risk prevention.

- **Implementation of MedSun (sentinel reporting)**--the Congressionally-mandated sentinel program for medical devices. MedSun will actively enlist hospitals and associated health professionals, in problem reporting. Because all types of medical products are involved in care delivered at these facilities, MedSun should expand to include reporting for drugs and biological products, once device reporting is under way.

- **Error and Accident Reporting System**--the reporting system for the collection of error and accident events that occur in the manufacture and use of blood products. Resources are needed to expand and upgrade the current reporting system to

accommodate reporting by unlicensed registered blood manufacturers and blood banking facilities.

- **Expansion of reporting systems (above) to other care settings**--including outpatient clinics, nursing homes, home health and others that provide an increasing share of health care services involving drugs, medical devices and biologics.

- **Development of additional data systems to monitor risk**--accessing numerous additional sources of data already collected for other purposes (e.g., emergency room, poison center reports, organ transplant databases) to provide insight into the clinical context of product use and problems encountered.

- **Development of specialized systems for particular product risks**--establishing patient registries for novel products or those with potential long-term safety risks.

- **Identification of key obstacles and strategies to improve problem reporting**--conducting the needed research that will lead to improved reporting rates and quality.

2. Programs to investigate, analyze and understand the risks.

Preventing risk requires understanding why the problem occurs. FDA needs the capacity to apply cutting-edge methods of analysis to correctly identify the sources of the safety problems and their solutions. To do this, the Agency must expand its capacity in a number of areas: detection and evaluation of safety signals (e.g., including pattern recognition techniques of artificial intelligence), on-site investigations, epidemiologic analysis, human factors analysis, and methodologic research. Steps that need to be taken include:

- **Establishing contracts for "pharmacovigilance" information** (this is the program Dr. Platt suggested would require $50 million in his testimony at the February 1 hearing). These contracts would allow FDA access to information about the extent and duration of medication and device use linked with

illnesses, hospitalizations and deaths from healthcare systems around the country.

- **Establishing a "benchmark" site program for medical products in partnership with the Centers for Disease Control and Prevention (CDC).** This program would combine near-complete reporting of events and efforts to reduce adverse event rates in specific hospitals, nursing homes, and outpatient clinics, similar to the program on hospital acquired infections currently operated by CDC. This program could yield both "benchmark" event rates and evaluations of interventions that could be translated into recommended "best practices" for error reduction.

- **Strengthening FDA's scientific and operational programs in safety analysis, epidemiology, and human factors analysis, including research efforts.** For example, research on name and package confusion should be pursued aggressively as should research on ways to make sure that users can understand and follow label directions.

- **Strengthening collaboration with the governments of Europe, Canada, and other countries to access information and experiences from other parts of the world.** These efforts would allow FDA to have broader and more rapid access to information as products are globally marketed.

3. Response programs to take action, to inform and intervene as needed to prevent further harm.

FDA has traditionally taken regulatory action, disseminated information, or done both, after a problem has been identified and understood. To fully effect changes required for safe product use, however, FDA must be able to partner aggressively with State governments and associations, other Federal agencies (e.g. the Health Care Financing Administration, Agency for Healthcare Research and Quality, and CDC), private sector organizations (e.g. Joint Commission on Accreditation of Hospitals), and other accrediting and regulatory bodies as well as professional groups. In addition, FDA must have its own strong professional and consumer outreach channels. Needed steps include:

- **Developing effective consumer and health professional programs** providing outreach and education that can successfully alter risk behavior.

- **Developing strong partnerships with State and Federal agencies** around safety programs for medical products.

- **Taking regulatory action where needed,** e.g. developing additional packaging, labeling, and testing standards directed at maximizing safe use for medical products (taking into account, where appropriate, human factors that affect the safe use of the product).

- **Performing research where needed,** e.g., testing and evaluating risk communication methods for FDA regulated medical products.

The comprehensive program would likely require $150 million in additional funding. Staged implementation over several years would be most feasible. We believe full implementation of this program will: 1) provide reliable data on the rates of adverse events and errors involving medical products needed to help formulate effective solutions to this problem and 2) reduce preventable harm associated with these products by 20 percent each year. The medical products industries as well as the healthcare community should have a role in these programs.

Thank you for making this a part of the public record. Please let us know if you have any questions, or would like additional information. A similar letter has been sent to Chairman Jeffords.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Addendum

Addendum

As noted in the attached letter, the accelerating volume of medical products, and their increasingly prominent role in healthcare delivery, make comprehensive safety systems for these products a critical priority. Reflecting the growing importance of medical products, the *Health Care Financing Review* recently referred to the "explosion of new drugs available on the market, and the equally explosive growth in utilization", and cited a Solomon-Smith-Barney analysis finding that the share of managed care plan costs for pharmaceuticals now approaches the share for hospital costs.[1] One of the primary drivers of cost growth, the number of new drugs, has been attributed, by industry,[2] to the combination of product research and development and accelerated FDA reviews, reflecting the impact of the Prescription Drug User Fee Act.

Surveillance systems, however, are not in place to identify emerging problems and help the clinical community address safety risks from the "explosion" of new and complex products. Answers to these questions are urgently needed as our aging population increasingly relies on medical products.

The following data outline the scope of product use, the size of the risk, and the potential for health and economic return on investments in safety systems:

Reports to FDA

- FDA receives about 400,000 reports of adverse events associated with medical products yearly; 250,000 are for drugs alone,
- Almost 20,000 of these describe fatalities; an additional 11,000 incidents are life-threatening,
- Another 60,000 annually require hospitalization or prolong a hospital stay, and
- Despite these large numbers, studies indicate that 90 percent of adverse events are not reported to FDA at all.

Hospital Care

- Approximately five percent of admissions to medical wards are the result of adverse drug reactions (ADRs), at least half of which are preventable.[3] Among the elderly, inappropriate prescriptions may account for up to three percent of medical admissions.

- About two percent of patients have preventable ADRs while hospitalized, with an average increased length of stay of 4.6 days and a cost of $4,700,[4] yielding a preventable cost of $3.16 billion per year.[5]

Nursing Home Care

- For every dollar spent on drugs in the nation's 16,700 nursing facilities, where 63 percent of all care is paid for by Medicare or Medicaid,[6] an estimated $1.33 is consumed in the treatment of drug-related morbidity, $3.6 billion of which is estimated to be avoidable.[7]

Home Health Care

- 2.5 million patients currently receiving care and 8.2 million discharges per year reported for 13,500 home health and hospice agencies (over 90 percent certified for payment by Medicare).[8] Total 1998 spending on care was $29.3 billion.[9]

- Rate and cost of medication and device-related errors is completely unknown, but is likely similar to findings in similar settings.

Ambulatory/Self care

Prescriptions

- Approximately 2.5 billion outpatient prescriptions dispensed in 1998.[10]

- Total spending on prescriptions estimated to be $90.6 billion.[11]

- The IOM report on medical errors cites a recent estimate of $76.6 billion in economic impact from ADRs in outpatient settings.[12]

Medical devices and over-the-counter (OTC) drugs

- Healthcare spending on OTC drugs and medical nondurables (e.g. bandages, heart valves) totaled $31.3 billion.[13]

- Healthcare expenditures on medical durables (wheelchairs, x-ray machines) totaled 15.5 billion.[14]

Dietary supplements

- Consumer spending on dietary supplements, which can interact with medications and cause adverse effects, is estimated at $12.8 billion.[15]

Much of the avoidable death, injury, and economic burden outlined above could be prevented through effective action. A comprehensive risk management program for FDA-regulated medical products is discussed in the letter accompanying this Addendum.

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[1] Zarabozo, Carlos, Explosion in the Medicine Chest, *Health Care Financing Review*, Spring 1999, Vol. 20, No. 3.
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Mr. FARR. Thank you. I'm not getting very far. I give up my time.

Ms. DELAURO. Ms. Emerson.

Ms. EMERSON. Thanks, Chairwoman.

Excuse me. Now let me go back and ask my question before, to which hopefully you got an answer, while I was gone.

And I wanted to know what percent of the bulk drug substances used by the pharmaceutical manufacturers in the United States are imported?

IMPORTED DRUGS

Dr. WOODCOCK. Approximately 80 percent.

Ms. EMERSON. And what percentage of finished drugs are manufactured abroad?

Dr. WOODCOCK. I don't know the answer to that. Do you have that rough, ballpark figure, David?

Mr. HOROWITZ. Not offhand, no.

Dr. WOODCOCK. No. It's a much lower percentage, but again, that is going to change, I think.

Various regions of the world have made it extremely clear that they want to take over drug manufacturing.

Ms. EMERSON. Right. So, you know, obviously, we talked about the challenges you face with the databases, so I'm not going to go there again.

Do you know what countries have the most number of establishments registered to manufacture drugs outside the United States?

Dr. WOODCOCK. David?

Mr. HOROWITZ. I think the GAO report indicates that the largest number of registered firms are in China, but it's not clear that those numbers are accurate, and it's not clear that they are limited just to manufacturing facilities.

They may include other things, like distributors and people who make herbal products, and folks that we wouldn't consider drug manufacturers.

Ms. EMERSON. Well, if the GAO was able to come up with a number, even though it might be too inclusive——

Mr. HOROWITZ. Yes.

Ms. EMERSON [continuing]. Why is it that you all can't come up with a number?

Mr. HOROWITZ. Well, that number is from our system, and as the GAO report describes, there are problems with our systems that make it difficult to come up with a number that exactly characterizes what you're seeking to get at, which is the actual number of manufacturers of drug products and ingredients in China.

INSPECTION OF FOREIGN MANUFACTURING FACILITIES

Ms. EMERSON. Okay. On average, how many of these establishments that you are aware of that are manufacturing facilities are inspected each year, outside the United States?

Mr. HOROWITZ. We do about 300 manufacturing inspections. That includes the preapproval and the so-called good manufacturing——

Ms. EMERSON. A year?

Mr. HOROWITZ [continuing]. Or GMP inspection. We did in 2007. That was more than we've done in previous years.

Ms. EMERSON. And if one of your databases says there's 3,800 manufactures, we've only—y'all have only had the capacity to look at 300, correct?

Mr. HOROWITZ. One of our——

Ms. EMERSON. Less than 10 percent?

Mr. HOROWITZ. The GAO report looked at the 3,000 number, for 3,000 foreign manufacturers, and yes, we did about 300 of those manufacturing inspections in 2007.

Ms. EMERSON. How many did you do domestically?

Mr. HOROWITZ. Domestically, I think we did about 1,200 drug quality inspections. Again, these don't include the bioresearch monitoring or all the other inspections that we do.

Ms. EMERSON. How many people do you all have on staff to do these inspections, both foreign and domestic?

Mr. HOROWITZ. Let's see. We have about 232 drug investigators, and they do some domestic work, some import work, and some foreign work.

Ms. EMERSON. And how long does it take—I mean, if I was going into a manufacturing facility as an inspector, how long would it take me to go through the checklist of things that you all require?

Mr. HOROWITZ. That really varies, depending on the complexity——

Ms. EMERSON. Give me the low end and the high end, just so I can——

Mr. HOROWITZ. You know, between one to three weeks.

Ms. EMERSON. Per facility?

Mr. HOROWITZ. Per inspection, yeah. One week is typical for a foreign inspection.

Ms. EMERSON. And why would we be spending less time, perhaps, in a foreign location and more time in a domestic?

Mr. HOROWITZ. I don't know that we always are, but, you know, a lot of the foreign facilities are these active ingredient inspections, and those inspections tend to be targeted because the manufacturing is more focused on a particular activity.

Ms. EMERSON. Let me go back and ask a followup to Sam's question to you.

Hypothetically, let's pretend—and we know you're a career civil servant, and the OMB runs rampant over every agency, and so we understand that, and I don't want you to have to say anything.

But hypothetically, let's just say funding or money constraints were not an issue.

IMPROVING INSPECTIONS

What course of action would FDA take to improve your inspection processes? What would be your first priority, and what would—yeah, and what would be your first priority?

Dr. WOODCOCK. Well, we'd have two first priorities.

Number one, we'd hire more investigators. Okay.

Ms. EMERSON. How many more investigators?

Dr. WOODCOCK. Enough to have a reasonable coverage of both domestic facilities and out of country facilities.

Ms. EMERSON. So you have 238 now, so you would say what, 2,000 would be——

Dr. WOODCOCK. I do not know. We don't have to——

Ms. EMERSON. You might need more?

Dr. WOODCOCK. We might. We'd have to run those numbers.

We don't have to be everywhere all the time, all right, we go intermittently.

We have agreements with other countries. We can talk to their inspectors. They may have been in the factory recently and done an inspection. We don't have to duplicate that. But we need the capacity to do that.

But that's number one.

Number two, we must implement all the plans that we would have for improving our databases so that we have a grip, so that we can control the inventory of drugs that enter into the United States, and we know who makes them, and where they are.

We know if they come in, whether they've come in or not, where they come from. We know everything about that.

Ms. EMERSON. So that if money was no object.

And so you report to the administrator, and it's your responsibility then to make that request, among all the other requests that your counterparts would have in the agency, correct, so it obviously hasn't been a priority.

It's been your priority, but it's not necessarily been the agency's priority to get a handle on this, Chairwoman, and appears to have ceased, momentarily, anyway.

Ms. DELAURO. Let me make a couple of observations, and I want to go to—based on something both Mr. Farr and Congresswoman Emerson are focused on.

Between 2001 and 2008, we provided a 62 percent increase to CDER. Can you hear me?

Dr. WOODCOCK. Yes.

Ms. DELAURO. A 62 percent increase.

Now, we do not take that money and divide it up. CDER takes that money and then deals with their money, and they figure out where their priorities are, and what they ought to try to do with the dollar.

REDUCED FUNDING FOR INSPECTIONS

It would appear that, during that time, we have seen foreign inspections drop about 30 percent. We've seen domestic inspections drop about 17 percent. The money for these efforts, the money for the efforts has dropped.

So that was an internal decision at the center, because we had a 62 percent increase in dollars during that period of time.

The other issue is that, and I would agree with you. I don't hold a brief here. This is not in terms of partisanship.

I said we had not had a hearing in the last 25 years, so that tells you where I'm coming from in this regard, so I look at the spectrum here.

And if you got less money at that point in that budget, shame on those who made that decision.

However, I would just say that it was because of this committee, and you've got questions, you know, later on about OND and OSE, et cetera.

But it was this committee that increased funding for drug safety, and that's to OSE, and that was in 2006 that we did that, and we increased it $10,000,000 more above what was requested for 2008.

It wasn't that you came in with a letter or with a request that drug safety was a very important critical issue that is in crisis, and asking for money.

We determined that it was in crisis, and the Congress in the last several years has been very responsive and quite frankly, the administration and the agency have not been responsive at all to what's happened.

Mr. Rothman.

Mr. ROTHMAN. Thank you, Madam Chairwoman.

Good morning, doctor.

Dr. WOODCOCK. Good morning.

Mr. ROTHMAN. I'd like to follow up on some of the questions of my colleagues, and I'm sorry I was late. I was at another hearing from another subcommittee, for another subcommittee.

You indicated in response to Congresswoman Emerson's questions that you would need to hire more investigators.

REQUEST FOR INVESTIGATORS

Did you speak to—did you make a budget submission to the FDA last year, for the present fiscal year?

Dr. WOODCOCK. We make budget submissions——

Mr. ROTHMAN. The answer is yes, you did?

Dr. WOODCOCK. Yes. Yes.

Mr. ROTHMAN. And in that, did you request investigators?

Dr. WOODCOCK. I will turn over to David Horowitz, who is actually—those resources for investigators, I understand that money was given to the drug program, to CDER in the last few years for drug safety.

The investigators are employed by ORA, our field organization.

Mr. ROTHMAN. Is ORA within your jurisdiction as the director?

Dr. WOODCOCK. No.

Ms. DELAURO. Doesn't the CDER appropriation include ORA?

Mr. ROTHMAN. It does include the ORA. That's a separate line item.

Mr. ROTHMAN. Okay. Dr. Woodcock——

Dr. WOODCOCK. Well, according to what I see.

Mr. ROTHMAN. Dr. Woodcock.

Dr. WOODCOCK. I'm sorry.

Mr. ROTHMAN. Yes. So you submitted a budget request, correct?

Dr. WOODCOCK. Yes.

Mr. ROTHMAN. In your budget request, did you request money for more investigators, in your budget request? Or don't you know what was in your budget——

Dr. WOODCOCK. I was not the head of CDER at that time. However, we have discussed endlessly the need for more coverage, yes.

Mr. ROTHMAN. Okay. Do you know if the person who was in charge of CDER when the budget request was submitted requested more investigators?

Dr. WOODCOCK. I believe what they did was request that ORA would have more investigators, because the investigators don't report to CDER.

Mr. ROTHMAN. So the answer is yes, they did?

Dr. WOODCOCK. Yes.

Mr. ROTHMAN. Okay. And were you turned down or were you approved for the number of investigators you requested?

Dr. WOODCOCK. The administration, as I said, must set various priorities, and the FDA must set various priorities within the FDA.

The foods program also has, as you probably well know, has very significant challenges, so forth. So, David——

Mr. ROTHMAN. No, Madam Director, I just want an answer to my question, if I can.

Did you get what you asked for or not? Did they give you more, less, or the same as you had at the time of the request?

Dr. WOODCOCK. Are you talking about at the FDA level or at whatever level——

Mr. ROTHMAN. The president.

Dr. WOODCOCK [continuing]. Of the budget process?

Mr. ROTHMAN. The budget process.

Dr. WOODCOCK. Oh. Well, the 2009 budget really doesn't contain a substantial request for additional drug investigators.

Mr. ROTHMAN. It doesn't contain a substantial request or any request?

Dr. WOODCOCK. I believe it has——

Mr. HOROWITZ. I think the, in the 2009 budget, there's included in that the generic drug user fees and the reinspection user fees.

If those were enacted, those would provide significant resources for additional drug inspections.

Mr. ROTHMAN. Is there anywhere in the budget where it says that if those resources come in, because of those increases in fees, they are dedicated or will be specifically used for inspectors, or investigators?

Mr. HOROWITZ. It's my understanding that the reinspection user fees would be dedicated to conducting additional inspectional activities.

It's also my understanding that the generic drug user fee proposal would include additional funding for the kinds of inspections that are necessary prior to approval of generic drugs.

Mr. ROTHMAN. And do you happen to know that if those things happened, what percentage of increase in inspections or inspectors are anticipated as a result?

Dr. WOODCOCK. I think we do know that, and we can get back to you on that——

Mr. ROTHMAN. Do you know now?

Dr. WOODCOCK. I don't know——

Mr. ROTHMAN [continuing]. Dr. Horowitz.

Mr. HOROWITZ. The only figure I have in front of me concerns the generic user fee proposal and an estimate that that would provide for 90 additional inspections.

Mr. ROTHMAN. Ninety inspections?

Mr. HOROWITZ. Ninety additional inspections would be funded by the generic drug user——

Mr. ROTHMAN. And how many inspections are there a year now?

Mr. HOROWITZ. We currently conduct——

Mr. ROTHMAN [continuing]. In that area?

Mr. HOROWITZ. We currently, in the area of manufacturing quality, conduct about 300 inspections foreign and 1,200 domestic. Foreign inspections are more resource intensive.

Mr. ROTHMAN. May I move on to another question——

Ms. DELAURO. If I could just amplify——

Mr. ROTHMAN. Certainly.

Ms. DELAURO [continuing]. What I understand here, and I thank the gentleman.

My understanding from Dr. Woodcock's testimony on Page 2, you talk about the increase in ORA field operations for improving the safety of imported drugs.

I think we need to be clear about what you requested. It's $1.2 million and three people. And I don't know what kind of an impact that that will have.

Page 4, you say the proposed generic drug—keep in mind that has not yet been authorized, and we don't have any—I don't have any information about whether or not the authorizor will move forward—would help oversee the exploding number of overseas facilities.

And it's very hard to explain—very hard for me to understand how $2.8 million and six people, that you get from the user fee, and use for the field, are going cope with what we talk about, the exploding number of overseas facilities.

Now, you didn't talk about inspectors. You talked about inspections. So that's what I ascertained——

Mr. ROTHMAN. Madam Chair, do I have time for another——

Ms. DELAURO. Absolutely, go forward.

Mr. ROTHMAN. Thank you.

Dr. Woodcock, in your testimony, you address the increased problem the drug safety community faces as the globalization of drug development and manufacturing increases.

FOREIGN COUNTERFEIT DRUGS

A specific problem is the issue of foreign counterfeit drug making, and these foreign counterfeit drugs making their way into our marketplace, especially through the Internet.

Such a case was brought to the attention of my office. A constituent was solicited by an on-line pharmacy based in Canada. My office performed an investigation and found the complaint to be true.

In turn, my health staffer called the Food and Drug Administration to log the complaint and allow for some sort of response or recourse by the FDA.

My office was told that the FDA would, quote, "handle it from here," unquote, and told that it was a policy that such matters are handled internally and there would be no final report on the outcome of the investigation.

In essence, we were told that, "Thank you for letting us know," but that the FDA was unable to investigate and prosecute all illegal web sites, and that the outcome of any investigation you might conduct in response to our notification would not be made public.

If the FDA expects not only to stop illegal drug trafficking but also to increase the public's trust in the agency, wouldn't you think

that complete transparency is essential, and what is the practice of the FDA in this regard?

Thank you, doctor.

Dr. WOODCOCK. David?

Mr. HOROWITZ. I don't have anything specifically on the issue that you're raising, but we, as you can imagine, receive a large number of complaints about spam e-mails and other complaints about Internet activity, and our jurisdiction, unfortunately, is very limited in terms of our ability to pursue some of the activity which occurs on foreign web sites and abroad.

Mr. ROTHMAN. Well, we advised you that there was a specific company soliciting Americans to purchase counterfeit drugs from Canada, from this company in Canada, and when we advised you of the company and its name, I would think that that is no longer this amorphous entity that's threatening Americans, this is a specific, named entity threatening Americans.

Is it your testimony that the FDA has no jurisdiction in this regard or that you——

Mr. HOROWITZ. No, not at all.

As you've described it, that would be something that we would follow up on and investigate, and I don't have the specifics here, so I can't tell you exactly what we did, but it would be our policy to look into that if we have jurisdiction, to follow up on reports of counterfeit drugs.

Mr. ROTHMAN. And would it be your policy to respond to let's say a Member of Congress who brought this to your attention, to advise this Member of Congress as to the results of your investigation?

Mr. HOROWITZ. I think that would be my policy.

Mr. ROTHMAN. Okay. Would you mind, for the record, so you can get back to me on this, look into that and find out if the staff person who spoke to our office misspoke that we were not going to receive any followup or advice as to what at results were received by the FDA in the event the FDA followed up on our call?

Mr. HOROWITZ. We'll follow up with you. Thank you.

[The information follows:]

In an effort to describe FDA's actions in response to the concern raised by Rep. Rothman's constituent about the on-line solicitation for drugs, FDA officials conducted a conference call with Rep. Rothman's office on March 4, 2008.

Mr. ROTHMAN. Thank you.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you.

COUNTERFEIT DRUG WEB SITES

I want to kind of jump on that a little bit more in terms of the scope of the problem with web sites that may have counterfeit drugs.

How big do you think that it is, and how do we best fight it, and do you do undercover purchases, do work with the IG's office, do you do any kind of sting type operations? Because I think that is a, you know, a serious issue.

Dr. WOODCOCK. Yes, I'll refer this also to David Horowitz.

Mr. HOROWITZ. Yeah, it's a very serious issue.

Our Office of Criminal Investigations, a large percentage of the work they do relates directly or indirectly to counterfeit drugs coming from around the world. It's a serious problem.

There have been a large number of prosecutions and arrests. I believe in the last year there were $25,000,000 in fines related to this.

Undercover buys are part of that program. Collaborating with foreign law enforcement around the world is also part of that program.

DRUG ESTABLISHMENT DATABASE

Mr. KINGSTON. Now, you talked about, in your testimony, implementing an electronic system for accepting and processing drug establishment registration and listing, and is your goal to have a comprehensive accounting of domestic and foreign?

Dr. WOODCOCK. Absolutely.

The law requires all the facilities that produce drugs that would be in the United States to register and to list, and what we would like to go to is that we have a common, single inventory of firms, each with a unique identifier, so we know what the firm is, where it is, how much volume it's importing, if it's a foreign firm, and how recently it's been inspected, and what the results of the inspection are, and to have that all in one database.

Mr. KINGSTON. Do you have to have an international agreement?

I mean, is that a State Department function, to do that? And how many countries are participating?

Dr. WOODCOCK. The companies would have to then register and list to get their drugs imported into the United States, so they would be stopped unless they actually belonged to this.

We check with that now. It's just, as Mrs. DeLauro said, our systems are not linked, and so it is very difficult sometimes.

REIMPORTATION OF DRUGS

Mr. KINGSTON. So an American company that did want to reimport could do this system, and that would give you an opportunity to monitor reimportation?

Dr. WOODCOCK. Yes. We would have to have a pedigree of those drugs, though, to make sure they hadn't magically turned into counterfeit drugs while they were off in some other country.

Mr. KINGSTON. But there is the loop of custody that you can follow?

Dr. WOODCOCK. We would have to do that.

Mr. KINGSTON. Now, we know that American drug companies do not want to reimport, but the farce on Capitol Hill is that it's a safety issue, and the real issue is a legitimate issue, is that the American drug companies actually produce and patent most of these drugs, and they need to recoup their costs, and in order to, you know, have more money for R&D, they have to have, you know, good cash coming in.

I mean, there's nothing wrong with that. It's just that they won't admit that that's the real reason.

But I'm hearing you say that the safety reason is taken care of now, largely.

Dr. WOODCOCK. No, I'm saying——

Mr. KINGSTON. The safety argument—I mean, I think we should just debate this issue, in truth, in reality, and I do not begrudge the drug companies as a private industry to protect their research and development.

Dr. WOODCOCK. I am saying that if we had Mrs. Emerson's ideal system up and in place, then we could much better assure anything that was imported, what it was, and the quality of its manufacture.

However, for reimported drugs, we would still have to look at a pedigree or tracing the path of those drugs.

Ms. EMERSON. Excuse me. Just let me interrupt for a second.

You do that now for all, you know, the bulk ingredients, as well as the finished product, right?

Dr. WOODCOCK. Yes. We check imports as they come in, to make sure that they are allowed into the United States.

Mr. KINGSTON. How many countries are in there?

Dr. WOODCOCK. Do you know how many countries? I remember——

Mr. KINGSTON. Would it be over 10, less than——

Dr. WOODCOCK. Oh, yes, many more than 10, yes. All over the world.

Mr. KINGSTON. 129?

Well, I know you don't set policy on this. I'm just appreciating your perspective on it.

Okay. I'll yield back.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you.

INSPECTORS

You responded to Mrs. Emerson and to Ms. DeLauro's prioritization that you would hire more, number one, you'd hire more inspectors. How many?

Dr. WOODCOCK. Well, I also responded I didn't know how many, but it would be a substantial number.

Right now, we've all agreed that we are inspecting approximately 10 percent of the foreign inventory, as far as we can tell, yearly.

Mr. FARR. But how can you make a priority that you would need more inspectors without even knowing how many?

Dr. WOODCOCK. We could certainly do the analysis, look at the target, how many firms we want to inspect every year, what would be the appropriate number, and then we could certainly calculate the number of people needed.

Mr. FARR. Why would you have to do that analysis, after you've already determined that you need more?

Dr. WOODCOCK. Well, you asked me exactly how many more.

Mr. FARR. Yeah. Well, that was your response, was that this is our first, highest priority.

I mean, this is the appropriations committee. We deal with money in this committee. And that's the issue, is how much, how much will it cost.

And if this is a priority, it's essential for the credibility of the department, and it's your highest priority, there ought to be an ask here, a specific ask.

Dr. WOODCOCK. We are certainly capable of getting—doing the calculation, but not in my head right now.

Mr. FARR. I would think you would do that before you'd come here and make that announcement.

Mr. ROTHMAN. Will the gentleman yield for a moment?

Ms. DELAURO. Can I, just I think one important issue, if the gentleman would yield.

INSPECTION OF FOREIGN FIRMS

I think it's important to know that there is no statutory requirements for FDA to inspect foreign firms.

Dr. WOODCOCK. That's correct.

Ms. DELAURO. In fact, the FDA says that it inspects foreign firms, and I quote, "at the request of foreign drug manufacturers."

So this notion of inspection and additional people, there's really some fundamental gaps here in how you get to what you have and what you need to expect.

Since October 1999, 59 percent of all foreign human drug firms in FDA's inventory, of inspected foreign drug firms, have been inspected only once.

About 63 percent of all foreign generic manufacturers were never inspected even once.

But we have no statutory requirement——

Mr. FARR. Ma'am——

Mr. ROTHMAN. Mr. Farr, would you yield?

Mr. FARR [continuing]. It's so shocking that if you would make a—we know these gaps, and you pointed out it's your number one priority, but we have no idea what the number is.

Yes.

Mr. ROTHMAN. I thank the gentleman for yielding.

Dr. Woodcock, the point I was trying to get at earlier, and Congressman Farr is elaborating on it as well, is a request was made to have an increase in investigators.

Presumably, there was some rationale given to the administration as to why you needed more investigators.

Presumably, you said how many you needed, and why you needed them, and what they were going to do if you got them.

So I find it puzzling that you don't have that information now, or it appears that you need to generate this data de novo, brand new.

Is it that you're just not aware of what was in the rationalization in the budget request that you folks made, that your predecessor made, or they never explained why they needed more or how many they needed?

CLINICAL TRIALS, DATABASE

Dr. WOODCOCK. It's that we have a broad number of needs.

The need I was just talking about was for inspectors, investigators who look at establishments.

We also inspect 1 percent of clinical trials, as far as we can tell, and we also do not have a database, as you pointed out, for clinical trials.

We also have other needs in other areas, as has been alluded to——

Mr. FARR. The second question is along the lines of the first one, because it's just your priorities, because you said that number one

was to hire more inspectors, and number two was to implement plans to modernize and integrate databases.

How much money do you need for that?

Dr. WOODCOCK. Again, that would be a substantial amount of money. It depends on what databases you're talking about.

Mr. FARR. Well, I don't know what substantial is. We deal with billions.

Dr. WOODCOCK. Well, good. I'll take it.

[Laughter.]

Dr. WOODCOCK. Well, no, the drug program budget is 500 and some millions of dollars each year, much of which goes to personnel.

Mr. FARR. You've talked about database integration, and we get that all the time——

Dr. WOODCOCK. Yes.

Mr. FARR [continuing]. With the USDA, and we know the Federal Government runs on databases.

Dr. WOODCOCK. Right.

Mr. FARR. And you said this was a number one request, to get these databases modernized, and as I've heard in other testimony, integrated with other agencies and departments so that you could effectively do these inspections and cover data.

Dr. WOODCOCK. That's correct. That was——

Mr. FARR. You have no figure as to how much that's going to cost?

Dr. WOODCOCK. We could easily come up with a figure. What I was trying to say, in response to the other question, was we have over the years, we have not gotten substantial increases, if you look over two decades, we have not.

Ms. DELAURO. I've suggested that it is not this notion that this has been an unresponsive body to your needs.

I don't believe you've calculated what your needs are and addressed them in terms of priorities and made the request, maybe not you, whoever was directing the agency, and in addition, the administrations, and I'll say administrations.

Most recently, we have seen pretty much the collapse of an agency that had truly the gold standard in the United States.

It's $2.3 billion from 2001 to 2008, the amount of money that you've received. What do we have to show for it?

Mr. FARR. Madam Chair, I'm not going to go further, because it's very painful not to get these answers.

Those are the kinds of things that, if it's broken, our job is to fix it, and we can debate on what a priority is to fix it, but this is—we need this data.

Dr. WOODCOCK. Well, may I just respond a little bit?

Mr. FARR. Hopefully, you have been, but it hasn't given me any confidence.

Dr. WOODCOCK. I understand.

Mrs. Emerson's question was simply about the drug quality piece of this, the drug registration listing imports and inspections and so forth. That relates to maintaining drug quality. That's one piece.

That is not the entire list of additional things that need to be done.

Mr. FARR. Is it still your number one priority?

Dr. WOODCOCK. I'd say that is a number one priority over all the different needs that we have, but there are other important——

Mr. FARR. Are you changing number two priority?

Dr. WOODCOCK. What do you mean, changing?

Mr. FARR. Well, if you just responded to a specific, as you interpret it to be, from Mrs. Emerson——

Dr. WOODCOCK. Yes.

Mr. FARR [continuing]. Now, you just stated that there's other issues.

Dr. WOODCOCK. There are.

Mr. FARR. Is number two the database or is it now something else?

INSPECTORS

Dr. WOODCOCK. Well, if you recall, I said we had two number one priorities, so if you want the number two or number three priority, it would probably relate to more inspectors to monitor the clinical trials, to go out and inspect clinical trials, both in the United States, and increasingly, is growing in Europe.

Mr. FARR. So the more inspectors—all I wrote down was more inspectors, because you didn't specifically say for what.

So now we need two types of more inspectors?

Dr. WOODCOCK. Correct, but one is called—inspectors, they look at the clinical trials. Another kind is the one that looks at the manufacturing quality.

Mr. FARR. Well, your answer to us when you come back is the total number of inspectors you're going to need for your number one, two, three priorities. All right. Thank you.

Ms. DELAURO. Ms. Emerson.

Ms. EMERSON. Thank you. Thank you.

Let me—this is really a process question.

Well, no. Actually, let me ask something. I'll just follow up with what Mr. Farr was saying.

DATABASE COST

Have you all, as a team at FDA, looked at, or at least with regard to your database, have you actually talked about what this would look like and have you gotten any bids, or have you even gotten that far to get any bids, on how much it would cost you?

Do we have to do a study to determine what kind of a database we want?

Dr. WOODCOCK. We have done extensive work on this.

Ms. EMERSON. Like what, specifically? Tell us.

Dr. WOODCOCK. What the design of the database is. We're ready to move this summer to electronic registration and listing.

We've been developing the application, the computer application under a CRADA, a cooperative research and development agreement.

So that we will be, thanks to the FDA Amendments Act, that mandates electronic activities in that regard, will be able to open the doors this summer, start populating the database. However, we will need to then link it to the field.

We also want it to become part of the entire FDA registration and listing systems, and that would require integration.

We've looked at that. We have the project scoped out. So that we're not just registering drugs here and foods here and veterinary drugs over there, but they would all be in a single FDA application.

So we have gone through and mapped out a plan about how to do this.

Ms. EMERSON. But the reason that you can't tell us how much it is is because it really would depend on the entire FDA system, which makes it a whole lot more expensive than just the piece that you're doing, in order to make it link and talk and everybody be able to access that information, correct?

Dr. WOODCOCK. That's correct.

Ms. EMERSON. Has the big FDA in general been helping, and are they interested in doing that, as well, with you all?

Dr. WOODCOCK. Yes. Well, I was actually speaking as deputy commissioner. This is something I did over the last couple years.

I got the bioinformatics board together. I got the different centers all to work together to make a plan to have single databases for registration and listing, and for adverse event reporting.

We would like to build a portal so that every—anybody, any consumer, anyone could log on and report a problem or adverse event to FDA from a single FDA web site, and so forth.

Ms. EMERSON. Okay. So the next step in the process to make this a reality is to determine how much it's going to cost.

Do you go out and ask IBM or some you know, IT companies to come in and bid on it?

I mean, I'm serious. I don't have a clue what happens next.

Dr. WOODCOCK. Yes. There are project plans in place to get these things done, and we have to go through contracting.

We also have to get a final regulation out on drug registration and listing.

Why do we need to do that? We need to modify the NDC number. Are you familiar with that?

That's the number that's used for billing. It describes each drug, each dosage from under this code.

We have to change that in order to get rid of all the volunteers, okay, who put things that aren't drugs into this database. Okay.

We have devices in there, we have unapproved drugs. They give themselves NDC numbers.

So we have to—and we have to do that by regulation, because there was already a regulation in place that said how you had to do it, by paper.

So those things are in process. We will get them done. We will be able to fund them this year with the monies that have been made available.

Ms. EMERSON. So I guess the bottom line is, at some point in time in the next month or two months, would you be able to tell us how much it would cost to do an integrated system that would at least satisfy your number one priority?

Dr. WOODCOCK. Yes.

Ms. EMERSON. At least tell us how much it's——

Dr. WOODCOCK. I believe, yes, we can do that.

Ms. EMERSON. And give us a business plan?

Dr. WOODCOCK. Yes.

Ms. EMERSON. Okay.

[The information follows:]

FDA is preparing a document that describes its business plan for an electronic registration and listing system. Consistent with the request made by Rep. Emerson during the hearing, FDA will submit a document to the subcommittee in 30 to 60 days.

Now, my next question has to do, back on the reimported drugs issue, you know, and this whole issue of web sites and not knowing whether or not we're dealing with counterfeit drugs or real drugs?

And I'm not talking about a web site from a Canadian pharmacy.

I'm actually talking about every single thing that goes into my junk mail, for example, that says, get, you know, Viagra, which I obviously don't need. You know, those sorts of things, but for a much cheaper price.

Do you—how do you oversee this, or can you, can you oversee all of those web sites that, in fact, promote cheaper drugs?

Dr. WOODCOCK. We've been struggling with this for years, because you can set up a web site easily, and you can come and go if somebody comes after you.

I think, David, you can talk about this more. You've been spearheading some of those programs.

Mr. HOROWITZ. It's very difficult.

The web sites are foreign. If you send them a letter, if they even have an address, a hard address, or you can send them an e-mail, a cyber letter we call it. They can change names and set up somewhere else.

What we've tried to do is collaborate with the Federal Trade Commission and other regulatory agencies, including foreign law enforcement, and to try to find the areas where they're the greatest concern and to try to target those.

But our resources are so limited, that we have to pick and choose——

Ms. EMERSON. So why do you think—Madam Chairman, I know my time is up, but let me just pursue this just for a second.

Can you—why do you think there are so many web sites cropping up trying to sell people drugs cheaper? Why do they exist? Why are they coming into—why are we having new ones every day?

Mr. HOROWITZ. I'll ask Dr. Woodcock if she knows the——

Dr. WOODCOCK. Well, first of all, some drugs aren't affordable for some of our population.

Second of all, as I learned from an attorney general once, a state attorney general, the criminals are always one step ahead of us, is what she said, and I think that's true. That's a problem.

And people, health fraud, there are people out there all around the world now, can reach our population and defraud them over the Internet.

Ms. EMERSON. So it seems to me that if in fact we're able to get this database fixed the way you really want it fixed, and you can maintain chain of custody, et cetera, et cetera, then it seems to me that if we have a legal type of reimportation program or parallel trading, as they do in the EU, then at least you would have the capability, which might drive prices down, and therefore we wouldn't have as many web sites cropping up where people are trying to sell drugs on the black market and make a fast buck, but also people who are desperate, you know, think they can afford it.

I'm just—so, I mean, that's my point. I'm just thinking that, Madam Chairman, the more that we are able to do to help them control the drug flow in and out and know what's going on, the more opportunity we have to try new systems to bring the drug prices down and obliterate these web sites.

Thank you.

Ms. DELAURO. Thank you.

DOWNGRADING ENFORCEMENT ACTION RECOMMENDATIONS

Let me just see if I can get a couple of questions in.

This is a document, as I understand it, it's the establishment inspector report, which is something that comes out from the agency. It's an FDA chart.

And what was difficult, in looking at this, when the violation falls into the highest category, which is official action indicated, which is this graph here, the need for immediate enforcement action, it would appear, is the highest.

It was disturbing to learn, this is 2004, that the CDER headquarters overruled almost all of the district recommendations for OAI classifications for foreign human drug facilities. Headquarters believed that only voluntary action was needed.

And according to the GAO report, this pattern was also evident in 1996 and in 1997.

And this was on your watch, Dr. Woodcock.

Why are we downgrading the recommendations from inspectors on this? Because this then winds up in the voluntary category.

Can you give me an answer to that, where you've got these recommendations for official action, enforcement action?

Dr. WOODCOCK. Yes. We've looked at this very carefully, because we've been trying to put together a quality system for our inspectional program.

And certainly where you have that amount of disagreement or whatever you might call it, between the investigator who goes out, the district recommendations, they're basically recommendations, that then are sent to headquarters, and then headquarters has a different opinion, then there's some misunderstandings about what the policies are amongst these different parties.

And so we look at these and decide what their level of importance is, whether they're legally supported, which is something we have to do, and so forth and so on, and make a final determination. That is the role of our office of compliance.

I have a note here from the head of our office of compliance, Deborah Otter, who says most of these that are overruled are the BIMO inspections, the inspections——

Ms. DELAURO. Pardon?

CLINICAL TRIAL INSPECTION TRAINING

Dr. WOODCOCK. The BIMO inspections, the inspections of clinical trials.

However, I agree with you that this is a sign that we're not all on the same page about what the policy is.

Now, we've had trouble, especially in BIMO, getting the inspectors in, getting them all trained, getting us all on the same page

about what is a violation, what isn't a violation, and how we should manage this program.

Ms. DELAURO. Is there any number about upgrading? In other words, upgrading the—how often do we upgrade these inspectors' recommendations?

Dr. WOODCOCK. You mean make them more stringent? We certainly do that.

We have done that recently in some cases. In some cases, we've actually taken regulatory actions.

We, over the last years, we've been training our GMP inspectors into what's called the pharmaceutical inspectorate, and that's a program where they get very advanced training, they come into the center, they meet with our reviewers, they learn everything. This has been extremely positive.

I would like to expand this to the BIMO inspector program as well, so that we can all get on the same page.

Ms. DELAURO. Okay. I appreciate that, and it just seems odd that, once again, we are in the voluntary mode of doing what people have to do versus official enforcement action.

And I don't have to regale this. I mean, I think we all know this always revolves around moving to voluntary guidelines, voluntary actions, and not any kind of enforcement action until, my God, we absolutely have to, and, you know, there is no recourse.

This was a comment that I think I made, a question that I asked.

Depending on the nature of the violations found during an inspection, it is FDA's practice to give individuals and firms an opportunity to take voluntary and prompt corrective action.

And as I understand it, FDA does not generally go back to inspect to see whether the changes were made until the company tells FDA it is ready for reinspection.

Again, one more time, where we are totally in the hands of the industry.

And I applaud you wanting to move on this, but we unfortunately have a base of information that tells us that our priorities and our focus are less on what's good for the public health versus what is good ultimately for the industry.

Let me move to a question on the domestic drug inspections, which resolves from what I was asking about here.

I'm going to be very quick about this.

This is with regard to the company that makes 65 percent of all generic, over the counter generic drugs in 2006.

FDA said the plant had been inspected seven times in five years as recently as March 2006. These folks recalled 11,000,000 bottles of, I'm sure I don't have it pronounced right, acetaminophen, because metal particles were found in some of the caplets.

GLAXOSMITHKLINE MANUFACTURING VIOLATIONS

In 2005, FDA had to have U.S. Marshals seize Paxil CR and Avandamint tablets at two Glaxo Smith Kline facilities because of severe manufacturing problems.

There were inspections back to 2001, 2002, warning letters sent 2002. FDA had additional inspections in November, December 2002, again in September, November

Glaxo Smith Kline is not a mom and pop operation. We keep going back and inspecting and inspecting. In 2002, there were various violations.

Thirteen inspections at four New Jersey and Puerto Rico facilities since 1998, where we found significant violations of the CG&P regulations related to the facilities.

U.S. Marshals last year seized hundreds of thousands of dollars worth of drugs and dietary supplements. FDA issued a warning letter to the company in 1999 about serious drugs, and yet, seven years went before we did nothing, FDA did nothing between 1999 and 2007.

Again, a plant with generic drugs, nine inspections in two years, a dozen recalls. FDA warning letters. Consent decree entered into in 1998 about manufacturing standards, warning letters 2002, 2004.

And again, we got a president and CEO pled guilty to 19 counts of distributing adulterated drugs. The new CEO in 2008 got a warning letter for multiple serious manufacturing violations.

There are lots of other examples.

We talk about inspections. We're going back and back and back to places again. We're talking Glaxo Smith Kline, Shearing Plough. This is not some mom and pop operation someplace.

And it's—do we have the inspectors overridden in these cases? Did we fail to have inspections? We didn't fail to have inspection.

Why don't we take decisive action at the time when these events occur the first time around, which would clearly free up money for inspections in this area and a variety of other areas.

Dr. WOODCOCK. David, do you have any comments on this?

Mr. HOROWITZ. I appreciate the need for a strong enforcement program, and to do it sooner rather than later is always better, and it's more efficient, and if we can nip it in the bud, I completely agree we need to do that.

We do get a lot of compliance by pointing out problems that were not otherwise known to the firm.

That's why we do inspections, in part, is to find problems and make firms fix them, and in the majority of cases, we are able to obtain the corrective action we need by pointing them out, through advisory actions, through inspections, and sometimes through letters that point out that this has to be taken care of.

When that's not done, we have to take other actions. Those are costly and take resources, of not just the FDA, but the Department of Justice, to bring judicial enforcement actions.

Ms. DELAURO. David, with all due respect, with all due respect, I don't make up these issues. We're talking seven inspections, seven years.

I mean, this is—there appears to be, as I said, no interest in taking authority and enforcing it, and in addition to which, getting new authorities, lest you might be forced to use it.

That is unacceptable, when we're dealing with—you deal with life and death, and I think you know that as well as I do. We're dealing with life and death with some of these instances.

A letter is nice. Corrective action is great, and if it's done, boom, that's finished, that's off the table. Seven years. Nine inspections. I don't want to go back through all this.

I mean, I think that that rises to negligence of an enormous proportion.

I thank you for your comment, but I really do believe that's serious negligence on behalf of the agency.

Mr. Kingston.

Mr. KINGSTON. Thank you.

REDUCTION IN WARNING LETTERS

Why have the number of warning letters gone down so much, according to your web site?

Dr. WOODCOCK. A policy decision was made to have more legal sustainability or support to the warning letters that were issued by the agency. I think that was—do you know when that—

Mr. KINGSTON. Is it a good thing, or—you know, I mean, you're going to be charged that this shows that you're being lax on enforcement.

And what I want to hear you say is no, this is a good thing, and here's why.

Dr. WOODCOCK. David.

Mr. HOROWITZ. Well, I think it's actually a complex phenomenon, and I and many others in the agency have concerns about the decrease in those numbers, because it's important that we maintain a credible turn, and that there is action that is taken promptly when there is not corrective action by the firm.

But there are a number of explanations for this.

One of them is that the compliance rate has improved in recent years, and so it's not surprising that, given that there is a smaller number of inspections classified as OAI, ultimately, that that would result in a smaller number of warning letters. But I do not believe this is the entire story.

I also think part of the story has to include resources. It's not the entire story, but it is part of the story here.

The field's resources declined significantly between 2003 and 2006, and that had an impact on a variety of different activities the field engages in.

Mr. KINGSTON. David, I don't want to interrupt you, but are you aware that the FDA commissioner refused to testify before this committee in 2006 until we zeroed out the funding on a bipartisan basis, and in fact, the chair, who was ranking at the time, offered the amendment to zero out the funding.

And I just want that to be—you know, I think that's relevant to the record. The only way we could get the commissioner to testify before this hearing was to zero out FDA funding, and when we did have the hearing, and Rosie, I don't remember the date, it seemed like it was, you know, maybe August or——

Ms. DELAURO. July or August.

Mr. KINGSTON. Yeah. It was later on.

So, you know, that was in 2006, and that's something to—you know, how let me say this. I'm pro FDA. I'm not here to—you know, I don't think there is a drug crisis, a safety crisis in America.

Frankly, what I want to hear you do is do a little more chest pounding and say, you know, "You guys are crazy. Let me give you the statistics."

And I guess with that, let me kind of throw the volley to you. That's what I want to hear.

I mean, if I have constituents and consumer groups telling me that there's a drug safety crisis in America and the FDA is spread too thin, negligent, lax on enforcement, in bed with the pharmaceutical, I want to hear you tell me why that is absolutely positively without question wrong.

INDUSTRY INFLUENCE ON FDA

Dr. WOODCOCK. It is absolutely not the case that FDA is excessively influenced by industry in its judgments about drugs.

Our staff has an adversarial relationship with industry, and they always have. It goes up and down, over the years. It's probably in an up phase right now.

We have approved multiple drugs over the past 10 years that have provided health advances for millions of Americans. We are seeing now more drug safety problems, and you can ask why.

The reason we are is that we can find them better. The science has advanced. The drug development programs and post-marketing programs that occurred 20 years ago have no resemblance to what we do now.

And so we are much smarter, we're much more able to detect these problems, and we have developed a policy of early warning. So we're telling everyone about them when we find them.

So the problems are discovered. If you look, you find things. When we find them, we get them out, so that the doctors and the patients are aware.

But that doesn't mean that the benefits to patients of the drug supply in the United States have diminished. They have increased.

Mr. KINGSTON. I will yield back, but Dr. Woodcock, you've done a good job, and David, you always do, and I just want to say thanks.

But, you know, what we are up against I think is an image of America right now of incompetence right now.

You know, were there weapons of mass destruction? There was bipartisan, it was agreed that there were. And yet it was a colossal intelligence failure. You know, if there were, we couldn't find them.

We've spent I think $120,000,000,000 in the Gulf, and maybe the face of the storm is 35,000 mobile homes dripping with formaldehyde or emitting formaldehyde or whatever.

And so there is this competency thing. And what I would love to hear more from the FDA on is, you know, "We're doing a doggone good job, and here's why."

Now, I'll tell you, my brother-in-law is a physician, and he deals with lots of senior citizens. He is the biggest pro-FDA guy.

And he's, you know, on the road, he's very, very non-political, but he tells me that your balance between scrutiny and approval is about where it needs to be.

And this is a guy who has, to me, a lot of influence, because he has no political agenda.

You can always find somebody who says you're approving too fast, and somebody who says you're approving too slow.

So, you know, I guess what I'd like to see you do more of is just sort of talk about some of the successes, because right now, there's

a lot of criticism out there, and we as members of the, you know, elected public, or representatives of the public, we're going to—you know, we've got to be very careful to make sure that the job is being done with competency.

Dr. WOODCOCK. Well, I thank you, and I think there is a great story to be told, despite all the issues that have been raised, that we really have a very strong program. We are the gold standard, still, in the world.

People around the world look to the FDA and the FDA drug program as where they want to be with their drug review programs, and we are continuing on that trajectory.

Mr. KINGSTON. Thank you.

Ms. DELAURO. There are going to be a couple of votes, and we do have a second panel.

Mr. ROTHMAN. Thank you, Madam Chairman. Dr. Woodcock, I agree with my colleague from Georgia, and I think every one of us here appreciates the enormity of the tasks and challenges before you and your colleagues at the FDA. We depend on you. We, as the chairwoman has said, we want to do everything in our power to provide you the resources and the tools to accomplish the very difficult tasks that you have to perform. You have witnessed this frustration at our inability to find out how we can best give you the resources that you need and encourage those in the administration to allow you to come to us with the information that we require to responsibly address our job, which is to be stewards of the public money as we give you what you need to do the work that serves our constituents. My question has to do with the morale at the Center for Drug Evaluation and Research amongst the employees. How would you describe the morale today?

EMPLOYEE MORALE

Ms. WOODCOCK. Well, we have recently done a comprehensive survey. We hired professional contractors. They did an anonymous survey of the staff as to the culture of FDA, and this was a professionally done survey, we had nothing to do with it, the management, except that we received the results, and we looked at what people think. I would say morale is fair, not terrible, it is not great. The amount of ad hominem attacks that the members of my staff have undergone over the past several years has caused some of our best scientists to leave the agency, and it has really diminished people's ability to feel comfortable doing their jobs.

Mr. ROTHMAN. Madam Chairman and doctor, you are quoted as saying that the reason for low morale was the user-fee mandated schedules, again this is from, to be fair, apparently in an article you wrote in September/October 2000, it is now 2008, do you still attribute some of this low morale to the PDUFA Act, is the PDUFA Act therefore counterproductive?

Ms. WOODCOCK. I would say that the workload installed by this Act has over time been a negative impact on morale. Currently, the Center is 550 people under the ceiling that was established by the increased resources that were provided this year. They were 150 people under the 2007 ceiling, and now we have received additional resources. If we can get that staff on board and trained, I think people are going to feel a lot better about the workload part of this.

But we are an agency under assault, and it is going to be difficult for us if this continues to attract the world-class scientists that we need.

Ms. DELAURO. I thank the gentleman. I understand what you are saying, Dr. Woodcock, but I think that several of your people have come under ad hominem attacks from the agency itself, that forced them to leave after having given opinions and given what may have seemed to be advisory opinions that someone somewhere at the top of the heap did not like, and they have been told they would be "traded from the team," and that is a quote. Mrs. Emerson?

FDA MEDICATION GUIDE

Mrs. EMERSON. Thank you all again so much for being here today, and we just want to help, so please know that. I have two questions I want to make for the record if you all could get back to me in the next week with answers, I would be grateful to you. The first one has to do with the FDA medication guide program, those leaflets that you all require when we go get medication. I just would like to know what the status of the Agency's reformed that medication guide or program, I think we asked you all to give us several steps last year to make it more effective for patients and more efficient for our pharmacists to obtain. You do not have to answer these now.

Ms. WOODCOCK. Well, we have had a public meeting on this, and we are moving on this, so we will be happy to get back to you.

[The information follows:]

FDA is examining its internal process to promote consistency in the selection, content, and format needs of medication guides. FDA is also implementing an enforcement strategy to ensure that sponsors are meeting their statutory obligations. In addition, FDA is exploring the means to improve electronic access to Medication Guides.

FDA plans to collaborate with pharmacy groups, including the National Boards of Pharmacy, to ensure that practicing pharmacists understand their responsibilities and the requirements for distributing medication guides.

Furthermore, under the Food and Drug Administration Amendments Act (FDAAA) most MedGuides will now be approved as part of Risk Evaluation and Mitigation Strategies (REMS). FDAAA includes enforcement provisions, including misbranding charges and civil money penalties, for failing to comply with the REMS provisions. FDAAA also requires FDA to provide postmarket drug safety information on a website, including a link to a list of all drugs with MedGuides, and to post approved professional labeling and required patient labeling.

CITIZEN PETITIONS-GENERIC DRUGS

Mrs. EMERSON. Okay, so hopefully in the next week. And then also, my last question has to do with the whole issue of citizen petitions with regard to generic drugs. I know that back in September the President signed the Food and Drug Administration Amendments Act, and we had a provision in there to deter the filing of the frivolous citizen petition.

Ms. WOODCOCK. Right.

Mrs. EMERSON. I just wanted to know where you all are in that process and why these delaying citizen petitions continue to hold generics off the market, and you can get back to me on that.

Ms. WOODCOCK. The lawyers tell me it is a very challenging provision, so we will be happy to get back to you.

[The information follows:]

FDA is making every effort to comply with Section 914, which added new section 505(q) to the Federal Food, Drug, and Cosmetic Act. This provision of FDAAA took effect upon enactment. Therefore, FDA is in the process of interpreting the new provision and developing implementing procedures while simultaneously addressing citizen petitions and petitions for stay that are subject to the new requirements. FDA has received at least 13 petitions subject to section 505(q).

FDA has taken a number of steps to implement this new statutory mandate. We have established a working group that includes members of several offices within the Center for Drug Evaluation and Research and the Office of Chief Counsel to address questions about interpretation of the statute, as well as new implementation procedures. FDA has had to make determinations relating to the certification requirements, scope, and whether particular petitions should delay the approval of a generic drug application. The first two petitions subject to section 505(q) were submitted on October 15, 2007. We issued our response to those petitions on March 24, 2008, within the required 180-day timeframe. We are working on responses to all the pending petitions that are subject to section 505(q). We note that although this provision may have been designed to limit the delay of drug approvals because of petitions submitted on behalf of innovator drug companies, almost half of the 505(q) petitions we have received were filed by or on behalf of generic drug manufacturers seeking to block or delay approval of other generic drugs.

We believe that it is too soon to evaluate the effects of the new provisions on the citizen petition process. We note that section 914 requires us to submit a report to Congress annually on the numbers of covered petitions and applications affected by those petitions, and we will submit that report after our first year's experience with implementing the law.

Mrs. EMERSON. Thank you so much.

RISK-BASED INSPECTIONS

Ms. DELAURO. I just have an expanded question for the record, but let me just mention that there has been a mention of risk-based inspections and that you are moving forward with plans to deal with risk-based inspections of drug manufacturers. And, as I have said to FSIS on the USDA side, I have no problem with risk-based inspections but risk-based inspection is only as strong as its scientific base. I must tell you, and I will submit the question to you, I was concerned when I did see the science report that called into question the agency's basic capacity in risk assessment and analysis, and it said there is insufficient capacity in modeling risk assessment and analysis. So I believe we ought to be cautious in moving in that direction without establishing the kind of risk-based analysis that we need.

The final question is again the Institute of Medicine, there was a report in 2006 that said there were problems with cultured FDA complex relationships between pre-approval group and the Office of New Drugs and the Office of Surveillance Epidemiology. Also, I guess in page eight or nine of your testimony, Dr. Woodcock, you say—and this is what is of concern to me, and this is Office of Drug Safety has become OSE, Office of Surveillance and Epidemiology, but you seem to be loading OSE up with tasks to relate less directly to the kind of work they have been doing on the safety profiles of drugs already on the market, such as the names of drugs and medication areas. And at the same time, you look as if you are loading up the Office of New Drugs with multiple people to take on a post-market safety in the very offices that have approved the drug for the market in the first place, and that seems to go back to what was said in 2006 in terms of the difficulties or the tension, if you will, between—this seems to be in opposite of what people

think is needed, which is a greater differentiation between premarket and post-market safety reviews. Could you just address that, please?

OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY

Ms. WOODCOCK. Certainly, yes. First of all, your first issue, no, the Office of Surveillance and Epidemiology, in its very incarnation, has already dealt with the name confusion, the trademark names, the medication errors and all these different issues, so that has been one of their responsibilities all along. We are going to try and beef up that function and clarify the roles and responsibilities and give them the lead. We are making agreements between OSE and OND and other offices within the Center for Drugs, so that everybody is clear about what their roles and responsibilities are. And these agreements have provisions that every office will have an equal voice in these decisions, their voice will be heard. OSE will take over, as it develops the capacity——

Ms. DELAURO. Could we get those agreements?

Ms. WOODCOCK. Of course.

[The information follows:]

FDA is in the process of finalizing a Memorandum of Agreement (MOA) between CDER's Office of New Drugs (OND), the Office of Pharmaceutical Science (OPS), and the Office of Surveillance and Epidemiology (OSE). This document outlines how OND, OPS and OSE will manage significant postmarketing safety issues associated with pending and approved human pharmaceuticals. Recognizing the expertise of OSE in observational epidemiologic studies, pharmacovigilance activities, pharmaceutical risk management plans, proprietary name review, and medication error prevention, as currently drafted, this agreement will designate OSE as the lead and primary decision-maker for certain regulatory actions in these areas.

Ms. DELAURO. Thank you.

Ms. WOODCOCK. I would stress that we are very close to signing it. OSE will take the lead on the pharmacology epidemiology studies, that is where their expertise lies. My goal, say if it is a clinical pharmacology problem, such as Warfarin, a drug safety problem, I want the clinical pharmacologist to have the lead voice, okay. I want the right lead voice in the center. If it is an epidemiologist, fine. If it is a medical specialist, fine. If it is a clinical pharmacologist with some of the problems we are having with Heparin, it is our lead chemist, that is the lead in trying to solve this problem. So my goal is not to say this office or that office, my goal is to get the right person and the right team on each problem.

Ms. DELAURO. I understand that, but you do have an office that is set up specifically to deal with the post-market effects of this effort. If you have charged them with that duty, one would presume that you have the competence and the capability in that unit in order to be able to react and not have the fox in the chicken coop.

I have to go to vote. I have about two minutes now to do that. I thank you very, very much and all the folks who have come from the FDA this morning. Contrary to what—I begin and end with this, more resources, better management, less influence of PhRMA and more influence for your scientists. That is where I come out of this and that is what my goal is about. Thank you.

Ms. WOODCOCK. Thank you.

Ms. DELAURO. And if we could ask our next panel to take their seats, we will be right back.

[Recess.]

WEDNESDAY, FEBRUARY 27, 2008.

CENTER FOR DRUG EVALUATION AND RESEARCH

WITNESSES

SIDNEY M. WOLFE, M.D., DIRECTOR, HEALTH RESEARCH GROUP OF PUBLIC CITIZEN

JOHN H. POWERS, III, M.D., FACP FIDSA, ASSISTANT CLINICAL PROFESSOR OF MEDICINE, GEORGE WASHINGTON UNIVERSITY SCHOOL OF MEDICINE AND UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

JOHN E. CALFEE, RESIDENT SCHOLAR, THE AMERICAN ENTERPRISE INSTITUTE

Ms. DELAURO. The hearing will resume. Let me just thank the panel. I thank you for your patience. I know we said we were going to go to one o'clock but it is a little after 1:00 here.

Dr. WOLFE. Pacific Time this morning.

Ms. DELAURO. Right, okay, thank you. Let me make introductions, and then we will move forward. We are very, very pleased to have Dr. Sidney Wolfe. Dr. Wolfe is the founder and the director of the Health Research Group at Public Citizen. Dr. Wolfe is an expert on issues of drug safety, medical devices, health care policy and the Food and Drug Administration. His background includes conducting research at the National Institutes of Health, specializing in aspects of blood clotting and alcoholism and was the adjunct professor of internal medicine at Case Western Reserve University School of Medicine.

Dr. John Powers currently is assistant clinical professor of medicine at the George Washington University School of Medicine and the University of Maryland School of Medicine. Prior to his current academic roles, Dr. Powers was the lead medical officer for the Antimicrobial Drug Development Resistance Initiative at the FDA.

John Calfee, I am pleased to welcome, is a resident scholar with the American Enterprise Institute where he studies pharmaceuticals, the Food and Drug Administration health care policy, advertising, the tort liability system and tobacco. He is the author of Prices, Markets and the Pharmaceutical Revolution, and a book published this fall about biotechnology and the patent system. Mr. Calfee writes for AEI's Health Policy Outlook series and has taught at the University of Maryland and Boston University School of Management.

I might just say I know you all have many, many, many, many more credentials. I am sorry to be brief, but I want us to try to move along and be able to listen to you. And I would also ask you that if you could, obviously your entire testimony will be part of the record, and if you can summarize in this time, it would be helpful, and then we would move on.

Thank you. Dr. Wolfe.

OPENING STATEMENT

Dr. WOLFE. Thank you for the opportunity to discuss what I think this morning confirmed is a dangerously deepening crisis at FDA, a crisis in management I think was illustrated this morning.

Between when I left NIH in early 1972 to start the Health Research Group and now, about two-thirds of our work has focused on the FDA, particularly drugs. The situation of the FDA has never been worse than now in the 36-plus years, and this can be attributed to a confluence of three factors: First, terrible leadership at the FDA, including the Commissioner and most, not all, but most of the center directors; two, increasing reliance on industry to fund FDA activities with almost two-thirds of the drug approval budget, and as you heard this morning, over half of overall CDER budget coming out of the $400 million last year PDUFA allocation; third, relative to the 1970s and 1980s a perilously, and I emphasize perilously low level congressional oversight notwithstanding this hearing today and previous hearings by Congressman Durbin when he was the head of this committee. I was speaking to one of your staff people and pointing out that one Senate committee, the Senate Small Business Committee, had 135 days of FDA oversight hearings in a 10 year period in the 1970s and the 1980s. There is nothing remotely like that now. And, of course, this is the same Congress that has abdicated funding for the FDA to the industry. They were also abdicating too much of their oversight. There needs to be much more.

So I will look at the CDER budget from funding of activities up through and then through approval and then post-approval. For the pre-approval budget and function, I do not think that the size of the budget is inadequate but the source is entirely wrong. The FDA's public health mission is too important to be left to funding by the drug industry with all the concessions and negotiations that industry extracts for paying the majority of the bill for the FDA approval process. Instead, adequate funds need to be appropriated by the Congress as they were for the first 86 years of FDA's existence, from 1960 to 1992, with structured regular mandatory oversight by appropriations and oversight committees.

I do not have time to go through the details of these examples, which are serious pre-approval mistakes, each of them based on data available to the FDA before approval, the drugs got approved, and when enough additional people were killed or injured from the same kinds of problems that were elucidated before approval, the drugs came off the market. None of these were really breakthrough drugs, so if there was a safety question, the FDA should have, as they did 20 or 30 years ago, say, "Wait a minute, let's answer this question before approval," and not with never-to-be-done properly post-approval studies and with the whole population being exposed as guinea pigs to a drug with safety problems.

Going to the third page of the testimony, because of a lot of these problems and a record number of drugs being approved in 1996 and 1997, 91 drugs, about twice as many as normally approved in a two year period, we decided to see what the problem was by conducting a structured survey of FDA physicians, medical officers. And we did that in late 1998. We actually got a higher response

rate to that survey than FDA did in a subsequent survey they did for a slightly different reason. And I will just hit some of the highlights of the response from 53 physicians, who were primary reviewing medical officers.

Nineteen of them identified 27 drugs in the past three years, which was 1995 to 1998, that they should not have been approved but were approved. A tiny number in comparison identified drugs that they thought should have been approved but were not, four or five drugs as opposed to 27. They felt the standards for safety and efficacy were getting lower. Twelve of them identified 25 new drugs that were approved too quickly, including a number of them winded up coming off the market. And 34 of them stated that the pressure to approve new drugs was somewhat greater or much greater compared with the earlier period, pre-PDUFA.

Participated in part by Dr. Woodcock's own concerns about PDUFA, the FDA did a survey to find out why everyone was leaving, why they were bailing out and leaving ship, and Dr. Woodcock's I think now famous remark about what she felt the impact of PDUFA was that because of PDUFA, Woodcock, 2000, "The intense schedules," these are free mandated approval schedules, "create a sweatshop environment that is causing high staffing turnover." If that does not tell you about the morale question. And when she was asked that this morning, she said, "Well, it is sort of fair," and that is an outside one. So the second survey finding on this problem was the FDA's own in 2001.

A third of the people surveyed by the FDA felt their work had more impact on product labeling and marketability than it does on public health. A third felt that the decisions, such as holds or refusal to file actions and non-approvals are stigmatized by the agency, so the idea of ad hominem attacks, as you pointed out this morning, is coming more from the bosses in the agency than from someone else.

If that were not enough, the inspector general in 2003 did a study looking at the same problem again at the FDA, 18 percent, almost one out of five, of FDA physicians surveyed felt pressure to recommend a drug be approved for sale despite the reservations about safety, efficacy or quality. Their conclusion five years ago was that these findings present a significant warning signal, Union of Concerned Scientists did a study a year and a half ago and then the one mentioned this morning also has really grim responses. She calls them "fair but not terrible," but "fair" in the context of what was being talked about is pretty terrible.

So that gets us to the post-approval part of the budget and FDA function. Post-approval safety review is so often, most of the drugs have been taken off the market, the removal was precipitated not by randomized trial as in Vioxx but by a number of adverse reaction reports that had no other explanation; the liver toxicity or whatever could not be explained by anything other than the drug. This practice does not work if the people who are raising these warning flags do not get paid attention to, and no amount of paper shuffling, safety first, to hear at 8:30 last night for the first time in 36 years that safety is first is an insult to start out with, and it is really a misrepresentation of what FDA's priorities are. Approval first is certainly the real priority, and there are too many

current examples at the FDA where safety is not first. We have been trying to get the FDA to ban these so-called third generation oral contraceptives because the FDA missed they double the risk of blood clots. They are still on the market. Darvon, a drug that kills about 200 people a year because accidental deaths from its cardio toxicity is still on the market. So these sort of belie the idea that safety is first.

Increased funding, especially with much of it coming from PDUFA and the absence of increased independence, and we are talking about drug safety post-approval, that would occur if the Office of Drug Safety were made independent of CDER, which is what we have recommended and others, Congress people, Senators Grassley and Dodd. So just more funding and paper shuffling is not likely to solve what is a dangerous imbalance of power between the post-market approval parts of the FDA and the review divisions. The funds must be directly appropriated from the government.

A couple of examples of decreased enforcement, again post-market, we have regularly been monitoring FDA's oversight over drug advertising, prescription drug advertising, and the chart we have is accounting one by one from the FDA's website. And what it shows is that from a peak of 157 illegal drug ads that were stopped by the FDA in 1998, these are ads that overstating the benefits, understating the risks, 157 stopped in 1998, last year 20 stopped. This is an 87 percent decrease and it started during the Clinton Administration and it has sort of plateaued down below 30 for the last six years. This means that companies can design ads, put them out there, not infrequently overstate the benefits, understate the risks, mislead doctors and patients into using these drugs thinking that they are safe or more effective, and the companies do not have too much worry about these ads being stopped as they did at least 10 years ago.

The next chart I have in here is from FDA's website again, it is overall warning letters from FDA to regulated companies, not just drugs, everything else, so in case someone thinks that things are only bad in the CDER, in the drug area, the chart shows a 53 percent decrease from the peak in 1997 of warning letters going out to companies down to 538 in the last year that we have data from, 2006.

Finally, or semi-finally, in the area of foreign drug inspections, as Dr. Woodcock admitted, for 10 years we have been finding out and knowing that there is a rocketing increase in manufacturing of drugs and ingredients in the foreign area. Why is it then that in the last five years, from fiscal 2002 to fiscal 2007, there has been a 25 percent overall decrease in the foreign inspection budget, not as great as the decrease in domestics but 25 percent. How many more of these drug disasters, whether it is coming from China or elsewhere, are we going to have to tolerate before the relatively small amounts of money compared with CDER's budget, the FDA budget, are expended and then some to get way more foreign inspectors and domestic ones as well?

And, finally, the last issue is China, more drug disasters waiting to happen. And this is extracted from GAO's own analysis on foreign inspections. Basically, what it finds, again these are using FDA's own data, China was of the foreign countries that are manu-

facturing things for the United States, the one with the largest number of establishments, 714. India was second at 410. But contrast India with China, India's 410 establishments made up about one-eighth, 12.65 percent of all foreign establishment and was appropriately the subject of 22 percent of all FDA foreign inspections. China, which has 714 establishments, made up 22 percent of all foreign establishments, was the subject of only 13 inspections in fiscal 2007 or only 4 percent of FDA inspections in foreign countries.

In summary, the FDA pre-approval budget is increasingly coming from industry, a trend which must be reversed as soon as possible. The post-approval budget for inspections was not only grossly inadequate in fiscal 2002 but has decreased a further 25 percent by fiscal 2007. There is an enormous amount of tough policing of the relatively toothless FDA in its budget needed by your appropriations committee. We will help you in whatever way we can.

[The information follows:]

Testimony of Sidney M. Wolfe M.D.
Public Citizen's Health Research Group
Before
Agriculture-FDA Appropriations Subcommittee
Hearing on FDA Drug Safety
February 27, 2008

Chairwoman DeLauro and Members of the Subcommittee, thank you for the opportunity to discuss the dangerously deepening crisis at FDA's Center for Drug Evaluation and Research (CDER). Between the time I left the NIH in early 1972 to start the Health Research Group and now, two-thirds of our work has focused on the FDA, especially drugs. The situation at the FDA has never been worse than now and this can be attributed to a confluence of three factors:

- Terrible leadership at the FDA, including the Commissioner and most of the Center Directors

- Increasing reliance on industry to fund FDA activities, with almost 2/3 of the drug approval budget coming out of the $400 million+ PDUFA drug allocation for FY 2008

- Relative to the 1970's and 1980's, a perilously low level of Congressional oversight and oversight hearings by the same congresses that have, since 1992, increasingly turned over FDA funding to the industry

I will discuss the CDER budget from the perspective of funding of activities up through approval and post-approval.

Pre-approval budget and function

I do not think that the size of CDERs budget for these activities is inadequate but the source is entirely wrong. The FDA's public health mission is too important to be left to funding by the drug industry with all of the concessions and negotiations that industry extracts for paying the majority of the bill for the FDA drug approval process. Instead, adequate funds need to be appropriated by the Congress, as they were for the first 86 years of FDA's existence (1906-1992) with structured, regular, mandatory oversight by appropriations and oversight committees.

An analysis of serious post PDUFA mistakes made by CDER in approving a number of drugs that had evidence prior to approval of bright red warning signs illustrates the problem of CDER funding by industry:

Duract (bromfenac): The FDA medical officer reviewing bromfenac sodium, the 20th nonsteroidal anti-inflammatory drug (NSAID) approved in the United States, unsuccessfully advocated a black box warning label as a

condition of approval because, "The review of the 'liver' laboratory data from the submission shows that bromfenac sodium causes hepatocellular damage to a greater degree than other NSAIDs"(R. M. Widmark, unpublished data; FDA medical officer review memo, bromfenac sodium, December 22, 1995). After at least 4 deaths and 8 liver transplants, bromfenac sodium was removed from the market.

Posicor (mibefradil): Data from congestive heart failure trials presented at a Food and Drug Administration (FDA) Advisory Committee meeting on whether or not to approve mibefradil suggested that more patients treated with the drug died of sudden deaths than those taking placebo. Several committee members voted against approval. The drug, the ninth calcium channel blocker approved in the United States, has since been removed from the market because of life-threatening arrhythmias from drug interactions. j

Rezulin: (troglitazone), the 11th drug for diabetes in the United States, was approved even though 1.9% of patients in the pre-marketing trials, 54% of whom had taken the drug for at least 6 months, had liver function test results greater than 3 times the upper limit of normal, and 0.4% and 0.2% had 10-fold and 20-fold elevations, respectively. Well before it was removed from the market, troglitazone had already been associated with a minimum of 43 cases of liver failure, including 28 deaths.

Trovan (trovafloxacin): Trovafloxacin was approved by the FDA in 1997. Like (bromfenac), there was also clear evidence of liver damage caused by Trovan in animals and in humans before the drug was approved in December 1997. In one pre- approval study in which the drug was used to treat prostatitis, 10% of the men (14 out of 140) given the drug developed evidence of liver toxicity. With eight other drugs in this fluoroquinolone antibiotic family available in the U.S, as well as dozens of other safer and equally or more effective drugs for infections, the removal of Trovan from the market by the FDA would not have deprived doctors or patients of a drug that could possibly be considered indispensable. Instead of banning Trovan in 1999, as was done everywhere else in the world, the FDA chose to "limit" its use in the United States to patients who were either hospitalized or in nursing homes. At the time of our petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three liver transplants. There were, as of December 31, 2004, a total of 58 cases of liver failure, including 29 deaths and nine people requiring liver transplants. This is especially alarming since for the past several years there were a total of only 350,000 prescriptions filled in the U.S.(from April 2002 through Feb 2005). As sales waned following the 1999 market withdrawal in Europe but more and more cases of liver failure and death occurred, Pfizer quietly discontinued making the drug in 2002. However, during the latest year for which U.S. sales data are available, there were still 18,000 prescriptions

filled in the U.S (March 2004 through February 2005), long after Pfizer quietly stopped manufacturing the drug.

Lotronex (alosetron): Seven cases of life-threatening ischemic colitis occurred in clinical trials for this drug with marginal benefits in treating the diarrhea variety of irritable bowel syndrome. Within six months of marketing an additional 16 cases had occurred. We petitioned the FDA to remove it from the market but, after its removal, it was approved with very limited distribution.

1998 Public Citizen Survey of FDA Medical Officers

In 1998, after two years (1996-7) of record numbers of FDA new drug approvals and the increasing numbers of these drugs that were rather promptly being taken off the market after post-approval deaths and serious injuries confirmed pre-approval concerns, Dr. Peter Lurie and I conducted a written survey of FDA medical officers to find out their views on the changes that had occurred post-PDUFA.[1] This was to be the first of several studies by others concerning this problem.

> Of the fifty-three Medical Officers who responded there were the following findings:
>
> Nineteen Medical Officers identified a total of 27 new drugs in the past three years that they reviewed that they thought should not have been approved but were approved.
>
> Asked how they would compare the current standards of FDA review for safety and efficacy to those in existence prior to 1995, 17 Medical Officers described the current standards as "lower" or "much lower," 13 described them as "about the same" and six described them as "higher." None described the standards as "much higher."
>
> One Medical Officer stated: "My feeling after more than 20 years at FDA is that unless drugs can not be shown to 'kill patients' outright then they will be approved with revised labeling and box warning."
>
> Twelve Medical Officers identified 25 new drugs that they reviewed in the past three years that in their opinion had been approved too fast.
>
> Thirty-four Medical Officers stated that the pressure on them to approve new drugs was "somewhat greater" or "much greater" compared to the period prior to 1995.

[1] Medical Officer Survey 1998

One Medical Officer stated: "We are in the midst now to approve everything but to describe drug weaknesses in the label. As one high ranking official said 'Everything is approvable. We can use the labeling creatively to lower the problems.'"

Eight Medical Officers reported 14 instances in the past three years in which they had been instructed, usually by the Office Director, not to present their own opinion or data to an FDA Advisory Committee when to do so might have reduced the likelihood that a drug would be approved.

Nine Medical Officers identified 19 new drugs that they had reviewed in the past three years that had been inappropriately shifted to the accelerated approval track

Thirteen Medical Officers identified 18 occasions in the past three years when a supervisor, usually their Division Director, had asked the Medical Officer to change his or her opinion to agree with the supervisor's, usually in a direction favoring approval.

One Medical Officer reported: "In the last 2 years, I recommended that two drugs not be approved. They were both approved without consulting me. This never happened before. In one case, the drug did not meet the standards set up by the division, so they nullified the standards."

2001 FDA Survey of CDER Personnel

One of the reasons the morale in CDER is as low as at any time in the past 35 years was aptly summed up by a statement of CDER Director Dr. Woodcock that " the intense [user fee mandated] schedules create a sweatshop environment that's causing high staffing turnover". [2]

In a survey by the FDA of CDER personnel in 2001, intended to discover the reasons for the high rate of staff turnover, the problems found included the following: "About one third of respondents did not feel comfortable expressing their differing scientific opinions...over one third felt that decisions such as holds, refuse-to-file actions, and non-approvals are stigmatized in the agency. Over one third felt that their work has more impact on a product's labeling and marketability than it does on public health. A number of reviewers added comments stating that decisions should be based more on science and less on corporate wishes." One of the

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[2] User Fees for Faster Drug Reviews: Are They Helping or Hurting the Public Health? FDA Consumer magazine September-October 2000

13 recommendations in the report is to "Encourage freedom of expression of scientific opinion."[3]

We believe that unless this occurs, along with healthy debates, the FDA will not be able to attract and keep its best staff. Debate, attention to dissident views, and freedom of expression are not only the hallmarks of good science; they are also the essence of democratic governance.

HHS Inspector General Study of FDA: 2003

The IG study confirmed that decisions concerning drug safety and effectiveness were being overturned. Eighteen percent of surveyed FDA physicians and scientists felt pressure to recommend that drugs be approved for sale despite their reservations about the drug's safety, efficacy or quality. The report concluded: "Overall, these findings present a significant warning signal."

Post-approval budget and function

The two topics I will discuss here are post-approval safety reviews of drugs, often precipitated by a series of well-documented adverse reactions to drugs, and post approval compliance activities including inspections of pharmaceutical companies.

The concept of generating a signal from adverse drug reactions is useful only if the signal is taken seriously and the action taken is prompt and proportional to the strength of the signal. This is especially important when the signal confirms earlier, preapproval evidence of dangers seen in randomized controlled trials, as in the 4 drugs cited above. There has been an historic split and an imbalance of power between FDA drug review divisions and the postmarked surveillance (offices of drug safety) divisions. In too many instances, serious post marketing safety problems identified by the offices of drug safety have not been acted upon because of resistance from FDA management and from the review division that originally approved the drug and now gets the majority of its funding from industry.

Increased funding, especially with much of it coming from PDUFA, in the absence of the increased independence that would occur if the offices of drug safety were made independent of CDER is not likely to solve this historic imbalance of power. The funds must be directly appropriated from the government.

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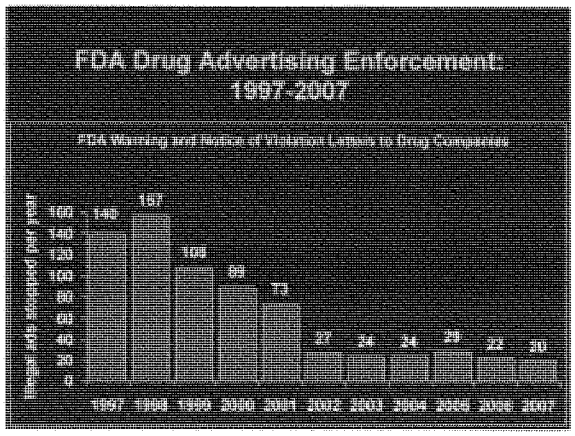
[3] Quality Assurance Program. Recruitment and Retention of CDER Reviewers: Final Report (FDA). 2001.

Enforcement of Laws and Regulations Concerning Prescription Drug Advertising

Although we have always supported more funds for DDMAC (CDER's Division of Drug Marketing Advertising and Communications), starting in 1999, there has been an enormous reduction in enforcement actions (warning letters and notice of violation letters) each demanding that an illegal ad be stopped. From a maximum number of such illegal ads that were stopped in 1998 (157 ads), the number has fallen drastically and dangerously to 20 last year in the face of an actual increase in the amount of money spent on prescription drug advertising. The figure below shows that by the end of the Clinton administration there had already been a decrease to 89 such actions (a 43% decrease) and that has fallen to 20 last year (an 87% decrease), having bottomed out for the past six years. This is inexcusable and is not proportionate to any decrease in DDMAC staff nor any evidence of a law-abiding epiphany by the drug industry. This means prescribing decisions are too often based on perceptions that drugs are safer and/or more effective than they actually are because of the misleading ads, misleading doctors as well as patients.

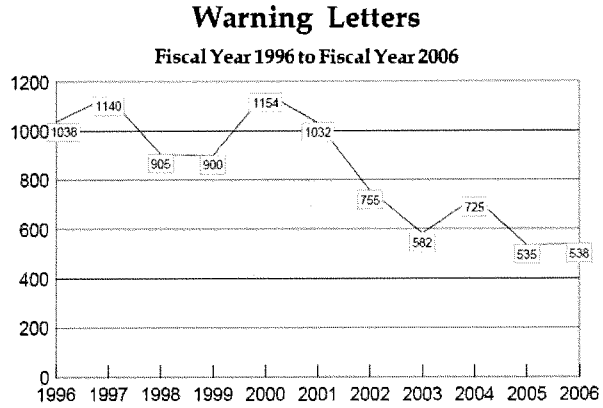


(data compiled from FDA web site)

Sharp Decrease in Warning Letters for all of FDA to Regulated Companies

As seen in the chart below, there has been a similar FDA-wide decrease in warning letters to all regulated companies. Unlike DDMAC activities that are accomplished centrally, much of the other compliance activities in FDA depend on inspectors, most of whom are in the field. The number of warning letters

decreased from a maximum of 1154 in 2000 to 538 in FY 2006 (a 53% decrease), the last year for which data were available.



Foreign Drug Company Inspections: Sharp Decrease in funding

Although more funding could be used for domestic inspections which make up the bulk of the companies receiving warning letters and other enforcement actions, the situation with respect to inspections of foreign drug facilities is desperate and the consequences are increasingly being brought to attention in the form of dangerous products being produced in these inadequately inspected plants.

From FY 02, when the FDA foreign drug company pre-market inspection budget was $ 8.274 million to FY 07 when it was $5.836 million, there was a decrease of 30% in funds for foreign inspection Similarly, the post-approval inspection budget decreased from $ 5.256 billion in FY 02 to $4.345 in FY 07, a 17% decrease. Overall, the foreign inspection budget had a total decrease, during this recent 5-year interval, of 25%. This unfortunately, for the health of American consumers of drugs, comes at a time when the number of foreign plants manufacturing drugs for import into the U.S., especially countries such as India and China, was rapidly increasing.

In summary, the FDA pre-approval budget is increasingly coming from industry, a trend which must be reversed as soon as possible. The post-approval budget for inspections was not only grossly inadequate in FY 02 but has decreased a further 25% by FY 07.

There is an enormous amount of tough policing of the relatively toothless FDA and its budget needed by your appropriations committee. We will help you in whatever way we can.

Ms. DELAURO. Thank you very much, Dr. Wolfe. Dr. Powers.

OPENING STATEMENT

Dr. POWERS. Good afternoon. Thank you, Ms. DeLauro and members of the committee, for inviting me to testify. I am a practicing physician, a medical researcher, a scientist at FDA for almost eight years until I left a year ago, and a consultant for several companies. I will share with you today my perspectives regarding the resources needed for FDA to protect the public health.

FDA cannot protect and advance public health without adequate resources. In 2007, the budget for the Montgomery County Maryland Public Schools was $1.9 billion while FDA's budget was $1.6 billion. Obviously, public education is essential, but it is important to realize that the funds allocated to educate 138,000 children in a single county is more than the funds allocated to regulate $1 trillion worth of food, drugs, biologics, devices and cosmetics for almost 300,000,000 Americans across the country.

However, if Congress appropriates more funding to FDA, Americans should expect something in return. The user fees paid by companies as part of prescription drug user fee acts come with negotiated expectations that FDA personnel accomplished certain tasks and meets specific timelines to expedite drug review. Likewise, it is only logical that Congress should require FDA personnel to develop a comprehensive plan for allocating appropriated funds with specific action items, due dates and accountability for completing non-PDUFA-related activities. And, in fact, this morning it seemed like a lot of the questions related to accountability of where the money is going.

This need for accountability is highlighted in the 2007 FDA Science Board Report, which noted a history of excellent evaluations of FDA's functioning "followed by little to no action to achieve the recommendations." Congress and FDA should include several action items in a plan for use of appropriated funds, such as updating the adverse event reporting system, modernizing information technology, providing resources to inspect manufacturing sites, ensuring the integrity of the data companies submit, overseeing the conduct of clinical trials and institutional review boards, and evaluating the accuracy of drug advertising in a timely manner, many of those things discussed already this morning.

Recent reports by the Institute of Medicine, the inspector general, the GAO and the FDA Science Board that now go back actually for over a decade, all show a need for FDA to improve in these areas.

FDA's most precious resource, however, is the people who work there. In the 1970s, the court clarified that the experts to whom Congress referred in the Food, Drug and Cosmetic Act were the scientists at FDA. There is no single "the FDA," although I just said "the FDA." FDA is composed of individuals, just like any organization, and can only function as well as those individuals function, both singly and together as a team.

To fulfill their public health mandate, FDA scientists must be encouraged without censorship to be active participants in the scientific community. There should be sufficient funding and mentorship from senior FDA officials for FDA staff to pursue scientific activi-

ties, such as attending and presenting at scientific meetings and publishing articles in books and medical journals. FDA scientists see a vast amount of data that no one else has the opportunity to see and taxpayers will benefit if FDA scientists are able to share that knowledge with the scientific community, as well as gain knowledge from scientists outside of FDA. In fact, the purpose of clinical research is to acquire generalizeable knowledge, which obviously cannot be generalized unless you share it with other people.

FDA scientists should be scientists first, not bureaucrats first. The evidence, however, shows that there are issues with morale among FDA scientists, as we have already discussed. They perceive that priorities other than good science are used in regulatory decision-making. As a result, many well-trained scientists choose to leave FDA. Surveys of FDA scientists in 1998 by Public Citizen, as Dr. Wolfe just discussed, again in 2002 by the Office of Inspector General and a third time in 2006 by the Union of Concerned Scientists, all raise the issue that FDA scientists are concerned about the state of science at FDA.

In regulatory decision-making, good science needs the appropriate explanations, consistent application and enforcement of the appropriate scientific standards as they are legally mandated in the Food, Drug and Cosmetic Act. The law and regulations clearly define the meaning of "adequate and well-controlled trials" for drugs and biologics. Unfortunately, medical devices are not held to this same standard. However, FDA officials do not always uniformly adhere to their own legally-mandated standards.

The Institute of Medicine Report addresses issues of the culture at FDA, and to address these issues, there needs to be transparency in the decision-making process with scientific justification and explanation for how and why decisions are made, with that documentation of those decisions made publicly available. Public presentation of one's work is part of the scientific process and should not be seen as "second guessing." Also, there needs to be individual accountability for the decision-making that does occur. As I said, FDA is not one unified body, someone makes a decision and those people should be held accountable for those decisions. To accomplish these goals, FDA needs leadership that shows in actions as well as in words that it is dedicated to protecting the public health first.

FDA needs adequate resources to protect the public's health and Congress should provide oversight to make sure that those resources are spent wisely. It appears that the public is losing confidence in FDA's ability to protect citizens with a Harris poll showing seven out of every 10 adults giving FDA a negative rating. A Consumer's Union Survey showed 84 percent of respondents agreed that the government should "have the authority to take any action necessary″ to ensure drug safety. Therefore, it seems the public is in favor of FDA exercising its authority to protect them.

We need to restore public confidence in FDA by providing the authority, funding and leadership FDA needs to do the job of protecting and advancing public health.

[The information follows:]

Providing Adequate Resources for FDA:

A Necessity for Public Health

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House Appropriations Committee

Subcommittee on Agriculture, Rural Development, Food and Drug Administration and

Related Agencies

February 27, 2008

Good morning. Thank you for inviting me to testify. I am a practicing physician, a medical researcher, a scientist at FDA for almost 8 years until I left last year, and a consultant for several companies. I will share with you my perspectives regarding the resources needed for FDA to protect the public health.

FDA cannot protect and advance public health without adequate resources. In 2007 the budget for Montgomery County Maryland Public Schools was $1.9 billion,[1] while FDA's budget was $1.6 billion.[2] Obviously, public education is essential, but it's important to realize that the funds allocated to educate 138,00 children[3] in a single county is more than the funds allocated to regulate $1 trillion worth of food, drugs, biologics, devices and cosmetics for almost 300 million Americans across the country.[4]

However, if FDA receives more appropriated funding, Americans should expect something in return. The user fees paid by companies as part of Prescription Drug User Fee Acts (PDUFA) come with negotiated expectations that FDA personnel accomplish certain tasks and meet specific timelines to expedite drug review. Likewise, Congress should require FDA personnel to develop a comprehensive plan for allocating appropriated funds, with specific action items, due dates and accountability for completing non-PDUFA related activities. The need for accountability is highlighted in

[1] http://www.montgomeryschoolsmd.org/departments/budget/citizens/pdf/Citizens_BudgetFY09.pdf
[2] http://www.StrengthenFDA.org
[3] http://www.montgomeryschoolsmd.org/about/
[4] http://quickfacts.census.gov/qfd/states/00000.html

the 2007 FDA Science Board report, which noted a history of excellent evaluations of FDA "followed by little to no action to achieve the recommendations."[5]

Congress should include several action items in a plan for use of appropriate funds, such as updating the adverse event reporting system, modernizing information technology, providing resources to inspect manufacturing sites, assuring the integrity of the data companies submit, overseeing the conduct of clinical trials and Institutional Review Boards (IRBs), and evaluating the accuracy of drug advertising in a timely manner. Recent reports by the Institute of Medicine[6], the Inspector General[7], the GAO[8], and the FDA Science Board show a need for FDA to improve in all these areas.

FDA's most precious resource, however, is the people who work there. In the 1970's, the courts clarified that the "experts" to whom Congress referred in the Food Drug and Cosmetic Act were the scientists at FDA.[9] There is no single "the" FDA. FDA is composed of individuals and FDA can only function as well as those individuals function both singly and together as a team. To fulfill their public health mandate, FDA scientists must be encouraged --without censorship -- to be active participants in the scientific community. There should be sufficient funding and mentorship from senior FDA officials for FDA staff to pursue scientific activities, such as attending and presenting at meetings and publishing articles in books and medical journals. FDA scientists see a vast

[5] http://www.fda.gov/ohrms/dockets/AC/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf
[6] http://www.nap.edu/catalog.php?record_id=11750#toc
[7] http://oig.hhs.gov/oei/reports/oei-01-06-00160.pdf
[8] http://www.gao.gov/new.items/d08428t.pdf
[9] Weinberger v Hynson, Westcott and Dunning, US Code section 412, section 609, 1973.

amount of data and taxpayers will benefit if FDA scientists share their knowledge with the scientific community, as well as gain knowledge from scientists outside of FDA.

FDA scientists should be scientists first, not bureaucrats first.

The evidence, however, shows that there are issues with morale among FDA scientists. They perceive that priorities other than good science are used in regulatory decision making. As a result, many well-trained scientists choose to leave FDA. Surveys of FDA scientists in 1998 by Public Citizen[10], in 2002 by the Office of the Inspector General[11] and in 2006 by the Union of Concerned Scientists[12] all show that FDA scientists are concerned about the state of science at FDA. In regulatory decision-making, good science means the appropriate explanation, consistent application, and enforcement of the appropriate standards legally mandated in the Food Drug and Cosmetic Act. The law and regulations clearly define the meaning of "adequate and well-controlled trials" for drugs and biologics. Unfortunately, medical devices are not held to this same standard. However, FDA officials do not always adhere to their own standards.

The Institute of Medicine report addresses issues of the culture at FDA, and to address these issues there needs to be transparency in the decision making process, with scientific justification and explanation for how and why decisions are made with documentation made publicly available. Public presentation of one's work is part of the scientific process, not "second guessing". Also, there needs to be individual accountability for the

[10] http://www.citizen.org/publications/release.cfm?ID=7104
[11] http://www.oig.hhs.gov/oei/reports/oei-01-01-00590.pdf
[12] http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html

decision-making that does occur. To accomplish these goals, FDA needs leadership that shows in actions as well as words that it is dedicated to protecting public health first.

FDA needs adequate resources to protect the public's health, and Congress should provide oversight to make sure resources are spent wisely. The public is losing confidence in FDA's ability to protect citizens, with a Harris poll showing seven out of every ten adults giving FDA a negative rating.[13] A Consumer's Union survey showed 84 percent of respondents agreed that the government should "have the authority to take any action necessary" to ensure drug safety.[14] Congress needs to help restore public confidence in FDA by providing the authority, funding and leadership FDA needs to do the job of protecting and advancing public health. Thank you.

[13] http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1060
[14] http://www.consumerreports.org/cro/health-fitness/news/2007/04/consumer-reports-survey-finds-strong-backing-for-drug-reforms-4-07/overview/consumer-reports-survey-finds-strong-backing-for-drug-reforms.htm

SUPPLEMENT ARTICLE

Increasing the Efficiency of Clinical Trials of Antimicrobials: The Scientific Basis of Substantial Evidence of Effectiveness of Drugs

John H. Powers

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In the United States, drug sponsors must obtain approval from the US Food and Drug Administration before licensure and widespread clinical use of drugs. In this article, I discuss the definition and history of the regulatory requirement for "substantial evidence" of effectiveness from "adequate and well-controlled" clinical trials of drugs. These requirements apply to antimicrobials as they do to other therapeutic drug classes, and they may be even more important in their application to antimicrobials, given issues of antimicrobial resistance. I will discuss the evidence requirements, using examples from clinical trials in diseases such as acute otitis media, acute bacterial sinusitis, and acute exacerbations of chronic bronchitis. Examination of the principles of substantial evidence also points to opportunities to improve the efficiency of confirmatory clinical trials of antimicrobials to obtain more clinically relevant and useful information without increasing the uncertainty regarding the safety and efficacy of these drugs.

Across the globe, various regulatory agencies review the data on the effectiveness and safety of medical interventions before their approval for general clinical use. In the United States, the Food and Drug Administration (FDA) performs the function of reviewing the data on effectiveness and potential harms submitted by drug sponsors in new drug applications for new drugs or new uses for older drugs. The FDA also performs continuing review even after approval of drugs for clinical use, to evaluate changes in both the safety profile and effectiveness of drugs.

Unfortunately, some view the regulatory process as a "hurdle" or "obstacle" to overcome rather than a scientifically based process. Some seem to imply that "registrational" trials have little clinical importance or relevance. Scientific worthiness is a prerequisite for ethical clinical research, so registrational trials can and should answer clinically relevant questions [1].

History shows that regulation of drug products is needed and beneficial to the public by setting an appropriate standard to both advance and promote public health. Scientifically appropriate standards also are useful for regulated drug sponsors, because they allow planning of drug development programs and ensure that their competitors must follow the same standards. Regulatory standards, however, must change as science and our understanding of it change. Some have implied that, once they reach an agreement on a trial design with the FDA, the trial design cannot be changed. However, the federal Food, Drug, and Cosmetic (FD&C) Act, which authorizes the FDA, states that a trial's design and its interpretation can be changed when a "substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun" [2].

The history of clinical trials closely follows the history of drug regulation. Of note, investigators first used many of the modern methods that allow evaluation of the causal relationship between medical interventions

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and outcomes, such as randomization and blinding, in trials evaluating infectious diseases at approximately the same time as the passage of the FD&C Act, in 1938. The British Medical Research Council's trial of patulin for the common cold, published in 1944, was one of the first examples of the use of a placebo in a multicenter trial [3]. This same group, led by Austin Bradford Hill and others, first used random numbers as a method of randomization in testing streptomycin in pulmonary tuberculosis [4]. Regulatory agencies have adopted these principles in the past and helped to advance their use, and they can still use their influence today to advance the scientific process of evaluation of new medical interventions. The mandate of advancing public health points to the need for innovative but scientifically valid approaches to clinical trials and a need for leadership from regulators, not merely passive adherence to "precedent."

The old adage of "might makes right" should be reversed in the case of regulatory evaluation of medical interventions. Instead, "right" should make "might." That is, instead of merely following rules for rules' sake, the authority to review new medical interventions should derive from appropriate scientific principles. An examination of the history of US drug regulation shows that this is, indeed, the case, and legislation authorizing the existence and function of the FDA has been and still is based on appropriate science.

One of the reasons for the misunderstandings regarding regulatory issues may be a lack of understanding regarding their scientific basis. Therefore, in the present article, I will review the scientific and legal foundations for drug evaluation in the United States, which are based on "substantial evidence" of drug effectiveness from "adequate and well-controlled trials" balanced against an adequate assessment of the potential harms of a drug. I will then examine how clinical trials may fulfill the criteria of substantial evidence of effectiveness and evaluate potential harms utilizing novel trial designs in infectious diseases. Such trials may provide more clinically relevant information to practicing clinicians, streamlining the drug development process without increasing uncertainty regarding safety and effectiveness.

THE SCIENTIFIC AND LEGAL BASIS OF DRUG REGULATION: DEFINING "SUBSTANTIAL EVIDENCE"

The scientific method, first described in the 13th century and based on the principles of inductive reasoning explored by Aristotle, is based on 4 steps: (1) observation of events in nature, (2) formation of a hypothesis based on those observations, (3) testing the hypothesis through experimentation, and (4) confirmation of the results of the experiment, to evaluate the probability that the results could have occurred by chance alone [5]. The process of evaluating medical interventions follows these same steps. The initial impetus for evaluating new therapies comes from observations in clinical practice. Clinicians may note the medical need for treatment of a particular disease and may even note that some patients appear to respond favorably when administered an experimental agent. However, although observations may provide associations with outcomes, associations are not direct evidence of a causal relationship between outcomes and administration of a drug [6]. A medical need is a reason to perform a study but does not de facto imply that a drug is effective and safe, nor does it imply that less evidence is needed. Therefore, investigators form a hypothesis, aided by early evaluations of the drug in vitro, in animal models, and in healthy volunteers, as well as by preliminary evaluations of drug safety and effectiveness in early clinical trials. These evaluations of mechanism of action and early safety signals form the ethical and scientific basis for exposing larger numbers of subjects to the potential harms of experimental agents. Confirmatory trials form the experiments on which one bases the evidence of the effectiveness and safety of a drug. When clinical trials show a net positive effect of a medical intervention on clinical outcomes important to patients, it is still necessary to confirm those results with evidence from other trials, to ascertain whether they might have occurred by chance.

To discuss more efficient and more informative trial designs, one must first understand the scientific and regulatory bases for evaluating the evidence of drug effectiveness and safety. These form the standards to which any novel designs still must adhere. In 1906, the US Congress passed the Pure Food and Drug Act. At that time, there was no requirement for evaluation of safety and effectiveness before the use of a drug in clinical practice, and the law was mainly related to adulterated foods; the government merely responded to crises involving drugs. It is interesting to note that further changes in legislation were associated with issues related to drugs used to treat infectious diseases. Spurred on by >100 deaths among children administered elixir of sulfanilamide, Congress passed the FD&C Act in 1938. At that time, the act required an evaluation of only the safety of a drug before licensure. Phocomelia associated with the use of thalidomide (a drug now indicated for the treatment of leprosy) resulted in the passage of the Kefauver-Harris amendments to the FD&C Act in 1962. These amendments required an evaluation of the effectiveness, as well as the safety, of a drug before approval [7].

The Senate hearings related to the passage of the 1962 amendments and subsequent court cases made several important points. First, they made it clear that evidence of effectiveness is necessary to balance any potential harms of drugs. Without evidence of effectiveness, any adverse events in patients, no matter how rare or minor, are not justifiable [8]. Second, testimony at the hearings and subsequent court cases made it clear that the impressions of clinicians, use of a drug in clinical

practice, or robust sales did not form an adequate basis for drug approval [8–10]. This reflects the scientific principle that observations alone, without experimentation and confirmation, do not constitute evidence of effectiveness. The amendments also pointed out that poorly controlled experiments were not adequate evidence, highlighting that the experimentation must be of sufficient rigor to distinguish the effect of the drug from random error, confounding factors, and bias [10]. Third, the amendments provided a clear definition of "substantial evidence." During Senate hearings, President Kennedy conveyed to Congress that an undefined standard of "substantial evidence" was not adequate to ensure that drugs are effective for the claims made for them [8]. This means that the definition of substantial evidence for drugs is not the same as that used for legal cases. The definition of substantial evidence for legal cases is "more than a mere scintilla of evidence such that a reasonable mind might accept as adequate to support a conclusion" [11]. Obviously, such a definition would leave a good deal of vagueness as to what a "reasonable mind" might conclude regarding the effects of a drug. Rather, the amendments to the FD&C Act provided that the only evidence acceptable to support the effectiveness of drugs would be evidence from "adequate and well-controlled trials" [8–10, 12].

Congress tasked the FDA with defining the terms of "adequate and well-controlled" trials in the Code of Federal Regulations. In 1970, the FDA put forth regulations that defined the criteria for "adequate and well-controlled trials," that, with few changes, are still in place today [13]. The Pharmaceutical Manufacturers of America sued the FDA in the same year, holding that the criteria were too onerous. The Pharmaceutical Manufacturers of America held that Congress intended that any drug "believed by a substantial number of experts" to be effective could be approved even if the view of the majority of experts was that the drug was ineffective. The courts rejected this opinion and reiterated that experts' beliefs are not the basis for evidence of drug effectiveness [8]. The courts also found that the criteria described in the regulations were in no sense unduly rigid or narrow, allowed substantial flexibility for investigators, and were entirely reasonable in describing the scientific content of an investigation. The courts also pointed out that these criteria were minimal requirements for the evaluation of drug effectiveness. Compliance with these criteria was necessary for any study to have a chance of scientific validity. However, trials using these criteria may still fail to provide evidence of effectiveness if, for instance, investigators fail to appropriately select patients with the disease or do not measure outcomes appropriately [8]. In other words, merely performing a trial is not sufficient in itself, but the trial must meet these criteria for one to consider it adequate and well controlled.

Importantly, the courts also held that the FDA was not to apply these criteria for adequate and well-controlled trials only prospectively [8, 10]. With the advent of new information or a new understanding of clinical trials, the FDA should reassess the evidence of previously approved drugs. Indeed, in their suit, tbe Pharmaceutical Manufacturers of America themselves stated, "Undoubtedly, even more advanced principles will be developed as testing know-how improves. They, too, should be applied to trials commenced after their development, when appropriate" [8]. The idea of reassessment of previous theories and prior evidence is a fundamental principle in science. Science is an ever-changing field, and, to advance and promote public health, regulatory agencies must keep current with the most up-to-date understanding of clinical trial design and analysis. If we know now that previous approvals were based on evidence that today is known not to meet the standard of adequate and well-controlled trials, the FDA can and should reassess those drugs to protect the public's health. This may require a reevaluation of the evidence regarding safety, effectiveness, or both. This is even more important for antimicrobials, because an antimicrobial that lacks substantial evidence of effectiveness still is capable of spreading resistance not only to that drug but to other antimicrobials as well. In this sense, antimicrobial resistance is clearly a safety issue, because ineffective drugs may harm not only the person who takes the drug but also those who do not take it. The use of drugs for less serious diseases for which effectiveness is unclear may obviate the use of that same drug and other drugs for more serious diseases for which there may be substantial evidence of effectiveness. In addition, there seems to be a widely held misunderstanding that, once FDA and drug sponsors reach an "agreement" on a study design, regulatory agencies should accept the results of such trials as substantial evidence of effectiveness even though it may be clear at the time of study's completion that changes in the science or understanding of clinical trials no longer support this conclusion [14]. As stated above, the FD&C Act specifically states that the FDA should reassess trials when the science has changed. The idea of "fairness" should apply first and foremost to the patients who would be exposed to the drug without adequate evidence of effectiveness. Regulators and investigators should employ the most up-to-date principles in evaluating the results of clinical trials, even if science has advanced since the inception of the trial. It is not appropriate for public health for clinicians and regulators to address these issues "when the next drug comes along" or to avoid addressing these issues because drugs in the past received approvals through the use of older methodology now known to lack scientific credibility or not to meet the FDA's own standards.

MOVING FORWARD

Seven criteria define adequate and well-controlled trials in US regulations that, in turn, form the basis for the evidence needed to evaluate drug effectiveness [13]. In addition, these same trials

also provide the evidence for evaluating the preliminary safety of a drug. The 7 criteria plus the requirement for evaluating potential harms with "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" [2] form 8 criteria by which to assess the balance of risks and benefit of drugs. As stated above, this is an iterative process, because one must first demonstrate evidence of effectiveness to justify any risks and reassess the balance of risks and benefits when new evidence becomes available.

FDA guidances, including those published under the auspices of the International Conference on Harmonization, provide more detail on the application of these criteria [15, 16]. These same criteria apply to all therapeutic areas, including the study of antimicrobials in infectious diseases. The only differences in trial design are those related to the natural history of the diseases under study. For instance, the definitions and timing of outcomes measurements would differ between an acute self-resolving disease whose natural history lasts a few days and a serious and life-threatening chronic disease lasting several months or years. In 1998, the FDA published draft guidances regarding the trial design for several infectious diseases [17]. Since that time, several other FDA guidances, including those published by the International Conference on Harmonization, have outlined advances in thinking about trial design [15, 16]. The 1998 guidances, at present, are inconsistent with some of these newer principles and, in some places, are frankly at odds with the requirements of adequate and well-controlled trials. Therefore, there are several opportunities for advancement in antimicrobial trial design that may help to provide better evidence related to both effectiveness and safety while acquiring data in a more efficient manner and fulfilling FDA requirements. These principles can serve as a guide for future trials of antimicrobials in infectious diseases and are described below.

1. Clinical trials should have a clear objective. Antimicrobial trials are based on the evaluation of the treatment, prevention, or diagnosis of a recognized disease, not on the evaluation of "response" to specific pathogens [18]. The goal of administering antimicrobials is to decrease the risk of death, improve function, or cure symptoms in patients with a given disease. It is important to realize that clinical trials measure average effects in groups of subjects. This is a major difference from clinical practice, in which one is concerned with the outcome in an individual patient. In most cases, it is challenging, if not impossible, to ascribe causality of drug effect in an individual case. This is the point of randomizing trials and studying groups of subjects to control for confounding variables and to evaluate the effect of the drug compared with spontaneous changes in the course of the disease, placebo effect, or biased observations. There are differences in the population, enrollment and outcome criteria, natural history, concomitant medications and interventions, and other factors across various infectious diseases, even if they are caused by the same pathogen. Including patients with various sites of infection in a single trial makes it challenging to interpret the results in terms of causally relating outcomes to the drug administered. Relating outcomes to the drug prescribed is the very point of conducting a trial. In addition, the sample size for various types of infections may be insufficient to draw conclusions about drug efficacy in various diseases. For instance, it would be challenging to interpret the effect of a drug in individual diseases in a trial that included patients with pneumonia, sinusitis, and meningitis. These diseases have widely different natural histories, and it is likely that there would be few patients with meningitis included in such trials.

Another issue in trials in infectious diseases is deciding whether the trial is evaluating treatment or prevention of disease. Confusing treatment and prevention makes it challenging to define a population to enroll, to define outcomes, and to ascertain the causality of the effect of the drug. For instance, with regard to empirical antifungal therapy in persistently neutropenic patients, investigators have debated whether the goal is to treat occult fungal infections or to prevent fungal infections [19]. The distinction is important in defining enrollment and outcomes, because one cannot prevent a disease that is already present in the patient.

It is also important to distinguish between "explanatory" and "strategy" trials [20]. Explanatory trials attempt to evaluate the causal relationship between the drug and measured outcomes to determine the drug's effectiveness. Strategy trials measure the various conditions under which the drug might be useful in clinical practice, after determining that the drug is effective. For instance, one might determine that a drug is effective in the setting in which diagnosis of a disease is clear on the basis of laboratory testing in an explanatory trial, but then a strategy trial might show that a drug lacks effectiveness as used in clinical practice in the setting of empirical therapy, in which the diagnosis is less certain. Confirmatory explanatory clinical trials evaluating drug effectiveness should precede strategy trials. It is unlikely that a drug that lacks effectiveness in an explanatory trial can have benefits for patients in a strategy trial. There is also the ethical issue of exposing patients to potential harms in a strategy trial without knowing that the drug is beneficial, because patients without the disease who cannot benefit are exposed to potential harms. It is often challenging to determine causal relationships between drug administration and outcomes in strategy trials, and, therefore, it may be difficult to provide generalizable knowledge for clinical practice. For instance, many trials of antiseptics combine educational campaigns with the topical antiseptic under study. If the trial notes a decrease in the number of infections with this strategy, it will not be clear whether the antiseptic, the educational campaign, or both

were responsible for the benefits. Once one determines that a drug has effectiveness for treatment of a defined disease, then trials can evaluate various strategies for use.

2. Trials should have a quantitative comparison with a control. All clinical trials are comparative [21]. That is, they compare the measured outcomes in a group of subjects who receive a medical intervention with what would have happened had they not received the intervention. Because, in most cases, it is not possible to ascertain with any degree of certainty the outcomes in subjects who would not receive the intervention, trials often use concurrent controls. Investigators may design trials with 1 of 5 types of controls: (1) no-treatment concurrent controls, (2) placebo concurrent controls, (3) exposure response controls, (4) active concurrent controls, or (5) external (historical) controls [13].

Investigators design trials to evaluate whether a test drug may be more effective than a control (superiority trials) or to rule out that the test intervention may be less effective than the control by a chosen amount (noninferiority trials). Many trials in infectious diseases are designed as noninferiority trials. Noninferiority trials cannot show that 2 interventions are "equal," and the conclusion that 2 interventions are "as good as" each other or "equivalent" is not justifiable unless the test intervention is statistically superior to the control. It is clear that there is a need for a better understanding of the issues related to the design, conduct, and analysis of noninferiority trials, as well as the situations in which noninferiority trials are rational and the situations in which they are not capable of providing the evidence necessary to demonstrate drug effectiveness [22]. To design a credible noninferiority trial, investigators must (1) ascertain the reliable and reproducible magnitude of the benefit of the control drug compared with placebo from previous historical evidence, such as placebo-controlled or historically controlled trials; (2) evaluate the constancy of the effect of the control drug in the planned noninferiority trial by keeping the major design features of the current trial (enrollment criteria, timing and definitions of outcomes, concomitant medications, etc.) essentially the same as in the previous placebo-controlled trials; and (3) choose a margin of inferiority that preserves some of the benefits of the control and is smaller than the amount of benefit of the control compared with placebo [15, 16]. It is not enough merely to know that a control drug "works," but, as noted above, because the comparison with a control is quantitative, one must know the amount by which the control's effect exceeds that of the placebo in the setting of a planned noninferiority trial.

It is now clear that previous placebo-controlled trials did not provide evidence of a reliable and reproducible margin of benefit of antimicrobials compared with placebo in some infectious diseases, such as acute otitis media, acute bacterial sinusitis, and acute exacerbations of chronic bronchitis [15, 16, 23–27]. Without this evidence, it is not possible to design a credible noninferiority trial. Noninferiority margins should not be based on clinician opinion alone but must be based on adequate data. The issues regarding noninferiority trials in infectious diseases have been discussed at numerous advisory committees and workshops over the past half decade [15, 16, 23–27]. International guidance published since 2000 already outlines the issues that investigators need to address in planning noninferiority trials, and these issues apply to trials in infectious diseases as they do to other therapeutic areas [15, 16]. Regulators need to clearly specify when noninferiority trials are not scientifically justifiable on the basis of data, as in the study of sinusitis, bronchitis, and otitis. Regulators should also clearly outline the data that sponsors should provide to justify the use of noninferiority trials in diseases in which this trial design is acceptable. It seems incongruous to claim that the need for new antimicrobials is based on the lack of efficacy of older agents in diseases as a result of resistant pathogens and then to design trials to show how much less effective a new drug might be compared with an older drug whose effectiveness is in doubt. Labeling claims for disease due to resistant pathogens are tacit superiority claims for the new drug, compared with the drug to which the organism is resistant [18]. Therefore, one needs to clearly show superiority on the basis of the data in clinical trials. Superiority trials can and should be performed in various situations, such as when the benefit of antimicrobials compared with placebo is not known with certainty for a given disease, for the evaluation of combination therapies, when there are no available therapies for given disease, or for the evaluation of the superiority of newer drugs in a disease caused by resistant pathogens. It seems ironic that the field of infectious diseases introduced the use of placebos in clinical trials [3], yet now investigators in this field argue most strongly against their use. It is not unethical to perform placebo-controlled trials when the efficacy of the control drug is uncertain, when the disease is not serious and life threatening, and when subjects are adequately informed of the trial's design. There are advantages to receiving placebo, because subjects are less likely to experience adverse events. Indeed, the meaning of the Latin word "placebo" is "to please." Conversely, it is unethical to enroll subjects in trials that have no chance of providing generalizable knowledge [1]. Finally, in many situations, superiority trials require a smaller sample size than noninferiority trials, which may increase the efficiency of obtaining generalizable data and expose fewer subjects to potential harm.

3. Trials should ensure that patients have the disease under study. The development and use of rapid diagnostics would aid both clinical trials and clinical practice. A better ability to diagnose infections at the point of care would streamline enrollment by allowing enrichment of trials for patients whose disease is due to resistant pathogens and would allow the study

of narrow-spectrum drugs. The use of rapid diagnostics in clinical practice would decrease the inappropriate use of antimicrobials for viral disease, help to preserve the utility of older drugs, and decrease adverse events in patients who received a drug that they did not need. The use of biomarkers to help define the disease under study could revolutionize both clinical practice and infectious diseases trials. Again, there is an important distinction here between clinical trials and clinical practice. Whereas patients in practice may receive drugs empirically, in clinical trials, subjects are exposed to experimental agents whose toxicity is not known. Therefore, it is even more important to ensure they have the disease under study. Exposing subjects to the potential toxicities of experimental agents when they do not have the disease under study in treatment trials exposes them to potential risks for no benefits, which raises ethical issues, as well.

*4. **Trials should ensure baseline comparability of patients.*** The process of randomization and blinded allocation concealment helps to give an equal probability of baseline comparability in trials and guards against selection bias. However, randomization is not foolproof, and baseline imbalances still can occur. Imbalances are more likely when the population under study is highly heterogeneous, such as when patients with a wide array of diseases are enrolled in a single trial, as noted above. Choosing the appropriate population is a matter of balance between choosing a population that is heterogeneous enough to extrapolate the results of the trial to general practice and choosing one homogeneous enough to obtain useful results. A trial that lacks internal validity cannot have external validity in clinical practice. One of the first reported randomized trials evaluated streptomycin in pulmonary tuberculosis. However, some investigators have suggested that observational studies should become the standard in some situations for evaluating drug effectiveness [28, 29]. Referring back to the scientific method, observational studies provide what their name implies—namely, observations. These observations measure associations, but it is challenging to imply that these associations provide evidence of a causal relationship between drug effect and clinical outcomes. Austin Bradford Hill's landmark work on evaluating associations and causality [30] points out that experimentation is one of the clearest ways in which to adequately evaluate causality. Observational studies can be useful to generate the hypotheses for future randomized clinical trials.

*5. **Trials should attempt to minimize bias.*** Investigators should double blind trials whenever possible. Microbiological test results should also be blinded (or partially blinded) whether the administration of drugs is blinded or not. Clinicians often make clinical decisions on the basis of microbiological test results that are surrogate end points for the clinical outcomes of patient symptoms, function, and survival. In some cases, there is a poor correlation between clinical and microbiological outcomes [28, 31, 32]. If clinicians deem a patient as having experienced treatment failure in clinical trials on the basis of microbiological testing when the patient is clinically cured, this inserts a bias into the trial. This also actually can make it more difficult for a given drug to show effectiveness and decreases the efficiency of the trial. The utility of "provisional breakpoints" to define susceptibility of organisms is not clear in most cases and may introduce bias into trials. Because investigators will follow patients closely for clinical outcome and, in many cases, will not know the susceptibility of organisms until several days into therapy, investigators should use the data from clinical trials to measure the correlation of organism "susceptibility" with clinical outcomes. Assigning outcomes according to microbiological criteria alone indicates an assumption that one's hypothesis is true before it has been tested.

*6. **Trials should have well-defined and reliable end points.*** Developing appropriate end points is perhaps one of the most intriguing and complex areas in drug development. A detailed discussion is beyond the scope of this article; however, several basic principles apply. End points should measure outcomes that are clinically relevant to patients and should capture the net harms and benefits of an intervention on those outcomes. Trials should measure these end points without bias. Biomarkers do not directly measure outcomes that are clinically relevant to patients and can provide misleading results if they are not developed appropriately [33]. Investigators need to compare outcomes with biomarkers and clinical outcomes, but, in short-term diseases, there is less of a need to measure biomarkers as surrogate end points, because investigators can measure the actual clinical outcome directly [32]. Biomarkers are most useful in evaluating chronic diseases in which the clinical end points can take months or years to measure. Use of a combination end point of clinical outcomes plus biomarkers can actually make it more difficult to demonstrate the effect of a drug in some situations. For instance, patients with pneumonia are often clinically cured long before the chest radiograph findings normalize. If one used a combination end point of clinical cure plus normalization of chest radiograph findings, the true effect of the drug on clinical outcomes would be underestimated.

Much of the confusion regarding surrogate end points in infectious diseases stems from a belief that a negative culture result "should" predict a successful clinical outcome. This confuses mechanism of action with outcome and confuses measurement of risk factors with measurement of drug effect [32]. Biomarkers may be useful in diagnosing a disease, but this does not mean that they will be similarly useful in evaluating outcomes. The term "presumed eradication" should be removed from clinical trials, because it presumes what one is trying to measure in the first place—namely, the correlation between clinical and microbiological outcomes—and illogically substi-

tutes the clinical outcome for the surrogate outcome, obviating the need for a surrogate. Use of patient-reported outcomes (PROs) can provide a more patient-centered and, perhaps, more sensitive way of measuring clinically relevant patient outcomes. PROs can also provide information in addition to the more conventional end points that measure mortality. Investigators have used PRO instruments in other therapeutic areas, such as analgesia, to measure patient-centered outcomes, and their use in infectious diseases like sinusitis, in which the findings of the disease in patients are related primarily to symptoms, is entirely rational. Infectious disease investigators were leaders in this field; the trial of patulin to treat the common cold, published in 1944, used PROs as the primary end point [3].

End points based on investigator discretion or on "cause-specific" outcomes related to infection often cannot be measured without bias. Another way of evaluating the effect of antimicrobials, especially in short-term diseases, would be to evaluate the time to clinical cure. PROs would allow collection of data on a continuous basis, and such continuous data would allow greater power to determine differences between drugs and allow a more rational consideration of the benefits of a drug, in terms of shortening the disease, balanced against the risks. For instance, clinicians may consider the balance of risks to benefits to be clinically relevant if an antimicrobial shortens the course of illness by 5 days but not if it shortens it by 5 h. It is hard to justify serious adverse events like anaphylaxis and liver failure for small benefits in self-resolving diseases. If we are willing to tolerate symptomatic adverse events like nausea and diarrhea to prevent death due to diseases like pneumonia by administering a drug, should we not also consider it beneficial to prevent death due to adverse events and to tolerate uncomfortable symptoms in self-resolving diseases by withholding drugs? This is a point that needs further discussion. Finally, time-to-event analyses may allow us to more accurately measure the duration of antimicrobial therapy necessary to result in a cure and to individualize the duration of antimicrobial therapy. Prescribing less drug for the same effect may decrease adverse events, decrease resistance, decrease costs, and increase adherence to medication. Patients have already performed the "observational study" for us, because many patients discontinue therapy after resolution of their symptoms, and most do not experience relapse.

7. Trials should have an appropriate analysis of the data. Investigators should evaluate the information obtained from a trial in a way that allows an estimation of the uncertainty regarding the conclusions. Statistical testing is a tool that investigators use to evaluate the variability in the data and the probability that the results may occur by chance alone. There are a number of issues in clinical trials in infectious diseases that would benefit from increased discussion and research, such as the appropriate analysis populations (intent to treat, per protocol, or both) to use in various trial designs and the appropriate analysis of secondary end points and subgroup analyses. For instance, the 1998 FDA guidances point to the "per protocol" population as the primary analysis population in noninferiority trials. However, such analyses are really post hoc subgroup analyses that do not include all randomized patients and may not preserve the integrity of randomization, which, in turn, may result in selection bias and misleading findings [34]. There are issues with the intent-to-treat population in noninferiority trials as well, because this population may bias toward a finding of noninferiority. Consistent findings across various analysis populations provide the most convincing evidence of drug effectiveness. Investigators in infectious diseases trials have given little discussion to the topics of adjustment of the type 1 error for multiple comparisons of different end points, comparisons of the same end point over time, or multiple subgroup analyses with the attendant increased risk of false-positive results. One should address these issues in addition to specifying any secondary or subgroup analyses before initiation of the trial.

8. Trials should provide an adequate evaluation of the safety of a medical intervention. Unlike the evaluation of drug effectiveness, confirmatory trials of drugs are not evaluating a hypothesis related to drug safety. One often does not know the adverse events caused by a drug before testing in confirmatory trials to form a hypothesis. Rather, confirmatory trials may provide safety signals for further evaluation. The sample size for confirmatory trials often is based on an evaluation of effectiveness and is insufficient to draw statistically based conclusions regarding potential toxicities of a drug. Therefore, the absence of a statistically significant difference in adverse events in a trial does not imply that there is no difference between interventions. If no serious adverse events are noted, a database of 300–500 patients is required to rule out a risk of 1.0% with 95% confidence [35]. When the evaluation of safety in this number of patients does show a potential signal for a particular type of toxicity, sponsors should perform follow-up studies to more clearly evaluate that toxicity in a more rigorous way. Approval of a drug, usually based on findings in a few thousand subjects, is only the beginning of evaluating the safety of a drug, and vigilant postapproval studies should become standard practice. The principles of differentiating associations and causality espoused by Hill [30] are helpful in evaluating safety signals.

BALANCING RISKS AND BENEFITS

There has been substantial discussion regarding the need for new antimicrobial therapies at a time when major pharmaceutical firms are choosing to exit research and development in this field [36]. Despite the gloomy news, there have been more antimicrobials with novel mechanisms of action approved in the past few years than in the previous 40 years combined.

Addressing the medical needs related to antimicrobial resistance will require the concerted efforts of clinicians, researchers, regulators, patients, and policy makers. It is important to keep in mind, however, that a medical need is exactly why we need adequately designed trials to address important public health questions. As stated above, a medical need provides the rationale for why one performs a trial, but it should not imply a lower standard for evaluating such therapies. The story of laetrile, a drug made from apricot pits, which many claimed to have effectiveness in a variety of cancers, is illustrative of this problem. Despite the claims of many advocates, investigators subsequently showed the lack of effectiveness in randomized trials, despite the claims of medical need [12].

One of the issues for which there is an urgent need for further discussion is the overall assessment of the risks and benefits of antimicrobials. It is clear that trials attempting to evaluate the effectiveness of antimicrobials for self-resolving diseases like acute otitis media, acute bacterial sinusitis, and acute exacerbations of chronic bronchitis have not met the FDA's own standards of substantial evidence of effectiveness from adequate and well-controlled trials. In September and December of 2006, 2 separate FDA advisory committees voted that noninferiority trials did not provide substantial evidence of effectiveness for various drugs in acute bacterial sinusitis and acute exacerbations of chronic bronchitis [26, 27]. The same issues apply in acute otitis media. If we do not have adequate evidence of effectiveness for antimicrobials, we risk promoting the very problem we are trying to solve. The widespread use of antimicrobials for self-resolving infections without evidence of effectiveness will promote antimicrobial resistance. Resistance will then limit the effectiveness of that same drug as well as that of other drugs in serious and life-threatening diseases for which there may be substantial evidence of effectiveness. In addition, because self-resolving infections are more common than serious and life-threatening diseases, the absolute numbers of patients experiencing adverse events will be greatest for these diseases. However, the benefits for these patients will be the least, in terms of both the magnitude of the effect and the qualitative nature of that effect, which is usually only shorter symptom duration. This is in contrast to the large decrease in mortality among patients receiving effective antimicrobials, compared with those receiving placebo, for serious and life-threatening diseases. The inherent mind-set that antimicrobials are highly effective in all diseases regardless of their natural history and that prescribing them "won't hurt" has led to widespread antimicrobial resistance and adverse events that are not justifiable, especially in patients with viral illness. Even if antimicrobials are effective in self-resolving bacterial diseases, appropriate trials that measure the magnitude of the benefit in terms of time to resolution of illness and that compare the number needed to treat to benefit with the number needed to treat to harm are urgently needed to address the important societal question of when the risks are justified by the benefits. The medical community needs to have a serious discussion about these important issues of balancing risks and benefits. For instance, if antimicrobials indeed shorten the duration of ear pain associated with otitis by a day but cause as many or more cases of diarrhea and less commonly cause serious adverse events like liver failure and death, is this treatment justifiable in small children? Several studies show that there may be long-term consequences of treatment with antimicrobials, as well [37]. Superinfections such as *Clostridium difficile*–associated disease, which can occur as a result of antimicrobial administration, are also becoming more common. Traditionally, clinicians have overemphasized the benefits while minimizing the adverse effects of antimicrobial therapies. The societal problem of antimicrobial resistance is well known, but the issue of unwarranted adverse effects in patients in whom the benefits are small or unmeasurable should receive equal discussion.

Clinicians need relevant information on situations in which new drugs may be superior to older drugs; therefore, there is a need to perform superiority trials to provide this information. Even in trials in serious diseases like severe pneumonia, in which the end point should be all-cause mortality, investigators can evaluate appropriately designed secondary superiority hypotheses to evaluate outcomes like time to clinical success with one drug compared with another. It is long past time that we adequately evaluated the hypothesis of whether increased in vitro potency has important clinically relevant benefits for patients or whether the host immune response makes such differences in vitro irrelevant to patient outcomes. This is especially important when more potent drugs in vitro have more adverse effects in vivo. For instance, many authors have pointed to vancomycin as a suboptimal alternative for serious and life-threatening diseases due to *Staphylococcus aureus*, but randomized controlled trials have not shown new drugs to be superior to vancomycin in terms of clinical outcomes. On the other hand, some investigators have hinted at the superiority of newer drugs on the basis of subgroup analyses, but these analyses leave considerable uncertainty as to the true effect of these drugs [38]. Such subgroups can form the basis for further randomized trials.

The use of meta-analysis and pooling of results of very different trials may give misleading results as well [39]. Recent meta-analyses quoted as showing an "effect" of antimicrobials in various infections combine trials involving very different populations, different definitions of disease, and different definitions of outcome [40, 41]. In addition, these meta-analyses often do not include all of the available data and instead include only the trials producing the data the authors wish to evaluate [40]. Studies show that, almost half the time, subsequent randomized trials do not confirm the results of previous meta-

analyses [42]. Although properly conducted meta-analyses may be useful, meta-analyses combining flawed trials do not eliminate the inherent biases and confounding factors in the trials included in the analysis and actually increase the potential bias and resultant inaccuracy of pooled results despite apparently acceptable statistical tests for homogeneity. The increased sample size in meta-analyses allows more precision, but this is of little utility if the answers at which we arrive are just more precisely incorrect.

The various sectors of the medical community need to work together to answer the important questions regarding the treatment and prevention of infectious diseases. Problems that seem "too hard" to solve individually can be solved with our combined efforts. Patients need to understand when antimicrobials are indicated and when they are not. Clinicians need to make appropriate diagnoses and to demand the data that they need to make accurate decisions. Researchers need to study rapid, point-of-care diagnostics that clinicians can use to accurately diagnose infections, as well as study the natural history of disease to design trials most appropriately. Clinical trialists need to design infectious disease trials to answer these important questions and provide relevant information to clinicians. Finally, regulatory agencies need to provide timely, accurate, and scientifically based advice on how to design clinical trials that are based on the best information we have today and not on outdated guidance that does not follow the FDA's own regulations. There is an urgent need to remove the outdated 1998 guidances from the FDA Web site, because they provide misleading information to sponsors. There is an even more urgent need to replace these older guidances with updated guidances based on appropriate scientific principles, which are the true basis of drug regulation. These principles are already outlined in general FDA guidances, so applying them to the setting of infectious-diseases trials should be not be an insurmountable task [15, 16]. Drug sponsors should also realize that it is time to move beyond the noninferiority trial design and provide clinicians with the evidence that they need to make appropriate clinical decisions and show the added benefits of drugs. Clinicians do not "reserve" drugs that truly are proven to be clinically superior, so there are advantages to sponsors in providing evidence of the clinical superiority of one drug compared with another. Implying superiority on the basis of in vitro testing does not provide clinicians with the clinical evidence of superior outcomes in patients that they so desperately need. These important public health goals are eminently achievable if we all pool our resources for the common good.

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Ms. DELAURO. Thank you very much, Dr. Powers. I just want to tell you I have a copy of your article, and I didn't get all the way through it, but I promise you that I will get all the way through it and get back to you with some questions.

Dr. Calfee.

OPENING STATEMENT

Dr. CALFEE. Thank you, Ms. Chairwoman. I am honored, as are the others, to testify in these hearings on drug safety. I would like to summarize five points, each of which are presented in greater detail in my written testimony.

First, there is no systematic evidence that the United States faces a drug safety crisis or that drug safety is appreciably worse now than it was a decade or two ago. In a September 2006 report on drug safety, the same report that motivated the recent FDA Amendments Act of 2007, the Institute of Medicine stated, and I quote, "The committee did not attempt to document whether or not a drug safety crisis exists and this report should not be interpreted as commenting on that claim one way or the other."

That same report emphasized that no matter how well the FDA does its job, some drugs will reveal unexpected safety problems. We may be surprised at exactly which drugs reveal problems but the fact that some drugs prove problematical is not surprising. The question is whether in dealing with these drugs before or after approval, the FDA staff inappropriately de-emphasized safety. The record has failed to reveal that anything like that has happened. In the case of Vioxx, for example, extensive research has now made clear that practically all drugs in the much-prescribed NSAID class, including older drugs such as Viclophenax along with Vioxx and other COX-2 inhibitors probably involve elevated risk of heart attacks and strokes. That risk was discovered for the COX-2 inhibitors simply because those drugs have been researched far more extensively than the older NSAIDs with which they compete.

And I recommend that the committee also pay attention to Janet Woodcock's remarks earlier this morning in which she made much the same point about the fact that we learn more about drug safety problems these days than we used to because we learn about drugs period than we used to, at least we learn far more rapidly.

Second, it is extremely unlikely that the FDA staff will ever downplay the risk of new drugs. Over and over again, the FDA staff has been reminded that when an approved drug causes serious problems, an onslaught of public criticism is sure to follow, as we can see today in these very hearings. On the other hand, when the FDA staff gives too much weight to safety so that new drugs take too long to reach market, public criticism is far more muted. Economists call this a Type 1/Type 2 error problem. Its effects have been well documented. And just as this reasoning predicts, what at first appears to be a dereliction of duty by the FDA usually turns out to have a far more benign explanation.

Third, the constant pressure on the FDA to ratchet up its emphasis on drug safety must in the end upset the balance between risks and benefits. In the case of SSRI antidepressants, for example, the FDA's hasty imposition of strong suicide warnings seems more likely to have increased suicides by discouraging treatment than to

have prevented suicides. At the same time, the FDA seems to be getting tougher on new drug testing and approvals even as remarkable advances in biological science offer a rich variety of promising new therapeutics for cancer and many other diseases.

Fourth, far more attention should be paid to another potent force: market-driven manufacturer incentive to maintain drug safety. These incentives operate with powerful effect in other high-tech markets such as automobiles, petroleum and electronics. As in other industries, pharmaceutical manufacturers rely heavily on maintaining a good reputation with customers.

Fifth and finally, there are ways to improve drug safety without making the FDA ever more cautious in approving new drugs and uses for old drugs. The FDA clearly needs more resources, especially for information technology and basic and applied science.

And as former Commissioner Mark McClellan and others have pointed out, there are fruitful opportunities to collaborate with the private sector to make far better use of mechanized databases and other tools. Carefully targeted increases in FDA funding could open up numerous pathways to improved drug safety.

Thank you.

[The information follows:]

Written testimony before the

United States House of Representatives

Committee on Appropriations

Subcommittee on Agriculture, Rural Development,

Food and Drug Administration, and Related Agencies

In Public Hearings on

FDA Oversight of Drug Safety

Wednesday, February 27, 2008

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I am honored to testify in these hearings on the drug safety and the Food and Drug Administration. Since the Merck Company voluntarily withdrew its pain reliever Vioxx from the U.S. and other markets worldwide on September 30, 2004, the FDA has come under intense criticism for its handling of drug safety. Much of this criticism arose from a series of events involving the Cox-2-inhibitor class of pain relievers (Vioxx, Celebrex, and Bextra), the SSRI class of antidepressants (where the possibility of suicidal behavior is the main issue), the diabetes drug Avandia (involving excess adverse cardiovascular events in clinical trials), the antibiotic Ketek, and others.

Some observers have suggested that we face an ongoing crisis in drug safety and that the FDA lacks the determination and institutional tools necessary to deal adequately with drug safety (Avorn 2007; Curfman, et al. 2006; Fontanaros, et al., 2004; Furberg, et al., 2006; Hennessy and Strom 2007; Kohn and Bor 2004; *New York Times*, September 28, 2006; Okie 2005; Psaty and Furberg 2005; Smith 2007; Strom 2006; Topol 2004b). Among the FDA's alleged problems are weak leadership, weak incentives to give due weight to drug safety, an institutional structure ill-designed to deal with drug safety before and after drug approval, and a lack of resources. Although the FDA Amendments Act of 2007 (FDAAA) was designed to address many of the problems, vigorous criticism of the FDA continues.

I believe these criticisms are largely unfounded. On the whole, the FDA is giving adequate, and indeed, more than adequate weight to safety in its deliberations over drug development and approval and in its handling of approved drugs in the marketplace. This was true before passage of FDAAA and it remains true today. To be sure, changes at the FDA and in the entire health care sector could improve drug safety at reasonable cost, but that does not mean that the FDA has been neglectful.

Is There a Drug Safety Problem?

Perhaps the oddest part of the past few years' debate of over drug safety is that so far as I am aware, no one has adduced systematic data indicating that drug safety is in a crisis or has even significantly worsened. Probably the most cited report on drug safety is *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, released in September 2006 by the Institute of Medicine, a part of the National Academy of Sciences (NAS 2006; all citations are to the "uncorrected proofs" released at that time). That report did not even attempt to assess whether there is indeed a drug safety crisis: "The committee did not attempt to document whether or not a drug safety crisis exists, and this report should not be interpreted as commenting on that claim one way or the other" (p. 1-1). Nonetheless, the report generally assumed that the FDA's handling of drug safety was seriously endangering the American public, and the authors strongly recommended numerous changes.

In reaching its conclusions, however, the IOM authors relied upon deeply flawed evidence and reasoning. For one thing, the report was notably unscholarly. On direct-to-consumer advertising of prescription drugs, for example, the authors cited a few largely irrelevant older articles while ignoring a flood of recent econometric research (Berndt 2006; Calfee 2007b) and a much-cited randomized trial that revealed large health benefits from antidepressant advertising (Kravitz et al. 2005). On another crucial topic – "off-label" prescribing for uses not explicitly approved by the FDA – the only citation (pp. 2-7) was to a *Washington Post* article (Boodman 2006) instead of the *Archives of Internal Medicine article* (Radley et al. 2006) that the Post article was about. On yet another central issue – whether FDA drug warnings are effective – the report (pp. 2-16) cited a trade press report (*Medical News Today* 2006) rather than the *Archives of Internal Medicine* study it was about (Lasser et al. 2006). What the *Archives of Internal Medicine* study actually found was that medical harm from prescriptions that violated warnings was extremely rare (an estimated total of sixteen such events among the 324,548 patients in the study). In general, the IOM report adduced little systematic evidence for its criticisms or in support of the efficacy of its many recommendations for change.

Quite aside from the IOM report, the leading drug safety anecdotes of the past few years have been treated in a largely misleading manner, greatly exaggerating safety problems and especially, the adverse nature of FDA actions. The triggering event was Merck's withdrawal of Vioxx on September 30, 2004, after an ongoing clinical trial revealed excess heart attacks among Vioxx users (Psaty and Furberg 2005). As the FDA presciently pointed out at the time, it was far from clear that Vioxx or its competing Cox-2 inhibitor, Celebrex, was significantly riskier than the much older non-steroidal anti-inflammatory drugs (NSAIDs) they replaced, given that these older drugs had never been subjected to rigorous clinical trials like the one that brought Vioxx down. Subsequent research has largely vindicated that view, with the entire class of NSAIDs (old and new, Cox-2s or not) now bearing heart attack warnings (Calfee 2005; Kearney et al. 2006; Warner and Mitchell 2008).

The second-ranking triggering event was controversy over previously non-public clinical trial results in which children and adolescents taking one of the SSRI class of antidepressants (Prozac or Zoloft, for example) were more likely to exhibit suicidal "ideation" or thoughts (but not to attempt or commit suicide). Faced with relentless criticism from litigators, politicians, popular press editorialists, and elite medical journals, the FDA implemented its strongest warning (a "black box," which appears on the FDA-approved label) for all antidepressants, not just SSRIs (because again, there was little reason to think that older drugs, which can cause fatal overdoses, are safer). Subsequent research taking a variety of approaches has found that SSRI use is strongly associated with lower, not higher, suicide rates, and that the highly publicized warnings probably did more harm than good by reducing antidepressant use. In particular, a series of reports has found that there is a striking, inverse relationship between SSRI prescriptions and youth suicides in a variety of data sets and that the imposition of new FDA warnings (beginning with public health alerts) is strongly associated with reduced antidepressant prescribing for children (and younger adults) and higher suicide rates (Shogren 2004; McKeown, Cuffe, and Schulz 2006; Ludwig, Marcotte, and Norberg 2007; Brent 2007; Gibbons et al. 2007; Lubell et al. 2007; Bridge et al. 2007; Pfeffer 2007).

Finally, there is Avandia, a popular diabetes drug first approved in 1999 (see Calfee 2007a for more details on this and other matters). On May 21, 2007, the *New England Journal of Medicine* published a meta-analysis of adverse cardiovascular events in clinical trials of Avandia (Nissen and Wolski 2007). Coauthored by a prominent critic (Nissen) of the FDA's handling of Vioxx, the meta-analysis revealed excess heart attacks and strokes among Avandia users. Accompanying the meta-analysis was an editorial by two well-known advocates of FDA reform (Psaty and Furberg 2007), one of whom (Psaty) was among the IOM authors. They declared that the Avandia meta-analysis revealed FDA neglect and was reason enough to implement one of the more radical reforms, the creation of an independent drug safety board (something the IOM report declined to recommend).

We soon learned that the meta-analysis authors and the journal editors were politically motivated (Usdin 2007b, Gottlieb 2007b [May 29]). Dissent quickly emerged from the academic medical community regarding both policy and research methods (*Lancet* 2007). FDA staff, researchers at Glaxo-Smith-Kline (the manufacturer of Avandia), and others pointed out that significant cardiovascular risk had not been revealed by large randomized trials, including the ongoing Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes (RECORD) trial, which was designed to address cardiovascular safety (Krall 2007; Home et al. 2007). In July 2007, an editorial in the journal *Nature Clinical Practice* vigorously attacked the Avandia meta-analysis on methodological grounds and criticized the *New England Journal* for rushing it into print and causing confusion among patients (Fuster and Farkouh 2007).

Academic and scholarly debate has continued, with one meta-analysis finding, again, excess heart attacks (but slightly fewer deaths) for Avandia users (Singh et al. 2007), and another, slightly reduced cardiovascular risk for Actos, Avandia's chief competitor (Lincoff et al. 2007). The imprecision and questionable reliability of meta-analyses have been made clear, as articles have demonstrated how modest changes in data and statistical methods (which involve considerable judgment even on such basic matters as whether to include trials in which no adverse events occurred) can dramatically alter

the results. Many, if not most, endocrinologists clearly want to maintain treatment options for a condition (diabetes) that is notoriously variable among patients and correspondingly difficult to treat. Thus a July 30, 2007, joint meeting of two FDA advisory committees voted 23-1 that Avandia involves an elevated risk of (minor) heart attacks compared to placebos, but also voted 21-3 in favor of keeping Avandia on the market while asking for new label warnings (but not the FDA's strongest "black box" warning) (Usdin 2007c). In the meantime, Avandia clinical trials continue, under FDA oversight as always. Obviously, experts can disagree over such matters as the nature and timing of cardiovascular warnings for Avandia, but that is very different from a finding that the FDA tended to downplay risks while approving Avandia and monitoring its risks afterward. In fact, the debate has come to focus mainly on the use of "surrogate markers" (in this case, glycemic control) instead of "clinical outcomes" (such as heart attacks or amputations) in approving new drugs. Critics of FDA policy want to avoid surrogate markers, but as the FDA and others have pointed out, this would drastically increase research costs and delay new drug approvals by several years (Joffe, et al., 2007).

Other frequently cited examples of FDA failure also do not withstand scrutiny. An example is the pioneer antibiotic Ketek. Far from rushing to approve Ketek, the FDA was actually slow, mainly because of fraud in one of the pivotal clinical trials, and it finally approved Ketek partly on the basis of five years of experience in Europe, where it remains in use to this day. This unorthodox process provoked much criticism, but any new class of reasonably safe and effective antibiotics is a valuable addition, and despite the controversy, there is little reason to think this particular drug is especially dangerous (Usdin 2006a, 2006b).

Why the FDA Tends Toward Over-caution in Drug Safety

Clearly, there is little persuasive evidence of FDA neglect of drug safety in recent years. On the other hand, there are compelling reasons to think that in balancing safety against the benefits of new drugs, the FDA tends to give too much weight to safety and not enough to benefits. The reasons lie in the biased incentive structure facing the FDA

staff. The unrelenting criticism visited on the FDA since the Vioxx withdrawal illustrates a profound disparity how the public penalizes two different kinds of regulatory error. When FDA staff members decide whether the benefits of a proposed new drug exceed its risks, they know that if they commit what is often called a Type I error – the approval of a drug that turns out to be insufficiently safe once marketing begins – their error will usually become known (a "public error"). This can and often does lead to impassioned criticism of the agency and to correction of the error (although more often than not, critics fix upon something that was probably not an error at all). On the other hand, a Type II error – the failure to permit marketing of a drug that would in fact provide benefits in excess of harms – is typically detected by relatively few people (a "private error"), and its deleterious effects can persist more or less indefinitely.

The effect is to bias even the most conscientious FDA regulators toward exercising excessive caution and requiring excessive drug testing. This first became apparent in a stream of research on the "drug lag" of the 1960s and 1970s, when FDA approvals trailed far behind those in European nations. This research revealed no consumer benefit in terms of safer drugs, yet similar approval lags continued for years afterward (Peltzman 1973, 1974; Wardell and Lasagna 1975; Katin and Brown 1995). Yet slow drug approvals here did not bring extra safety. An analysis of the United States, Spain, and the United Kingdom yielded essentially identical drug-withdrawal rates despite the more rapid drug-approval timelines in the European countries (Bakke, et al. 1995). Also, research has made clear that the advent of user-fee funding via the 1992 Prescription Drug User Fee Act has worked to the benefit of patients by accelerating the arrival of new drugs (Philipson, et al., 2005).

There is anecdotal evidence that soon after the Vioxx withdrawal and ensuing criticism, the FDA became even more cautious in approving new drugs and new indications (Harris 2005). Last year, for example, the FDA refused to approve the pain reliever Arcoxia and the weight-loss drug Accomplia even though both had been approved by the European Union and many other nations (Gottlieb 2007a [April 17]; Wadman 2007). The FDA has also been unreceptive to some promising new drugs for

advanced cancer, including Provenge, Genasense, and others (Usdin 2007a; Miller and Henderson 2007; Miller 2007; Pardoll and Allison 2004). The 2007 FDAAA legislation, which rooted in the view that the FDA staff has consistently neglected drug safety, has probably reinforced the FDA's innate tendency toward over-caution (Calfee 2007).

Neither Congress nor the IOM report has paid much attention to another potent force: market-driven manufacturer incentives to maintain drug safety. Such incentives operate with powerful effect in far less regulated high-tech industries such as automobiles, petroleum, and electronics. As in other industries, pharmaceutical manufacturers rely heavily upon maintaining their reputation among customers (especially physicians) for product safety and efficacy. Post-approval clinical trials play a central role in this process. These trials are undertaken to expand markets, but they necessarily open the door to new and possibly alarming (as well as reassuring) safety information. Often, post-approval trials are bigger, longer, and more informative than the trials undergirding drug approvals. Often, they force revisions in accepted views of such basic matters as, for example, the benefits of lowering serum cholesterol or the safety of all NSAID pain relievers (Topol 2004a; Wadman 2007).

What Can Be Done to Improve Drug Safety

Much could be done to improve drug safety without making the FDA even more cautious in approving new drugs and new uses for old drugs. The FDA clearly needs more resources, especially in information technology and in personnel with strong training in basic biological sciences and related fields. As former Commissioner Mark McClellan and others have pointed out, there are fruitful opportunities to collaborate with the private sector – not the pharmaceutical industry but also health insurance and other industries – in order to make far better use of the voluminous and ever-improving databases that are already in place (McClellan 2007). Carefully targeted increases in FDA funding could open up numerous under-exploited pathways to improved drug safety as well as better use of pharmaceuticals generally.

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Ms. DELAURO. Thank you all very, very much. I think maybe Congressman Kingston and myself should leave and have this reviewed just to sift this out with your various viewpoints. I think that would be quite an interesting and informative discussion.

LACK OF FUNDING

Let me just try to move to some questions. Dr. Powers, let me just ask you one thing that I have become concerned about is the FDA using, and I stated this earlier today, using the lack of funding as an excuse for not accomplishing congressionally-mandated goals? During your time at the agency, did you get a sense that the agency was using this excuse too much?

Dr. POWERS. I think first of all it is important to say that there are things that FDA cannot accomplish because they do not have the resources to do so, and we heard a lot about that this morning. I think though that when you get into the situation where there is something that is controversial or difficult that you do not want to address, it can become convenient to say, "Well, we just cannot get around to this because we do not have resources." And I would like to give an example. We know, for instance, in that what I deal with in the antibiotic world that in the past people thought that the amount of resistance to good old penicillin was actually going up in an organism that causes pneumonia. We now have a body of information that says maybe we did not define resistance correctly and penicillin is still quite effective for the majority of people. A bunch of academics put this information together and actually submitted it to FDA in a citizen's petition and get back a response that was several sentences long that said, "We still need to think about this." And when they brought it up to FDA personnel, we are told, "We really do not have the resources to get around to this." I know having worked there, since resistance was what I did, that this is something that the microbiologists and the scientists at FDA are completely capable of addressing, and all that information was put together in that citizen's petition. So it seems like is this a case where really we do not have a lack of resources or do we have a lack of will to want to address the problem in that situation?

OUTSOURCING REGULATORY FUNCTIONS

Ms. DELAURO. Let me just do a quick follow-up there, and then I have a question for Dr. Calfee as well, and then we will do a few rounds here. Another issue that gets brought up is that the lack of resources, and I would be interested in your view, it might lead to some inside and outside the FDA to suggest that regulatory functions be outsourced. My view, and I am not a scientist, but my view would be that that would cause more problems. Would it not cause more problems?

Dr. POWERS. I think the example I just gave relates exactly to that, and that is that when you are going to define antibiotic resistance, which we all agree is increasing, it is a public health issue, who defines resistance? Actually, it is the FDA scientists who do that at the time that a drug is approved. But unlike other classes of drugs, the effectiveness of antibiotics changes over time too, not just the safety issue. So this is how effectiveness and risk are really two sides of the same coin.

The new FDA Amendments Act requires FDA to re-look at all these antibiotics at least every five years. During the discussions for that Act, there were several suggestions that that function be outsourced to people outside of FDA. It seems though that something so directly related to the conditions of use of a drug like antibiotics is clearly within FDA's purview. And then there were insinuations and letters sent to FDA that FDA personnel did not have the expertise to be able to do that, which I know is actually not true. The folks at FDA are very qualified to be able to do these things.

And you can see the potential conflict of interest that would come trying to put these things outside of the FDA. And one of the things about working at FDA is that you are really one of the only folks that are really completely devoid of any kind of conflict of interest, to be able to look at this in a dispassionate way. So I agree with you, I think sending some of these things outside the agency, including the issue of inspections, et cetera, probably is not a good idea. It is why the FDA is there, to be the dispassionate arbiter of some of this information.

Ms. DELAURO. I beg apologies for ignorance. In terms of the final amendments under PDUFA, we are not moving in the direction or should we be vigilant about watching to see whether or not any of those functions are outsourced?

Dr. POWERS. That did not happen as part of the FDA Amendments Act, but I think we still need to be vigilant that those things do not get outsourced. It is vogue to talk about public/private partnerships. As a part of my testimony, I talked about FDA does not need to be a silo, we do need to get information from outside. That doesn't mean you send the actual functions of determining safety effectiveness and appropriate conditions of use outside the agency for others to decide. I think this also relates to the use of advisory committees as well. In the advisory committees, really they are called "advisory" for a reason. They do not make ultimate decisions on drug approvals and yet they are often asked if there is substantial evidence of safety and effectiveness. But in almost 10 years of going to advisory committees, I never heard an FDA official explain what "substantial evidence" was to the committee. And that is the article that I submitted to the docket there on what is substantial evidence? It is very clearly defined in FDA's regulations what it is, but if you do not tell the advisory committee members what that standard is, how are they supposed to give the agency good advice? Instead, if you do not instruct the jury, they then substitute their own opinions, which may not actually be coinciding with what FDA's legally-mandated standard is.

And I wanted to go back to what Mr. Kingston said, that the FDA does not taut itself enough about how good a job it does nor explain to people what the standards are. And they are actually pretty good standards when you actually look at it, and they are scientifically justifiable standards as well. They may be higher than some people might want, but that is what FDA is legally mandated to use, so it is not a surprise sometimes that there is a disconnect between what advisory committees advise and what FDA then ultimately does because the advisory committee is not told where the bar sits.

Ms. DELAURO. That is an interest angle, if you will, on the advisory committees. I am glad my colleague, Mr. Hinchey, is here because he has been particularly concerned about the conflicts of interest that exist with the advisory committee, which should bring up another point, which is about really the charge to the advisory committee and our having to make sure what that charge is or the explanation of it in terms of those determinations because it is a mystery sometimes. With this Avastin, that there was a decision in December it was no, and now just about a week ago, they have now said yes. And, look, I do not claim to be a scientist, and I do not know what the basis of the decisions were but they are interesting, more than interesting, they are quite important in terms of overall efficacy and outcomes of its decisions.

My time is up. I will move to Mr. Kingston.

Mr. KINGSTON. Thank you. Dr. Powers, let me engage in a philosophical discussion with you about your example on the Maryland Public Schools $1.9 billion versus the FDA budget and so forth. As you know, with $1 trillion worth of food and drugs and so forth and medical devices, that there really would not be enough money under any conceivable scenario to have inspectors at every step of whatever process, therefore the reliance on the private sector is certainly tremendous, and it has served us well along the way. The reason, as I understand it, PDUFA—and how old is PDUFA?

Dr. POWERS. 1992.

PRESCRIPTION DRUG USER FEE ACT

Mr. KINGSTON. Twenty or twenty five years old. The idea was to infuse a little bit more in it, and I think in terms of Congress and the demands for money, PDUFA was probably a good concept, but having worked at FDA, do the scientists there actually know who the contributors are, so to speak? I will give you an example, in our congressional offices, we are better served when our legislative staff, who advises us and reads legislation, where they do not know who your donors are. They might know if you are pro-life or pro-choice or some of the big picture stuff but 99 percent of the bills do not fall into a well-known category like that, and therefore it is better when they do not know really where the money is. Do the scientists who are in the lab, do they know who the participants are under PDUFA?

Dr. POWERS. I think the issue is actually a more subtle one than that, and that is that since the goals of PDUFA are negotiated with members of the pharmaceutical industry before the bill is passed, it is not that the individual staffers at FDA are very cognizant that their check is being signed by PhRMA, it is that those goals then come down to those reviewers and those goals are specified in PDUFA. And I will give you an example. For instance, when I was at FDA, we had to fill out regular time sheets, which calculated how much time we spent on PDUFA-related activities, and some of the codes that went into that were how much time you spent at the copy machine, how much time you spent emailing, things of that nature. So your every minute was documented as to whether it went to a PDUFA-related activity or not, so you were not really thinking that this is influencing what I am doing but in a more subtle way it does because you had to actually keep track of every-

thing that was related to PDUFA. Now, I think actually that that accountability is a good thing, but I think that accountability also needs to be on the other side related to non-PDUFA-related activities and drug safety as well. It makes sense if we are doing it on the one hand that we should be doing it on the other.

Mr. KINGSTON. Well, you could put in a firewall though that would be a better protection from the scientists, correct?

Dr. POWERS. The way I look at it is this, to get my medical license I have to pay a fee to defray costs. To get my driver's license, I have to pay a fee to defray cost, but I do not walk into the Division of Motor Vehicles and walk up to the counter and negotiate with that person how those fees are going to be used, so it seems to me logical that when a sponsor submits something to be reviewed, defraying that cost makes sense for people reviewing that at FDA but then to have to negotiate what those monies are used for, I think that is where the firewall breaks down that you are talking about.

Mr. KINGSTON. It is a parallel study though, correct? Would it not be true that Pfizer or whomever has already studied this drug and knows a tremendous amount of the science already, if not all the science, but FDA is the third party objective going in there and saying, yes, your conclusions are right or wrong?

Dr. POWERS. Well, actually FDA follows along all during the development of that drug, so when a drug is first studied in animals, for instance, a drug sponsor will submit that information to FDA. FDA reviews it to see if it is even safe to put that drug into a human being or not. So FDA is actually following along all the way, it is not just at the end they say yea or nay. And that is why I said it is really important for them to publish information because they have got this great view of not only that drug but other drugs related to it that could help other drug sponsors as well to be more efficient about how they develop their drug.

UNION OF CONCERNED SCIENTISTS

Mr. KINGSTON. Okay, now I am not familiar with the Union of Concerned Scientists. I do know that groups generally have a bias, can you tell me about them?

Dr. POWERS. Well, I am not speaking for them obviously.

Mr. KINGSTON. But you go to them, right?

Dr. POWERS. Right, right, and they are a consumer group that is interested in integrity in science.

Mr. KINGSTON. Well, okay, I understand everything on the boiler plate, I really and truly do not know, is this a purist group or do they have——

Dr. POWERS. It is a nonprofit group and, again, the reason I know about it was because I was at FDA and filled out the survey when it came.

Mr. KINGSTON. But do you know them to be an objective group?

Dr. POWERS. I would say they are, yes.

Mr. KINGSTON. Because I am not familiar with them, but I do know that many, many groups have great names and great mission statements and they are absolutely—they have a bias as worse as anybody they are pointing a finger to, and I do not know if this group does. Now, the reason why that is relevant is that the most

current study, the 1998 study, which Dr. Wolfe mentioned, that is eight years—excuse me, 10 years old now, and so I am trying to find out how accurate that data is in terms of the pressure on scientists or the pressure that they feel to approve something.

Dr. POWERS. Right, I think when you look at any one of these things, instead of taking them in isolation, and that is the reason why I put three of them in there, is that you could make some claims about maybe they are not entirely accurate or maybe they should have surveyed more people.

Mr. KINGSTON. But a 10 year old survey would not even be relevant.

Dr. POWERS. Exactly but the point is——

Mr. KINGSTON. And then you also quoted a 2002 survey.

Dr. POWERS. Right.

Mr. KINGSTON. The reason actually that I am really not even interested in the survey, here is what I am interested in the Type 1 and Type 2 error that Dr. Calfee mentioned because I see a tendency in all bureaucracies not to make a decision. Now, you have brought up something very important, that the FDA is not a "the," it is a collection of scientists, and it would probably be a whole new dynamic to say Dr. Jones stamped this drug. And I know that the Chair and the whole committee, we would love to see the USDA, for example, have a little bit more accountability, but they do not make decisions because you cannot be wrong when you do not make a decision. And then if you make a decision and there is something that goes awry, the consequences of that are just as bad. As Dr. Calfee says, one of them is a public error that is well known but the other one, of making a decision, is private and you do not really ever know. Now, I know I am out of time but that is what I really want to head to on what goes on when the guy wearing the white coat in the lab.

Dr. POWERS. Right, so I think one of the issues there is though if you can hide behind the term "the FDA," and there is no personal accountability, it is not like me going to a scientific meeting and getting up and presenting my research, and then other people get up to the microphone and say, "Excuse me, Dr. Powers, but my lab shows this, it does not coincide with your results." That kind of—I call it critiquing rather than criticism—is actually a good thing. And if you are making a decision that is going to affect millions of people, I do not see why you should not be able to defend that and the science behind what you did.

Mr. KINGSTON. I agree, and I think frankly sometimes you have to encourage people. The transparency—and I am out of time, I am going to ask you about this some more and the transparency issue because it does touch on that, which I know gets into patent issues, so let me quit talking and let Steve talk.

HUMAN CAPITAL SURVEY RESULTS

Ms. DELAURO. Well, I just thought, Jack, that you ought to know in terms of the surveys, FDA Human Capital Survey results, management at FDA, there are a lot of federal agencies, the FDA participated in OPM, this is OPM, 2006 Human Capital Survey. I think it is important that you know about that the morale at CDER has been documented, and this is FDA responses to this gov-

ernment-wide survey by OPM. The report found that more than 30 percent of FDA employees disagreed with statements that, "Employees feel free to speak their mind about what they believe." For example, there is no fear, threat or repercussion for disagreeing or dissenting. They expressed concerns. Twenty-nine percent said that they were not satisfied with the policies and practices of senior leaders. Okay, you could say that that is disgruntled. Nineteen percent disagreed that their organization's leaders maintain high standards of honesty and integrity. Twenty-five percent said that they did not have high-level respect for the organization's senior leaders. Thirty-five percent disagreed that in my work unit steps are taken to deal with a poor performer who cannot or will not improve. Forty-two percent disagreed that pay raises are dependent on how well employees perform in their jobs. They said their workload was unreasonable, 24 percent of them did.

Mr. KINGSTON. If you will yield a minute, they are saying that it is a problem that they are getting paid based on performance?

Ms. DELAURO. No, no, but the opposite.

Mr. KINGSTON. Okay, they want that, okay.

Ms. DELAURO. They do not get paid on performance. But I think it is important to note that they view that there is fear, there are threats and repercussions for disagreeing or dissenting. I think that is a pretty staggering number of people, and that is 2006, no private group, no nonprofit group, this was OPM. This was the Federal Government that conducted this survey.

Mr. KINGSTON. That is important, that is interesting. I wonder how that compares to other federal agencies because I bet you Fish and Wildlife or the U.S. Army, half of human resources, you would have the same kind I do not want to rock the boat kind of push back.

Ms. DELAURO. What do you say if you have an agency with real serious matters of public health and a lot of instances life and death matters. This is not a park, it is not a bridge, it is not some sort of—but they are serious, serious—and the point has been made over and over again, a lot of the ad hominem attacks have been on people within the agency who resigned or left and so forth and have come back after several months. I think that was the case with AVNDIA and other places where the accusations were correct and a person was berated and left, maybe of their own volition, but then in fact you saw that there were substantial difficulties with the product.

Mr. Rothman.

PROBLEMS WITH THE ADMINISTRATION

Mr. ROTHMAN. Thank you, Madam chairman. A question for each of our panelists, and thank you for being here. You each touched on this to some degree, but I would like you to expand on it a little more, are things that bad and out of whack, out of the norm at the FDA? And, if so, how did that come to be? There is a public perception that in this administration it might be a matter of ideology to under-fund or under-regulate this industry or is it a matter of poor management if in fact one believes that things are abnormally bad or dysfunctional at the FDA? Dr. Calfee, would you like to begin?

Mr. CALFEE. Well, frankly it is difficult because if there is anything dysfunctional at the FDA, most of that is very well hidden from what the rest of us can see. I was very interested by the things that Dr. Powers said because he has been there and been there relatively recently. I am the last person who would be surprised at learning that there are many ways in which this government bureaucracy operates in ways that are quite inefficient and which there are lots of disagreements among the various levels, and that there are some people who do good jobs and do not get rewarded, there are some people who do bad jobs and do get rewarded, et cetera.

I am struck by looking at these surveys, the only one I have looked at carefully has been the Union of Concerned Scientists because that was published, and I have a lot of doubts about how much we can learn from that survey. As I recall, when you read this survey, the questions it asks are rather leading questions. When it explained why they were conducting this survey, it was made perfectly clear that they were conducting the survey in order to reach people who were upset with what was going on.

Mr. ROTHMAN. Doctor, can I interrupt you for a second?

Mr. CALFEE. Yes.

Mr. ROTHMAN. Is then the absence of objective criteria on which to make a judgment in and of itself a failure of the agency of transparency, if you will?

Mr. CALFEE. That might be a failure in the sense that it would be very good if the agency could get a much better handle on how their staff is doing, what their attitudes are and so on. I do not know how well they know about their staff——

Mr. ROTHMAN. Well, not just on staff morale but on the issue of——

Mr. CALFEE. Well, my experience from being in government elsewhere is that you are right, they really ought to know a lot more difficult than one might think to get really concrete data on——

Mr. ROTHMAN. So the point is you don't have really enough data to answer my question?

Mr. CALFEE. I think that is probably true.

Mr. ROTHMAN. Okay, Dr. Powers?

Dr. POWERS. I want to get back to something Dr. Calfee said, that even if you say there is not a crisis currently, the old adage that "an ounce of prevention is worth a pound of cure," all of the reports, through the inspector general, the GAO, the Institutes of Medicine, the recent Science Board report, all point to if not we are on the edge of a big problem, we are going to have one very shortly, so rather than allow that to proceed, it makes sense to try to do something about it now at this point.

I think the point I wanted to make, to get back to Mr. Kingston's question too, was you can poke holes in any one of these particular surveys but what is interesting about them is they are all consistent in their findings, both the ones that come from the government and the ones that come from the nonprofit organizations as well. Obviously, if some were showing one thing and some were showing the other, you could have some doubts but they all tend to point in the same direction.

I think one of the other issues about FDA is not like other government agencies, it is like some, is that you have got this inherent tension between science and management, and the IOM report points this out, because you are a good scientist, it does not mean you are a good manager and because you are a good manager, it does not mean you are a good scientist. So you have to manage—somehow get those two things to jive at the same time.

Mr. ROTHMAN. I know that we are going to hear from Dr. Wolfe also, but this may just be part of the—not substantiated or substantiated goal but there is a view in some quarters that the ideology, in terms of the strength of intervention in the marketplace or this industry is in some way affecting the work at FDA. Do you accept that in whole or in part or do you dismiss it?

Dr. POWERS. Well, I think that again you cannot color everyone at the FDA with the same brush, but I can tell you from personal experiences, when you sit in a FDA meeting and someone says, "Well, we cannot ask them to do this trial in the correct way because we are enrolling too many patients and the company will not want to do it that way," that to me says that there are things impacting on the decision of how—and let me be clear, companies do not want to have inappropriate advice, they want to know up-front what the right way to do things are. The worst thing the company wants is to be told one thing by FDA, go out and spend millions of dollars to do the study, and then FDA says, "Oh, sorry, that did not meet our standards." So I have a friend in the drug industry that says, "Tears today is better than tears tomorrow." They want to know what that advice is up-front. So FDA is not doing people any favors by giving them inappropriate advice up-front, but the fact that that statement is even made about how is this going to impact a company—and, in fact, how can anybody at FDA know how it is going to impact a company financially? You have no data upon which to make that decision. So the fact that that is even said or hinted at, I think gets to the point that there are things other than science that are being—and I do not mean to say that that is across every division in FDA. I think some of them function very properly but the question is do we want an agency where everyone is on the same page.

Mr. ROTHMAN. Dr. Wolfe, could you just address these questions? Thank you, chairman. And one other aspect, do you have an opinion as to whether to the extent you agree with Dr. Powers there is any element of undo concern about industry sensibilities, what does exist, is that ideological, if you will, or a particular bias present in any greater or lesser extent in any other administrations that you are aware of?

PRESCRIPTION DRUG USER FEE ACT

Dr. WOLFE. I do not think that, much less so than almost any regulatory agency, FDA staff does not turn over with a new administration with the exception of the Commissioner, people in the circle around the commissioner, the general counsel, the rest of the people stay the same. The problems that we focused on really arose during the Clinton Administration. They were I believe in part due in the passage in 1992, right in the beginning of the Clinton Administration, of the Prescription Drug User Fee Act. And the way

we designed our questions in our survey, which again as Dr. Powers says, the findings are consistent with surveys by the FDA, by the inspector general, by everyone else. Things have gotten worse since PDUFA was passed, and they have felt in 1998 that going back to the way things were more or less pre-PDUFA's full impact, things had gotten worse. The standards were different, they were more under the gun of the negotiated kinds of deadlines and so forth, so I think that it is PDUFA more than a political philosophy. PDUFA itself can be looked upon as a political philosophy, it is the philosophy that the appropriations for the FDA should not be coming from the Treasury, as they have been, as I said, for 86 years, but the industry should pay for it. And, as a matter of fact, have a certain amount of say not on a drug by drug basis but on the overall way in which user fees are structured. So I think that not the administration, it is PDUFA. It really needs to be reversed. It is growing like cancer, it gets bigger and bigger every year. It started out with drugs, it is devices, it is a number of other things now, and I think that there is no question that substantial numbers of people at the FDA feel that impact. When the head of Drugs says, "It creates a sweatshop mentality," and by "it," she is talking about PDUFA, not this administration. It is a serious warning signal, that was several years ago, and the sweatshop has gotten more sweaty since then.

Mr. ROTHMAN. Thank you, madam chairman.

Ms. DELAURO. Thank you. At some point, let me just leave this piece with regard to PDUFA because it was never meant to create the imbalance that it has, and I think that the Congress has not kept its part of the bargain in terms of the appropriations side. I would truly love to have a conversation with all of you about how we tried to address that imbalance, and how we can try to move forward and not deal with creating impasses like there were 10 years ago when folks decided that this was a direction to go in.

TRASYLOL

Dr. Wolfe, let me, I have a question. You are currently investigating the drug, is it Trasylol, which is used to reduce bleeding during open heart surgeries. Studies in the New England Journal of Medicine linked the drug to an increased risk of death and kidney damage. According to the report, patients taking Trasylol were found to be 27 percent more likely to die a decade after surgery. Another study found that 78 percent increased risk of death within week following surgery. And there were two FDA advisory committees that recommended that Trasylol remain on the market despite the concern. I also understand that the Bayer Corporation had information in studies which in fact the advisory committee was not made privy of too. And that is an issue of how do we feel with finding out that that is the case? And also what could FDA have done differently to avoid the problems with the drug Trasylol?

Dr. WOLFE. Well, I think there are two issues with Trasylol, which is now off the market, much later than it should have been, after killing large numbers of people. They may not be as large as estimated by Dr. Mengano in this 60 Minutes program but there are large numbers of people who have died needlessly from it because it should not have been on the market when a lot of them

were given the drug. One is the regulatory issue, why even after FDA learned from more than one study that there was a problem, they did not demand that it be taken off the market? And the other is an issue of possible criminal liability. There is no question that Bayer had the results of the study that was published a week ago in the New England Journal, that they had these results in the fall of 2006 before the committee met, and there is no question that they did not send the results to the committee until one of the people that did the study said that that is not right and belatedly, after the committee had met without seeing these results, that they were sent to the FDA. To my knowledge, the FDA has not initiated any criminal investigation as to why Bayer did not send the study in the first place and why Bayer basically lied during the hearing. They were specifically asked, "Do you have any other kinds of studies that shed light on this issue?" and they said, "No." It is not likely or possible that the huge number of people testifying for Bayer that day, back in fall of 2006, did not know about this study because they paid for the study, and the main study purpose in their view was to try and neutralize their earlier study that showed harm. And when it did not neutralize it but it confirmed it, they did not like that, they did not want to talk about it at the hearing, they did not want to acknowledge that it existed. Only when pushed by someone else did they submit it. So a regulatory decision to ban a drug too late, the company initiated way later, the FDA should have initiated it sooner, and the company did its own internal investigation of this issue of lying or whatever, hired a fairly prominent Washington law firm to do an investigation and guess what? They were all exonerated. This is no way to pursue justice, to have a company fund a study where the answers are sort of, hey, they did not do anything wrong, there is just a little mistake here, a mistake involving a study with 78,000 patients taking this drug and having a substantially increased risk of death, so two regulatory lapses: they didn't take a drug off the market soon enough and, to my knowledge, they have not initiated a criminal investigation.

Ms. DELAURO. Do they have the authority to do that?

Dr. WOLFE. They certainly do, and there are laws that prevent companies from withholding information from the FDA and there are certainly laws, they were not under oath, but there are laws that sort of say it is not nice to lie before a FDA advisory committee.

Ms. DELAURO. I am going to ask you to strike this conversation. This goes back to December, this article that was in the Wall Street Journal, "FDA and Drug Marketers Plan to Tell Doctors of Off-Label Uses as Being Crafted." Can you just comment on that? Again, I am not a doctor, I am not a scientist.

UNAPPROVED USES OF DRUGS

Dr. WOLFE. Yes, before 1997, it was illegal in way, shape or form for a company to promote a use of a drug that had not been approved. So a drug is approved for treating one disease, and the company was not allowed to approve it, to market it for a disease for which it had not been approved because by definition there was not sufficient evidence that the benefits outweighed the risks. If

there were, they would have submitted these, and they would have been approved. There was some pressure from the industry in 1997 to try and change that law to allow companies to submit, to doctors, hundreds of thousands if they wanted to, copies of medical journal articles, from peer-reviewed medical journal articles that talked about the unapproved uses. And the proposal, legislatively, started out with just that, if you have an article, a peer review journal that says that this drug works even though it is not approved, you can send that out. The FDA then, in a much more cautious mode, in 1997, strongly opposed this provision. They said it is too dangerous because it allows information that may not in the final analysis show benefits outweigh risk to essentially send out as promotional material. A compromise was reached in 1997 so that instead of just being able to hand out the hundreds of thousands of pamphlets, the companies had to first send them to the FDA, to have the FDA look at them and approve them in the context of other studies that had been done. And, secondly, the company had to promise within three years, they would actually submit a new drug application amendment to get the drug approved for that new use, and that is the law that passed. And that law, I didn't think it was a good idea but at least it was a reasonable compromise with more safeguards than what has been put forth by the industry and opposed by the FDA. The law expired in October of 2006, and the companies came crawling to the FDA, the former FDA lawyer, Dan Troy, brought some of his industry friends into the FDA, and they literally asked the FDA to do something that eventually was put forth as a proposed regulation two weeks ago, to go back to this original version, only to send out these pamphlets without having the FDA clearance, without having the promise to get the drug approved, and that is now completely opposite of what FDA's stand on this was 10 years ago, it is now FDA's policy. There is a serious question as to whether it is legal or not. The industry has argued, I think falsely, that there is some legal precedence that have occurred in between that affected that. That is disputed by a number of people. So the FDA has again gone backwards on where they were 10 years ago in proposing, with 60 days of comment allowed, that for the first time allow promotion of unapproved uses without these safeguards that have existed for nine years.

Ms. DELAURO. Well, fast forward to February 15th, a week ago, "The FDA Seeks to Broaden Use for Drugs," that was in the New York Times. Let me just ask you this—what kind of tools, and I suppose I should know this but I do not, what kind of tools do we have to stop this? What are our opportunities? There is a six day comment period, how do we prevent this from happening?

Dr. WOLFE. Well, what this guidance does, which is exactly what former FDA lawyer, Dan Troy, wanted is a promise from FDA that even though they, in my view, violate the existing law because the existing law goes back to pre-1997, cannot do any of this at all, the FDA promises not to prosecute them, they promise not to go after them as long as they follow this guidance, which is a pretty loosely worded guidance compared to what was in existence for nine years. So I think serious questions should be asked of FDA why they completely reversed the policy that the FDA had and testified on 10 years ago, what new things are there? And if they cite these legal

cases, they will be very easily disputed because they do not point in this direction. I think they need to be asked that. No one has really asked them that yet.

Ms. DELAURO. Thank you. Mr. Kingston.

HATCH-WAXMAN

Mr. KINGSTON. Thank you. Dr. Wolfe—well, actually all of you, are you familiar with Hatch-Waxman?

Dr. WOLFE. Yes.

Mr. KINGSTON. Under Hatch-Waxman, do you think that it can be gained and do you think there is pressure on the scientists to believe that a drug really has changed in order to keep the generic off the market so that the patent gets renewed when the original patent is expired?

Dr. WOLFE. Do I start?

Dr. POWERS. Yes, I am not clear on the question yet.

Mr. KINGSTON. I understand that when the patent expires, that the drug companies have a certain amount of time to prove to the FDA that they have changed the drug in order to keep the generic off the market, and sometimes I have heard that that change can be as simple as a redesign of the bottle or a re-scoring of the shape of the tablet or whatever, and I was wondering if that is the case, do scientists at FDA have pressure to extend the patent or to approve this as a new drug as opposed to, no, let's let the generic get out on the market?

Dr. POWERS. Actually, I think the folks in the Office of Generic Drugs work hard to make sure that generics are available to people. I think the issue has been more outside of FDA and that is that it is almost routine for people to file these things that hold up generic companies from actually making the drug.

Mr. KINGSTON. So it just buys time?

Dr. POWERS. Right, but that has nothing to do with FDA. That is outside of their purview, that they file in court to say we are going to delay this.

Mr. KINGSTON. Okay, that is a matter of the law, that is not regulatory.

Dr. WOLFE. Can I just try and answer that, which is an additional outside FDA mechanism, which has been documented very well, and there are still more examples, I do not know the details being pursued, is that the brand name companies selling $50 to $100 million a year of the drug and for economic reasons, they do have a fiduciary responsibility to their stockholders, they want to keep making more money, they bribe literally the generic company, pay them $50 to $80 million to delay making the application for putting the generic drug on the market. This is not rhetoric, this has happened a number of times. Hopefully, it will be stopped but it is something—the issue that you are raising, whether it is really different or not, here it is exactly the same drug, no one is even claiming that it is different, but the generic company succumbs to this large amount of money and allows the brand name company to make a much larger amount of money than they are paying the generic company to keep selling exclusively.

Another version, which we call "smoke and mirrors," drugs, organic drugs, come in pairs, a left-hand and right-hand version, op-

tical isomers, and frequently the first drug patented is a combination of the left and right, so the company, in order to extend their patent, will look at just the left, if that is the right one, which it often is, and get a patent just on the left-hand version. Nexxium is essentially an example of that. There are a number of other examples of that. From the standpoint of benefits and risks, there is absolutely no difference but by promoting it, with the FDA not enforcing the promotional laws, they make it appear as though the new left-hand version of what was a mixture is better even though there has really never been any evidence that they are. So there are a number of tricks—I could go on but I will not—that allow brand name companies to keep their hands in an iron grip on their product by changing it minimally, getting a new patent on it. I think it is a fault, as Dr. Powers said, a lot of it is outside the FDA, there are serious problems with the patent laws that allow a new patent on something that functionally has no difference from the old one.

Mr. KINGSTON. Dr. Calfee.

Mr. CALFEE. Yes, if I could get back to your original question, which is whether Hatch-Waxman can be gamed. I think the short answer is it can be gamed. It sometimes is. It fortunately is not gained very often. This is usually a matter, as these gentlemen have said, not of FDA law or regulation, it is usually either patent law or antitrust law. The FTC has looked at this quite carefully, and basically their conclusion is pretty close to what I said before, which is you can have situations in which people are gaming the law. It is not obvious. It is a fairly fact-intensive situation, especially these arrangements between a manufacturer of a pioneer drug and a generic firm, such as Dr. Wolfe was referring to, because sometimes there are genuine uncertainty as to when a patent really will lose all of its protection. In that case, there can be situations in which a settlement between the manufacturer and the generic firm does make sense from an economic standpoint and public policy standpoint and situations in which those arrangements are actually quite contrary to the public interest. It is being sorted out by the FTC and the antitrust authorities. Like I say, it is not a perfect system but is working actually remarkably well on the whole. We are getting an awful lot of very cheap generic drugs.

Mr. KINGSTON. It is amazing, I never thought the generic drug industry would be so saturated as it is now. Ten years ago, it just seemed like everything was lined up against them.

I have a question for you, Dr. Powers. In terms of PDUFA, and I do not quite understand the negotiation between the pharmaceuticals and FDA when they saying this is what we would like to finance or whatever, but is it a result of that that the higher profit drugs are approved and getting the most attention as opposed to something that might be a lower profit?

Dr. POWERS. I do not think that is the case.

Mr. KINGSTON. Well, does it follow medical demand?

Dr. POWERS. Yes—well, in a way. So FDA already has guidances in place about, as Dr. Woodcock brought up this morning, what would result in a drug getting a priority review. The things about profit have nothing to do with that. It does have to do with though is there a medical need, is this a life-saving drug that will be effec-

tive and safe in places where there is no therapy for people? So there is a guidance on what qualifies as priority review but it does not include how much money a sponsor makes on the other end.

Mr. KINGSTON. Well, that might be something that we as a committee would like to see and could get from Dr. Woodcock would be what are those questions when they decide how the PDUFA money is going, what is the battery that it goes through. I think that might be helpful because you could direct some things through that.

Ms. DELAURO. Well, I think you are absolutely right, and I think unfortunately even with the latest PDUFA agreement, which I had a serious problem with, but they were passed both in the Senate and in the House, we ought to be making, in my view, the determination of what we are doing there rather than having to respond to what the industry wants to get out of this in terms of approval, time frames, et cetera, so that I do think we have a reasonable chance at that level. It may be too late this go around to do something about it, but I think—I am not sure, I think we ought to have more to say about what happens here but not be listening to the industry in terms of how those negotiations go.

Dr. WOLFE. Could I just comment on that?

Ms. DELAURO. We appropriate the user's fees for God's sake and therefore, as an appropriations committee, we ought to know the terms of the agreement and if the terms of the agreement do not set with us, then we ought to go back and figure out what needs to get done. Dr. Wolfe?

Dr. WOLFE. Just a quick comment on what you were saying, which is in some ways, even though you appropriate the amount of the user's fees in the appropriations committee, the appropriation is handled by the industry so you have a whole new dynamic going on between the industry and the FDA saying, "Okay, we gave you $400 million last year. CDER, these are the terms of it." And I think some of these negotiations are not public. I would think that it would be much more appropriate, the most appropriate thing would be just to repeal PDUFA and go back to the government funding of it, and in the interim, the appropriations committee really has as much or more to say than the industry does as to how the money is spent.

Ms. DELAURO. If I could say, there is one effort, I do not know if we will get around to talking about it but the whole area of what we did as a subcommittee level with the consumer advertising user's fees is said no. And what we did, and I am not talking about the millions of dollars involved in the approval of profits, but we talked about $6 million because of the President saying he was going to veto the bill. We lowered that number to something like $5 to deal with direct consumer advertising, and I think sometimes we have to really push very hard. Well, we are not authorizers as well, and there is a lot of very big forces here that are addressing these issues, but I think we have to get more aggressive and have quite frankly more stomach in turning back some of these areas.

Dr. WOLFE. Stomach and spine both.

Ms. DELAURO. Thank you very much. Dr. Calfee? I apologize to you.

Mr. CALFEE. Yes, I am concerned that PDUFA is getting a bum wrap here that it does not really deserve. I think we have to remember the basic outlines, which is industry provides money to CDER, CDER has to meet certain deadlines, it has to make decisions by a certain time. It does not have to make the decisions for the drug, it just has to reach a decision period. This has generated a lot of research, and of the nice things about the IOM report is that it did a good job of summarizing the scholarly research of PDUFA, partly because one of the authors happened to be someone who had done quite a bit of research, and the research is interesting and it is impossible, when you read that research, you simply do not get an indictment of PDUFA. It has accelerated drug approvals. There is no evidence it has compromised drug safety. There is no evidence that it has done anything harmful.

Dr. WOLFE. Other than create a sweatshop environment at the FDA for drug approval.

Mr. CALFEE. Well, that is not the same issue.

Dr. WOLFE. It is the same issue.

Mr. CALFEE. It does not matter. If you have those deadlines, if you had the same deadlines and the same number of people, it does not matter who is paying for it, you still have the sweatshop mentality. The problem there is resources, not the source of the money.

Ms. DELAURO. Well, I think one has to question, and again I would have the views of others in terms of those deadlines and are they in fact deadlines that can be met, are they deadlines just to deal with the industry, that they view that the deadline is imperative and is it a real deadline? And I for one am not going to say I am an expert at doing that. I would go to others and talk about whether or not that makes any sense and, frankly, I have heard from a number of folks that the imposition of those deadlines and some of the other demands have created very difficult situations within the FDA, which I think compromises in many respects some of what their outcomes can be.

Dr. Powers.

Dr. POWERS. I think that Dr. Calfee has a point though in that there has to be a balance between these two things. Dr. Woodcock pointed out this morning that before PDUFA, that there were no deadlines on when you had to finish a drug review and let's face it, you do the things that are on your calendar that have to be completed, but there needs to be a balance of when that gets to the point of that—it is sort of like keeping the trains running on time at FDA, everybody has got to work based on these deadlines. And although you are right, you do not have to make a decision to approve a drug, there is an insidious pressure to do so, so if not for anything else than to get the work off of your desk, and I do not think people should have that attitude.

It should be what does the evidence really show? And the way to really handle this is again using an appropriate scientific standard: does the drug measure up to what FDA has legally mandated standard is or doesn't it rather than trying to say things like do you feel comfortable that this drug is safe and effective, which I have heard at many advisory committees. It is not whether you feel comfortable, it is does it meet what the standard is? But the science, the science has moved so very, very quickly that we need

to do something so that they are more aware of what is going on, they can interact better, et cetera.

OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY

Ms. DELAURO. Let me just, I got into this at the end of our last panel with Dr. Woodcock, and I would love to have you all respond to this. This is what was the Office of Drug Safety and now the Office of Surveillance and Epidemiology and ONB, and the tension within those agencies in terms of pre-market approval, post-market approval, and now this new configuration, which the FDA is moving toward with the agencies, and, as I have pointed out, looking at medication errors and looking at some of the labeling issues, I suppose let me just put it this way to you, I need to have your view as to are we not going in the right direction with regard to pre-market and post-market based on what we have heard are significant problems there, but are we going to create more problems and is there a better way to try to deal? And I would welcome, Dr. Wolfe, Dr. Powers.

Dr. WOLFE. Yes, this is the seventh or eighth time in the 36 years that I have been doing this that they have changed the name of that part of the FDA, usually in response to some crisis, and it is essentially have form trump function. The function of that division, the post-marketing surveillance, any of these names apply to mainly the same thing, has not really improved at all. And the amount of energy in changing names and getting these kinds of people and then you say, "Well, it is too early to tell whether it is working at all," and then by the time another crisis comes along, they say, "Yes, we better change the name again so we will buy some more time to see whether it works or not." And I think, as I mentioned in the testimony, I did not get into the details at the time, is that there is a historic imbalance of power that has been going back to when I started this group in 1972. The people who are most funded is the Drug Review Division, now by the industry. They have a lot at stake, some understandable, that when they made a decision to approve a drug, that they were right. And in the face of evidence to the contrary, either before approval or after approval, they are more resistant to admitting that there is such a problem that merits taking the drug off the market or putting on a black box warning. The people in the Office of Drug Safety do not have that "vested interest" in the sense that they did not approve the drug. They are to look to see what happens afterwards, and there are too many instances to even mention where they have been right, and they have raised an issue where only one or two or three years later, after many people were needlessly killed or injured, did their suggestion get taken. Why was it not taken earlier? As Dr. Powers has said, both in the reviewing division is it safe and effective through randomized controlled trials and afterwards is there new evidence, not available at the time of approval, that suggests we should take it off the market or have a new black box warning. That is not the way it works now because the latter kind of evidence is poo-poohed and kicked under the rug, which is why again, as I said earlier, Senators Grassley and Dodd proposed empowering the Safety Division, leaving it in FDA but taking it out from under the thumb of CDER. The brief outline that I saw last

night at 8:30, whenever they put it up, is to pretend that you are doing that but it is no more than a pretense. Ultimately, the decisions are made by the same industry-funded bureaucracy at CDER who have been making them in the past. There is a pretense of more independence and more power, I do not believe it because I have seen it happen too many times.

Dr. POWERS. So I think that when you look at—Dr. Wolfe is bringing up sort of the interplay between form and function. When you look at organizations that function properly, and I think the Founding Fathers got it right with our government, it is systems that have checks and balances built into them already. That is why there are three branches of government. Right now, the Office of New Drugs controls the decision that gets made before the drug gets approved, and they also control the decisions that get made after the drug gets approved with consultative input from the name of the week, Office of Surveillance and Epidemiology. So that is a far cry from OSE having the authority to do something about it.

And to me it seems like regardless of—putting aside who has expertise where, that a system that has checks and balances built into it might function better. Now, comes the question of, well, do the people in the Office of Surveillance and Epidemiology know this drug really well like the people in the Office of New Drugs do? Well, but that is a form issue then. We can put people in both sides of that that actually understand, and one of the suggestions in the IOM report is to have people over here on the Office of New Drugs side who follow the drug along as it goes, but it seems to me that having sort of a balance of power built into the system, and that does not mean that the people in the Office of Surveillance and Epidemiology just see a small signal and take the drug off the market. The problem here is observational studies are more prone to systematic biases and error than are the randomized trial that get a drug approved in the first place. But Austin Bradford Hill in 1965 pointed out that smoking and lung cancer and got fought against for many years before people accepted that. That is what you do not want to see happen. It is when you warn, it is once a signal becomes available. You do not tell people this drug is causing this problem, you say we are seeing an association with this, we are still looking into it. I think the FDA is doing a better job of that now, and Dr. Woodcock in her testimony pointed out that now they are doing early communications and trying to get that out to people in a better way, but then you have got examples of like Avandia where my aunt landed in the hospital with heart failure on Avandia, thank goodness I worked at FDA at the time, and I knew about the problem but it had not been labeled that way yet, so you wonder how many other people had that kind of an issue and it is getting the warning out to people in a timely way. When FDA does do that warning, such as neurological problems with a flu drug, nobody is criticizing FDA. We do not know that that flu drug causes neurological problems but now that studies are done with it, people are looking into it more, so warning allows you to actually do the studies which figure out whether there is a causal relationship in the end.

Mr. CALFEE. I think there is a reason why there has been so much fumbling on this issue for so long, and that is when you get

right down to it, it is impossible to really separate the assessment of risk from the assessment of benefits. You have to balance the two. Dr. Wolfe and others have argued that the Office of New Drugs, that they have a bias after they have approved a drug. That may be true. I doubt that it is a big bias but it may be there. And, as Dr. Powers pointed out, if you had a separate group whose only job is to sound the alarm and even perhaps have the authority to pull off a drug, you are going to get too many alarms and you are going to get too many useful drugs that are pulled off the market. You cannot really separate those two.

And I would note that the Institute of Medicine in their investigation, it is perfectly clear from their report that they very, very carefully considered the idea of having a totally independent Office of Drug Safety, and they rejected that option precisely because they do not want to separate the assessment from risk and benefits. It is not an easy job, but it is not obvious to me that it is being done badly, and I am not sure that what FDA is doing right now is really going to make much of a difference.

Ms. DELAURO. Dr. Wolfe.

Dr. WOLFE. Just to comment, unfortunately, talking about conflict of interest as it was talked about before, the FDA funded this Institute of Medicine study and it was to me highly unlikely—I was asked to testify there—that they were going to come out with any conclusion that really offended FDA, which would be to make that kind of suggestion. There are certainly others who have made that kind of suggestion, but I think the number of incidences where someone in Drug Safety says there is a problem and something should be done about it, I am not sure I am aware of any really false positives, false signals. If anything, they have been right such an extraordinary amount of the time that a mechanism of having them more empowered to act on these things just needs to be done, otherwise you are going to just keep limping along, waiting one or two or three or four years. We told people who read our website to stop using Vioxx in 2001 based on a randomized control trial. The FDA got pushed around by Merck for several years and did not even do anything, never put a black box warning, as we and others advised them to do, so huge amount of valuable time went by, massive promotion and misleading by Merck, ignoring the fact of the heart attacks and more people got the drug, got heart attacks and died because the FDA's people on the side, the post-marketing, were pushed into the ground.

Dr. POWERS. I want to get back to something Dr. Calfee said and that is that there are instances in the Office of New Drugs though as well where a risk comes up with a drug, for instance there was an antibiotic that caused liver failure, at the time then you need to also reassess effectiveness at that point. When you are going to reassess safety, what do you need to reassess about the benefits of the drug that we did not know at the time the drug was approved, so there was a lot of discussion that no, no, there is a safety problem, we can only look at the safety. Well, it turned out that we knew at the time that the studies that were used to evaluate effectiveness for those antibiotics in self-resolving diseases, like sinus infections and bronchitis did not prove—or provide evidence, I should not say "prove"—that those drugs were any better than a

placebo but there were people internally who did not want to address that issue. Well, I agree, we need to readdress the effectiveness part as well as the safety, so even on the OND side, there needs to be a realization that when something comes up, we need to reassess both sides of the coin, the effectiveness as well as the risk side. It is constantly reassessing what you thought you knew before based on new evidence.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you. Dr. Calfee, a question on the empirical results of PDUFA because I guess when it started in 1992, there was a need, presumably a backlog or something, do you think that FDA keeps adequate records in terms of here are the results of it? Because it is interesting Dr. Wolfe wants to eliminate it, you want to preserve it, but there ought to be some relatively empirical evidence that says here is what good it has done?

Mr. CALFEE. The easy data I think FDA does a pretty good job of collecting that is how long they spend reviewing drugs, when they make decisions and so on, it can be fairly complicated because, as Dr. Woodcock mentioned earlier, sometimes they do not actually reach a decision. They sort of send it back to the company, ask for more information and so on, and that makes it a little bit difficult to actually tally the times that are spent, how the review times relate to deadlines, et cetera. The much more difficult issue is whether or not when they approve new drugs, meeting these deadlines, whether in any sense they are pushing themselves to approve rather than reject a drug, whether they are in some sense compromising safety a little bit, and people have argued about that. I do not think that there is any data that that has actually happened. And when several economists have looked at this in a fairly systematic way by looking at things like the speed of approvals, when they were approved, how often drugs were removed from the market, how often you get warnings and so on, it is very difficult to tease out from all that data any tendency for the FDA to sacrifice drug safety since the PDUFA thing became operative. So, yes, they collect a lot of data, the data does not tell you everything you would want to know about this program.

CONGRESSIONAL OVERSIGHT

Mr. KINGSTON. Now, on the subject of oversight, Dr. Wolfe, why do you think in the 1980s Congress quit having hearings?

Dr. WOLFE. They did not quit having hearings, just the volume or frequency of hearings is probably just a tenth or less than it used to be. And I think it is related—if Congress is the sole appropriator of funds and all of the accountability is to the Congress, I think that is a whole era or spirit in which there is likely to be more oversight. If, as occurred 16 years ago, Congress says, okay, now, we are sort of bringing the industry in on the funding and the accountability and everything, I think it changes the atmosphere, but that is just part of it. The larger part is that there were a number of people in the Senate and in the House then who had decades of history with FDA oversight and conducted hearings—particularly on the Senate side, there were way more staff people there with expertise in the FDA that could ask the questions and instead of the FDA making a serious mistake, of which they have made

many, and not having to worry, as they do today, not having to worry about being called on the carpet. Senator Grassley's hearing was three years ago on Vioxx and those kinds of things, there have not been too many more drug-specific hearings since then, so I just think it is a different era of the kinds of people and staff in Congress, present company excepted, and a difference in the general attitude of the Congress as manifest by the fact that they passed PDUFA, those two things.

Mr. KINGSTON. One of the things that is interesting about PDUFA is the medical device folks are telling us they cannot get fast approval, and there is a whole new wave, as you know, of technology coming out in medical devices and it is a lot more sophisticated stuff, and they want—and I do not know how to pronounce their medical equivalent of PDUFA.

Dr. WOLFE. MADUFA.

Mr. KINGSTON. They actually I think want to ramp that up. Similarly, the folks involved in packaging have to get approval from the FDA to change a package and the material used in packaging. And last year, I believe it was zeroed out in the budget, and I do not know that they want a PDUFA model but there could be an application for them. Do any of you guys want to comment on that?

DIFFERENT STANDARDS FOR DEVICES AND DRUGS

Dr. POWERS. I just want to make a comment on devices first of all. There is a very clear standard, back in 1962 when the evidence standard was passed for FDA, for drugs and biologics, there is a very clear standard for that that by 1976, when the device legislation came along, the hearings in 1962, President Kennedy actually sent a memo saying that a reasonable standard is not good enough, we need to have very clear standards when in fact what it says for devices is "reasonable evidence." So from 1962 to 1976, we have two very different standards. It has never been clear to me why that should be. We want just the same kind of evidence for devices as we do for drugs and biologics.

The other issue though is that we have talked about sort of all the issues with what PDUFA has done in terms of timelines and morale at CDER, why would one want to replicate that in the Center for Devices and Radiologic Health? You already brought up the issue of putting up a firewall, so it may be that here is a way that you can do it in a different way that allows people to get timely reviews done. And I think CDRH has done a good job with timely reviews, so take the good things from PDUFA and not the bad things and maybe create a different system.

Dr. WOLFE. Just a comment on devices, not only is the standard for approval different but if you change one atom from a chlorine to a fluorine for instance in a drug, you have got to go back and do animal studies and do human studies. If you change half a device and can convince the FDA that it is "substantially equivalent" to an old device, you do not have to do pre-market studies at all. Most of the new devices that go on the market do not go through anything that even resembles, even with its lower standard, the FDA approval standard for drugs. There is a huge problem of the standard for approval at the device division as opposed to drug,

which it is now 31 years or 32 years since the law was passed, that may need to be revisited.

Mr. CALFEE. And there are a lot of reasons why devices would be treated so very differently from drugs. You have an imaging device, you can improve the software so you get a slightly sharper images. Well, if it was a drug, you could never simply say to the FDA, "Our drug is a little bit more potent, is that okay?" They would not say that.

Dr. WOLFE. But that does not go through a whole prior approval.

Mr. CALFEE. But devices where you have—a lot of these things are basically tools. If you make your tool better, it does not make sense to start all over.

Dr. WOLFE. Like a heart valve, for instance?

Mr. CALFEE. Right, that is true.

Dr. POWERS. There is an incredible variety of issues, you take a stint and now you coat it in a drug. So I think Dr. Calfee is right, if you make a catheter and you just make another catheter and that is what you are supposed to do, but suppose you then take that catheter and you coat it in something else, and then you make an inferred claim of, well, all that coating is supposed to do is preserve the life of the catheter when in fact you coated it with an antibiotic and what you are really trying to do is assume that you are preventing infections. Well, is that substantially equivalent? I would not say so. Suppose you are allergic to the antibiotic that it has been coated in, so I think it gets to the balance of when do you determine when it is different enough that you need to do studies or similar enough that you do not?

Mr. KINGSTON. Where do you decide devices need to have a prescription?

Dr. WOLFE. A prescription by a doctor, is that you mean?

Mr. KINGSTON. Yes.

Mr. CALFEE. I think anything that goes through the PMA process requires a prescription, but I am not certain about that, most do not but some do.

Dr. WOLFE. The Class 1 devices are band-aids, tongue depressors, things like that, and those obviously are available over the counter in drug stores or supermarkets. There is no reason on earth that they should require a prescription. I think that is true of most if not all so-called Class 1 devices, but when you get to the ones that have to go through pre-market approval, most—I think all of those really require a doctor's. As everyone has said, there is a huge spectrum of devices ranging from the simple obvious to ones that are much more complicated, that need to be surgically implanted. Obviously, anything in that category needs a physician to do it.

Mr. KINGSTON. I have another question.

Ms. DELAURO. Go ahead.

VIRTUES OF MARKET-DRIVEN INCENTIVES

Mr. KINGSTON. Dr. Calfee, I want you to talk about the virtues of market-driven incentives, as I believe those are very important.

Mr. CALFEE. I will give an example at the risk of offending some friend I might have somewhere, the Heparin issue in China. Basically, the wrong ingredients were used by Baxter in manufacturing

their brand of Heparin. The question was about the market-driven incentives for manufacturers, which I think can be quite impotent—quite potent. And when I heard about the issue with Heparin and China, my reaction was I am not nearly concerned with the FDA is doing as with what Baxter is doing. I would go to Baxter and say, "We have got a problem." I am not sure that I know anyone from Baxter, but I strongly suspect that Baxter is going to fix their problem. They are going to figure out how they can put a product out there that their customers can trust. They have a bigger interest than anyone else does in figuring out where they can get good ingredients, whether this particular outfit China is not reliable and it is not reliable and so forth.

Let's face it, half of us drove to work today in a car, most of them with anti-lock brakes, which rely upon incredibly complicated mechanisms, including a software and hardware, computer chips and so on, none of which—I mean all of which is manufactured in plants all over the world, none of them are inspected by anyone but the manufacturers who sell the cars have a huge incentive to make sure things do not get screwed up.

UNAPPROVED UUSES OF DRUGS

Dr. POWERS. To make a comment about market incentives in terms of at least drugs, and it relates back to Congresswoman DeLauro's issue about off-label usage of drugs and passing out reprints, one of the dangers of that is if you get your drug approved for a single usage, you can then pass out all sorts of reprints. One of the dangers of that is that if you get your drug approved for a single usage, you can then pass out all sorts of reprints about other things that have not been adequately studied. Maybe it has been studied in 10 people without an adequate control drug, et cetera. The problem with that is that it is very difficult to actually know whether those drugs are safe and effective in that setting, but if you infer that they are and you choose to believe it, you have got yourself a nice, big market there. So I think that there are places where the market incentive does not jive with what good science or good safety would tell us to do, and I think that is the concern. The other issue is that we know that there are issues in the peer-reviewed literature, and it is not perfect. There was a recent study in JAMA that said that many clinicians do not understand the basic principles of how to analyze clinical trials data.

And friends of mine that are out in practice used to tell me when I was at FDA, "We are relying on you guys to synthesize this information for us." And one of the things at FDA that you do is that you synthesize a whole body of information. Passing out a single study, any single study can be wrong. Suppose there is a single study that says something is effective for use but there are four other studies that say it is not. How would you balance that out when you are passing out reprints? So I think in this setting, the market incentives do not always jive with what is best for public health in some instances.

Ms. DELAURO. I would just add to that though if you just take a look, and I know and maybe this is legalistic, and I know, Mr. Calfee, that you do liability and tort reform. Merck Vioxx, $4.8 billion to settle the lawsuits, Cephalon checked into its marketing

practices. That has to do with safety. Drug makers, insuring products and for factory lapses, that is safety. Bayer agrees to pay U.S. $257 million in drug fraud. Yes, this is all related to safety.

Mr. CALFEE. Can I address some of those?

Ms. DELAURO. Go ahead.

ABBOTT MANUFACTURING VIOLATIONS

Mr. CALFEE. For example, on the manufacturing violation, Abbott went through years of negotiations with the FDA, had a bunch of plants that shut down, eventually settled for something like $600 or $700 million, a really big settlement. There were lots of products that went through those plants. What is interesting is that not for a single one of those products, from a single plant did the FDA ever suggest that anyone should avoid using what came out of those plants. They were very concerned about how the plant was organized, recordkeeping and so on, but they never thought that there was any safety issue with any of the stuff going t through there but these manufacturers, when they were hit by the FDA on manufacturing issues and so on, they have to negotiate, they have to settle. They cannot go to court. They cannot go to the court—General Motors if they are fighting with NITSA, they can go to court. They can say, "We think we are right, they are wrong." Manufacturers cannot do that because if they lose in court on any issue whatsoever, no matter how minor, than they are prohibited from selling anything to CMS and the penalties are gigantic, and they always settle, and usually—not always—but usually the products involved are actually with the manufacturing issues, actually usually there is no safety issue at all. It has to do with how things are organized, recordkeeping and so on, but usually the products flow right along, they are not recalled. Heparin is unusual.

Ms. DELAURO. How do you square your notion like in the Baxter incident, Baxter ought to be held accountable and not the agency, they just said the agency did not say anything here so therefore—does the agency have any responsibility in terms of the Heparin issue in China and to find out what they are doing, what the ingredients are, et cetera, and deal with inspections and equivalent standards, all those things, they are a regulatory agency. The point is like on food safety, we do not make food, we do not do that, but our job is to set up the framework that says these are the performance standards, we now deal with inspection of that, and we deal with accountability and we deal with enforcement, but there is a tendency that regulation has maybe such a bad connotation that the mission of the agency is just not—it does not hold sway any longer?

Mr. CALFEE. One can debate all day, I think it is clear from what Dr. Woodcock said and from what others have said that on both drugs and especially on foods, you will never have a regulatory agency that is on top all the factories all over the food, but we will have a bunch of manufacturers with brand names who are jealousy guarding their brand names and they have overwhelming incentives for things not to go wrong with their brands.

Ms. DELAURO. Well, I think that that is true, I think it is partially true, but I also believe that I do not think that these folks determine that it is so bad in terms of whatever they are paying

for or what they are doing that they will go on and continue, but they would rather not have a strong regulatory agency dealing with them ultimately. I think that that is what we have seen with regard to the culture, I think you are right in terms of your brand. And my point in terms of food safety, I cannot imagine the industry, I know the western growers have come and asked us for regulation because they are going out of business, but these folks are not going out of business. They have a ton of money, they keep making it, so if there are big bumps, if there are small bumps and big bumps along the way, they can take it. That is my personal view.

REGULATORY BURDENS

Mr. KINGSTON. My personal view is more free enterprise on this, but I think it is important that as we put regulatory burdens on that what you end up with is only the big boys can play.

Ms. DELAURO. I challenge the term "burden." Our job, that is our responsibility is to regulate the agency.

Mr. KINGSTON. Well, I believe the regulatory burden is an appropriate term, it might not necessarily be a bad burden. I might be a burden on you, but you know I am a very good one.

[Laughter.]

So I am a burden of your conscience for capitalism but the problem that I see over and over again in regulatory issue, you know what happens in Congress, who gives the campaign contributions? It is not the small companies, it is the not the small medical manufacturers, is it the big ones, and they will live all day long with more regulation because they want it. It will eliminate their pool of competitors and so you will have a oligopoly. And so one of our challenges is to keep that Steven Jobs working out of his garage thinking so that he can come up with the Apple Computer of drugs but if we say, "You have to have $5 million to start," then what we have done is something we cannot measure and that is that Type 2 error where we have gotten hundreds of thousands of people suffering from something, and we do not even know that we could have had a cure for it. So it is very important to kind of keep this——

Dr. POWERS. I think the point you are making, and you see this all the time in government, is you have a layer of regulation and then you add another layer and then another layer and then you get to the end where you are right, boy, it takes an awful lot of money to do that. And sometimes maybe it takes going back and looking at this, "Can we do this more efficiently?" But efficiency does not mean—I can not drive here from Connecticut on an eight of a tenth of gas, I am not going to make it no matter way, it means getting to where you want to go but using less resources to get there. So sometimes it takes reassessing what are we doing to folks and then reassessing what are we doing to folks and then reassessing all those layers that we have laid on them and can we condense them?

Mr. KINGSTON. Which is why I have asked a couple of times today about the results of PDUFA because I do remember Richard Kesler sitting in the chair you are sitting in a hearing talking about the average approval time was eight years for a new drug

from lab to market or whatever, and in Europe it was three years, and our goal as a society was to reduce that so we could get it out. You just want it so that the entrepreneur and the competitiveness is out there because I think that the generic drug thing is a great success story but it sort of happened despite lots and lots of boundaries and not because of.

Dr. POWERS. Well, look what happens when user fees go up. This gets to the exact situation you are talking about. The more user fees go up and up, the more only the big boys can play because maybe a small company cannot afford to pay that amount of user fee to get in the door.

Dr. WOLFE. Or if that were appropriated from the Congress, you would have more competition, to use your phrase.

PRIVATE-SECTOR INCENTIVES

Mr. KINGSTON. Yes, however, I am going to give you a parallel. There are 74 million food-borne illnesses a year, we have had lots of testimony on this. It is a pretty high number, 74 million cases, 250,000 or 260,000 people go to the hospital, about 4,000 to 5,000 people die. That is a lot of folks but now take a step back and multiply 300 million people in America eating three meals a day, we do not eat snacks, we are very careful, there is no obesity problem, and then multiply that times 365 days a year and suddenly you have got like 32 billion meals a year that are eaten and put that into 74 billion food-borne illnesses, and you have got a success rate of 99.98 percent in food and it is not because of FDA, it is because of the private sector because the FDA simply is not big enough to monitor all the plants. Now, I am not saying there is not a role of FDA or USDA in it, but I am also saying the miracle of the private sector is there are huge incentives in there for them to worry about drug safety or food safety or whatever and it can be pure Adam Smith "invisible hand in search of the profit," but that is something that we always have to keep in mind.

Dr. POWERS. When you think about it, FDA is supposed to be the back stop in terms of if something gets to the point of where FDA inspects and it has gone wrong, it is because a number of risk evaluation points even in that factory have gone wrong. And Dr. Calfee's point, these folks do not want this to go wrong in their own factory, so I look at it like speeding on the highway, right, the police do not stop every single person who speeds but the fact that they stop some people is a positive reinforcer for people to do the speed limit, so FDA is really there only as a backstop. They cannot possibly inspect everybody but it is an incentive for people to do the right thing.

Mr. KINGSTON. And I am in total agreement with you on that.

Ms. DELAURO. My friend, it is almost three o'clock.

Mr. KINGSTON. And I do not remember saying that Dr. Wolfe could excuse himself suspiciously from a minute ago maybe to eat or drink or to relieve himself. Was that okay, I do not know?

[Laughter.]

Dr. WOLFE. I have written permission from my doctor.

Ms. DELAURO. I just want to say thank you, yes, for your patience in waiting and the amount of time you spent with us today, but for your testimony and the clarity in which you deal with these

issues. There are some things that we just did not get to. I would very, very much like the opportunity to talk about how we deal with tightening up post-market surveillance, how we do deal with PDUFA, and what should be as part of those negotiations, where are the areas where additional money ought to be channeled and what can we do? What kind of restructuring can be done? This is not just about the highlighting of problems but are an attempt to try to move to look at, whether they are structural changes and whether they are management changes or just resources or what I talk about in terms of the influences, less from the industry and more from the science, and how to try to get that. And I understand as well that you do not do that overnight, and you do not do that in one year of a two year session of the Congress. So I would love to have the opportunity to meet and talk with you about how in fact we do try to move in this direction and what kind of legislation we ought to be looking at in terms of tightening up the structure.

I mentioned to you that we have got the FDA biologics hearing come up in the next couple of weeks as well, and we will try to address some issues in those areas as well, so I thank you very, very much, and I know my colleagues thank you for all the time that you put into this hearing.

Mr. KINGSTON. And I just want to go back to your opening statement, if the three of them want to go out and have lunch and work this out and come up with a list of recommendations, we will be very open to it.

Ms. DELAURO. Thank you.

Dr. WOLFE. It is almost dinner time.

[Laughter.]

Ms. DELAURO. I thank you.

Questions for the Record
Agriculture Appropriations Hearing – CDER
February 27, 2008

QUESTIONS SUBMITTED BY REPRESENTATIVE FARR

ESTRIOL

On January 9, 2008, FDA announced that it was banning the use of estriol in compounded estrogens prescribed by doctors for the treatment of menopause systems in women. The announcement was apparently the outcome of a citizen petition by a pharmaceutical company and not via the normal regulatory rule making process.

Mr. Farr: Can you explain why a normal rule making process was not followed in this instance?

Response: First, FDA has *not* announced a ban of compounded drugs that contain estriol. To the contrary, as explained more fully below, FDA repeatedly stated that it respects a healthcare provider's decision that his or her patient should receive estriol. In such cases, these patients should have access to estriol, whether compounded or produced otherwise, pursuant to an FDA-sanctioned investigational new drug application (IND). INDs are well known, understood, and widely used in the healthcare community. They afford patients access to drugs that – like estriol – are not FDA approved. As important, INDs assure that patients taking these drugs receive clear disclosure of their potential risks and benefits, and that adverse events associated with the drugs are reported to FDA. This assures patient safety.

Regarding why FDA chose to take enforcement action in place of rulemaking, it would be unprecedented to require FDA to undertake notice-and-comment rulemaking as a prerequisite to conducting enforcement activity. Such requirements would severely impede FDA's ability to protect the public health. In cases such as these, where firms misrepresent the considerable risks of their products, such delays put patients at risk.

As important, FDA generally does not pursue rulemaking where, as here, it has clear authority to take focused and case-specific enforcement action. Indeed, a broad rule prohibiting estriol use would negate a healthcare provider's decision that his or her patient should be treated with this drug. Such a result does not serve the public health and is inferior to the model proposed by FDA: treatment with estriol pursuant to an IND.

Mr. Farr: Please provide the committee with any specific concerns FDA had with estriol prior to the filing of this particular citizen petition.

Response: In January, FDA sent letters warning seven pharmacies that the claims they were making for their compounded "bio-identical" hormone replacement therapy (BHRT) drugs were unsupported and potentially misleading to patients and healthcare providers. These pharmacies also compounded drugs using the ingredient estriol.

Estriol is not a component of an FDA-approved drug and the safety and effectiveness of estriol has not been demonstrated by reliable scientific evidence.

The pharmacies that received the warning letters made unsupported claims that their products were better than FDA-approved hormone therapy drugs and that their products could be used to prevent and treat serious diseases including Alzheimer's disease, stroke, and various forms of cancer. One pharmacy, for example, claimed that its compounded BHRT drugs "can benefit a woman by . . . reducing the risk of heart disease [and] reducing the risk of Alzheimer's . . . ." Another pharmacy touted BHRT products to treat "Fibrocystic breasts, Depression, Poor concentration/Memory lapses, [and] Heart disease/Arteriosclerosis." A competitor claimed that its compounded BHRT drugs "imitate the body's natural processes as much as possible, thereby eliminating most of the unwanted effects and long term risks of the traditional synthetic hormone replacement therapies." Yet another pharmacy claimed, "Because progesterone is a naturally occurring hormone, there are very few side effects of natural hormone replacement therapy of progesterone."

FDA is aware of no credible scientific evidence to support such claims. Nor is FDA aware of sound evidence showing that the risks of compounded BHRT drugs that include estrogen and progesterone as active ingredients are different than the risks of similarly-formulated FDA-approved hormone therapy drugs. Compounded BHRT drugs may actually increase the risks of heart disease, dementia, and breast cancer in some women.

The warning letters also cite the pharmacies' use of the term "bio-identical" to describe their compounded hormone replacement drugs. "Bio-identical" has no defined meaning in any medical or conventional dictionary, and FDA does not recognize the term. Even different medical groups define the term differently. Many compounding pharmacies use "Bio-identical" as a marketing term to imply that their drugs are natural, or have effects identical to those from hormones made by the body. FDA is not aware of credible scientific evidence to support these claims. Compounded products that have identical chemical structures to synthetic hormones can be expected to have the same benefits – and risks – related to FDA-approved hormone therapy.

Finally, the warning letters took issue with the pharmacies' use of estriol as an active ingredient in their compounded BHRT drugs. No drug containing estriol has been approved by FDA and the safety and effectiveness of estriol is unknown. Under long-established FDA policy, FDA opposes compounding of any drug – BHRT or otherwise – with an active ingredient that is not a component of an FDA-approved drug, unless that compounding occurs under an FDA-sanctioned IND.

Mr. Farr: How many women are potentially affected by the FDA decision to ban estriol? What does the FDA estimate it will cost these women to return to their doctors and get a new prescription for an alternative treatment?

Response: FDA has *not* announced a ban of compounded drugs that contain estriol. To the contrary, FDA repeatedly stated that it respects a healthcare provider's decision that his or her patient should receive estriol. In such cases, these patients should have access to estriol, whether compounded or produced otherwise, pursuant to an FDA-sanctioned IND. INDs are well known, understood, and widely used in the healthcare community. They afford patients access to drugs that – like estriol – are not FDA

approved. As important, INDs assure that patients taking these drugs receive clear disclosure of their potential risks and benefits, and that adverse events associated with the drugs are reported to FDA. This assures patient safety.

FDA does not have information on the number of women currently taking compounded estriol products. This is due, in part, to the fact that FDA has imperfect information about both the number of compounding pharmacies and the scope of pharmacy compounding operations because, in general, there is no requirement for pharmacies to register or list the drugs that they produce with FDA.

We do not have information about the costs that women incur in connection with compounded or approved estrogen therapies. However, because healthcare providers can continue to treat patients under an FDA-sanctioned IND, FDA does not believe that there is a need for women to return to their health care providers for new prescriptions and treatments. Thus, patients would not incur additional medical costs.

Because estriol is not an FDA-approved drug, physicians wishing to prescribe estriol for their patients should obtain an FDA-sanctioned IND. There is no fee required to file an IND, although review fees may occasionally be charged by private Institutional Review Boards. It is unknown if these costs, when incurred, would be passed along to patients and, if so, how that would affect the cost of their treatment.

Mr. Farr: Can you cite specific scientific and medical research supporting the FDA's decision to ban estriol?

Response: FDA has *not* announced a ban of compounded drugs that contain estriol. To the contrary, FDA repeatedly stated that it respects a healthcare provider's decision that his or her patient should receive estriol. In such cases, these patients should have access to estriol, whether compounded or produced otherwise, pursuant to an FDA-sanctioned IND. INDs are well known, understood, and widely used in the healthcare community. They afford patients access to drugs that – like estriol – are not FDA approved. As important, INDs assure that patients taking these drugs receive clear disclosure of their potential risks and benefits, and that adverse events associated with the drugs are reported to FDA. This assures patient safety.

Mr. Farr: Can you please provide the committee with documentation of specific adverse events from the use of estriol during the past three decades? Please include the dosage levels at which these adverse events occurred.

Response: Because compounding pharmacies do not report adverse events to FDA, except in rare circumstances, it is impossible to know to what extent adverse events are occurring. This gap is especially pronounced for compounded hormone therapy products, where there can be a lengthy latency period between administration of the drug and identified adverse events.

Although it is impossible for FDA to determine the extent of adverse reactions associated with compounded estriol products, FDA does have anecdotal evidence of adverse events. FDA is aware of 26 spontaneous adverse event reports as of February 2008 associated with estriol use. These include 10 reports of breast cancer. These reports may be confounded by the patients' use of other hormones at the same time. In addition, a preliminary search of the medical literature concerning estriol revealed 47 studies (with 2,194 subjects taking estriol alone) from which safety data is available. A

total of 196 adverse events were reported. Of these, 13 were serious and 1 death was reported.

Mr. Farr: Under what authority can FDA direct a doctor to seek an IND in order to write a simple prescription containing an ingredient with a USP monograph?

Response: FDA does not regulate the practice of medicine; the authority that Congress has provided by statute to the Agency relates to *drugs*, and the agency directs its efforts towards assuring that the drugs administered to patients are of the highest quality and meet all approval and labeling requirements. Further, FDA has repeatedly stated that it respects a healthcare provider's decision that his or her patient should receive estriol.

This statutory authority includes the requirement that "new drugs," as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (FDCA), have either an FDA-approved new drug application or an FDA-sanctioned IND under section 505 of the FDCA. In enforcing these requirement, the Agency would expect to direct its actions is not towards doctors, but towards firms that market and distribute unapproved and potentially unsafe drugs.

Mr. Farr: Can you provide the committee information on the steps FDA has taken to develop this simplified IND, including which members of the medical and pharmacy community have been consulted?

Response: FDA has repeatedly stated that it respects a healthcare provider's decision that his or her patient should receive estriol. At the same time, FDA must assure that patients receive accurate information about the risks and benefits of unapproved drug therapies so that patients can make informed decisions about those therapies. The requirement for patients to give informed consent when receiving a product under an IND ensures that patients receive important safety information. Thus, when a licensed practitioner decides that his or her patient's specific medical needs will be best served by a compounded hormone therapy drug containing estriol, FDA asks that the practitioner obtain an IND.

Another advantage of INDs is their requirement that practitioners collect and report adverse event information. Because compounding pharmacies do not report adverse events to FDA, except in rare circumstances, it is impossible to know to what extent these events are occurring. This gap is especially pronounced for compounded hormone therapy products, where there can be a lengthy latency period between administration of the drug and identified adverse events.

Consistent with FDA's recognition that women should have access to estriol-containing drugs, and that the IND process affords this access while assuring that women understand estriol's potential risks and benefits – FDA offered to work with the American Pharmacists Association, the International Academy of Compounding Pharmacists, the National Community Pharmacists Association, the National Alliance of State Pharmacy Associations, the American College of Apothecaries, and the National Association of Boards of Pharmacy, to develop and publicize a template that would streamline the IND process for healthcare providers seeking to treat their patients with estriol. We are awaiting a response from these

groups and hope that they will work collaboratively with us to pursue a strategy that supports patient and physician choice, while ensuring that this choice is based on clear and accurate communication of key safety information.

Mr. Farr: Also, if the intent of the FDA was to continue to allow estriol to be available with an IND, why wasn't this new process in place prior to the FDA's January 9 announcement?

Response: The IND process is well-established and significantly pre-dated the January 9 initiative. In announcing this initiative, FDA clearly communicated that patients could receive estriol-containing hormone drugs pursuant to an FDA-sanctioned IND. INDs afford patients access to drugs that – like estriol – are not FDA approved. As important, INDs assure that patients taking these drugs receive clear disclosure of their potential risks and benefits, and that adverse events associated with the drugs are reported to FDA. This assures patient safety.

Consistent with FDA's recognition that women should have access to estriol-containing drugs, and that the IND process affords this access while assuring that women understand estriol's potential risks and benefits – FDA offered to work with the American Pharmacists Association, the International Academy of Compounding Pharmacists, the National Community Pharmacists Association, the National Alliance of State Pharmacy Associations, the American College of Apothecaries, and the National Association of Boards of Pharmacy, to develop and publicize a template that would streamline the IND process for healthcare providers seeking to treat their patients with estriol. We look forward to a positive response from these groups and hope that they will work collaboratively with FDA to pursue a strategy that supports patient and physician choice, while ensuring that this choice is based on clear and accurate communication of key safety information.

Mr. Farr: What is the statutory authority for developing a simplified IND process?

Response: Section 505 of the FDCA and the regulations in 21 CFR part 312, including in particular 312.10, provide FDA with ample authority to work with the healthcare community to develop INDs that will efficiently assure the availability of estriol to women while at the same time assuring that women know the risks and benefits of the therapy they are receiving, and that adverse events relating to estriol use are reported to FDA.

Mr. Farr: How much has the agency spent so far on the issue of preventing the use of estriol?

Response: Dr. von Eschenbach: FDA has not adopted the position to prevent the use of estriol. To the contrary, FDA has repeatedly stated that it respects a health care provider's decision that his or her patient should receive estriol. In such cases, these patients should have access to estriol, whether compounded or produced otherwise, pursuant to an FDA-sanctioned investigational new drug application (IND). INDs are well known, understood, and widely used in the healthcare community. They afford patients access to drugs that, like estriol, are not FDA approved. As important, INDs assure that patients taking these drugs receive clear disclosure of their potential risks

and benefits, and that adverse events associated with the drugs are reported to FDA. This assures patient safety.

FDA does not have a time reporting system or other means to track the level of detail necessary for estimating how much it has spent on the estriol issue. Instead, let me explain the activities that FDA has engaged in on the estriol matter.

On January 9, 2008 FDA issued a press release on the subject of "FDA Takes Action Against Compounded Menopause Hormone Therapy Drugs." The press release announced that "FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called "bio-identical hormone replacement therapy," or "BHRT" products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA is concerned that unfounded claims like these mislead women and health care professionals. The pharmacy operations improperly claim that their drugs, which contain hormones such as estrogen, progesterone, and estriol (which is not a component of an FDA-approved drug and has not been proven safe and effective for any use) are superior to FDA-approved menopausal hormone therapy drugs and prevent or treat serious diseases, including Alzheimer's disease, stroke, and various forms of cancer."

FDA also issued a press release and initiated a public health awareness campaign about the risks and benefits of hormone replacement therapy, that included publication of a consumer friendly article on bio-identical hormones, titled "Bio-Identicals: Sorting Myths from Facts."

The public health benefit of FDA's estriol activities, including the issuance of the warning letters, press release, public health awareness campaign, and IND submissions all help assure that patients are aware of the potential risks and benefits associated with estriol products as well as facilitate the collection of adverse event information about them.

The issuance of the press release preceded the diligent work done by FDA staff investigating the pharmacy operations' advertised claims on the benefits of estriol.

QUESTIONS SUBMITTED BY REPRESENTATIVE HINCHEY

Mr. Hinchey: Without tort suits triggering disclosure of hazard information, will consumers be less likely to obtain crucial safety information in a timely fashion?

Response: Not all tort lawsuits regarding FDA-regulated products will be preempted. For example, if a plaintiff claims to have been harmed by a sponsor's *failure* to meet the conditions of FDA's approval for a drug, biologic, or device, then state-law liability on that basis would not interfere with Federal law and manufacturers would get no protection from such claims. Even without tort lawsuits, existing mechanisms in FDA's regulatory scheme allow newly discovered hazard information to be disseminated to consumers in a timely manner through product labeling.

As we explained in the proposed rule that you reference, FDA regulations at 21 CFR §§ 314.70(c)(6)(iii), 601.12(f)(2), and 814.39(d) allow sponsors of drugs, biologics, and medical devices to make changes to product labeling based on newly available and

scientifically reliable information in order to add or strengthen a contraindication, warning, precaution, or adverse reaction upon submission, but prior to FDA approval, of a supplemental application fully explaining the basis for the change. Such supplements are commonly referred to as "changes being effected" or "CBE" supplements.

In addition, the Food and Drug Administration Amendments Act, or FDAAA, Pub. L. 110-85, 121 Stat. 823, enacted Sept. 27, 2007, provided new authority to FDA to initiate labeling changes for approved drugs and biologics. Under this authority, and I quote, "If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug," FDA may trigger a process to rapidly amend the labeling for the product. This authority appears at 21 USC 355(o)(4)(A).

FDA can also communicate emerging safety information to consumers through physician and patient information sheets, press releases, and its MedWatch website.

Mr. Hinchey: Isn't it clear that the proposed rule will further erode consumers' rights to hold pharmaceutical companies accountable, create a larger workload for FDA staff, and ultimately result in warnings of health risks that come too late for the American consumer?

Response: FDA takes care to ensure that the labeling of medical products includes appropriate information about the products, including information about warnings and adverse events. This includes ensuring that product labeling describes the most important warnings, and that it not include warnings that are unsupported by evidence and that therefore may deter beneficial use of products. Product sponsors may change their products' labeling to include new warnings under FDA regulations. the proposed rule is intended to clarify FDA's existing policies with regard to one such method of changing labeling to ensure that scientifically valid and appropriately worded warnings will be provided in the approved labeling for medical products. Accordingly, FDA does not agree that the proposed rule, if finalized, would erode consumers' rights to hold companies accountable.

"Changes being effected," or CBE, supplement regulations provide that certain labeling changes based on newly available and scientifically reliable information may be placed into effect upon submission of the supplement, prior to the sponsor's receipt of a written FDA order approving the supplement. Those labeling changes that may not be placed into effect until receipt of a written FDA order approving the supplement are "prior approval" supplements. FDA does not consider this proposed rule to substantively change the standards for submission of CBE supplements or prior approval supplements. FDA therefore does not expect that it will increase the number of prior approval supplements or otherwise increase agency or staff workloads.

FDA does not agree that this proposed rule will result in late warnings of health risks to the American consumer. The proposed rule, if finalized, does not change a sponsor's responsibility to change labeling promptly to include new warnings when there is sufficient new evidence of association between a drug and an adverse event.

Mr. Hinchey: How many voting waivers did the FDA give in all of FY 2007, as a total number and percentage of all the people participating in advisory committees meetings? Also, how many voting waivers has the FDA given since the beginning of FY 2008?

Response: In FY 2007, FDA issued 109 waivers authorizing voting participation in an FDA advisory committee meeting. The total number of meeting participants was 786 and the percentage of meeting participants granted waivers was 13.9%.

To date in FY 2008, FDA issued 42 waivers authorizing voting participation in an FDA advisory committee meeting.

Please note that we have calculated these figures based on definitions and conventions used in reports submitted to Congress. Accordingly, those participating in advisory committees include all individuals who are required to be screened for conflicts of interest under applicable laws. This means that we have included all individuals attending each advisory committee meeting with the exception of industry representatives, non-Special Governmental Employee guest speakers, and FDA employees. Also when FDA grants a waiver to allow a person with a potential conflict of interest to participate in a meeting, the agency is sometimes required by law to issue a waiver under both 18 U.S.C. 208 and section 712 of the Federal Food, Drug, and Cosmetic Act for the same financial interest. Before section 712 went into effect with the enactment of FDAAA, FDA issued waivers under 18 U.S.C. 208 and 21 U.S.C. 355. Based on the convention used in previous reports to Congress, we count each paired waiver as one waiver.

Mr. Hinchey: Will the FDA issue the final version of the guidance that was proposed in March 2007?

Response: Yes, FDA plans to issue a final guidance on procedures for determining conflict of interest and eligibility for participation in FDA advisory committees.

After the draft guidance was issued for public comment, FDAAA added new conflict of interest provisions, effective October 1, 2007. The final guidance will be informed by the legislative changes as well as the public comments we received.

FDA is committed to ensuring the highest levels of transparency and integrity in its advisory committee program, and we recognize that the new legislation in FDAAA generally discourages the use of waivers. To that end, we are committed to staffing our committees with experts who are free of potential conflicts whenever possible and to grant waivers only in those instances where they are both necessary and appropriate.

Mr. Hinchey: Will you give the committee a response to their letter?

Response: We apologize for the delay in issuing a response to the letter from the Center for Science in the Public Interest, the Consumers Union, and others, dated December 3, 2007. At the time, we viewed this letter as a response to FDA's November 15, 2007, press release on advisory committee improvements that referenced

the October 2007 Eastern Research Group, report, and as such, did not itself require a response.

The Eastern Research Group report highlights the difficulty of assembling highly qualified experts who are free of conflicts and finds that those who have received waivers appear to be significantly more qualified than those who have not received waivers. We believe that the December 3 letter, in concluding that FDA advisory members with conflicts of interest could easily be replaced, misinterprets the data.

As noted in the letter, it took ERG 88 person-hours to identify potential committee members with equivalent or greater expertise than that of actual members who received waivers. However, this was only a first step in what the study recognized as a multi-step process. The literature search that attempted to identify potential conflicts of interest is an even more resource-intensive step that was not included in this time frame. Furthermore, it would not conclude the process of determining who would need a waiver to participate in an FDA advisory committee.

The ERG report notes that applying the study methods to the real-world context of identifying qualified experts is problematic. Significantly, three of the 17 individuals who actually required waivers for conflicts of interest reported no conflicts in articles that they published. The report also recognizes the difficulty of assessing expertise unless specific meeting topics are identified, and the importance of factors not addressed in the study method. For example, fair balance goals required by the Federal Advisory Committee Act and personal factors such as experience on FDA advisory committees and ability and willingness to work to resolve issues in the advisory committee context are also important considerations in choosing qualified advisory committee members.

WEDNESDAY, SEPTEMBER 17, 2008.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

WITNESSES

DAVE ACHESON, M.D., F.R.C.P., ASSOCIATE COMMISSIONER FOR FOODS, FOOD AND DRUG ADMINISTRATION

MICHAEL R. TAYLOR, RESEARCH PROFESSOR, GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

JEFFREY LEVI, PH.D., EXECUTIVE DIRECTOR, TRUST FOR AMERICA'S HEALTH

GREG MURRAY, MURRAY FARMS, GA

Ms. DELAURO. The hearing will come to order.

Thank you all very much and I want to say thank you to the subcommittee and welcome back. August seems a long way off, in any case, but it is the first hearing since we've been back after the August recess; and, I want to thank all of you for being here and again say thank you to you for your patience.

FOODBORNE ILLNESS OUTBREAKS

We were scheduled to move before the August break, but the appropriations schedule took precedence and so I appreciate your all coming back here today. We are here today to examine the salmonella outbreak this year that sickened over 1,400 people across 43 states and the District of Columbia, providing yet further evidence that our current food safety system is broken. It fails to protect consumers from unsafe foods and has the capacity to harm producers and growers in the process.

My goal this afternoon is not simply to rehash this summer's salmonella outbreak. We are looking for bigger answers, searching for the solutions that will allow us to avoid these breakdowns in the future. Certainly in recent months food safety has taken center stage like never before, and I am encouraged to see many issues that have been on the back burner for years such as traceability finally make their way into the mainstream discussion.

Now, it's time to put the words into action. Seventy-six million food borne illnesses, 325,000 hospitalizations, 5,000 deaths occur each year because of unsafe foods, and their cost to our nation is great—$7 billion economic losses annually. A major outbreak's impact lasts long after it has faded from the headlines. Mr. Farr can attest to that. The spinach market still has not fully recovered from an e-coli outbreak two years ago.

According to the California Department of Agriculture, spinach production in California is still approximately $60 billion less than pre-outbreak levels. As Mr. Murray will discuss and our colleagues from Florida and from Georgia have seen first-hand, the tomato industry now faces a similar struggle. FDA first implicated tomatoes

as the potential source of this summer's salmonella outbreak, before turning its attention to jalapeno and Serrano peppers.

Now the FDA may be looking into the possibility that tomatoes caused the earlier infections and peppers were the source behind later cases of the outbreak. Most distressing, however, is that no one seemed to be in charge. And, in fact, no one is in charge. During a complex and constantly evolving food safety crisis, the public and the industry both looked to their government for guidance and assurance that the situation was under control, but with little leadership, the situation quickly got out of control and continued to threaten public health and consumer confidence for weeks.

FOOD SAFETY MODERNIZATION ACT

For 15 different agencies responsible for administering 30 laws related to food safety, it is no wonder investigations are mismanaged, short-sighted and stalled. Address these failings and prevent dangerous products from slipping through the cracks, I believe we need to create a single food safety agent. As an incremental step toward that goal, next week I plan to introduce the Food Safety Modernization Act, creating a food safety administration within the Department of Health and Human Services with responsibility for all food safety issues currently administered by the FDA.

While maintaining the USDA's independent food safety responsibilities, the new law would establish a commissioner of Food Safety and Nutrition Policy, a presidential appointment requiring advice and consent of the Senate to lead the new Food Safety Administration designed to create a streamlined federal agency focused exclusively on protecting our food supply. Instead of having to balance food safety with competing priorities, it would allow food safety experts and researchers to do their jobs. To be sure, our ultimate goal must remain an independent, single food agency. But I believe in order to begin fixing our broken system, we must act now, and this is the best way forward.

The Food Safety Modernization Act will address traceability, process controls, inspections, and imports. We have further to go to be sure, but with this first step, we will have come a great distance, allowing the food safety experts and researchers to do their jobs, provide increased oversight, and fulfill their regulatory responsibility.

GAO REPORT

A recent GAO report outlined the critical components that are necessary for an effective food safety system, including trace-back procedures, cooperative arrangements between public health issues and mandatory recall authority. I believe these measures could be implemented most effectively under a system governed by a single food safety agency. While there has been movement on food safety reform, we are not there yet.

Finally, it is worth noting that the GAO report highlighted other nations' effective farm to fork approach to food safety. If we want to see similar success and restore our own country's gold standard for food safety, we must also focus on the entire food supply chain, place primary responsibility for food safety on producers and ensure that food imports meet equivalent and safety standards.

We know what is at stake, and today we will hear about the consequences of our inaction and the opportunity to embrace tangible reforms. It is time to show that we have learned these hard lessons and make public health our top priority. We cannot afford to wait any longer.

Thank you, and before I introduce today's witnesses, let me turn things over to our ranking member, Mr. Kingston, for an opening statement.

PRIVATE SECTOR CONSEQUENCES

Mr. KINGSTON. I thank the chairwoman for convening this meeting. This certainly is an important topic and certainly one that she and the committee feels very strongly about.

I do have a view that's a little more grounded in the private sector in their actions than probably most people in this town. And that is basically from numbers we get in our hearings here. There's 74 million food-borne illnesses a year in America that we know of, a big number, 74 million people. But it is a number everybody agrees on.

Now, if you take that number and you look at the number of meals we have per day in a country of 300 million people eating three meals a day, we have no visitors and we never eat any snacks. So just say that's 900 million meals a day, 365 days a year. When you look at the 74 million, that number becomes smaller in fact. The food-borne illness number comes down to something like .02 percent, a very, very small number.

But, if you're one of the 74 million, certainly it is very significant and I would not tell you that it isn't. But here's why I use those numbers for this illustration is that why is that food system so safe. And if we can agree that it's 99.98 percent safe, according to the statistics, which have been testified over and over again to this committee, then we need to ask ourselves why is it safe? Because one thing we do seem to have a constant theme of is the government is broken down. Indeed, in this case, the FDA added to the problem and wiped out the tomato production profit for this year in many states and many sectors.

Why wasn't the government a voice of reason? And it wasn't because government is going to err on the side of caution and bow to the political pressure that we in the elected side of government always seem to add to the problem. So think about the private sector. Let's just say I don't really care about customers, but they want the customers to come back and buy more so they can make more money.

Therefore, they've got to have a good product whether they like the customer or not. As Adam Smith said, over and over again, the search, the invisible hand, the individuals, the market force moving towards a profit incentive is a great mechanism. The market has served well for food safety, far better than the government. And so I have concerns about giving government increased powers or increased money.

I'd kind of like to hear today, Dr. Acheson, who in the FDA was responsible for the hysteria. You know, I'm sure it was an honest mistake, but nonetheless it was a mistake that caused the private sectors and farmers like Mr. Murray millions of dollars—not nec-

essarily him individually, but him collectively—millions and millions of dollars.

So my job, I feel, often is to try to bring in some of these numbers and look at what is going on in food safety right now. The success that we have, I would say, is because of the private sector, far more than because of the government. I would never tell you the government doesn't have a role to play in it at all; and, I think that there's plenty of room for discussion on that and particularly doing a better job than we are.

But, I would say the food you ate for lunch an hour or two ago is safe, largely because of the private sector, not because of the government, not to say the two can't have a shared, common interest in the friendliness of the ham sandwich and the tuna that you ate, but we need to keep that in mind as we go through this process as we continue to do so.

And, Madam chair, would it be appropriate for me to introduce Mr. Murray at this time? Or are you going to do that later?

Ms. DELAURO. After you do this, I will do that and introduce Mr. Murray.

Mr. KINGSTON. Okay, great. Thank you.

Ms. DELAURO. I thank the gentleman and let me move forward to introduce today's witnesses and I thank you all again for being here. And why we don't often hold to the five-minute rule here in terms of statements, we are going to ask you to make your statements five minutes long.

INTRODUCTION OF WITNESSES

Dr. David Acheson is Associate Commissioner for Foods at the Food and Drug Administration where he provides advice and counsel to the commissioner on strategic and substantive food safety and food defense matters. Previously, Dr. Acheson served as chief medical officer and director of the Office of Food Defense, Communication and Emergency Response at FDA's Center for Food Safety and Applied Nutrition, leading the emergency response, as well as outreach and communications to industry, state and consumers on issues pertaining to the center.

Dr. Steven Sundlof, who is head of the Center for Food Safety and Applied Nutrition, was formerly head of the Center for Veterinary Medicine.

Mr. Michael Taylor is research professor for health policy at the George Washington University, has previously served as administrator of USDA's Food Safety and Inspection Service, Deputy Commissioner for Policy at the Food and Drug Administration, and FDA staff lawyer and executive assistant to the FDA Commissioner.

Jeffrey Levi is the Executive Director of Trusts for America's Health, where he leads the organization's advocacy efforts on behalf of a modernized public health system. Dr. Levi oversees TFAH's work on a range of public policy issues, including its annual reports assessing the nation's public health preparedness and investment in public health infrastructure.

Mr. Kingston, would you do the honors for Mr. Murray?

Mr. KINGSTON. I thank the chairwoman, and I wanted to introduce Mr. Greg Murray at the same time. I wanted to co-introduce

him with Mr. Bishop, because he is actually a constituent of Mr. Bishop's and not mine, and so I wanted to yield the floor to you.

Mr. BISHOP. Thank you very much. It is really a privilege for us to have Mr. Greg Murray, who is the person who knows first-hand what the challenges are, particularly with our fruit and vegetable growers, and in particular, tomatoes in the last few months. He is very active with the Georgia Fruit and Vegetables Association. He was active with the Farm Bureau of Vegetables, and he does a tremendous job and offers tremendous leadership in the industry, particularly with regard to production quality and quality assurance, as well as food safety.

And so I certainly am delighted that we have a person of the stature of Mr. Murray with us today and that he can bring us, I think, cogent information that will help us as we examine these very, very important food safety issues, and as we also reflect on the impact that mismanagement by the agency has had on the private sector with tremendous losses that have been incurred by particular tomatoes and other vegetable growers because of misdiagnoses of where some of these problems have arisen.

So I want to welcome Mr. Murray and I want to thank Mr. Kingston for yielding back.

Mr. KINGSTON. Thank you, and I wanted to point out that Mr. Murray actually farms on a farm that's 109 years in your family at this point. And sitting right behind him is his fine looking young man, grandson Zack, and Zack actually sneaked out of school today, Mrs. Chairwoman, so he claims he is getting credit. [Laughter.]

Mr. KINGSTON. I am going to have to sign-off on that. I don't know.

Ms. DELAURO. Welcome, Zack, and it's a joke, but Congressman Kingston is right. I guess Mr. Murray's great grandfather started the farm in 1899, so it is generational.

So, welcome to you all, and Dr. Acheson I'm going to ask you to begin. And, again, I'm going to ask obviously the entire statement will be part of the record. And if you could keep it to five minutes, we would be appreciative. Thank you.

DR. DAVID ACHESON TESTIMONY

Dr. ACHESON. Thank you.

Thanks for allowing me to appear today. Joining me is Dr. Steven Sundlof, Director of CFSAN, and Dr. Steven Solomon sitting behind me, Deputy Associate Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs.

As you know, on June 30th, the President signed the Fiscal Year 2008 supplemental into law, and thanks to the efforts of this subcommittee, the supplemental provided a budget increase of $150 million to FDA. These increased appropriations will allow the agency to further implement the Fruit Protection Plan and the Action Plan for Import Safety. The supplement contains $72.3 million to support the Fruit Protection Plan, and these resources combined with the appropriation from 2008 will allow FDA to launch a number of important priorities, including hiring more investigators, the ability to hold public meetings in the fall, to follow-up on traceability, establishing offices in five countries and different

parts of the world, providing technical assistance to foreign countries building a database of information for foreign partners, conducting research to improve risk-based preventions, validating rapid detection tools, identifying food vulnerabilities, and establishing better assistance to inform consumers rapidly when problems occur.

In 2008, the administration released the 2009 budget request, which proposed an additional $50.7 million for FDA, including $42.2 for food programs. Then on June 9, 2008, the administration announced a budget amendment to further increase the '09 request by $275 million. And we appreciate the subcommittee's action on June 19 to approve the President's amended budget request.

The June budget amendment brings the administration's total proposed 2009 budget authority to FDA to $325.7 million. More than half of this amount supports the important food safety priorities. Our food protection investments for '08 and '09 will allow the agency to increase our professional staff by at least 500 FTEs across public health programs. This increase includes 375 FTEs to support domestic and foreign inspections. By the end of 2010, when these individuals are trained and deployed, we will be conducting 850 more foreign food inspections on an annual basis, 2,000 more domestic food inspections, and 40,000 more import food field exams.

Turning now to the St. Paul salmonella outbreak, as you are well aware, this was one of the most complex investigations in recent memory. I'd like to provide, initially, a brief description of a typical product tracing process, which begins when CDC's epidemiological investigation identifies a possible food associated with the foodborne illness.

At that point, CDC notifies FDA, and then FDA begins its trace back process. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen and trace back through the whole supply chain from the retailer or the restaurant, by inspecting and investigating points throughout the supply chain to determine where that contamination may have occurred.

That includes examining documents, bills of lading, invoices, and other records maintained by the firm. Product tracing investigations for fresh produce are particularly difficult because the food is perishable, often no longer available. Fresh foods and vegetables are often sold loose without packing. And practices such as commingling make the whole process more complex.

It was on May 31 the Centers for Disease Control notified FDA of a significant statistical association between the consumption of certain types of tomatoes and the multi-state outbreak of salmonella St. Paul, and in response on May 31 the FDA began its trace back process. On June 30, CDC advised FDA that the epidemiological data from the ongoing outbreak indicated that jalapeno and Serrano peppers might also be implicated, and in response to that, the agency expanded its investigation into peppers.

On July 17 FDA lifted its warning to consumers regarding tomatoes and announced that tomatoes on the market were no longer considered to be a possible source of the continued illnesses. And it was on July 21 that FDA announced that jalapeno pepper samples obtained during inspection at a distribution center in Texas

were contaminated with the outbreak strain. The peppers were grown in Mexico, but that didn't mean that the contamination occurred in Mexico. But based on those findings we advised consumers to avoid eating jalapeno peppers and foods made with them.

Further investigation took us back towards Mexico, and FDA's investigation took us to farms and packing facilities and distributors in northeastern Mexico. And a sample of Serrano peppers and a sample of irrigation water collected from a farm in Mexico contained the outbreak strain of salmonella St. Paul. On August 28, the CDC announced that the outbreak appeared to be over.

I would like to address FDA's efforts to improve product tracing and to better understand the universe of track and trace systems and best industry practices. FDA is reaching out to a variety of external entities to do this. Using this information, we want to develop recommendations for the fresh produce industry to improve its internal product tracing systems. We plan to hold public meetings this fall—one in Washington and one on the West coast—to examine the information technology systems best practices that will enhance product tracing. We have been working extensively with the states and the fresh produce industry to encourage incorporation of product tracing procedures and technology.

Finally, I would like again to thank you for your support of FDA's budget. Thank you for the opportunity to discuss these important food safety issues and FDA's continuing efforts to secure the safety of the food supply in the United States.

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

STATEMENT OF

DAVID ACHESON, M.D., F.R.C.P.

ASSOCIATE COMMISSIONER FOR FOODS

FOOD AND DRUG ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

UNITED STATES HOUSE OF REPRESENTATIVES

September 17, 2008

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Chairwoman DeLauro and members of the subcommittee. I am David Acheson, M.D., F.R.C.P., Associate Commissioner for Foods at the Food and Drug Administration. Joining me for today's hearing is Stephen F. Sundlof, D.V.M., Ph.D., Director of the Center for Food Safety and Applied Nutrition and Steven M. Solomon, DVM, MPH, Deputy Associate Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs (ORA).

FDA FUNDING TO PROTECT AMERICA'S FOOD SUPPLY

On November 6, 2007, the Administration released the Action Plan for Import Safety (APIS), a comprehensive, strategic roadmap to strengthen import safety. In conjunction with this action, FDA released its Food Protection Plan (FPP), a comprehensive initiative to protect America's food supply.

The FPP is a risk-based, production-to-consumption strategy to ensure the safety of domestic and imported food. FDA's plan relies on three core elements – prevention, intervention, and response – and calls for ten new legal authorities. The plan is designed to identify potential food defense and food safety threats and to counteract those threats before they harm consumers. FDA is implementing the FPP and APIS with the resources that the Subcommittee appropriated for FY 2008.

Food Protection Funding for FY 2008: On June 30, the President signed the Supplemental Appropriation for FY 2008 into law. Due to the efforts of this subcommittee, this appropriation act provided a budget increase of $150 million for FDA. The increased appropriations will allow FDA to continue to transform our regulatory strategies to meet the challenges of the evolving global marketplace for food and medical products. The increased appropriation will also allow FDA to further implement the Food Protection Plan (FPP), the Action Plan for Import Safety (APIS), and important medical product priorities.

$72.3 million of the FY 2008 Supplemental Appropriation will support FPP priorities. These resources, combined with an additional $55.6 million for food protection from the FY 2008 appropriation signed into law on December 26, 2007, will allow FDA to launch or enhance the following prevention components of the FPP and better protect America's food supply by building safety in from the start.

- FDA will invest at least $14 million to build in safety upfront for domestic and imported foods. FDA will better ensure the safety of imported food by increasing FDA's presence beyond our borders and by working with our foreign partners to build greater capacity to achieve food protection. This priority includes establishing an FDA presence in five countries or regions of the world.

- FDA will invest nearly $10 million to provide technical assistance to foreign countries to improve their ability to comply with FDA food standards.

- FDA will invest at least $12 million to better target risk-based inspections and import surveillance. This will include building a database that contains information that we receive from our foreign partners about food inspections and quality.

- FDA will invest nearly $3 million to identify food vulnerabilities and assess food risks by strengthening our capacity to collect and interpret data necessary for risk-based prevention and by conducting research to improve risk-based prevention strategies.

- FDA will invest nearly $9 million to develop and validate rapid detection tools to detect food contamination in domestic and imported food.

The intervention element of FPP relies on using targeted risk-based inspections and testing to verify that preventive controls are working and to verify that FDA is applying its resources in the areas of greatest concern. Successful intervention also requires enhanced risk analysis and new detection technology to analyze samples faster. The FY 2008 increase will allow FDA to conduct the following intervention activities to better protect America's food supply.

- FDA will invest at least $32 million to hire additional field investigators to significantly expand the number of foreign and domestic inspections and import exams. FDA will conduct these exams using better risk-based targeting to further safeguard the food supply.

- FDA will invest at least $13 million to improve its ability to integrate and assimilate risk-based information into data systems, detect signals of intentional and unintentional food contamination, and enhance surveillance by increasing laboratory capacity and deploying rapid detection tools to identify pathogens. To advance this objective, we have formed a Risk-Based Steering Committee to ensure that FDA uses a comprehensive risk-based approach to food protection.

Finally, FDA will invest nearly $27 million of the FY 2008 increase to improve response capability and reduce the length of time between detecting and containing foodborne illnesses.

- FDA is reaching out to various organizations to gain a better understanding of best industry practices for product tracing. FDA will hold public meetings in October and November 2008, in Maryland and California, to gather more input from stakeholders about the product tracing process. FDA will use the information gathered through public

meetings to develop recommendations for the fresh produce industry to use to improve its internal product tracing systems.

- FDA will improve communications to consumers, industry, and other regulatory partners during outbreaks of foodborne illness. We will strengthen our ability to respond to food safety threats by providing incident command training to FDA offices around the country and to States.

Food Protection Funding for FY 2009: In February 2008, the Administration released the FDA budget request for FY 2009, which proposed an additional $50.7 million for FDA, including $42.3 million to protect the food supply and continue to implement our Food Protection Plan.

On June 9, 2008, the Administration announced a budget amendment to further increase the FY 2009 request for FDA by $275 million. The June announcement brings the Administration's total proposed FY 2009 budget authority increase for FDA to $325.7 million. Of this amount, the increase for food protection activities is $167.2 million. These funds will allow FDA to advance important food defense and food safety priorities, in addition to those we will commence with FY 2008 funding.

We appreciate the Subcommittee's action on June 19 to approve the President's amended budget request for FDA for FY 2009.

Overall, our food protection investments for FY 2008 and FY 2009 will allow FDA to increase our professional staff by at least 500 full-time employees (FTE) across all public health programs, including at least 375 FTE to support Office of Regulatory Affairs' (ORA's) domestic and foreign inspection program. By the end of FY 2010, when the ORA investigators hired with FY 2008 and FY 2009 increases are trained and deployed, the increased inspection program resources will give FDA the capacity to conduct an additional 850 foreign food inspections, an additional 2,000 domestic food inspections, and an additional 40,000 import food field exams.

FPP ACCOMPLISHMENTS

On July 2, FDA published a progress report listing improvements in the safety of America's food supply accomplished since FDA unveiled the Food Protection Plan in November 2007. I want to highlight some of FDA's accomplishments so that you can see our progress to implement the FPP and better protect America's food supply.

FPP Prevention Accomplishments: FDA is implementing its landmark China Agreement, and we held our first bilateral meeting in March 2008 in Beijing, China. FDA is moving forward to establish an FDA presence in China. An FDA

delegation also met with our Indian counterparts to discuss establishing an FDA presence in India. In addition to these activities beyond our borders, FDA is developing ingredient, processing, and labeling standards for pet food and ingredient and processing standards for animal feed.

On June 2, FDA announced in the Federal Register the availability of funding for research related to the safety of fresh produce. The objective of this research is to conduct laboratory-based studies to assess whether consumers are handling fresh-cut produce in ways that may compromise the microbiological safety of the product before it is consumed. Another objective of the research is to identify and assess problems that occur during the transportation of fresh produce between producer processing facilities and point of retail sale to the consumer.

Also in the area of research, FDA recently identified several natural plant bacteria that are effective in preventing contamination of tomatoes with Salmonella Newport.

On August 22, FDA approved the use of irradiation to treat iceberg lettuce and spinach to control pathogens on these foods. This approval provided another tool for processors to use to bring safe products to consumers. Although irradiation can provide an additional level of assurance that dangerous foodborne bacteria are minimized on fresh produce, it should not be viewed as a silver bullet. Furthermore, irradiation does not diminish the importance of other preventative controls.

During August 12-14, FDA held the "Gateway to Food Protection – FDA Federal, State and Local Partners National Meeting" in St. Louis, Missouri. This meeting brought together stakeholders to discuss food safety collaborations and implementation of the Food Protection Plan. The meeting also focused on building partnerships between Federal, State, and local food safety regulators. The meeting included presentations on the Food Protection Plan and the Action Plan for Import Safety. These plans serve as the framework for food safety and food defense.

A number of action steps emerged from the meeting in St. Louis. The action steps include the commitment to build partnerships to ensure better integration of State and local expertise and partnerships to allow regulators to acquire data to safeguard the nation's food supply as we implement the Food Protection Plan.

On September 2, 2008, FDA published a *Federal Register* notice requesting comments, scientific data, and information to help FDA improve the guidance to industry in the 1998 Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. FDA is seeking specific information in four areas: the current agricultural practices and conditions used to produce, harvest, pack, cool, and transport fresh produce, the risk factors for contamination of fresh produce associated with these practices, possible recommendations or additional measures

to enhance the safety of fresh produce, and information about the estimated costs and benefits of current practices and the cost and benefits of any recommendations.

FPP Intervention Accomplishments: FDA is working to develop a prototype system, known as PREDICT (Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting), to improve electronic screening of imports. FDA completed a three-year plan to increase State inspections, and ORA will hire additional employees to conduct food field exams, conduct inspections, and collect food samples for analysis.

On July 10, 2008, FDA issued a Federal Register notice to solicit input on third-party certification programs, and FDA is interacting with a variety of industry groups to explore third-party certification further. In an effort to measure the effectiveness of third party certification, FDA is seeking third-party certification bodies that certify foreign processors of aquacultured shrimp for compliance with FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) regulations to volunteer to participate in a pilot program to be conducted by the Center for Food Safety and Applied Nutrition (CFSAN) and ORA.

FPP Response Accomplishments: FDA is working with industry to identify best practices for product tracing. FDA's public meetings in October and November 2008 in Maryland and California will gather additional input from stakeholders regarding the tracing process. FDA is collaborating with other federal agencies and with State, local, tribal, and foreign governments and with industry to develop the science and tools necessary to better understand the current risks to the food supply. FDA is also collaborating with these parties to develop new detection technologies and improved response systems that rapidly react to food safety threats. FDA issued a Request for Applications for funding to establish State Rapid Response Teams to investigate foodborne illness outbreaks, perform product tracing of implicated foods, and evaluate data from investigations to identify trends. FDA plans to award funds for Rapid Response Teams before the end of FY 2008. Finally, FDA is exploring how best to use multiple channels of communication to alert consumers quickly about food safety threats.

The July 2008 FPP progress report and the full list of accomplishments are posted at http://www.fda.gov/oc/initiatives/advance/food/progressreport.html.

SALMONELLA SAINTPAUL

There is no question that the *Salmonella* Saintpaul outbreak investigation was one of the most complex investigations in recent memory. I assure you that FDA is committed to working with all our food safety partners to examine ways to remove or mitigate some of the complicating factors to expedite the product tracing process. In my testimony, I discuss some of the factors that made this

investigation so complex. I also describe some of the challenges we face both in preventing fresh produce from becoming contaminated in the first place and in investigating outbreaks associated with fresh produce. I also discuss some of the specific measures FDA is taking to enhance the safety of fresh produce and other foods to prevent future outbreaks and to improve the product tracing process when an outbreak occurs.

Food can become contaminated at many different steps – on the farm, in packing, processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other Federal, State, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan and the Action Plan for Import Safety.

CHALLENGES OF FRESH PRODUCE

The number of illnesses associated with fresh produce is a continuing concern for FDA, and we have worked on a number of initiatives to reduce the presence of pathogens in these foods. Fresh produce presents special challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. This is a positive development from a nutrition perspective, but also a new dynamic that challenges our food safety efforts.

Because most produce is grown in an outdoor environment, it is vulnerable to contamination from pathogens that may be present in the soil, in agricultural irrigation, or processing water, in manure used as fertilizer, and due to the presence of animals in or near fields or packing areas. Produce also may be vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate production safeguards, and inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing, packing, and processing chain can be amplified throughout subsequent steps in the chain. The fact that produce is often consumed raw or with only minimal processing, without any type of intervention that would eliminate pathogens (if they are

present) prior to consumption, contributes to its potential as a source of foodborne illness.

Consequently, addressing the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination. In recent years, FDA has initiated several activities to address safety concerns associated with the production of fresh produce. Some of these activities include: working with industry to develop guidance on ways to prevent or minimize potential contamination, conducting educational outreach to consumers on safe food handling practices, sampling and analyzing both domestic and imported produce for pathogens, and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting, and processing practices. One example of recent FDA actions in this area is the June 2008 training in good agricultural practices that FDA conducted in Costa Rica.

Research is also a critical element of our efforts to improve the safety of fresh produce. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and toxins in a variety of foods. More rapid and precise testing methods to identify contaminants are important for detecting contamination if it is present and minimizing the spread of foodborne disease once it occurs. In addition, we are working with academia, industry, other Federal agencies, and State governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end users along the supply chain.

THE PRODUCT TRACING PROCESS

I would now like to provide a brief description of the typical product tracing process. Once CDC, through its epidemiological investigation with State and local governments, identifies the possible food(s) associated with a foodborne illness outbreak, CDC notifies FDA. At that point, FDA starts our product tracing investigation to identify the source of the contamination. We work with industry and with local, State, and Federal officials, and, when needed, with foreign governments, to identify the source of the contamination. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer or restaurant and inspecting or investigating points throughout the supply chain to determine where the contamination most likely occurred. Tracing food through a supply chain requires us to find and examine documents such as bills of lading, invoices, and other records maintained by the firm. We also obtain information on the practices and conditions under which the product was stored and handled at each point to better determine shipments of interest and whether contamination may have occurred at each point.

Product tracing investigations involving fresh produce are more difficult because the food is perishable and is usually no longer available for testing by the time consumers become ill. In addition, fresh fruits and vegetables are often sold loose without any packaging that could provide information about its source. Further, practices such as commingling, packing, and repacking produce from multiple sources add complexity to product tracing process investigations. As each product tracing investigation is different, I would like to mention three recent examples that illustrate the different degrees of difficulty.

Peanut Butter: In 2007, CDC notified FDA of a multi-state outbreak of *Salmonella* Tennessee infections associated with the consumption of peanut butter. In this case, because it was not a perishable food, consumers who had become ill still had jars of peanut butter available for testing. This enabled investigators to confirm the presence in that food of the contaminant associated with the outbreak. Further, because the food was packaged, the investigators were able to gather much information regarding lot numbers through the information on the contaminated jars. This is an example of rapid product tracing in which the necessary information was readily available.

Fresh Spinach: In 2006, CDC informed FDA of a multi-state outbreak of illnesses associated with the consumption of fresh spinach contaminated with *Escherichia coli* O157:H7. Although this outbreak involved a perishable food, the food was sold in a package. The product tracing process investigation was facilitated because several consumers who had become ill still had packages of fresh spinach in their refrigerators. The information from the packages that tested positive for the outbreak strain allowed investigators to narrow the specific lot number that had been responsible for the outbreak. By looking at the processor's records, the investigators were able to identify the implicated farms associated with the identified production lot of bagged spinach. This is an example of product tracing of medium complexity that took a little longer than the peanut butter example but was aided by the information on the package.

***Salmonella* Saintpaul:** The recent outbreak investigation, which initially focused on certain types of raw tomatoes, provides an example of one of the most difficult product tracing investigations. On May 26, 2008, CDC informed FDA of the hypothesis of a possible association between ill persons and the consumption of raw tomatoes. On May 31, CDC formally notified FDA of a significant statistical association between consumption of certain types of tomatoes and a multi-state outbreak of *Salmonella* Saintpaul infections. In response, FDA initiated investigations attempting to trace the tomatoes reported to have been eaten by ill persons back to their sources. Raw tomatoes are a perishable commodity and, thus, are unlikely to be in the consumer's home after the consumer becomes ill, obtains a diagnosis, and a foodborne illness outbreak is identified. Further, raw tomatoes are often sold loose, without any form of packaging. In this case, we learned that many tomatoes had been shipped to washing, packing, and repacking facilities where they were or might have been

commingled with other tomatoes from many different sources. This commingling has the potential to multiply the quantity of food that is contaminated. It also increases the difficulty in determining which tomatoes were the source of the illnesses.

A further complicating factor was caused by entities in the supply chain using different terminology to describe the tomatoes. For example, one party might describe the tomatoes as "hothouse" or "greenhouse" tomatoes while the next party in the chain might describe the same tomatoes simply as "tomato bulk." Yet another party might use a descriptor such as "green six-by-six." This inconsistent nomenclature makes it more difficult and more time-consuming to connect the links in the chain and to identify the source of the tomatoes.

SALMONELLA SAINTPAUL OUTBREAK INVESTIGATION

From May 31, until late August 2008, many FDA employees in the field and at headquarters worked continuously on the outbreak investigation to identify the source(s) of the illnesses. To help the public distinguish tomatoes not associated with the outbreak, FDA adopted the policy of specifically designating the types of tomatoes implicated in the outbreak as well as listing growing areas that were not part of the outbreak. Based on information provided by CDC, State officials, and from our own investigations, FDA regularly updated the information on its website, conducted media calls, and updated Federal, State, and local partners, and the affected industries.

As is our usual course, FDA's recommendations for consumers were focused on protecting public health and were based on epidemiological information from the State agencies and CDC. From the epidemiological information, we initially learned that illness was statistically linked to consumption of raw tomatoes. Ill persons reported consuming red round, red plum, and red Roma tomatoes. We also had information from our ongoing product tracing investigation that a limited number of geographic regions were identified as possible sources of the tomatoes that were associated with the outbreak. A number of States informed FDA that growers within their jurisdictions either were not shipping tomatoes during the period of concern or they would not have shipped tomatoes as widely as would have been required to account for this multi-state outbreak. This aggregated information allowed us to advise consumers that they could eat certain types of tomatoes and all tomatoes from a number of countries and States, or certain regions within a State, with confidence that they were not from the sources that were identified in the product tracing investigation.

On June 30, CDC advised FDA that epidemiological data developed by the States and CDC from the ongoing outbreak indicated that jalapeño and Serrano peppers also might be implicated in the outbreak. Accordingly, on July 1, FDA expanded its investigation into peppers and advised consumers at increased risk of

complications from infection – elderly persons, infants, and persons with impaired immune systems – not to consume raw Serrano and jalapeño peppers.

On July 17, FDA lifted its warning to consumers to avoid certain types of raw tomatoes. FDA announced that tomatoes currently on the market were not considered to be a possible source of the continuing *Salmonella* Saintpaul illnesses because the tomatoes coming to market were harvested from different growing areas than those initially implicated. We also reiterated our recommendation to consumers at increased risk of infection to avoid eating Serrano and jalapeño peppers while the investigation continued.

On July 21, FDA announced that jalapeño pepper samples we tested genetically matched with the outbreak serotype, *Salmonella* Saintpaul. This finding was strong evidence that jalapeño peppers were involved in the outbreak; however, it did not exonerate other foods. While this one positive sample did not provide the whole story, this genetic match was an important break in the case that helped us pinpoint one source of the contamination. FDA obtained the jalapeño peppers sample during an inspection of the Agricola Zaragoza produce distribution center in McAllen, Texas. The company voluntarily issued a recall. The peppers were grown in Mexico, but that did not mean the peppers were contaminated in Mexico.

Based on this finding, on July 21, FDA advised consumers to avoid eating fresh jalapeño peppers and foods made with them. This advisory did not include cooked or pickled jalapeño peppers. As the product tracing investigation continued into the source of the pepper's contamination, the review of the current product tracing investigation and harvesting dates, matched with the dates that people became ill, combined to indicate that the contaminated jalapeño peppers originated in Mexico and not at the plant in Texas. Therefore, on July 25, FDA announced that there was no indication that domestically grown jalapeño or Serrano peppers were implicated in the outbreak. We updated our consumer advisory to indicate that our advice to avoid raw jalapeño and Serrano peppers then applied only to peppers grown, harvested, or packed in Mexico. In addition to domestically grown raw jalapeño and Serrano peppers, canned, pickled, and cooked jalapeño and Serrano peppers from any and all geographic locations also were not connected with this outbreak. Serrano and jalapeño peppers are often grown together, are often served in the same foods, and often travel along the same distribution routes. The finding of the contaminated jalapeño pepper does not mean that Serrano peppers were not also associated with the outbreak.

FDA's investigation of farms, packing facilities and distributors in North Eastern Mexico included collecting numerous samples of peppers and environmental specimens. A sample of Serrano peppers and a sample of irrigation water collected from a farm in Tamaulipas, Mexico contained the outbreak strain of Salmonella Saintpaul. FDA announced this finding in a July 30 press release. As a result of these findings, FDA advised consumers to avoid raw Serrano peppers

from Mexico, in addition to raw jalapeño peppers from Mexico, and any foods that contain them. FDA worked with State regulatory agencies and the food industry, including restaurants, grocery store chains, and wholesalers to ensure that this new, more narrowly focused advisory was clearly understood by everyone.

On August 28, 2008, the CDC announced that the outbreak appeared to be over, but that CDC and State health departments were continuing to conduct surveillance for cases of infection with the outbreak strain. Also in late August, FDA completed the product tracing associated with the outbreak of *Salmonella* Saintpaul. FDA is continuing to review the information that we gathered during the outbreak investigation.

One of the lessons learned from this investigation is the importance of the state and local public health infrastructure that we depend on to help identify foodborne illness outbreaks, investigate them and identify the contaminated food.

RECENT FDA ACTIVITIES TO IMPROVE TRACING OF FRESH PRODUCE

I would now like to describe some of our recent activities to improve product tracing of fresh produce. The ability to trace pathways of any food, including tomatoes and other fresh produce, through every point in the supply chain is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses. The pathways that fresh produce travels from field to consumer have become increasingly complex, with items sometimes changing hands many times in the supply chain.

FDA formed an internal multi-Center group to meet with external entities (such as industry, consumers, and Federal, State, local, and foreign governments) to better understand the universe of tracing systems that are currently in use or being developed. FDA has reached out to various organizations, including trade associations and consumer groups, to gain a better understanding of best industry practices for product tracing, including the use of electronic and other technologies that speed and enhance the tracing process and the use of systems that connect all the links in the produce supply chain. FDA is using this information to develop recommendations for the fresh produce industry to use to improve its internal tracing systems. We plan to hold two public meetings in the fall to further the exchange of information on available technology and best practices for enhanced product tracing.

We have been working extensively with States and the fresh produce industry to encourage incorporation of tracing procedures and technology. For example, FDA assisted the Florida Tomato Commission and the University of Florida Institute of Food and Agricultural Sciences in the development of Florida's

Tomato Best Practices Manual. This Manual incorporates Good Agricultural Practices, Good Handling Practices, and product tracing recommendations for industry. The Manual formed the basis of the State of Florida's tomato safety rule.

Another recent example is the final guidance for fresh-cut produce, which FDA issued this year. The guidance includes a section on product tracing and a section on documentation and recordkeeping. FDA also provided industry its "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations," which is used by our investigators.

Last month, FDA issued a Request for Applications to provide funding to six States to establish Food Protection Rapid Response Teams to investigate multi-state outbreaks of foodborne illness. Enhancing the infrastructure of State food protection programs and strengthening joint Federal/State responsiveness at a local level are an important way to protect consumers by expediting product tracing investigations.

We also are planning to host a workshop at the University of Maryland during 2009 to review the status of a product tracing study on tomatoes and dairy that the European Union is currently conducting. This review will allow FDA to incorporate relevant findings from the EU study in our decision making. The EU began its four-year product tracing study in 2007 with the goal of ensuring total product tracing of food and feed along the whole chain from production to consumption. As part of this effort, the EU is developing, testing, and evaluating two full pilot product tracing systems, including one for the tomato food chain. We will continue to work with Federal, State, local and international food safety partners and with industry to conduct research, develop educational outreach materials, and initiate other commodity-, practice-, or region-specific programs to enhance the safety of fresh produce.

ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN

To enhance safety across the range of imported consumer products, in November 2007 Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of 12 departments and agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan, a framework to identify and counter potential hazards in domestic and imported food. Achieving the food safety enhancements identified in the plans requires the involvement of all our food safety partners – Federal, State, local, tribal, and foreign governments, and industry, academia, consumers, and Congress. Both plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. They contain three core elements: prevention, intervention, and response.

The Food Protection Plan identified ten legislative authorities necessary for achieving full implementation. We encourage Congress to provide these authorities, which would:

- Allow FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain
- Authorize FDA to issue additional preventive controls for certain high-risk foods
- Require food facilities, such as packers, processors, and manufacturers, to renew their FDA registrations at least every two years and allow FDA to modify the current food product categories for purposes of registration
- Authorize FDA to accredit highly-qualified third parties for voluntary food inspections. Third party organizations could be federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest
- Require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practice (cGMPS) requirements
- Empower FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet FDA standards
- Allow FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products
- Authorize FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied
- Empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective
- Give FDA enhanced access to food records during emergencies.

CONCLUSION

FDA is working hard to ensure the safety of food, in collaboration with its Federal, State, local, tribal, and international food safety partners, and with industry, consumers, and academia. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. However, the *Salmonella* Saintpaul foodborne illness outbreak underscores the

challenges we face and the need for further change to safeguard the food supply and consumers.

In the meantime, we have been making progress and are moving forward to develop a detailed implementation plan. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's budget for food protection and FDA's continuing efforts to enhance food safety and tracing. I am happy to answer any questions.

MICHAEL TAYLOR TESTIMONY

Ms. DELAURO. Thank you, Dr. Acheson.

Mr. Taylor.

Mr. TAYLOR. Thank you, Madam Chairwoman, ranking member Kingston and members of the Committee. I thank you for the opportunity to testify today.

The outbreak of illness that Dr. Acheson has just discussed sickened over a thousand people all across the country and did devastate the tomato industry, and the inability of public health officials to promptly and definitively identify the food vehicle and ultimate source of contamination has been a matter of great public concern. And I agree that the management of this outbreak must be carefully examined, both to see what if any breakdowns occurred and to learn lessons for the future.

However, regardless of whether we find that this particular outbreak could have been managed better, one thing is crystal clear to me. The fundamental problem is with the system itself, not with how it operated in the case of salmonella St. Paul. Many capable people work hard and do the best they can to investigate outbreaks, but they work with an institutional arrangement and with tools that are not up to the task.

Unfortunately, these same observations hold for the food safety system as a whole. Thus, I hope Congress will invest effort not only in fixing outbreak response and investigation, but also in modernizing our entire food safety system. Fundamental system change is badly needed to achieve a cost-effective food safety system that does a much better job of preventing outbreaks and other occurrences of food borne illness.

To be sure, prompt, accurate, and complete outbreak investigations are an essential part of an effective food safety system. First and foremost, they enable us to contain outbreaks, which prevents more people from getting sick, but equally important, good outbreak investigations provide critical information that both industry and government can use to prevent future outbreaks.

As we have been reminded recently, however, large multi-state outbreaks are inherently difficult to investigate. Time is of the essence, and any agencies are involved at all levels of government, and they come with widely varying degrees of expertise and resources. Data from multiple sources must be compiled and analyzed, and decisions with potentially great public health and economic impact must be made and communicated in the face of unavoidable uncertainty and unrelenting scrutiny. To perform well in these circumstances, the system for responding to investigating multi-state outbreaks must include at least 87 elements in my judgment, and they're really just a matter, I think, of common sense.

The first is focused federal leadership and accountability for managing the overall effort. The second is well-defined institutional roles all across the federal, state, and local system. Third is necessary expertise and capacity at all levels in the system. We also need effective trace back systems as we've heard, much more seamless data collection and sharing across this system.

Industry engagement is critical in coordinated public communication. I think these are the seven elements that are necessary for effective outbreak investigations, multi-state in particular. And, fortunately, I think we've learned that the current system is really lacking in various respects in every one of these basic elements.

At the federal level there is no single agency, the chairwoman indicated, or federal official who is clearly in charge and accountable for the overall management of the effort. Collaboration among federal, state and local agencies during multi-state outbreaks is essentially ad hoc. The expertise and capacity of state and local agencies vary widely. The trace back system is antiquated and slow. There are no standardized approaches to collecting, analyzing, and sharing the epidemiological data and other information needed to flow unobstructed in multi-state outbreaks.

And, finally, there are no established mechanisms for tapping the expertise and information of the food industry. And in some cases, there is a lack of adequate coordination of communications with the public.

Madam Chairwoman, these observations are not new. They've been made by others before, but I hope the most recent salmonella outbreak will finally provide the motivation to act and to establish a real system for managing multi-state outbreaks. As I've noted, however, the problems with outbreak response and investigation are just a microcosm of what plagues the food safety system as a whole. Lack of a clear focal point for leadership and accountability, fragmentation of government food safety efforts, and a lack of adequate resources and modern tools, Congress needs to fix the system as a whole.

The most fundamental step, I believe, is for Congress to give the government's food safety system something it has never had before, which is a modern, public health mandate, to prevent food borne illness. Our current statutes don't provide that basic mandate. Experts in government industry and academia, I think, all agree that the adoption of science and risk-basked preventive controls throughout the food system is the only way to truly protect public health and ensure public confidence in food safety.

Madam Chairwoman, you have recognized for years the need for comprehensive reform of the nation's food safety system, including a modern, prevention oriented, statutory mandate and the unification in a single agency of all federal food safety programs, including those at FDA, USDA, and EPA. Over the long run, I agree such unification to a mandate is the only way to make cost-effective use of the resources the Federal Government invests in food safety.

But you also realized the first major step towards comprehensive reform should be to address the fundamental problems, I should say, in the HHS, food safety programs, including this at both FDA and the Centers for Disease Control and Prevention. And I'm delighted to hear of your announcement of plans to introduce legislation to address this. Their efforts, as well, of course in the Senate and elsewhere in the house, address this issue of modernization of a statutory mandate for FDA. But, again, in my view Congress should not stop there.

You have indicated organizational reform is also essential, and I really do believe that we've got to go all the way and create a struc-

ture within HHS, the cures of the fact that the current system at FDA is fragmented, is buried in the bureaucracy, and really doesn't have the cloud in the system to provide the necessary leadership, nationally and internationally on food safety that we should be getting from the FDA and HHS food safety efforts.

Finally, this subcommittee is well aware of the resource challenge facing FDA's food safety program; and, as Dr. Acheson indicated, the appropriations for 2008 are I think a healthy step in the right direction, but further increases are needed in 2009, I believe, and beyond, to support the necessary modernization of the system.

I would urge Congress to step back and undertake a serious study of how to establish an adequate, stable, and predictable funding base on the HHS, FDA, food safety program, for the long term, and to consider the full range of options for funding that budget. In the meantime, however, this subcommittee can help drive change toward the risk-basked and prevention oriented system to which we all aspire by funding high priority initiatives to implement the risk-based, prevention oriented approach to food safety embraced in FDA's own food protection plan and in the kind of legislative proposals that you're talking about.

Such funding initiatives could include identifying the highest priority risks and devising risk management strategies to reduce them. It could include establishing and funding within HHS a real focal point with increased resources for food safety epidemiology the tools we need to detect and prevent problems, implementing preventive controls to ensure the safety of fresh produce, which the industry itself is calling for, and conducting an independent, I think, important foundation if we're going forward to conduct an independent compliance audit of FDA's seafood HACEP program to learn from experience how best to ensure the effectiveness of preventive control programs.

Madam Chairwoman, recent events do provide strong motivation to improve our organizations food safety system, and I do applaud the efforts of this subcommittee to drive change and to achieve assistance, to which we all aspire.

Thank you.

[The information follows:]

Testimony of

Michael R. Taylor*

Before the

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Committee on Appropriations

U.S. House of Representatives

July 30, 2008

Madam Chairwoman, Ranking Member Kingston, members of the subcommittee, thank you for the opportunity to testify at today's hearing.

Introduction

The outbreak of foodborne illness associated with *Salmonella saintpaul* has sickened more than 1,250 people in 43 states, the District of Columbia and Canada and has devastated the U.S. tomato industry. As the outbreak has continued, the inability of public health officials to identify definitively the food vehicle and ultimate source of contamination has become a matter of great public concern, as well it should. There is an understandable desire to want to find fault for the perceived failure of our food safety agencies in this case. And I agree that the management of this outbreak must be carefully examined, both to see what, if any, breakdowns occurred and to learn lessons for the future.

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However, regardless of whether we find that this outbreak could have been managed better, one thing is crystal clear. The fundamental problem is with the system itself, not with how it operated in this case. And the sad truth is that we have no system for managing multi-state foodborne illness outbreaks that can credibly be called a system. Many capable people work hard and do the best they can, but they work within institutional arrangements and with tools that are not up to the task.

Unfortunately, these same observations hold for our food safety system as a whole. Thus, while rightfully drawing lessons from the current outbreak, I hope Congress will apply those lessons to the system as a whole and invest effort not only in fixing outbreak response and investigation but also in modernizing our entire food safety system. Fundamental system change is needed to achieve a cost-effective food safety system that does a much better job of preventing large-scale, multi-state outbreaks like the one we are experiencing with *Salmonella saintpaul*.

In my testimony today, I will outline what is lacking today in having a real system for managing multi-state outbreaks and what that suggests for system-wide reform. I'll then suggest some funding priorities I believe are necessary to begin moving the Food and Drug Administration (FDA) toward a preventive approach to food safety, as called for in the Food Protection Plan FDA issued last December.

The Importance of Outbreak Investigations and Need for a System

Prompt, accurate, and complete outbreak investigations are critical to protecting public health and to building an effective food safety system based on the principle of prevention. First, they serve to contain the outbreak and prevent more people from getting sick. But then, good outbreak investigations can also provide critical information about the root cause of the outbreak. Armed with this information, industry and government can plan future prevention efforts, both in particular operations and possibly for the system as a whole.

Outbreaks, especially large multi-state outbreaks, are inherently difficult to investigate. Time is of the essence. Many agencies are involved at all levels of government, and they come with varying degrees of expertise and resources. Data from multiple sources must be compiled and analyzed. Decisions with potentially great public health and economic impact must be made and communicated in the face of unavoidable uncertainty and unrelenting scrutiny.

To perform well under these circumstances, a system for responding to and investigating multi-state outbreaks must include at least these seven elements: (1) Focused Federal Leadership and Accountability, (2) Well-Defined Institutional Roles, (3) Necessary Expertise and Capacity, (4) Effective Traceback Systems, (5) Seamless Data Collection and Sharing, (6) Industry Engagement, and (7) Coordinated Public Communication.

The current "system" lacks every one of these basic elements.

1. **Focused Federal Leadership and Accountability** – FDA, the centers for Disease Control and Prevention (CDC) and the Department of Agriculture (USDA) (when meat and poultry may be involved) each play important roles in multi-state outbreaks, but no single federal agency or official is clearly in charge and accountable for the overall management of the effort.
2. **Well-Defined Institutional Roles** – Federal, state and local agencies necessarily collaborate on multi-state outbreaks, but the collaboration is essentially ad hoc: there are no formally established mechanisms or protocols for such collaboration or even clarity about when responsibility for managing an outbreak properly shifts from the state or local level to the federal.
3. **Necessary Expertise and Capacity** – The expertise and capacity of state and local agencies vary widely, and, in general, due to chronic under funding and lack of sufficient staff dedicated to outbreak investigations, capacity at all levels of government is thin.

4. **Effective Traceback Systems** – There is no effective system for ensuring rapid government access to critical traceback information, which places extra burdens on already strained resources and delays investigations.
5. **Seamless Data Collection and Sharing** – There are no standardized approaches to collecting and analyzing epidemiological data, which undercuts the scientific foundations of a multi-state investigation; and conflicting interests and policies often obstruct the flow of information among agencies that should be operating as a cohesive team in managing a multi-state outbreak.
6. **Industry Engagement** – There are no established mechanisms for tapping the expertise of the food industry on such matters as industry structure, practices, and distribution patterns, which could both expedite and improve the accuracy of investigations.
7. **Coordinated Public Communication** – The lack of clarity about who is in charge of an investigation can result in lack of clarity in communicating with the public, as information about an outbreak is commonly made available from multiple government sources.

Madam Chairwoman, these observations are not new. Political-level leaders and professionals working in federal, state and local agencies have known for a long time that we lack the key ingredients of an effective system for managing multi-state outbreaks.

In December 2000, as an outgrowth of President Clinton's Food Safety Initiative, top officials of the Department of Health and Human Services (HHS), USDA and the Environmental Protection Agency (EPA) entered into a memorandum of understanding to establish an inter-agency body called the Foodborne Outbreak Response Coordinating Group (FORCG). This group, to be co-chaired by the Assistant Secretary of Health at HHS and USDA's Under Secretary for Food Safety and to include representatives of state and local agencies, was intended to address many of the system problems I have outlined. Its charge called for a high-level federal focal point for managing multi-state outbreaks, defined roles and responsibilities, and better communication among agencies

and with the public. FORCG was on the right track, but it disappeared with a change in administration.

More recently, professionals working at CDC, FDA, USDA and in state and local agencies came together in 2005 to form the Council to Improve Foodborne Outbreak Response (CIFOR). In June of this year CIFOR issued for public comment a detailed set of draft guidelines for improving response to foodborne outbreaks, including better planning and preparation, model approaches for harmonizing data collection, better coordination and communication, and clearer definition of leadership roles, especially in multi-state and other multi-jurisdictional outbreaks.

Again, CIFOR is on the right track, but the implementation of its draft guidelines will require sustained political-level commitment and leadership, policy change, and new resources.

The current Salmonella outbreak only underscores these lessons from the past. The challenge now is to act on these lessons and establish a real system for managing multi-state outbreaks. But, in considering how to act, Congress should recognize that the problems with outbreak response and investigation are just a microcosm of what plagues the food safety system as a whole: lack of a clear focal point for leadership and accountability, fragmentation in government food safety efforts, and a lack of adequate resources and modern tools. To fix outbreak response and investigation, Congress needs to fix the system as whole.

The most fundamental step is for Congress to give the government's food safety system something it has never had: a modern public health mandate to prevent foodborne illness. Experts in government, industry and academia all agree that systematic prevention by the adoption of science- and risk-based preventive controls throughout the food system is the only way to truly protect public health and ensure public confidence in food safety. Moreover, if there were such a mandate, improving foodborne illness surveillance and investigation of foodborne outbreaks would immediately gain a higher priority. It is

simply not possible to do prevention well unless we do surveillance well and learn everything we can from outbreaks. Thus, a mandate for prevention is a de facto mandate for investment in learning all we can about foodborne illness through outbreak investigations and other means.

The Bigger Picture of Food Safety Reform

Madam Chairwoman, you have recognized for years the need for comprehensive reform of the nation's food safety system. Bills you have introduced, including the Safe Food Act of 2007 (H.R. 1148), would bring about both the statutory modernization that is needed to have an effective, prevention-oriented food safety program and the unification in a single agency of all federal food safety programs (including those at the Department of Health and Human Services (HHS), USDA, and EPA). Over the long run, such unification under a modern statutory mandate is the only way to make cost-effective use of the resources the federal government invests in food safety.

Congress has an immediate opportunity, however, to address the fundamental problems in the HHS food safety programs, including those at FDA and the Centers for Disease Control and Prevention (CDC). The House Committee on Energy and Commerce is working on legislation to modernize FDA's legislative mandate for food safety. That is the right place to start, but I hope Congress won't stop there. Successful food safety reform at HHS – and improved outbreak response and investigation – also require changing the organizational structure and, of course, ensuring adequate and predictable resources.

With regard to organization, HHS needs a structural framework that enables it to provide national leadership on food safety and run a coherent, well-planned program that makes the best use of available resources to improve food safety. The current structure, especially within FDA, does not provide such a framework.

First, within FDA, the food program consistently takes a back seat to the drug and medical device programs in the competition for management attention and resources.

This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products. It is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a single leader. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. Responsibility and accountability for food safety within FDA is further clouded by the recent establishment in the Office of the Commissioner of an Associate Commissioner for Foods, who serves as a spokesperson and coordinator but lacks budget or line authority for programs.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the necessary clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

In my view, the food-related components of FDA must be unified into a single organization and elevated within HHS under the leadership of a presidentially appointed official reporting directly to the Secretary. This official would be responsible and

accountable for leading the necessary transformation of the FDA (and HHS) food safety program.

This needed structural reform would also go a long way toward addressing the federal leadership and accountability problem associated with management of major outbreaks. But it still would not go far enough. It is essential that the food safety epidemiology function now housed at CDC be made directly accountable to this senior departmental food safety official and become better integrated into the national effort to prevent foodborne illness.

Resources for a Modern, Prevention-Oriented Food Program at HHS

This subcommittee is well aware of the resource challenge facing FDA's food safety program. Congress needs to act. In addition to meeting FDA's immediate needs through the 2008 and 2009 budget processes, Congress should undertake a serious study of how to establish an adequate and predictable funding base for the HHS food safety program for the long-term and should explore a range of resource options, including:

- Requiring HHS to prepare for Congress a five-year food safety financial plan and an annual "professional judgment" budget sufficient to implement a modernized statutory mandate.
- Funding that budget entirely through appropriated funds.
- Establishing by law a statutory inspection mandate, with consequences built in for failure to meet it, to serve as an anchor for appropriated resources.
- Authorizing HHS to collect establishment registration fees and import fees to provide a steady base of resources for the food safety program.

In the meantime, however, this subcommittee can help drive change toward the risk-based and prevention-oriented system to which we all aspire by funding high priority initiatives, including ones needed to advance FDA's own Food Protection Plan, such as these:

Analyze Risks and Priorities for Standard Setting and Risk Management

The foundation for a cost-effective, risk-based program to prevent foodborne illness is solid scientific knowledge about the most significant hazards in the food supply to guide both industry action and government programs to reduce risk. Congress should fund FDA to: (1) identify the most significant hazards in the food supply, meaning the specific combinations of foods and microbial or chemical contaminants that are likely to have the greatest adverse impact on public health, (2) prioritize these hazards based on the magnitude of the potential risks they pose and the availability, likely effectiveness, and cost of measures to reduce the risks, and (3) develop risk reduction strategies for the highest priority hazards, including appropriate safety standards for each hazard, an inspection and enforcement plan to ensure the standards are met, and a plan to monitor the effectiveness of the strategy in reducing risk to the public.

Establish an HHS Focal Point for Food Safety Epidemiology

Taking full advantage of what epidemiology can contribute is essential to any risk-based approach to prevention of foodborne illness, but the current structural and cultural divide between FDA and CDC keeps this from happening. To address this, pending the unification and elevation of the HHS food safety program I recommended earlier, Congress should fund within the Office of the Secretary a focal point for coordination of efforts by CDC, FDA, USDA and state and local health officials to generate the epidemiological data and analysis and other information needed to implement the risk-based food safety strategy in FDA's Food Protection Plan, including information on the attribution of illnesses to specific hazards and foods.

Implement Preventive Controls to Ensure the Safety of Fresh Produce

Recent events underscore the need for preventive controls and enforceable standards to better ensure the safety of fresh produce. Congress should fund FDA to initiate the

necessary rulemaking and support any applied research that might be needed to set and enforce such standards.

Conduct a Compliance Audit of the FDA Seafood HACCP Program

FDA's current seafood HAACP rule provides a potential model for more comprehensive implementation of preventive controls in processing plants and importer accountability for food safety. Congress should fund FDA to contract for an independent compliance and effectiveness audit of the seafood HACCP program for both domestic and imported seafood. The goal would be to improve the seafood program and draw lessons for future implementation of preventive controls in other sectors and modernization of import oversight.

In addition to these priorities, Congress must address the deficiencies in legal authority, oversight mechanisms and resources of FDA's import food safety program.

Conclusion

Madam Chairwoman, recent events, including the current Salmonella outbreak, provide strong motivation to improve our nation's food safety system. I applaud the subcommittee's efforts to drive change. For the most part, we know what to do. The challenge now is to do it.

Thank you again for the opportunity to testify today. I look forward to your questions.

JEFFREY LEVI TESTIMONY

Ms. DELAURO. Thank you, Mr. Taylor.

Mr. Levi.

Mr. LEVI. Chairwoman DeLauro, Ranking Member Kingston, and members of the subcommittee, thank you for the Specific to testify before you today regarding the appropriations for food safety activities at the FDA. Trust for America's health is a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority, and we applaud the committee for continuing its examination of the food safety functions at the federal level.

My written testimony describes some findings from our report on food safety and my oral remarks. I want to focus on two issues related to assuring a modernized food safety system: The FDA's Food Protection Plan and the funding levels needed by the FDA for implementing that plan. Anyone who picked up a newspaper in the summer of 2008 knows America's food safety system is broken. Too many people got sick, and too many millions of dollars were lost from American businesses before the real problem was correctly identified. More than ever, the American people deserve an FDA with a plan and resources it needs to protect them, or an independent food safety agency with the plans and resources it needs to protect.

The Food Protection Plan issued in November 2007 sets broad goals for improving food safety in the United States. However, while it provides an agenda for Congress, it lacks the specificity about goals and objectives and implementation strategies that would allow the Congress and the public to determine what resources are needed to implement the plan and what milestones could be used to measure the progress of the FDA in making our food system safer.

At a hearing in June, Dr. Acheson was unable to report exactly how much money the FDA actually needed to be more effective and to implement the Food Safety Plan. I fail to see how the FDA can go from being an agency in crisis to a modern, capable preventive body without clearly stating its funding needs.

We would suggest that if the agency cannot identify the dollars that are needed to implement the Food Safety Plan that Congress should deny the FDA the ability to spend increased funds until it receives a realistic budget request for the FDA's long-term modernization road map. We're not asking you to cut the base funding, but to withhold any increases until they deliver that detailed plan.

Dr. Acheson's testimony today is a good start in identifying how the agency plans to spend the fiscal 2008 increases, but it is unclear how these allocations fit into the mid- and long-range implementation of the Food Protection Plan. The FDA should be able to provide similar details regarding the fiscal 2009 increases that have been requested. In any event, this doesn't answer—even that information does not answer the fundamental question about long-term cost of implementation of the Food Protection Plan and measurable milestones associated with funding increases.

TFAH has always advocated for a stronger investment in the public health system, but we also expect accountability and trans-

parency with respect to that investment. Indeed, if the administration is serious about modernizing the food safety system, each step of the implementation plan would carry with it a professional judgment budget number describing the appropriations necessary to achieve the goal, not just the legislative authority needed. FDA should then regularly report to Congress and the public with measurable benchmarks of its progress in implementing the plan and the funding levels to move it forward.

We recommend that in the upcoming, as I mentioned, in the upcoming appropriation for the FDA, the committee deny the authority to obligate some or all of the increased funding contingent on the committee's receiving a detailed multiyear budget for implementing the Food Protection Plan, or in the event of a continuing resolution, the committee could indicate its intention to make additional funds in the final appropriation, conditional on FDA leadership sharing its plans for expenditures before the expiration of the CR.

Let me also address the issue of specific funding levels. Others with far more expertise than we have identified a series of shortfalls within the FDA's budget overall and for food safety. We strongly endorse the recommendations of the FDA Science Board and recommend that Congress provide the requested funding levels in two ways.

Congress should provide no year funding to allow FDA to develop a long-term plan for infrastructure transformation. The kind of rebuilding the FDA must undertake requires capital investment. The Science Board recommends increasing FDA's base by $450 million over the next five years for information technology modernization alone. Knowing that the full funding for a multiyear endeavor is guaranteed will facilitate this kind of investment. That said, Congress can and should expect definition of milestones and regular progress reports on spending that money.

Absent specific budgetary goals associated with the Food Protection Plan, the committee can provide targeted funding in fiscal 2009 for specific policy initiatives such as those identified by the Science Board and by Professor Taylor in his testimony today.

Congress must also assure that increases are provided in the FDA's base appropriation to sustain the investment that was made as part of the supplemental funding recently approved. We are pleased that the administration asked for and Congress approved that supplemental funding, but increased funding must be sustained over time to allow for effective strategic planning. FDA has added 1,300 professional staffers in the last five months, so funding must be consistent from year to year to sustain this level.

Our federal food safety system is broken. The American people are looking to this committee and the Congress to assure that the FDA both has the resources it needs to fix the system, and provides us a clear road map for achieving a modernized food safety system.

Madam Chairwoman, you and your colleagues have the opportunity to begin that process through the appropriations before you.

Thank you for including me in this important discussion, and I look forward to your questions.

[The information follows.]

Written Testimony of
Jeffrey Levi, PhD
Executive Director
Trust for America's Health

Before the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies
House Committee on Appropriations
July 30, 2008

Chairwoman DeLauro, Ranking Member Kingston and members of the Subcommittee, thank you for the opportunity to testify before you today regarding appropriations for food safety activities at FDA and USDA. I am Dr. Jeffrey Levi, Executive Director of Trust for America's Health (TFAH). TFAH is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We applaud the Committee for continuing its examination of the food safety functions at the federal level.

In April, TFAH released a report entitled *Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork.* Our report finds that food safety represents a significant public health threat. The food safety system is fragmented, dependent on archaic laws, and chronically underfunded. The current system is reactive, not preventive, meaning we are wasting millions of dollars on responding to threats rather than building proper controls into the production system. The ongoing salmonella crisis provides an all too real demonstration of the dangers of a reactive system, as 1,300 people in 43 states have

been sickened, and we are only now beginning to close in on the true source of the outbreak. The economic repercussions from the delayed response are still being felt in the agricultural, restaurant, retail and food production industries, and the health and trust of the American people has been shaken by this failure in prevention and traceability. Our report finds that Congress has not provided the Food and Drug Administration with a modern, public health mandate to prevent foodborne illness; has not updated the agency's legal tools to meet the challenges of a high-tech, globalized food supply; nor has it provided the funding stream necessary to carry out research and inspection. At the same time, the agency has not adequately expressed its resource needs as it moves forward with its Food Protection Plan.

Food safety represents a significant public health threat. One in four Americans is sickened by foodborne disease each year, and an estimated $44 billion is lost each year in medical and lost productivity costs. According to FDA's website, since May of this year alone, FDA has issued over 30 recalls, alerts, withdrawals and warnings of unsafe or mislabeled food, including several alerts related to the salmonella crisis. This figure does not even take into account similar alerts related to USDA-inspected foods. These numbers are far too high, and major gaps in our nation's food safety system are to blame. Indeed, if we had a modernized food safety system focused on prevention, we would not need to be issuing this number of alerts and recalls. That said, given the disjointed and underfunded nature of our food safety surveillance system, we cannot be sure that the alerts and recalls issued by FDA truly even reflect the extent of the problem today.

The public is deeply concerned about this issue. A 2007 public opinion poll conducted on behalf of TFAH found that 67 percent of Americans are worried about food safety. This number ranked above the threat of pandemic flu or natural disasters, illustrating just how strongly food safety truly touches every American. The food supply is vulnerable to a variety of pathogens, toxic metals and other pollutants, product tampering, and emerging diseases. The current food safety system is reactive, not preventive, meaning we are wasting millions of dollars on responding to such threats rather than building proper controls into the production system.

I want to turn now to two critical issues related to assuring a modernized food safety system: the FDA's Food Protection Plan and funding levels needed by the FDA for food safety.

The Food Protection Plan issued in November 2007 sets broad goals for improving food safety in the United States. However, while it provides an agenda for Congress, it lacks specificity about goals and objectives and implementation strategies that would allow the Congress and the public to determine what resources are needed to implement the plan and what milestones could be used to measure the progress of the FDA in making our food safety system safer.

TFAH has always advocated for a stronger investment in the public health system. But we also expect accountability and transparency with respect to that investment. During a hearing before the Energy & Commerce Committee last month, at which TFAH testified,

the FDA Associate Commissioner for Foods, David Acheson, was unable to tell members of the Subcommittee exactly how much money FDA actually needs to implement the Food Protection Plan. Whether constrained by political realities of his position or the fact that the Agency had simply not made such a determination, we strongly urge the FDA to begin making those strategic calculations. When the FDA released its Food Protection Plan Progress Report this month, it demonstrated that the Agency is committed to implementation of a modernization strategy by explicitly stating action steps it had taken, and we hope they continue to make this a transparent process. However, I fail to see how FDA can go from an 'agency in crisis,' as experts and Members on both sides of the aisle have referred to it, to a modern, capable preventive body without resource requests attached to the Food Protection Plan.

Indeed, if the Administration is serious about modernizing the food safety system, each step of the implementation plan would carry with it a professional judgment budget number describing the appropriations necessary to achieve the goal, not just the legislative authority needed. FDA should then regularly report to Congress and the public with measurable benchmarks of its progress in implementing the plan and the funding levels necessary to move it forward. Just as the federal government has begun incorporating program evaluation for state and local entities into its grantmaking process, Congress could explore the possibility of integrating reporting and strategic planning disclosure requirements into the appropriations process. We recommend that in the upcoming appropriation for the FDA, the Committee deny FDA the authority to obligate some of the increased funding until it receives a detailed and acceptable multi-year

budget for implementing the Food Protection Plan. Or, in the event of a continuing resolution (CR), the Committee could indicate its intention to make additional funds in the final appropriation conditional on FDA leadership sharing its plans for expenditures *before the expiration of the CR.* This way, both the Committee and the Agency could adequately prepare for steady funding when the regular appropriations process resumes next year.

We make these recommendations not simply for the sake of transparency, but to strengthen FDA's argument for additional funding. There are precedents for such an approach. For example, the Administration released a National Strategy for Pandemic Influenza along with a request for $7 billion to carry out the strategy. The initial strategy articulated broad concepts and principles for pandemic preparedness, just as the Food Protection Plan does. But as Congress moved forward and provided the necessary funding for pandemic influenza preparedness, the strategy was accompanied by an Implementation Plan, which contained actionable steps for multiple federal departments, including interim milestones against which Congress and the public could measure progress.

In addition, several agencies within HHS are legislatively mandated to provide, directly to Congress, so-called bypass budgets that reflect their professional judgment of funding that is needed without having to receive OMB clearance. Dr. von Eschenbach had experience with this process during his tenure with National Cancer Institute. Each year, both the National Cancer Institute and the Office of AIDS Research provide Congress

bypass budgets, which include the resources necessary to maintain existing research and the money required to achieve specific expanded or new initiatives. The recent "dance" we saw leading to the formal request for an additional $125 million for the FDA's food safety work was an ad hoc version of this approach. The Subcommittee may want to work with the authorizing committees to enact a regular bypass budget for the FDA as it embarks on this important process of modernization.

Let me also address the issue of specific funding levels. Others with far more expertise than we have identified a series of shortfalls within the FDA's budget – overall, and for food safety. We strongly endorse the recommendations of the FDA Science Board and recommend that Congress provide the requested funding levels in two ways:

- Congress should provide "no-year" funding to allow FDA to develop a long-term plan for infrastructure transformation. The kind of rebuilding that FDA must undertake requires a capital investment. The Science Board recommends increasing FDA's base by $450 million over the next 5 years for information technology modernization alone. Knowing that full funding for a multi-year endeavor is guaranteed will facilitate this kind of investment. That said, Congress can and should expect definition of milestones and regular progress reports.
- Absent specific budgetary goals associated with the Food Protection Plan, the Committee can provide targeted funding in FY 2009 for specific policy initiatives such as those identified by the Science Board and by Professor Taylor in his testimony today.

- Congress must also assure that increases are provided in the FDA's base appropriation to sustain the investment that was made as part of the supplemental funding recently approved. We are pleased that the Administration asked for and Congress approved supplemental funding for FDA's food safety function. But increased funding must be sustained over time to allow for effective strategic planning. Given the uncertainty of food safety funding, it is exceedingly difficult for the federal food agencies to implement modernization plans. Although FDA recently announced plans to hire 1,300 science and medical staff, including 600 new positions, it is unclear if the resources to fund those positions will be stable from year to year. The supplemental money also does not solve the problem of out-year planning. FDA is an agency in transition, so its appropriations parameters should allow for such transformation. Instead of budget requests that allow for only incremental changes from previous fiscal years, we recommend the Committee look into the possibility of multiyear or no-year funding streams for FDA's food safety function, at least until the agency can be modernized and fully staffed. At the same time, FDA should develop multiyear plans to correspond to its budget requests. This kind of strategy would allow FDA to more easily link its Food Protection Plan with specific funding requests and facilitate recruiting and retention of quality staff. And it must be stated, although supplemental funding for FDA this year is important, appropriators should bear in mind that increased funding should be rolled into baseline appropriations in FY 2010, rather than returning to previous funding levels. Fluctuations in financing levels in response to public catastrophes such as the Heparin and Salmonella crises do not allow for effective planning.

Increased funding for food safety is a start. But our report notes that the federal government is spending existing funds on outdated, inefficient practices. The federal food safety system is an example of misallocation of funds due to adherence to an archaic framework. For example, the FDA oversees foods responsible for 85 percent of foodborne illnesses, yet receives just over half the appropriations that USDA receives for its food safety activities. According to Center for Science in the Public Interest, FDA inspects most American food facilities an average of once each decade. The USDA's FSIS spends most of its resources visually inspecting every beef, pork, and poultry carcass in ways not too different from practices used 100 years ago, although the health of animals has greatly improved and most foodborne illnesses cannot be detected visually. Likewise, FDA's food safety statutes date back to 1906 and 1938. Thease statutes resulted in a system that is built to be reactive to problems prevalent in early 20th Century food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur, yet modernization continues to happen in a piecemeal, incremental way.

Our federal food safety system is broken. While Congress blames the FDA for implementing the plan too slowly, FDA claims Congress has not provided the Agency with the authorities it has requested. The time for finger-pointing is past, and we should instead focus on the steps both Congress and the FDA can take to provide the Agency with the legal and financial resources it needs to implement the strategy. While your colleagues in the authorizing Committees clearly have significant work ahead of them,

there are opportunities for this Committee to help ensure FDA has the tools it needs to modernize and unify the fragmented system. As you know, the problem cannot simply be fixed with additional funding, but with aligning appropriations with the Agency's modernization plans. If this Committee is successful in requiring the FDA to cross-walk its strategic vision with specific budget requests, it could set a precedent for a more transparent, responsive, and agile federal government.

Thank you for including me in this important discussion. I look forward to your questions.

Ms. DELAURO. Thank you.

Mr. Murray.

Mr. MURRAY. Madam Chairperson, Ranking Member Kingston, Congressman Bishop and other members of the Appropriations Committee, thank you for holding this hearing and allowing me the opportunity to speak with you. I'm Greg Murray of Bainbridge, Georgia. I farm in partnership with my brother Dale. We have farmed together since 1979 on the same farm that our great grandfather started in 1899.

Over the years we have grown various crops, but today we depend on tomatoes as our primary crop. Tomatoes provide more than 90 percent of our farm income. In 2007, Georgia's tomato industry represented a value to our growers of over $60 million with approximately 6,000 acres of tomatoes in production. However, Georgia's tomato acreage is decreasing due to the economic pressures faced by our growers. According to a survey from the University of Georgia, the amount of acres planted in 2008 is down by 20 percent from 2007.

In the 25 years of growing tomatoes, our farm has experienced floods, hailstorms, freezes, droughts, poor yields, poor markets, disease and insect infestations and many other difficulties. But the one thing we have never had to face was the public hysteria attack caused by the media and the agencies of the Federal Government.

The 2008 crop started out very good. We started picking tomatoes on June 2, 2008. The next day, the FDA issued a nationwide consumer advisory not to eat Roma red round tomatoes, which are the varieties that we grow, grown in Florida or Mexico. At first it did not appear to be a big problem. Tomato prices fell from $18 a box to $16 a box. Still a good profit.

Shortly thereafter, the FDA issued an advisory and recommended retail outlets and restaurants in Texas and New Mexico take fresh round and fresh Roma tomatoes off their shelves or menu. The tomato market crumbled overnight. Immediately, retail and food service providers across the nation, not just in Texas and New Mexico, began alerting the consumers that tomatoes were no longer available due to the salmonella St. Paul outbreak as announced by the FDA.

We are very appreciative that the FDA established a list of safe states that were identified as not being part of the outbreak. However, every day the salmonella St. Paul outbreak was the leading news story. New salmonella cases were reported, but these are from a safe state. The message was very confusing. This was being treated by the media as if it was a disease that was killing millions. The safest thing to do was to just not purchase retail or consume tomatoes.

Over the next four weeks, tomato sales and prices at Murray Farms dropped to almost nonexistent. Even though we used good agricultural practices that provide a safe and traceable product, we left half of our crop in the field because we could not sell it. Of those tomatoes that we could sell, the price dropped to as low as $2 per box rather than a normal year at more than $12 a box. The fact that Georgia tomatoes were never implicated as having a prob-

lem did not matter. With prices at $2 a box, we finally threw in the towel and left over a million-and-a-half pounds of tomatoes in the fields to rot. This many tomatoes would have fed 90,000 Americans for a year.

The University of Georgia's Center for Agribusiness Development released a study on July 25 estimating Georgia's growers suffered more than $14 million in economic losses based on a three-year average price of Georgia tomatoes as reported by the National Agricultural Statistics Service. The study also reported more than 41 percent of Georgia's tomato crop was not harvested, or the tomatoes were harvested and packed but dumped because the product could not be sold. The tomatoes that never made it to the market cost growers from 12 to 17 thousand dollars per acre.

Who is to blame for this fiasco? We understand the need for an agency to be responsible for the safety of America's food supply. However, the economic disaster and loss of consumer confidence caused by the tomatoes and the jalapeno pepper announcements have been devastating to our growers. This is evidenced by the reduction in tomato acreage on our farm and other farms in Georgia now for the fall crop. We normally plant over 100 acres of fall tomatoes. However, this fall we cut back to 57 acres.

In closing, I ask you to do three things. First, I ask for you to take swift action to pass mandatory food safety guidelines for produce that take into consideration regional production differences, product risk levels, and not be a one-size-fits-all.

Second, I ask you to require FDA to develop a plan of action that demands state and federal agencies to work together within the industry so that future responses will not become another false food safety awareness fiasco.

And thirdly, I ask for swift passage of H.R. 6581, which will partially compensate farmers for some of the losses due to the food safety scare caused by the Federal Government. We believe we are in the same situation as growers of other commodities whose crops were destroyed by a natural disaster. In this case, our natural disaster was initiated from Washington.

Thank you for this opportunity to share this with you. I will be happy to answer any questions.

[The information follows:]

TESTIMONY
OF

GREG MURRAY
MURRAY FARMS
Bainbridge, GA

BEFORE THE

SUBCOMMITEE ON AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION,
& RELATED AGENCIES

OF THE

HOUSE APPROPRIATIONS COMMITTEE
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 17, 2008

I am Greg Murray of Bainbridge, GA. I farm in partnership with my brother Dale. We have farmed together since 1979 on the same farm that our great-grand father started in 1899. Over the years we have grown various crops, including livestock, but have come to depend on tomatoes as our primary crop which provides more than 90% of our farm revenue. As does most vegetable growers in south Georgia, we have a spring crop and a fall crop. For the spring of 2008 we had 84 acres of tomatoes. I also speak to you today as a member of the Georgia Fruit and Vegetable Growers Association, representing over 350 fruit and vegetable growers/suppliers in Georgia and the southeast; and past Chair of the Georgia Farm Bureau Vegetable Advisory Committee.

Introduction

In 2007, vegetables grown in Georgia (including tomatoes and specialty peppers) had a farm gate value of over $900 million dollars. Georgia's tomato industry alone represented a value to our growers of over $60 million dollars with approximately 6,000 acres of tomatoes in production. Historically Georgia is the third or fourth largest tomato producing state in the U.S. behind Florida and California.

Tomato growers have faced many challenges in recent years and Georgia's tomato acreage is decreasing. According to a survey of growers by the University of Georgia the acreage for Spring 2008 tomatoes had been reduced and was only 80% of the 2007 acreage. This reduction is being driven by the extreme economic pressures put on our growers because they are consistently losing money on their tomato crop. The costs for disease and insect protection along with crop fertilization have significantly increased. Some growers estimate fertilization costs alone have increased over 300% since 2005. While the production input costs are sky rocketing, the price we receive for our crop has remained flat.

Most vegetable crops have a defined marketing window driven by the plant's physiology to economically produce quality fruit. Georgia's marketing window for tomatoes is late May/early June through mid-July.

Food Safety Production Practices

Food safety is a major focus at Murray Farms. I am the person on our farm that oversees the farm's food safety compliance. It is my responsibility on a day to day basis to be sure we are in compliance with Good Agricultural Practices (GAP) and that all of our operations follow the approved standard operating procedures.

While I cannot speak for all Georgia tomato growers, I do know our large tomato producers in Georgia follow similar food safety procedures to those we follow on our farm. Each year our farm is audited by an outside 'third party inspection' company. These 'outside audits' include a checklist of over 125 items which the inspectors review or have tested at an outside lab. Those items tested include irrigation water, well water, cooling tank chlorine and ph levels, water used on the packing line, refrigeration/cooler temperatures, and several others. In addition, the

Georgia Department of Agriculture will make unannounced visits during the packing season to spot check our produce to insure there is no disease or pesticide residue on the produce.

Food safety is critically important to our Georgia growers. In fact, this issue is so important that our association has a full time staff person working with our GFVGA membership to insure Georgia produce has been grown under the best management practices and our growers adhere to good agricultural practices.

All growers that are certified by the Georgia 'GAP' (Good Agricultural Practices) Program and other third party food safety inspection companies are required to have the ability to trace product – one step forward, one step back. At Murray Farms this means when a pallet load of tomatoes are shipped out of our cold storage (there are 70 - 25 lb. boxes on a pallet), we can identify where the product came from (field and date of harvest) and where it is going (distribution warehouse, customer, etc). Our identification standard at this time is for the pallet, not for each individual box.

A number of industry organizations, the Florida Tomato Exchange, the California Tomato Commission, and United Fresh Produce Association along with other state and regional associations have been focused on tomato safety for several years. The tomato industry is most likely the lead commodity in developing a comprehensive food safety program nationwide. Recently the second edition of "Commodity specific Food Safety Guidelines for the Fresh Tomato Supply Chain" has been published. These guidelines recommend food safety practices to minimize the microbiological hazards associated with fresh tomatoes and fresh-cut tomato products at all points of the fresh tomato supply system. The industry is moving to adopt these guidelines and trace-back regulations.

The Salmonella Outbreak

As noted earlier, the financial health of Georgia's tomato industry has been questionable for several years due to high input costs and low prices. In the 25 years of growing tomatoes, our farm has experienced floods, hail storms, freezes, droughts, poor yields, poor markets, disease and insect infestations and many other difficulties. But the one thing we have never had to face was a public hysteria attack caused by the media and agencies of the federal government. No amount of planning could have prepared us for what we faced this June as we started harvesting our spring crop of tomatoes.

The 2008 crop started out as if it might be a 'salvation' year for Georgia growers. We had a perfect crop and prospects of very high market prices. We started picking tomatoes on June 2, 2008. The next day the Food and Drug Administration (FDA) issued a nation-wide consumer advisory not to eat Roma or Round red tomatoes (which are the varieties that we grow) grown in Florida or Mexico. At first it did not appear to be a big problem. Tomato prices fell from $18.00/box to $16.00/box, still a good price.

Shortly thereafter FDA issued an advisory recommending retail outlets and restaurants in Texas and New Mexico take fresh round and fresh roma tomatoes off their shelves/menus and the tomato market crumbled nationwide. Immediately retail and food service providers across the

nation, not just in Texas and New Mexico, began alerting the consumers that tomatoes were no longer available due to the *Salmonella saintpaul* outbreak as announced by FDA.

With each day, the *Salmonella saintpaul* outbreak was the lead news story. New cases were reported by the FDA, Center for Disease Control (CDC) and news media daily and the price of a 25 pound box of tomatoes continued to drop. This was being treated in the media as if it was a disease that was killing millions.

We are appreciative FDA established a list of 'safe states' that were identified as not being a part of the outbreak and tomatoes from those states were safe to consume. Georgia was included on the very first 'safe list' but most consumers were afraid of any kind of tomato. Each day the CDC and FDA were announcing more *salmonella* cases had been reported. The messages were confusing. Consumers could not understand the reported *salmonella* cases were from product consumed three to five weeks ago, not product currently on the market. So the safest thing for a consumer, or a food outlet, to do was just not purchase or consume tomatoes.

Over the next four weeks tomato sales and prices at Murray Farms dropped to almost non-existent. We left half of our crop in the field because we could not sell it. For those tomatoes we could sale, the price dropped to as low as $2.00 per box rather than a normal year at more than $12.00 per box.

The fact that Georgia tomatoes were never implicated as having a problem, did not matter. With prices at $2.00 a box, we finally threw in the towel and left over 1.5 million pounds of tomatoes in the fields to rot. This many tomatoes would have fed 90,000 Americans for a year.

This incident has been a severe financial hardship to our farm. We expect to lose over $2 million of income, not profit, due to this food safety scare. This $2 million loss is money that we need to pay for our production costs such as, mulch, fertilizer, pesticide, irrigation and labor to harvest those acres we did pick.

In addition to the loss of income to our farm, one of our main concerns is the loss of consumer demand for tomatoes this fall and next spring. We have reduced our fall crop by 50% for fear the consumer will not return to tomatoes in the fall.

The University of Georgia Center for Agribusiness Development released a study on July 25, 2008 that estimated Georgia growers suffered more than a $13.9 million economic loss based on a three year average of Georgia tomato prices as reported by the National Agricultural Statistics Service (NASS). However, there is disagreement over the three years average price per box used to develop this loss in that it is unrealistically low for the commercial market. Therefore the statewide loss to growers could escalate significantly once growers report and document their individual production and average sales.

The University of Georgia also reported more than 32% of Georgia's tomato crop was not harvested, and 9% was harvested and packed but dumped because the product could not be sold. This represents a total of 41% of Georgia tomatoes that never made it to the market costing our growers from $12,000 to $17,000 per acre.

Georgia growers have suffered major losses from an outbreak that was blamed on tomatoes from other growing regions. Yet, at no time during the investigation did FDA or CDC find a single tomato that was contaminated with the *Salmonella saintpaul* bacteria.

Who is to blame for this fiasco? We understand the need for an agency to be responsible for the safety of America's food supply. However, the economic disaster and loss of consumer confidence caused by both the tomato and the jalapeno pepper announcements has been devastating to our growers. This is evidenced by the reduction in tomato acreage that our farm and other farms in Georgia have for the fall crop. We normally plant over 100 acres of fall tomatoes; however, this fall we cut back to 57 acres.

Recommendations

I am here today because I want to be a part of the solution. I hope the information offered in my testimony will help this sub-committee address this serious problem and keep another ***'false food safety awareness fiasco'*** from happening again. The following recommendations are offered to this subcommittee and supported by the Georgia Fruit and Vegetable Growers Association:

1. First, I ask for you to take swift action to pass a mandatory food safety program nationwide based on commodity risk that will insure our food supply is safe. To restore consumer confidence, it is critical to the entire produce industry that FDA adopts such a **mandatory** policy for tomatoes and other produce, based on the risk factor for that product. Any guidelines should take into consideration regional production differences, product risk levels, and not be a one-size-fits-all. In addition FDA must look to the industry for input and consultation in the development of these policies.

2. Second, I ask you to require FDA to develop a plan of action that demands state and federal agencies to work together with industry so their future responses will not become another ***'false food safety awareness fiasco'.*** FDA should put forth a plan detailing how agencies and industry can work together and prevent another economic disaster like this last *Salmonella saintpaul* outbreak. Such cooperation would have been helpful back in May, June and July when tomatoes were the false target. In order to move quickly to solve the problem and identify the illness source, full cooperation with a transparent process must be developed in advance of future outbreaks. A model could be the Investigation Team at an airliner crash site assembled by the National Transportation Safety Board. No public statement is made until the 'cause of the crash' has been determined.

3. And thirdly, I ask for swift passage of HR 6581 which will partially compensate farmers for some of their losses due to the food safety scare caused by the federal government. We believe Congress should provide relief to growers and shippers in Georgia for the real losses we suffered and we will continue to suffer at no fault of our own. We believe we are in the same situation as growers of other commodities whose crops were destroyed by a natural disaster.

In closing, I urge both government and industry representatives to work together to develop commodity specific guidelines with an acceptable trace back system. We must not allow the disaster that our growers experienced in June and July to happen again!! AND we must build consumer confidence in our product again!!

Madame Chair, Ranking member Kingston, and other members of the committee, thank you for holding this hearing. I appreciate the opportunity to participate.

FDA AUTHORITIES

Ms. DELAURO. I'd like to say thank you to all of you for your testimony. Dr. Acheson, as I said in my opening statement, I do not want to spend a lot of time re-litigating the salmonella St. Paul outbreak investigation.

Dr. ACHESON. Yeah.

Ms. DELAURO. But given the enormity of the public health issue, the upheaval to parts of our produce industry, and the public confusion about exactly what went wrong here, I would like to ask you a simple, forward-looking question. Is there a critical piece of authority or tool that FDA currently lacks that we did not have that would have been helpful to you in getting to the bottom of the salmonella outbreak faster and would have lessened the problem? I would also like to ask Mr. Taylor, Mr. Levi, and Mr. Murray to comment on that as well. So I want to get your answer about what critical piece of authority or tool.

Dr. ACHESON. Thank you. Let me caveat my answer with supporting earlier comments about the need to look at the whole public health infrastructure. Protecting the public health along the lines that we're discussing is not just FDA's role. It involves local, states and CDC.

But to your question, specific FDA authorities, the key piece is prevention. We've already requested authority to require preventative controls for high-risk foods, which would unquestionably include fresh produce of certain types, and tomatoes would be part of that, as would leafy greens. So that's one piece, prevent the problem in the first place.

TRACE-BACK AUTHORITY

The second critical part to this is something that wasn't included specifically in our legislative proposals, is to consider whether a mandatory requirement for traceability would be appropriate. We are going down a road of examining what is going to work, what's the characteristics of an intraoperable system that is connected from one end to the other, and that needs more thinking, but I think if that were in place and everybody was adhering to it, from the very small to the very large, it would have an impact. If it was just the large, it would not be effective.

Ms. DELAURO. Quickly, in your opinion, does FDA currently have the authority to mandate trace-back?

Dr. ACHESON. FDA does not have explicit authority to do that, although there is some legal question whether it could be worked in through——

Ms. DELAURO. Former Commissioner Kessler says that you do have that authority.

Dr. ACHESON. Our attorneys do not believe we have explicit authority.

Ms. DELAURO. Whose responsibility is it, a trace-back?

Dr. ACHESON. FDA's.

Ms. DELAURO. It's FDA's? I'm happy to hear you say that. Earlier on, my understanding was that the response was the industry's responsibility. That was a quote from—that trace-back is an indus-

try responsibility. But your view—I want to get to the answer today, which is it's FDA's responsibility.

Dr. ACHESON. It's FDA's responsibility from a federal level, but it's industry's responsibility to have a system that will allow us to do it.

Ms. DELAURO. But it's FDA responsibility at the federal level to have a trace-back mechanism?

Dr. ACHESON. I would say so, yes.

Ms. DELAURO. Okay. Mm-hmm. Let me ask—and the question that I ask, because I want to hold to my five because there will be several rounds here today. Critical piece of authority or tool the FDA lacked in terms of this issue. Mr. Taylor, Mr. Levi, Mr. Murray, and then also ask you about the trace-back piece. Mr. Taylor?

Mr. TAYLOR. I think we would all agree that prevention in the first place and the authority to require preventive controls and to actually go forward and do that I think is a critical piece of the tomato industry.

Ms. DELAURO. Mandatory?

Mr. TAYLOR. Mandatory, enforceable standards on the farm for preventive controls.

Ms. DELAURO. As Mr. Murray was pointing out?

Mr. TAYLOR. Yes, the same basic idea.

FDA AND CDC INTERACTION

Ms. DELAURO. Okay. Mm-hmm.

Mr. TAYLOR. The issue of—it's not a legal authority issue per se, but the separation between CDC and FDA in treating the CDC epidemiological investigation to identify the food vehicle and then turning it over to FDA to do the trace-back as though those aren't really the same integrated investigation is a serious mistake, and that's why we got off on the wrong track I think and didn't have the information, all the information on the table at the same time, including what industry could say about distribution patterns and so forth. And so it slowed the process down.

The trace-back issue, I'll give you my take on trace-back. I think the government should set a standard and hold companies accountable for being able to give to FDA promptly the information about where food came from, whether you're a retailer or a processor. The government shouldn't be doing gumshoe, you know, shoe leather work, to go through records and trace this down. Companies need systems, but there ought to be a public accountability for being able to turn over that information quickly so then government can go and investigate the places where the product has been and determine what the problem was and to do that containment work, and also that discovery of root cause work.

Ms. DELAURO. Mr. Levi.

Mr. LEVI. I would second all that and add one other piece to it, which is it's not just the communication between CDC and FDA, but also the information flow from the states to the CDC. CDC is in a sense dependent on what comes from the states, and the capacity of states to provide timely, accurate information is also tremendously variable. And I think there's a national interest given how food production occurs for the Federal Government to assure a minimum standard that occurs at the state level as well.

Ms. DELAURO. Mr. Murray.

Mr. MURRAY. Well, it has to be mandatory. I mean, I already do it voluntarily, but it doesn't matter, you know, if someone, you know, damages the food supply. But the question is, can we mandate what Mexico does? This problem apparently came from Mexico.

The other question with the trace-back is—I mean, that's to me not a difficult situation. I mean, we already code our boxes with the date and the harvest. We should be putting, you know, each produce farm should have a number, an identifier number that's unique to that farm. I think we already have one with the Biosecurity Act of 2002. But, you know, it's simple enough. It's not rocket science, I mean.

PRODUCT TRACEABILITY INITIATIVE

Ms. DELAURO. Your point is well taken, Mr. Murray. I'll make a couple of just quick points. The fact is, Dr. Acheson, and I think you know this, that the industry effort called the Produce Traceability Initiative has been just finalized a plan, timeline for implementation of case-level traceability standards. Industry has learned a lesson after working with weakened trace-back rules under the Bioterrorism Act. They're now being very proactive on it. I don't happen to believe that that ought to supplant a Federal Government regulation, but I applaud the work of the industry on this effort, and a comment I'm going to just make, FDA has come late to this issue of trace-back and this initiative, to the table, in my view.

In terms of prevention, as Mr. Taylor pointed out as being mandatory, this prevention aspect, when you said prevention in your view is that mandatory as well?

Dr. ACHESON. Absolutely.

Ms. DELAURO. Okay. Thank you. Mr. Kingston.

IMPORTED FRUITS AND VEGETABLES

Mr. KINGSTON. Thank you, Madam Chair. Mr. Murray, on market share to Mexico and other countries, do you have any statistics on, say, fruit and vegetable and how much we're buying overseas?

Mr. MURRAY. The last figure I've seen a year or two ago was we were at the point that we were soon going to be buying more of our food from overseas produce. We were reaching that point.

[Interruption to the proceedings.]

Mr. MURRAY. We were reaching the point about a year or so ago where we would be importing more of our food than we were exporting.

Mr. KINGSTON. And Dr. Acheson, what are you going to do about that?

Dr. ACHESON. That's economics and consumer preferences that's driving that. Our role is to ensure that it's safe, whether it's coming from a foreign country or domestic.

Mr. KINGSTON. Well, the economics may be driven by an inefficient, ineffective government regulatory environment, which we could be approaching pretty quickly. Mr. Levi made a very good point about lavishing money on a government agency without a plan, which is in fact what happened last year, $150 million on

FDA without any plan whatsoever. And we're seeing the plan now, but it's funny. I've never seen a plan in Washington that did not ask for more spending and more authority, because that's what government agencies tend to do. But it would appear to me that, you know, under the good intentions of food safety that the next thing we know, even though Mr. Murray is calling for mandatory regulatory environment, the next thing you know, the government is going to be his partner down on the farm, and might be big enough to afford it, but there will be others who can't afford that, and then we'll have less opportunities for mom and pop farms, more opportunities for the big farmers, not necessarily the Murray family, but big corporate kind of farms. And, you know, it's going to be great for the big guys, but it's going to run off the small players who often are the market mechanism that keeps the food supply affordable. And what you just said is that, you know, you don't have any authority on imported food, correct?

FDA BEYOND OUR BORDERS

Dr. ACHESON. That's not what I said.

Mr. KINGSTON. Oh, okay. Excuse me. You said it was a function of market or——

Dr. ACHESON. Well, you were asking me what we're going to do about the fact that imports are rising.

Mr. KINGSTON. Yes.

Dr. ACHESON. And there's nothing we can do about that.

Mr. KINGSTON. Well, I'm talking about from the food safety standpoint.

Dr. ACHESON. Oh, absolutely. There's a great deal we can do about that.

Mr. KINGSTON. And what are you going to do?

Dr. ACHESON. Well, we've developed a whole approach in terms of FDA beyond our borders, because philosophically, the agency has been focused on inspecting at the port of entry. We recognize that is not going to get to the production life cycle, which is what's key, what's going on in a manufacturer in China, in a farm in Mexico, and a cantaloupe grower in Honduras. Whatever it is, are those preventative controls in place? What's the production life cycle? To do that, we've got to understand where the risks are. To help do that, we've got to integrate better with industry, to understand what they're doing, with the foreign governments, to understand what they're doing to begin that process. We're establishing a presence overseas in a number of key areas, as I mentioned, in five different parts of the world, to begin that process. At the port of entry we are reexamining how do we use our risk-based approaches so that the inspections that are being done—because there's no way you can inspect or test your way through this. You can't test everything and you can't inspect everything. So you need a risk-based approach. How do we get there? We need the data from this information from overseas, from other sources, to help inform what should that risk-based inspection be, so you're actually testing the foods that are of greater concern, increasing your chances that there will be a problem.

PREDICT

The tool that we're currently examining to do that is something called PREDICT. We've rolled that out. We've experimented with it with seafood in the Port of Los Angeles that looks like it's good. It needs peer reviewing. It needs looking at, but my belief is that that will extend to seafood in other ports and ultimately to other foods. To do that, you've got to empower that system with the risk-based information, because it's only as good as the information flowing into it and the data.

Mr. KINGSTON. Why couldn't you do PREDICT on domestic food?

Dr. ACHESON. You could. You could. PREDICT was built to essentially focus on imports, but the concept of risk-based approaches to determining where you put your inspectional resources is a foundation of the intervention part of the Food Protection Plan.

Mr. KINGSTON. And just so that we're all on a common definition of risk-based inspection, what is that?

Dr. ACHESON. It means that where an inspector goes and what they sample and what they inspect is determined by the likelihood that where they're going and what they're inspecting will be linked to a foodborne illness, so you're not spending your time going and inspecting a facility which is very likely to be perfectly okay.

Mr. KINGSTON. Have you ever discussed that concept with our friends at the USDA? Dr. Raymond?

Ms. DELAURO. Dr. Raymond.

Mr. KINGSTON. Have you——

Dr. ACHESON. I have talked to Dr. Raymond about some of those things, yes.

Mr. KINGSTON. Well, I would encourage you to pursue that discussion. And my time is out.

Ms. DELAURO. A quick point of clarification, Dr. Acheson, and I talked about mandatory prevention. We're talking about mandatory prevention standards. Is that—when you talk about standards, performance standards, mandatory standards, is that what you mean by enforceable standards?

Dr. ACHESON. Absolutely. Yes.

Ms. DELAURO. I just wanted to have clarity on that in terms of traceability and on the standards in the way that folks have been talking about here today. Mr. Hinchey.

INCREASE IN TOMATO IMPORTS

Mr. HINCHEY. Thanks very much, Rosa. This is a very fascinating subject, frankly, and I very much appreciate everything that you've said. All the testimony has been very interesting. One of the interesting things to me, frankly, is the way in which the downgrade in the quality of agricultural products imported into the country and the impact, the health impact that they had on even vets in a couple of cases, has not just on those people but on the agricultural industry here in the United States. Now the initial reaction was to focus attention on a domestic product, and then the impact that had on that domestic product, if I understood Mr. Murray's testimony, it certainly did have a very positive impact on his economic situation there, isn't that correct?

Mr. MURRAY. Very negatively, yes.

Mr. HINCHEY. And you said that the amount of agricultural products is down by 20 percent over the course of the last year, or the tomato product, actually?

Mr. MURRAY. Yes, tomatoes, yeah. Tomatoes are—we are receiving a lot of imports now from Canada and Mexico that's hurt the tomato industry greatly.

Mr. HINCHEY. And as the imports come up, our dependence on foreign agricultural products, our ability to oversee, though, the safety and security of those agricultural products is downgrading, isn't it, Mr. Acheson?

Dr. ACHESON. Without an increase in resources and new technology and new approaches, the numbers of inspections that are going to be done are going to be dwindling relative to the total numbers of shipments.

Mr. HINCHEY. They're going to be dwindling, and they have been dwindling.

Dr. ACHESON. They have been, yes.

Mr. HINCHEY. And that's one of the deep causes of our concern, because we can be pretty secure that in a lot of places, the oversight, the dealing with these products, is not going to be handled in the most effective and efficient way, and safety and security is going to continue to decline unless we do something serious about it. I think what our chairwoman was suggesting was the establishment of a very specific security operation within FDA to oversee the safety of the agricultural products. I think that's a positive step forward. Don't you think so?

Dr. ACHESON. I would question whether it's wise to focus specifically on agricultural products. I think we need to be looking at the food safety system across the board. I mean, look at what we're dealing with right now is melamine contamination of infant formula in China. We need to be nimble to be able to respond to anything and everything whether it's microbiological, chemical and wherever in the world it comes from

Mr. HINCHEY. Well, that's what I'm talking about. I'm not just saying that it's the quality of what's grown, it's the way the products are handled as they're developed, as they're grown, and then as they're marketed. That's really the problem, and it doesn't get nearly enough supervision. There's not nearly enough security. Isn't that correct?

Dr. ACHESON. Let's differentiate security from safety. I think when you say security, do you mean food safety?

Mr. HINCHEY. What I mean by security is securing that when the products come into this country that enough oversight has been engaged in to make sure that they're not going to be contaminated in some way or they're not going to have some negative effect on the health and safety of America.

Dr. ACHESON. Exactly. And that gets back to the requirement for preventative controls.

Mr. HINCHEY. Preventative controls?

Dr. ACHESON. Exactly. And that—but that's only as strong as the enforcement capabilities to make sure that they are being followed. Simply writing the legislation and putting the law in place is only a part of it. You've got to be able to enforce it.

Mr. HINCHEY. Well, yes, but what's the defect in terms of the enforcement, providing you have those operations in place?

Dr. ACHESON. A defect? What——

Mr. HINCHEY. What is going to undermine the ability to enforce it, if you have those operations?

Dr. ACHESON. Frankly, a lack of inspectional resources to do that.

Mr. HINCHEY. Oh, yes. Okay. So that's what this—that's one of the main reasons why this committee is holding this hearing.

Dr. ACHESON. Yeah.

Mr. HINCHEY. Because it has the responsibility to ensure that the funding is proper and——

Dr. ACHESON. Well, it's critical to link the two.

Mr. HINCHEY. Yes.

Dr. ACHESON. You require the preventative controls and you make sure that they are being followed.

Mr. HINCHEY. Oh, yeah. We know that very well. But we've had a lot of disappointments with the Food and Drug Administration over the course of years, seeing the inadequacy and the way in which they deal with their obligations and responsibilities, and the impact that the expression of that adequacy has had on the safety and health of people.

So, it's not just the law, it's not just the funding. It's the seriousness of the people who are given the responsibility to carry out this obligation.

Dr. ACHESON. Let me assure you, we're very serious about FDA about ensuring food safety.

Mr. HINCHEY. Well, I like to believe that.

Dr. ACHESON. Please do.

Mr. HINCHEY. But I don't.

Dr. ACHESON. What can I do to convince you?

Mr. HINCHEY. You can continue to do something more than what's going on, because we have seen a lot of examples of a decline in food safety in a variety of ways. I mean, this is one example. It's a very serious example, but it's not the only example. We have seen a lot of examples over the course of the years. I don't think we've had a chance to talk to you about it before specifically, but we've talked to a lot of other people in FDA about this, and, frankly, got the clear understanding that in many cases, they didn't know what they were doing or how to do it. So that's one of the things that is of deep concern to us.

What about this issue of radiation? Isn't it possible, if not likely, that the idea that you're going to improve the safety of a product by radiating it, making it potentially possible that that's going to downgrade the security in some other way, the safety in some other way?

Dr. ACHESON. Irradiation is unquestionably to FDA's view not a silver bullet.

Mr. HINCHEY. Pardon me?

Dr. ACHESON. It is not a silver bullet. Irradiation is not a fix to the critical need for preventative controls. If you irradiate thinking you're going to be able to forget about preventative controls at the farm level, you're deluding yourself.

Mr. HINCHEY. Right.

Dr. ACHESON. It's not going to work. It's not going to be effective.

Mr. HINCHEY. How much attention is being focused on irradiation?

Dr. ACHESON. How much attention?

Mr. HINCHEY. Yeah.

Dr. ACHESON. At FDA?

Mr. HINCHEY. Yeah.

Dr. ACHESON. We just, as you know, we just put out this notice about iceberg lettuce and spinach to allow irradiation. There is a petition submitted to FDA looking at a number of other products. That's working through. Dr. Sundlof could certainly speak to what his center is doing on that.

Mr. HINCHEY. Thank you very much.

Ms. DELAURO. Mr. Latham.

MORE FUNDING FOR FOOD SAFETY

Mr. LATHAM. I thank the Chairwoman and I know her interest in food safety and we've shared that together for many years, and as all members of the subcommittee, we all know we need to do more to insure that the safety of our food supply is at optimum level.

And let me express frustration here today. Today is September 17, it leaves us only 13 days left in the fiscal year 2009 budget, and we passed only appropriation bill off the floor of the House. It has nothing to do with food safety or this subcommittee. And because we're facing the CR, this means that the 2008 levels of funding are going to continue in the next year. And FDA, we may have an anomaly here as far as a bump in the CR, but everybody here is arguing about more funding for food safety, and the fact of the matter is it isn't going to happen under a CR.

And it's not a fault of the Chairwoman; there's no question about that. It's not a fault of the administration. They don't pass appropriation bills. You can argue about funding levels at the end of it, but it's up to Congress to actually pass appropriation bills, and we have not done our work and woefully not done our work.

But whatever we decide is the proper funding for '09 for FDA, we need to have an appropriation bill to make that happen. And I just hope with the Chairwoman that we can get this done some day around here. Just when?

TOMATOES AND THE SALMONELLA OUTBREAK

So I ask you a question. Dr. Acheson, I just really am curious as to what actually happened. I mean you've got Mr. Murray here, who has been devastated, that it certainly appeared to everyone that, you know, there was the tomato problem, and then it's not the tomatoes. We don't know where they came from. I believe it's from Mexico, but let's, you know, wipe out the Georgia tomato producers in the meantime.

What is the responsibility? Have you actually identified what it was yet?

Dr. ACHESON. Do I need to take you through the process of a walk-through, or——

Mr. LATHAM. Well, where is your jurisdiction, and have you identified the cause of the outbreak?

Dr. ACHESON. The response to an outbreak is an integrated approach, as we've been discussing, beginning with local health departments, actually beginning with physicians and patients, and identification of a Salmonella outbreak, which starts at a local level. Ultimately, if it's multi-state it works up to the Centers for Disease Control.

This began in mid-April, the first people started to get sick. It took from then until the end of May before essentially the Centers for Disease Control and the local and state health authorities implicated tomatoes through epidemiological studies.

Mr. LATHAM. On what basis?

Dr. ACHESON. That was done through epidemiology case control studies. That is under the jurisdiction and control of Centers for Disease Control and the local and state health authorities. FDA has nothing to do with that, other than observing it and following it.

Mr. LATHAM. Okay. So you were not in the loop at that point?

Dr. ACHESON. We're in the loop in that we know that something is——

Mr. LATHAM. You're watching?

Dr. ACHESON. We're watching. We have liaisons at CDC. It's not like we don't know that something is coming. We know there's a Salmonella outbreak. What's it due to?

Then on May 31 FDA is told the case control study indicates that this is tomatoes, with a high degree of statistical probability. That was the same sort of information that was used to go after peanut butter with Salmonella. No positives in any samples at that time. It's just a strong statistical epidemiological association with a specific brand of peanut butter. That was in 2007.

Mr. LATHAM. No samples identified?

Dr. ACHESON. No. But that's typical. That's not unusual. At that point FDA on June 1 begins the trace-back process. And what does that mean? It means FDA goes to the restaurant or the retailer where that person purchased the tomato that made them sick, and asks, "Where did you get your tomatoes?" And they'll say, "Well we got them from three suppliers."

You go to each one of those suppliers, "Where did you get your tomatoes?" Each one will send us back to three distributors. And it just mushrooms out into a spider web of complexity. And we're doing this, and every one is one-up, one-back, one-up, one-back, inspect, get the records.

Many of the suppliers and distributors here were small, so they only had paper records. There was nothing electronic. We have to get these paper records, get them back to headquarters, look at them, analyze them, connect them to the next piece.

That essentially took us through the month of June, as we were working our back here. And we were implicating two growing areas. Because the goal here is to find out where did the problem occur——

Mr. LATHAM. At this point, had you put out the advisory at that point yet to the public?

Dr. ACHESON. Yes, we had.

Mr. LATHAM. So, okay. Go ahead.

Dr. ACHESON. And that advisory is put out based on the epidemiological association.

And we have two choices there. We either simply stay silent, waiting to try to find a positive as people continue to get sick. Or we go out with the best information that we have to inform consumers. And we choose the latter, because that's the optimal track to protect public health.

As was pointed out, in this particular outbreak, we tried to limit industry damage by developing a list of growers, which included Georgia, California, and other places, which were not implicated because they weren't in the growing season when this all began. And we were making concerted efforts to——

Mr. LATHAM. Did you tell the public that? I mean basically all I remember is you told, don't eat tomato.

Dr. ACHESON. We did tell the public this——

Mr. LATHAM. That it's okay if they came from Georgia or Florida, or no?

Dr. ACHESON. Let me rephrase this. We told the media many, many times about our exclusion lists. We did many media calls, we discussed that. What the media choose to report to the public is not under our control.

The fact that FDA has an exclusion list——

Mr. LATHAM. Now we have a common enemy. [Laughter.]

Dr. ACHESON. So this extended through the month of June. Focusing on tomatoes took us back to two places geographically, Florida, Mexico. We sent investigators down there. Could we find a problem? At the same time the outbreak was continuing, CDC and the locals were going back, asking new patients, "What did you eat? Where did you eat it?" And that's when Serrano and Jalapeno peppers began to come out as a potential problem.

Mr. LATHAM. Did they ever find a trace in the peppers?

Dr. ACHESON. Yes. We were able to trace peppers back through originally to a distribution center in Texas; we found positive pepper samples at that distribution center that had the outbreak strain. That took us back to farms in Mexico, and we found the positive outbreak strain in irrigation water in Mexico——

Mr. LATHAM. Aren't you still——

Ms. KAPTUR. Will the gentleman yield—Mr. Latham, could I just ask where in Mexico?

Mr. LATHAM. I have very limited time is the only thing.

Ms. KAPTUR. Where in Mexico?

Dr. ACHESON. Talapuas, yes.

Mr. LATHAM. Okay. But you said earlier that you're investigating tomatoes?

Dr. ACHESON. No.

Mr. LATHAM. You're not? Tomatoes are all okay now?

Dr. ACHESON. Well, we made an announcement in the middle of July that tomatoes were okay.

Mr. LATHAM [continuing]. Pepper—maybe, you never conclusively said that.

Dr. ACHESON. No, we——

Mr. LATHAM. Never reported that you had completely eliminated tomatoes as a cause of the outbreak.

Dr. ACHESON. No, that's not what I said. Don't let me confuse you. In the middle of July we announced that tomatoes that were on the market in the middle of July were not associated with the outbreak and were perfectly okay to consume.

Mr. LATHAM. Did they ever test the peppers?

Dr. ACHESON. Who?

Mr. LATHAM. The CDC?

Dr. ACHESON. The CDC typically don't test the foods, we do. And so do other regulatory agents. We tested a lot of tomatoes and a lot of peppers, and we found nothing positive on tomatoes, but we did find positive peppers.

Mr. LATHAM. Okay. The CDC—and just indulge me here so I can get this—but you said you were observing the CDC and the epidemiologist thought it was tomatoes.

Dr. ACHESON. Correct.

Mr. LATHAM. Did they look at peppers?

Dr. ACHESON. In those early epidemiological associations I think peppers were part of the general questions, but peppers did not come to the surface as a likely vehicle in the first round.

Mr. LATHAM. Even though they were found positive?

Dr. ACHESON. Even though what?

Mr. LATHAM. Even though later they were found to be positive.

Dr. ACHESON. Yes. In a subsequent case control study, they did come to the top of the list, peppers, all peppers.

Mr. LATHAM. Okay. Thank you, Madame Chairwoman.

Ms. DELAURO. I just want to, just for clarity's sake, because I think Mr. Taylor said something early on. It's not the work that was done, it's not the well meaning of the people who were doing the work. All of that is—the people pour their heart and their soul and their knowledge, et cetera, into trying to figure it out. It is the system that is broken.

You still do not have mandatory traceability, mandatory performance standards with which to gauge this.

You're looking for a needle in a haystack, because the system is broken. And nor are we seeing yet today the changes, fundamental changes that need to be made in the system in order not to repeat this fiasco.

And that is what is—what I say, and I speak for myself. We can go back and go back and re-litigate it. But the point is: How do we break what's been done? If need be, start from scratch and figure out the system that doesn't put this man out of business and doesn't send people to the hospital or kill them, because we can't put a system in place and design it. That is what is at issue.

Mr. Bishop, I'm sorry to—you've got plenty of time. But let's not get caught up in the past, but let's look to the future, and what we need to try to do.

Mr. Bishop?

NATIONWIDE FOOD SAFETY PROGRAM

Mr. BISHOP. Thank you very much, Madame Chairman.

I certainly appreciate the passion with which you are attacking this issue. I also appreciate the challenges that are faced by all of the people sitting in front of us, particularly Mr. Murray.

I want to go back to—recommendation—Mr. Murray's testimony. Basically Mr. Murray recommended that we do pass a mandatory food safety program nationwide, based on commodity risk. And Madame Chairman has offered the Food Safety Modernization Act. And I think that we are very, very interested in the comments that each of you have made and are making in response to that.

Secondly, Mr. Murray suggested that that system needed to have as a part of it a much stronger interaction between the federal and the state agencies that are charged with food safety.

H.R. 6581

And the third aspect which Mr. Murray brought forth is the swift passage of H.R. 6581, which—the compensation for the tremendous economic loss that was suffered.

Now of course, we will have to address that, and of course legislation has been offered in the form of this authorization bill, as well as a request for consideration in our CR and supplementals that we may possibly be able to get before the end of the session. Request had been made for that. We don't know if it will be successful or not.

But with regard to the future—forward, as Madame Chairman suggested—do you think as a part of our system we need to look at crop insurance for economic disaster, as well as—we now are accustomed to natural disaster? But his is a manmade, and it's an economic disaster, so it's no fault of your own.

Should we not build in as a part of the system some form of crop insurance that would allow you to be compensated through some form of insurance for the risk for these economic losses? What kind of support would a program like that need, Mr. Murray? And if there are other members of the panel that would care to comment on that, I'd like to hear that. Because it seems as if it so often—I was just talking to Mr.—and he remembers spinach. And of course that was just a few months ago when we were talking about peanut butter, Salmonella in our area.

And there are all kinds of economic disasters. Can we as a part of the system build some kind of risk assurance, as a part of it, that would protect you, that would keep us perhaps from having to do an appropriations bill every time we suffer a loss, if we had a system in place to address that kind of risk——

REVENUE-BASED INSURANCE PROGRAM

Mr. Murray, and then I'd care to hear from the other members of the panel.

Mr. MURRAY. Absolutely. We've been pushing for a revenue-based insurance program for years, and they keep telling us that it's possible coming down the pipeline there are places in the country that do have revenue-based crop insurance on tomatoes. And it covers them regardless of the loss, whether it's low markets or low yields——

Mr. BISHOP. This is regional, it's not nationwide? It's just at certain locations?

Mr. MURRAY. Well, it's just in certain places.

Mr. BISHOP. So we need to make that——

Anyone else care to comment on that?

[No response.]

Mr. BISHOP. Anyone else on the panel care to comment on the proposal that the Chairlady has offered? The—separate agency within HHS that's responsible for all of the food safety issues that are currently being administered by FDA.

Mr. Acheson, do you have any comment on that? And of course, Mr. Murray and Mr.—and Mr. Taylor.

Dr. ACHESON. My only comment on that is to try to take it to a higher level and leave it up to the Chairwoman as to how this is done, but to agree that we need to be looking at food safety from a systematic perspective.

But it requires a public health infrastructure look. It cannot be done at FDA alone. It needs to go all the way down vertically to the local health department.

Mr. BISHOP. But should we have one agency with that responsibility, or should we continue to have it spread out?

Dr. ACHESON. As long as the system works, I don't think it matters how you do it. But certainly there are advantages and there are disadvantages to merging. I think we'd have to look at it carefully.

Mr. BISHOP. Well, we got a history with Homeland Security. We also have the history of intelligence agencies too. So we're interested in your comments.

Anyone else?

Mr. TAYLOR. If I could just add a thought or two, Mr. Bishop. I think the thing you have to start off understanding is that current situation within FDA in terms of management of the food safety program. But Dr. Acheson is the Associate Commissioner for foods, and has an officer of the commission coordinating function and obviously he's the point person for purposes of exercises like this. But the actual management responsibility, the operational management responsibility and the resources are actually controlled by three different operating components of FDA, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs.

There is no official in FDA whose full-time job is food safety, and who has line management authority over all those three operating components of the agency.

And as hard as Dr. Acheson works—and I think he's doing a fantastic job—he's in a virtually impossible positive, quite frankly, to really drive the change that needs to be driven in the FDA program.

And then you add to that how critical the CDC epidemiology function is to a preventive food safety system; that the knowledge that is generated through the use of epidemiology that happens at state and local levels, coordinated by CDC absolutely foundational to a preventive system. Because we can't prevent hazards we don't fully understand.

But that CDC epidemiology function is again managed completely separately, and is not by design or by any means in actual practice contributing what it needs to contribute to the knowledge base to support prevention. That's partly a resource problem, but it's also a—accountability and the role of that in the system.

So, you know, I think we need legislative reform, but if you don't fix the structure and create a leadership structure that's capable of driving change on a systems basis, as Dr. Acheson suggests, you know, the legislation will fail.

Mr. BISHOP. So you think it's a good idea?

Mr. TAYLOR. Absolutely.

Mr. LEVI. I would concur with what Mr. Taylor said, but add two points. One is I don't think the DHS example is relevant. It actually is the opposite of the DHS example. If we had today a separate food agency and a separate drug agency and tried to bring them together, that would be the DHS example. And in fact, what we're trying to do is make sure that we have focused leadership and attention within a single agency to these issues.

I think what gets more complex, and you know really requires some careful thinking, and I think that Dr. Acheson is absolutely correct, it's a vertical issue as well as a horizontal issue within the Federal Government. And that is a real challenge.

And so as this new agency is put together, we really need to think about then, what happens simultaneously at the state and local level, because we are never going to create a federal infrastructure of the state—nor should we—state and local level to do some of that initial data-gathering, and epidemiological work and all that sort of thing, because, you know, garbage in, garbage out. We can have the best possible system at the federal level, and if the states and localities can't bring in a timely and effective way the information you need to do your job, it's still not going to work.

Mr. BISHOP. So Mr. Murray's second recommendation is, you're in agreement with that?

Mr. LEVI. Yes.

Ms. DELAURO. Ms. Emerson.

Ms. EMERSON. This just gets more confusing. Thank you, Madame Chairman.

EPIDEMIOLOGIES

Let me just ask you a silly question, Dr. Acheson. Just because Mr. Latham and I have been sitting here talking about it. How—this is not among my questions, but how could the epidemiology show traces of, or be tomatoes, for example, versus green peppers, or whatever kind of peppers they were? I mean are those epidemiologies similar?

Dr. ACHESON. It gets down to a series of questionnaires in which the local health authorities, the state health authorities are asking the patients who got sick, "What did you eat and where did you eat it?" And a parallel set of control individuals usually neighbors living in the same area, close associates who didn't get sick, "What did you eat and where did you eat it?"

And you will ask many, many people in these situations, sometimes over 100, usually more controls than patients. And look at that information and use that as the basis. That's a case control study. To make a determination that this particular food was more likely statistically to be associated with illness than that type——

FDA AND USDA COORDINATION

Ms. EMERSON. Oh, a statistic but not scientific?

Dr. ACHESON. It was both. Statistics is—questionably science.

Ms. EMERSON. Well, no. You know what I mean. I mean you didn't have actual trace materials or blood work or anything like that?

Dr. ACHESON. What you don't have is Salmonella St. Paul on a piece of produce to say "This is it."

Ms. EMERSON. Right.

Dr. ACHESON. Or "This could be it." What you're dealing with is information from patients. "What did they eat? Where did they eat it?" And using a case control statistically epidemiological approach to figure that out.

But again, emphasize that is not what FDA does.

Ms. EMERSON. Right. I understand. It's what CDC does. But that begs a question then, back to the consolidation of all functions of food safety.

The U.S. Department of Agriculture, and if you take the APHIS piece out and that's what the Department of Homeland Security on some inspections, and then you've got USDA—at Tyson's Chicken, for example, I've got a chicken plant in my district, and so I know you've got USDA there. And I mean the whole coordination seems rather haphazard, and that's not criticism towards you; it's just rather confusing—you know, which is why the idea of perhaps a single agency doing all these functions is not a bad idea.

But do you think it would be more efficient—I mean you say horizontal and vertical. All those functions have to be—in keeping on my course the whole government notion that oh heaven forbid that you would take something away from me. In other words, FDA has had this function and USDA has that function, and you know, there's this possessiveness which of course doesn't suit, I mean it's not something that's so important for the public. What's important for the public is not their egos but the food safety.

Do you think it would be more efficient if there was an integrated approach, more efficient and more effective, so that perhaps we wouldn't have in this particular case a pretty well devastated Mr. Murray's bottom line this year?

Dr. ACHESON. There's no question that improved integration is key to improving food safety. Particularly when you're dealing with a national food safety system in the context of a global food market. It has got to be integrated, between those who are recognizing the disease to begin with—as we were just discussing—what's happening in that local health department? How is that linking out through the Centers for Disease Control to the regulatory agencies: If it turns out to be chicken and goes to USDA, if it turns out to be tomatoes, it comes to us.

Very different approaches, very different statutes. As you pointed out, there's an inspector in every chicken plant. We don't take the same approach at FDA.

What we do to address that at FDA is we do integrate within the agency and have liaisons at the Centers for Disease Control, and they have liaisons with us, so within the confines of the current system, we are doing our best to try to integrate approaches to——

Ms. EMERSON. But do you think—I mean why should you and USDA necessarily have different mechanisms?

Dr. ACHESON. I think it's because Congress set it up that way. [Laughter.]

Ms. EMERSON. Well, so if Congress set it up that way, Congress can undo it again. But all right.

EU FOOD REGULATION

Now let me ask you a different question. Does the European Union have a better approach to food safety than the United States?

Dr. ACHESON. I think the EU have a different approach.

Ms. EMERSON. And how is it——

Dr. ACHESON. I mean, what's better mean? Now to me better means who's getting sick, how many people are getting sick, and from what?

Ms. EMERSON. Yes.

Dr. ACHESON. And I mean I don't think twice about what I eat in Europe, just like I don't in the United States.

Ms. EMERSON. Okay.

Dr. ACHESON. And I think if you look at numbers of illness, we're very comparable. They have a slightly different way of getting there than we do. But the end result is the same, and I think that's an important——

Ms. EMERSON. But you know, I realize that there's mandatory labeling and lots of things in the EU countries that does differ from here. But I still am not quite sure, how do you do mandatory traceability when we import so many foods? That's the part that to me, I don't how the mechanism would work. If in fact—we would not import tomatoes, for example, from Mexico if there wasn't a means by which to trace those? I mean I don't know how that would work.

Dr. ACHESON. You know, I think where you're going is some of the key questions around whatever legislative proposal this might look like, and what are the limitations?, and what's the economic feasibility?

Ms. EMERSON. Right.

Dr. ACHESON. Because you can't ignore that. Because to do some of this stuff it would be expensive.

But I have spoken to firms that are growing tomatoes in Mexico, who have a state-of-the-art traceability system. They can do it, from the farm, from the greenhouse, almost to who's picked it, and on what day, right through to the retail store.

So it's technically doable, and they tell me it's not that expensive. But I mean that's just a—of one.

To be effective, you can't have a traceability system that ends at the port of LA; it's not going to work. It has to go beyond that.

Ms. EMERSON. Okay—I think that I'm out of time—Madam Chair, thank you.

Ms. DELAURO. I would just say to the gentlelady that I'll be happy to share with you information about the EU and their traceability efforts and also some domestic efforts at this, where they have looked very, very carefully at it, and—but it appears as if the technology is there. We have to look at to try to make it——

Ms. EMERSON. I appreciate that, Madam Chair——

Ms. DELAURO. And I'll get that for you.

Ms. EMERSON. Thanks.
Ms. DELAURO. I'm sorry. Mr. Farr.

AGENCY REORGANIZATION

Mr. FARR. I really appreciate you having this hearing and I appreciate your thought about reorganization. I think if we keep along the lines of the existing structure we're not going to be able to solve the problem.

When we look at the Federal Government you see this great, big label under the Department of Agriculture called the Food Safety Inspection Service, and they don't inspect a damn thing we're talking about, so it's one with a real limited jurisdiction.

It seems to me the players in this room and probably the most important one, is CDC, and they're not under the jurisdiction of this committee.

So we beat up on FDA when they're part of the problem, but not the entire problem and I just want to welcome the rest of my colleagues to food safety and recall issues.

I mean, when I was trying to get some help for spinach growers on a voluntary recall because we lost $200 million, which insurance didn't cover, there's no aid at all.

And one of our problems is that when there is a, kind of a false start here, it is as if our airplanes were bombing people and we're just saying sorry, we missed the target; we really didn't mean to wipe out the tomato growers, we thought that that was the target.

I think—well, I've learned a lot this summer. I mean, I had the E-coli and then I had the light-brown apple moth, ground zero for that; and then last summer in August, the forest in Big Sur caught on fire. It was the largest forest fire in history, and I saw how people respond and I do think that there is a need, as Dr. Levi talked about, for an incident command system here.

It certainly is much more effective because you have integrated the state, local, and federal folks in being able to know exactly what the shared responsibilities are at all levels; and whoever is the first—incident command, whoever is first at the incident and has the skills to handle it, stays as the commander, whether that be a little, local fire chief who can put out a $100 million fire.

AGENCY COORDINATION

So we have all this jurisdictional gigs and what I'd like to just suggest is that I think that we need a new thing. We need to have national protocols and standards, such as the California developer, the Leafy Green Marking Order. I mean, that is probably the best prevention protocols that we have in the nation right now for leafy greens, isn't it?

Dr. ACHESON. It is certainly very good, yes.

Mr. FARR. But that only applies to California?

Dr. ACHESON. Yes.

Mr. FARR. So the other states don't have to do that. So we need to standardize agreements like that as to best management practices. I think we need to create an incident command system where one can respond regardless of whether you are local government, state, or Federal Government as they do in fire. It is crazy to have these jurisdictional disputes.

I think we need to get the CDC in the room. In both cases, in all these cases, the CDC has alerted the FDA. The CDC says, here, it is tomatoes.

But FDA busts their tail going all over the country trying to find all of these tomatoes and giving these alerts and getting conditions. That doesn't matter. The news is out there. It is tomatoes, ladies and gentlemen. Don't eat tomatoes.

Out in California we didn't grow the kind of tomatoes that were infected. I have one guy lose his entire business, he and his kids. Four million dollars of their tomato business just sucked under and there is no insurance for it. There is nothing. It was a disaster, we get disaster relief.

So the CDC then comes along a month and a half later and says, oh, it is not tomatoes. We think it is now peppers.

What I really compliment you on, you know, once you found out it was jalapenos and it was probably from Mexico, the trace-back was pretty fast.

You went through a field in a foreign country and found the contaminated water. I thought it was remarkably fast that you could find that spot.

So there may be some problems with trace-back, but our growers are telling us you can trace back to a corner of the field. We want to know that is was my lettuce in my field, I can tell you that it came right over there out of that corner. That is how sophisticated because they are doing all of their packaging now with GPS mapping. That ought to be standard in this country.

There is no level playing field here. The growers that have to do the best management practices have to compete in a field where nobody else has to do that. And obviously there is not a fairness in the system and we've upgraded to protect health and safety, but we don't require everybody to abide by those rules.

I think we need to find out how CDC is making these decisions, because once they blow the siren and it is the wrong crop, as Mr. Murray pointed out, it is too late. That crop is wiped out.

So I think the Chair is really doing some good work here to try to figure out how do we find a system that does this: one that gets all parties on the same page, and I think that is an incident command, whether you take the CDC and FDA and Food Safety Inspection and growers, I think you have got to include the private sector in those protocols. I think you need national growing standards.

You need to have, as I said, an incident command system; and then, as Mr. Bishop pointed out, we need to have some recall damage coverage. So what if you make a mistake. If you find disease, I understand, or if Food Safety finds this disease in an animal, chicken or cow, and they orders those animals destroyed, they can compensate them for ordering them destroyed. The farmer doesn't have to, the grower doesn't have to, the rancher doesn't have to bear those costs.

But if you are a leafy green, unless you order it destroyed, and you don't because you don't have the authority, you have to go the states to get that, but if you said it would be great if you just recalled your product and they go out and spend all of their own money recalling their product for good public relations and there is

huge losses there, there is no way to get compensated. Insurance companies don't help and the Federal Government doesn't help.

So those are areas that I hope, as you design your legislation, that will go all the way from the people who analyze and blow the alarm, the CDC, to the people who end up having a trace-back and find out where it is actually coming from. I think there is a lot of work to be done.

Ms. DELAURO. Mr. LaHood.

LOSSES FOR TOMATO INDUSTRY

Mr. LAHOOD. Mr. Murray, thank you for being here. Could you tell us what your losses were?

Mr. MURRAY. We estimate our losses at slightly over $2 million.

Mr. LAHOOD. Do you know what the losses were for the tomato industry as a result of this huge mistake?

Mr. MURRAY. I know in Georgia it was over $17 million. I have heard different figures from other states so I would hate to quote those.

Mr. LAHOOD. How many states grow tomatoes out of the 50?

Mr. MURRAY. In the month of June you had Florida, Georgia, South Carolina, California, Alabama.

Mr. LAHOOD. So that is five?

Mr. MURRAY. Hm-mm.

Mr. LAHOOD. Would you say five times $20 million would be an accurate figure then?

Mr. MURRAY. No, I would say it is well more than that because Florida is much bigger.

Mr. LAHOOD. Okay. Do you have any idea what Florida losses were?

Mr. MURRAY. I have heard $200 million from Florida and $100 million from California.

Mr. LAHOOD. Did you receive any compensation for your loss?

Mr. MURRAY. No.

Mr. LAHOOD. Did you receive any kind of an apology from the Federal Government for the losses?

Mr. MURRAY. No.

Mr. LAHOOD. Dr. Acheson, do you think the Federal Government owes Mr. Murray an apology?

Dr. ACHESON. That is difficult to answer. I feel for Mr. Murray and I personally would like to apologize to him on my personal behalf because he was wrapped up in a situation that we are trying to avoid. I think the Federal Government in looking at the whole system as we discussed starts with the epidemiology, at the CDC local level. The FDA is then responding to that information. So does the FDA owe the farmers an apology? No.

You know, FDA was doing what FDA is supposed to do, reacting to public health information to protect public health, to jump on a trace-back as quickly as possible. We even went as far as trying to develop a program in this instance to try to help farmers that were in Georgia or in California or in these other states by developing this exclusion list, which was a challenge.

It was difficult. It was new. And I think there are a lot of lessons learned around this but fundamentally we shouldn't be going backwards. We need to be looking forward: How do we put in the sys-

temic solutions to minimize the likelihood of similar situations through better integration, horizontally and vertically.

Mr. LAHOOD. I appreciate the fact that you apologize to him, but I would like to know if you think the director or the head of some agency at least could have the courtesy to send Mr. Murray a letter and apologize for the fact that they screwed up his business. I am just asking you what you think about that.

Dr. ACHESON. Well, I think you have to question whether FDA, and I represent that agency——

Mr. LAHOOD. You know, I doubt if Mr. Murray cares if it is FDA, the CDC, the USDA, you know, I doubt if he cares. I am asking you if you believe that our government at some level, fairly high up, at least have the courtesy to send him a letter and say we are sorry that you lost your entire crop and we ruined your business.

Dr. ACHESON. I think there is still a question that is an important question as to whether this, indeed, was tomatoes to begin with. There is no evidence that it wasn't. We are dealing here with a situation where we know factually we have got salmonella on two different kinds of fresh produce: Serrano peppers, jalapeno peppers.

We know there are farms in Mexico that are growing all three types: Tomatoes and the two types of peppers. We know that all three are going through distribution centers. It is plausible that that original epidemiology was correct and we just never found a positive and we didn't find a positive on a farm.

I don't think we can say that it was wrong to implement tomatoes back at the beginning of this. I am not seeing any evidence to say that that was an incorrect assumption by the Center for Disease Control.

Mr. BISHOP. Will the gentleman yield?

Mr. LAHOOD. Of course I will yield.

Mr. BISHOP. You can't say that you were wrong but you can't say you were right, either.

Dr. ACHESON. You are right. That is absolutely correct. The only way to say we were right is to find a positive.

Mr. LAHOOD. Let me—are you done, Mr. Bishop?

Mr. BISHOP. Yes.

Mr. LAHOOD. Let me just say this, Dr. Acheson: I think that—well, I am not going to—let me say this, Madam Chair: I think what the committee should do is send a letter to the inspector general and ask for an investigation into how a whole industry could be ruined by people who apparently don't want to take the blame for it. I mean, the answer here is that no one really wants to take responsibility and it is unclear to Dr. Acheson whether tomatoes were or were not.

I mean, it is unclear to you. That is what you just said.

Dr. ACHESON. We don't have conclusive proof either way.

Mr. LAHOOD. I know. That is what you are saying. It sort of conflicts with what you said about 2:00 when we started this hearing.

Dr. ACHESON. In what way? Because if I have said——

Mr. LAHOOD. Because you said pretty conclusively that tomatoes were——

Dr. ACHESON. Now let me clarify this. This is important.

Mr. LAHOOD [continuing]. It sure as heck is important, very important.

Dr. ACHESON. Will you give me a moment? The point about this is that in mid-July FDA made an announcement that tomatoes that were coming onto the market in mid-July were safe to consume and were not implicated with the outbreak, thus clearing tomatoes from there forward. I did not mean to imply that FDA was saying that tomatoes were never responsible, and if I did, I apologize because that was not my intent.

Ms. DELAURO. And they can be responsible in the future then, according to you?

Dr. ACHESON. They could be.

Ms. DELAURO. The issue on tomatoes, it is open.

Dr. ACHESON. We have seen 13 significant outbreaks linked to tomatoes. It is not like we don't see problems with tomatoes. So I don't want to imply that I am saying that FDA thinks it never was tomatoes. We are basing this on the epidemiological data that we discussed followed by the trace-backs that we did looking for the positive tomato, looking for source, looking for a causative point. FDA did not find a causative point for Salmonella Saintpaul.

Mr. LAHOOD. This is the most flawed system that I have ever seen in 14 years of being involved in the Congress. This is a terribly flawed system, and for that alone Mr. Murray is owed an apology from you and from everybody that is involved; and secondly, I don't know how you ever compensate, but I am telling you, you all have ruined the tomato industry. You know that there are people in America today that won't eat a tomato, won't even look at one, because of some bulletin that was put out either by your agency or some other agency that said that they were contaminated. You all have ruined their industry and it will never recover. He will never be able to get back to where he once was.

Now you and others owe him an apology, and I appreciate the fact that you just apologized to him, not only for ruining his livelihood, but ruining the tomato industry and now to sit here and say one thing two hours ago and something else now is a little bit beyond belief. My time is up.

Ms. DELAURO. Mr. LaHood, you will recall the spinach outbreak—wasn't here when I said it. We are only back 60 percent. It is the same with bagged spinach, that people won't pick it up because, and again, it is about the system.

Let me just take this moment here to just to say to Mr. LaHood. This is the last hearing. Mr. LaHood has made a decision about his own life, about leaving the Congress, and there is probably no one finer with more integrity in the process than Ray LaHood. The subcommittee will miss you, but the Congress will miss you and the good work that you have done on behalf of the people who sent you here, put their trust in you, are going to miss that kind of representation. Mr. LaHood, thank you.

[Applause.]

Ms. DELAURO. Mr. Rothman.

LESSONS LEARNED

Mr. ROTHMAN. Thank you, Madam Chairman, and to thank you for holding this very important hearing.

Dr. Acheson, I do appreciate the necessity for relying on statistical probability unless the American people are ready to pay to

have an inspector inspect every single piece of food that enters the food chain. If that is the case and the American people want to pay for that, what do you think that would cost?

Dr. ACHESON. I dread to think what that would cost.

Mr. ROTHMAN. Give me an estimate.

Dr. ACHESON. Fifty billion.

Mr. ROTHMAN. Fifty billion. Do they inspect all of the—you thought the EU's food safety record was comparable to ours, about equal to ours. Do they inspect every single item that enters the food chain?

Dr. ACHESON. I don't believe they do.

Mr. ROTHMAN. I would love to know, and you used the words "lessons learned." What are the lessons learned? You have used the words "vertical integration" and others have said that the conclusion is only as good as the date that is provided to come to a conclusion. What would you do differently or what you have others do differently with the benefit of 100 percent hindsight, or 20/20 hindsight, with regards to the Salmonella Saintpaul situation?

Dr. ACHESON. FDA is currently going through a pretty deep process to investigate lessons learned around this, both internally what could we have done differently internally with the agency to make things flow more smoothly for improved communication; and likewise, what could we have done better——

Mr. ROTHMAN. I don't have much time. Do you have an answer or are you still looking into it?

Dr. ACHESON [continuing]. I can tell you a couple of key areas that need to be improved, and that is interaction across the federal agencies that are involved in food safety.

Mr. ROTHMAN. So what happens during that incident, if you will, that demonstrated to you a failure of interaction between federal agencies, that if it had been improved would have stopped some of the problem?

Dr. ACHESON. I think building trust and sharing data.

Mr. ROTHMAN. Okay, and if data were shared and there was greater trust, would that have affected the CDC's conclusion that you relied on?

Dr. ACHESON. No, I don't believe so. Well, that is a question you would have to address to CDC, frankly.

Mr. ROTHMAN. Well, I asked your opinion.

Dr. ACHESON. No, I think CDC's conclusion was based on the science that they were undertaking with the local inspectors.

Mr. ROTHMAN. So but maybe you don't have an answer yet. So the problem was, perhaps, and we should ask this of the CDC, but you seem to imply that their conclusion was not obviously wrong to you.

Dr. ACHESON. It was not obviously wrong to FDA, no.

Mr. ROTHMAN. Okay. But you don't know whether—well, maybe you do. Do you know whether the CDC's procedures in analyzing the data was correct?

Dr. ACHESON. I don't know the answer to that.

Mr. ROTHMAN. Perhaps, Madam Chairwoman, at some point we could find that out, maybe have some representatives from the CDC to find out. Perhaps we should be asking them what lessons

learned, if any, they have with regards to this incident, the Salmonella Saintpaul.

And also Mr. Taylor mentioned that there—I think it was Mr. Taylor or Dr. Levi, I'm sorry—they said there were three elements to the food safety in FDA and there is not one person in FDA who is in charge of all those three.

Dr. Acheson, or anyone else on the panel, quickly, do you believe that Congressional legislation is required to address that, or cannot simply the administration simply fix it? Appoint someone to oversee and take responsibility for those three areas of food safety responsibility within the FDA. Dr. Acheson.

Dr. ACHESON. I am not an attorney, but I would assume that that does not require Congress to do, although Congress could do it.

Mr. ROTHMAN. Thank you, doctor. I note that you testified that the FDA will be establishing, I think it is a great thing, a presence in five countries or regions around the world, which I think is terrific. Could you tell us what those five regions or countries will be, if you know?

Dr. ACHESON. China, India, Central/South America, Middle East, Europe. China, India, Central/South America, Middle East, and Europe.

Mr. ROTHMAN. And how many at this point, persons/staff people will you be sending to those five regions in total?

Dr. ACHESON. Approximately 40, slightly under.

Mr. ROTHMAN. That is probably the known world, so about 40 to cover China, India, Central/South America, the Middle East and Europe.

Dr. ACHESON. It is better than zero.

Mr. ROTHMAN. It is a start. Thank you, doctor. Thank you, Madam Chairman.

Ms. DELAURO. Ms. Kaptur.

Mr. KINGSTON. Let her go.

SICK AMERICANS

Ms. KAPTUR. Thank you, Madam Chair and thank you, ranking member, Mr. Kingston, I truly appreciate that. Gentlemen, welcome; not an easy hearing today. Let me ask you, for the record, how many Americans got sick from the outbreak? Anyone want to put that on the record? How many Americans got sick; how many died?

Dr. ACHESON. The latest numbers that I am aware of from Center for Disease Control are 1,453.

Ms. KAPTUR. All right.

Dr. ACHESON. Known to have got sick.

Ms. KAPTUR. Do we have any confirmed deaths?

Dr. ACHESON. I believe there were two deaths that were associated with this but not directly causally related, but that is a question to direct basically to CDC.

Ms. KAPTUR. Does anybody have a calculation of the cost to our health system of those who became ill?

Dr. ACHESON. I don't.

Ms. KAPTUR. Who would?

Dr. ACHESON. CDC, perhaps. I don't know.

Ms. KAPTUR. All right. And Mr. Murray, thank you so much for your presence today. You have given us some measure of the cost to the agriculture industry in our country, which is hundreds of millions of dollars. This is something major, no doubt about that.

Let me ask this question: The produce distribution center, Agricola Zaragoza, that was mentioned in your testimony Mr. Acheson, is somewhere in Texas; who owns it? How would we find out who owns it?

Dr. ACHESON. Can I refer that to my colleague from the Office of Regulatory Affairs? Do we know that? No, we don't know that but we can find out.

Ms. KAPTUR. Do you maintain those records of the company, the CEO, the profile of the company? Is it an American-owned company, the distribution center?

Mr. SOLOMON. We can get that for you.

Ms. KAPTUR. All right. I am very interested in knowing the company. I am interested in knowing its assets. I am interested in knowing if it is a U.S.-based company; is it a Mexican company. What is it? I would like to know something about this company.

Mr. SOLOMON. We can get you—we don't have——

Ms. DELAURO. Sir, you need to just identify yourself for the record.

Mr. SOLOMON. This is Steve Solomon from the FDA. We can get you the ownership information.

Ms. KAPTUR. All right, thank you very much. As much detail as you have on it; do they have a board of directors; are they publicly held; are they privately held? These are all questions that I have.

Dr. ACHESON. We will provide you with whatever we have, but we may not have all of the answers.

[The information follows:]

The following information describes the distribution chain associated with the contaminated pepper identified in a McAllen, Texas warehouse.

A U.S. company, Agricola Zaragoza, Incorporated, located in McAllen, Texas, is a warehouse that receives, holds, sorts, and distributes fresh raw produce, including jalapeño peppers and Serrano peppers, tomatillos. FDA does not have additional information on Agricola Zaragoza's business assets or the company's corporate or business status.

Agricola Zaragoza S.A. de C.V. is a Mexican-based company owned under a partnership between Mr. Raymundo Cavazos Cavazos, Mr. Juventino Lozano Cavazos, and their spouses, Mrs. Sofia Rodriguez Garza and Mrs. Celina Cavazos Garza. The company is located at Lorenzo Cavazos Tamez No. 600 NTE; Allende, N.L. C.P. 67350. The Mexican-based company is the parent of the American company, Agricola Zaragoza, Incorporated. The Mexican-based company is a packer, shipper, and warehouse of raw jalapeno and serrano peppers. This company is also a warehouse and shipper of other raw agricultural commodities such as onions, carrots, cabbage, and tomatillos.

FDA's main objective in Mexico was to immediately determine the distribution and production chain and the source of the implicated peppers. With this information, FDA could work to break the chain of transmission and stop the ongoing outbreak and thereby protect the public health. FDA collected company profile information – distribution, products, and most responsible persons/owners – necessary increased surveillance, prepare targeted press releases and health advisories to alert consumers, wholesalers, and retailers of the possibility of a contaminated product, and provide recommendations for prompt avoidance and removal of the product to prevent additional exposure.

The McAllen, Texas warehouse received product from Horticultores Unidos de Allende S.P.R. de R.L. Horticultores Unidos de Allende S.P.R. de R.L is a partnership between eight associates that include Messrs. Raymundo Cavazos Cavazos and Juventino Lozano Cavazos who own Agricola Zaragoza S.A. de C.V. This company has the same business address and office as Agricola Zaragoza S.A. de C.V. The names of the six other associates are Belisario Cavazos Flores, Francisco Sierra Garcia, Gerardo Reyna Aguirre, Juventino Cavazos Cardoso, Roel Cavazos Tamez. and Ruben Garza Cardenas.

Horticultores Unidos de Allende S.P.R. de R.L. received product from Pedraza Distribuidora. Pedraza Distribuidora Dba Fidel Pedraza Obregón is a broker and distributor of various raw commodities under the sole ownership of Fidel Pedraza Obregon and is part of the Pedraza Distribuidora network. However, Mr. Obregon stressed that each warehouse under the Pedraza Distribuidora is independently owned and operated. Pedraza Distribuidora Dba Fidel Pedraza Obregón is located at Mercado de Abastos-Estrella, Ave. Los

Angeles No. 1000, Bodega 321 Col. Garza Cantu, San Nicolas de Garza, Nuevo Leon, Mexico C.P. 66480.

Pedraza Distribuidora Dba Fidel Pedraza Obregón received product from Campo Blanco S.A. de C.V. Campo Blanco S.A. de C.V., aka "Antonio Ruan," is a grower, packer, and distributor of various raw commodities including jalapeno, serrano peppers, and roma tomatoes in the State of Tamaulipas, Mexico under the sole ownership of Mr. Antonio Ruan. According to Mr. Ruan, there are no related firms. It is located at Juan Ignacio Aldama #35, Barrió Las Piedras, Tula, Tamaulipas, Mexico, C.P. 879000.

PRODUCE DISTRIBUTION CHAIN

Ms. KAPTUR. All right. So these peppers somehow got up from Mexico into that distribution center so they were the recipient point for the contaminated material, correct?

Dr. ACHESON. One of the recipient points, yes.

Ms. KAPTUR. One of them. There could be others but we don't know.

Dr. ACHESON. Correct.

Ms. KAPTUR. Then, according to your testimony, the farm it was traced back to was, well, you said an irrigation ditch from a farm in Tamaulipas, Mexico. Have we traced this back to a specific farm?

Dr. ACHESON. We have traced the—let me be very specific here. The jalapenos that were positive at the McAllen, Texas distribution center actually trace back to a different farm through a distribution center in Mexico.

When we went to the distribution center in Mexico we discovered they received peppers from two predominant places, several, but two main ones. The jalapenos from McAllen traced back to one of them. We went there. We sampled. We did not find the outbreak strain. We went back to the other farm and found the outbreak strain on Serrano peppers and in the irrigation water.

Ms. KAPTUR. All right. So can you actually go back to the farm itself?

Dr. ACHESON. We did. Yes, we physically went back.

Ms. KAPTUR. Who owns that farm? Is it a private family or is it an agribusiness?

Dr. ACHESON. I don't know.

Ms. KAPTUR. Can we find that out?

Dr. ACHESON. We will do our best to provide whatever we got on that.

[The information follows:]

As part of its investigation and product tracing process, FDA identified the distribution channels for peppers that were shipped to the U.S. These distribution channels trace back to farms in Mexico. In addition, as part of a sample and analysis effort, we were also able to identify one particular farm in Mexico that had a sample that tested positive for the salmonella (St. Paul) that was implicated in the outbreak.

PRODUCE TRACE BACK

Ms. KAPTUR. All right. We want the same information on the business on the Mexican side.

H.R. 2997

I have a bill, H.R. 2997, that basically would get you compensation in the U.S. federal court system, Mr. Murray, because we have no international tort system right now that covers this kind of abuse. And this bill would make importers responsible through a certification process that would work through our country, the federal agency that would receive the commodities that are inspected on the U.S. side, we would end up in the federal courts of this country, because right now you don't have the same right that you would have to sue or to get damages from a company that you are doing business with in this country.

And I think the food companies just love it because they absolve themselves of all liability. This is a great system to hide behind the standards of the 19th century and it is exactly what they are doing and they are outside the bounds of our court system.

So I just want to say to anybody in the audience, pay attention to H.R. 2997. It is a great bill. It should pass but it hasn't made it out of this Congress yet because there is a lot of pressure against it.

COOL—COUNTRY OF ORIGIN LABELING SYSTEM

I wanted to ask: the COOL, the Country of Origin Labeling System, if that had been in place would that have made a difference?

Dr. ACHESON. This is David Acheson. It would have helped but it wouldn't have solved the problem.

Ms. KAPTUR. Okay, because the foods were blended?

Dr. ACHESON. The foods were blended and simply knowing the country of origin does not take you back to the farm or the distribution centers or anything in between.

Ms. KAPTUR. Okay, let me ask this question, Mr. Acheson: what is your inspection budget? What is the total budget you have to put these people all over the world and try to protect the American people's health?

Dr. ACHESON. I would have to get back to you with the actual number in which it includes the base and the new monies.

[The information follows:]

The FY 2009 Congressional Justification requested FDA with $619.612 million for Protecting America's Food Supply. Later that fiscal year, in June 2008 Congress provided an additional $72.295 million for FDA's Food Protection Plan. This Supplement included an additional $12.2 million in the Foods budget to establish FDA offices overseas.

INSPECTION BUDGET

Ms. KAPTUR. Okay, but who in the end pays for your budget? Where do you get your money?

Dr. ACHESON. Taxpayer.

Ms. KAPTUR. From the taxpayer. You don't get it from the company, do you?

Dr. ACHESON. Not in the least.

Ms. KAPTUR. Okay, so the very same people that are doing damage to us are then making money on the private side at unbelievable levels, absolving themselves from responsibility to operate under a rule of law in this country, as you do, Mr. Murray; and then they put all of their damages at the public trough, even in terms of the health cost to our country, whether it is the damage to this industry, and it is like nobody has responsibility. It is a system that absolutely abrogates responsibility to those responsible. And I am trying to figure out, that is why I want to know who these companies are.

I want to make them pay. I will talk about them on the floor of Congress. I will say what they did to your industry, but what is interesting is that nobody here today, amazingly, even asks those questions.

What is happening to the rule of law on this continent as a result of these trade regimes that we have gotten ourselves into that es-

sentially are erasing a century of effort to build a society that has some level of civility and responsibility. Thank you very much.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chair. I wanted to submit for the record, this is a public health questionnaire from the Minnesota Department of Health, and Dr. Acheson had mentioned that one of the things they have to do on the front line is have the individual county and state health departments—I can pass this around. I am just assuming this is typical.

This is a 23-page questionnaire. As you go through this, you can see why it is so difficult. There is so much shoe leather that has to be expended on it. I just thought members of the Committee would want to see one of those if they have not.

Ms. DELAURO. Without objection.

[The information follows:]

Interviewer name:_____
Date of interview: __/__/__

Standard foodborne disease outbreak case questionnaire

Introductory note

This questionnaire is an adaptation of a standardized questionnaire developed by the Minnesota Department of Health. It is intended for use as a template for investigating foodborne disease outbreaks. The content or format may require modification in accordance with the circumstances of a particular outbreak. Some aspects of the questionnaire you may wish to customize include:

1. If you suspect a food item that does not appear in this questionnaire, add questions about this food.
2. If a pathogen has been identified, consider adding or altering clinical questions and specifying the incubation period accordingly.
3. Decide how to code onset times when respondents give nonspecific responses such as "morning" or "am."

Part I. Demographics/Introduction:

Pt. Name: _____ DOB: ____ / ____ / ____
Age: _____ years
Address: _____
Home phone: _____
City: _____ County: _____

Zip: _____
Parent's Name (if child) _____
Occupation: _____
Work Phone: _____
Name and Address of Employer, daycare, school: _____

Hello. My name is _____and I'm calling from the _____ State Health Department. I'm calling because there have been several cases of _____ in our community and we are working to identify the source of infection, so we can prevent additional illness in the community. We understand that you are one of the people who had this illness. I would like to ask you some questions about your illness and foods that you ate before becoming ill, that will help us in this work. This will take about ____ minutes. Can we go ahead?

If no: Is there a convenient time I can call you back? Day _____
Time ___:___ am pm

Interviewer name:_____
Date of interview: ___/___/___

Telephone: _____

Who was interviewed? • Patient • Other person

Interviewer name:_____
Date of interview: ___/___/___

Part II. Clinical information

Which did you experience first: • vomit • diarrhea

Date of onset of vomit or diarrhea (whichever occurred first): ____ / ____ / ____
Onset time: *Circle closest hour. For onset times after midnight, double-check the onset day/date!*

1 am	7 am	13-1 pm	19-7 pm
2	8	14-2	20-8
3	9	15-3	21-9
4	10	16-4	22-10
5	11	17-5	23-11
6 am	12 noon	18-6 pm	24-12 midnight

Are you still experiencing vomit or diarrhea? Y N

Date of last day of illness with vomit or diarrhea: : ____ / ____ / ____
Time of last episode of vomit or diarrhea: ____:____ AM PM

Read questions exactly as written below. Circle Y for "yes," N for "no" and DK for "don't know, can't remember, not sure" etc.

Did you have:

Nausea	Y	N	DK
Vomiting	Y	N	DK
Diarrhea	Y	N	DK
If yes:			
Maximum number of stools in a 24-hour period: _____			
Bloody diarrhea	Y	N	DK
Abdominal cramps	Y	N	DK
Fever	Y	N	DK
Chills	Y	N	DK
Headache	Y	N	DK
Body aches	Y	N	DK
Fatigue	Y	N	DK
Constipation	Y	N	DK
Other:	Y	N	DK_____
			___

Interviewer name:_____
Date of interview: ___/___/___

Interviewer name:_____
Date of interview: ___/___/___

Did you see a healthcare professional, such as a doctor or a nurse?
Y N When? ____ /____/ ____

Were you hospitalized overnight? Y N
Where? _____

Was a stool culture done? Y N DK
Results: _____

Did you take any prescription medications for this illness? Y N DK
If yes, what medications? _____

Did anyone in your household have a similar illness? If yes, who?
_____

Do you know of anyone else with a diarrheal illness during the past week? Y N DK
If yes, who? _____
Telephone: When? ____ / ____ / ____

Part III. General information

Did you attend a large gathering the week before your illness? (e.g., wedding reception, showers, church events, clubs, school events, athletic events, office parties or banquets, parties, festivals, fairs) Y N

If yes, what events?
Event 1: _____location:_____ When? ____ / ____ / ____
Event 2: _____location:_____ When? ____ / ____ / ____
Event 3: _____location:_____ When? ____ / ____ / ____
Event 4: _____location:_____ When? ____ / ____ / ____

Do you know anyone else in your neighborhood/school/office/business/health club/church/synagogue etc. with the same illness? Y N
If yes: Where?_____
How many people?_____ Name_____ Tel_____
Name_____ Tel_____
Name_____ Tel_____

Interviewer name:_____
Date of interview: ___/___/___

Did you travel anywhere during the seven days before your illness? Y N
If yes, where? _____When? ____ / ____ / ____ to ____ / ____ / ____
If airline travel, what airline? _____
Outgoing flight no. _____ Return flight no._____
Foods eaten on plane going there: _____
return:_____ If you stayed at a resort please provide resort name:_____
If cruise ship, name of ship_____ Destinations _____

Have you had contact with children in a childcare setting during the seven days before illness? Y N
If yes, when: ____ / ____ / ____ Name of facility:
_____
Location_____Phone: _____
Are you aware of any other illness in the daycare? Y N DK

During the seven days before your illness, did you have any pets at home, have contact with household pets elsewhere, or visit a household with pets? (including reptiles) Y N
If yes, what type of pets? _____
If your own pets, where do you buy your pet foods? _____brand:
_____

Did you live on a farm, visit a farm, or visit a petting zoo in the seven days before your illness? Y N

If yes: what kind of animal(s) did you have contact with?_____
When? ____ / ____ / ____ Where?
_____

From what sources of water did you drink during the seven days before your illness?

Municipal tap water	Y	N	DK
Private well water	Y	N	DK
Untreated surface water (river, pond, lake)	Y	N	DK
Bottled water	Y	N	DK
Other _____			

Did you drink any untreated/raw water during the seven days before your illness? Y N
If yes, where? _____

Did you swim during the seven days before your illness? Y N

Interviewer name:_____
Date of interview: ___/___/___

If yes, where?	Ocean/sea	Y	N	*If yes:* Location_____
	Pool	Y	N	*If yes:* Location_____
	Lake	Y	N	*If yes:* Location_____
	Pond	Y	N	*If yes:* Location_____
	River	Y	N	*If yes:* Location_____
	Other	Y	N	*If yes:* Location_____

Where did you shop for groceries consumed the week before your illness?

Store name: _____ Location:_____
Store name: _____ Location:_____
Store name: _____ Location:_____
Store name: _____ Location:_____

Part IV. Specific food questions

In the week before your illness, did you eat any dish containing store-purchased ground beef (that is, cooked at home)? I'm referring either to bulk ground beef or pre-made beef patties purchased in a store by you or a relative/house-mate? Y N DK

If yes: where purchased? _____
When?_____
What was the brand name?_____
What type of ground beef was it (extra lean, lean, % fat, etc.)?_____

In the week before your illness, did you consume meat originating from any place other than a grocery store or restaurant, such as from hunting, a butcher shop, custom butchery? Y N

Where: _____ What:

_____

In the week before your illness, did you make or eat any dish that involved breaking and mixing four or more eggs? Y N DK

If yes: Where did you buy the eggs?_____ When?

_____
What was the brand?_____

Have you done any baking that used a raw egg in the preparation? Y N
Did you taste any of the uncooked batter? Y N

Interviewer name:_____
Date of interview: ___/___/___

Did you drink any unpasteurized milk, or cheeses such as queso fresco made with unpasteurized milk during the week before your illness? Y N

If yes, where? _____

Part V. Restaurants Exposures:

In the seven days before your illness, did you eat at any of the following types of commercial food establishment?

Restaurant	Y	N	DK
Fast-food establishment	Y	N	DK
Cafeteria	Y	N	DK
Deli	Y	N	DK
Read-to-eat food served in a supermarket or department store?	Y	N	DK
Street-vended food	Y	N	DK
Concession stand at sporting event	Y	N	DK
Snack bar	Y	N	DK
Gas station	Y	N	DK

Please list all such food establishments where you ate during the seven days before you became ill.

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Interviewer name:_____
Date of interview: __/__/__

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Interviewer name:_____
Date of interview: __/__/__

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Name: _____ date: ____ / ____ / ____
Address: _____ time: _____
Foods eaten:
_____
_____
_____

Interviewer name:_____
Date of interview: ___/___/___

Part VI. Open-ended food history:

List the location of the meal and foods eaten within _____ days before onset of symptoms. [Use the incubation period applicable to the agent/disease under investigation, e.g.,

Bacillus cereus: 1-24 hours | *E. coli* O157:H7: 2-7 days | *Staphylococcus*: 30 min - 8 hrs | Viral agent: 0-3 days
Campylobacter: 1-10 days | *Salmonella*: 0-5 days | *Vibrio parahemolyticus:* 0-2 days
Cryptosporidium: 1-12 days | *Shigella* 0-3 days

If a specific agent is not suspected at the time of interview, ask about the day of illness and the four days before illness.

Days before illness onset: 0 (Day of illness onset)	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
	Breakfast	•	•	_____	_____
Day of week:_____	Lunch	•	•	_____	_____
Date: ___/___/___	Dinner	•	•	_____	_____
	Other	•	•	_____	_____

Days before illness onset: 1 (Day before illness onset)	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
	Breakfast	•	•	_____	_____

Interviewer name:_____
Date of interview: ___/___/___

Day of week:_____

Date: ___/___/___

Lunch • • _____ _____ _____

Dinner • • _____ _____

Other • • _____ _____ _____

Interviewer name:_____
Date of interview: ___/___/___

Days before illness onset: 2	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
	Breakfast	•	•	_____	_____
Day of week:_____	Lunch	•	•	_____	_____
Date: ___/___/___	Dinner	•	•	_____	_____
	Other	•	•	_____	_____

Days before illness onset: 3	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
	Breakfast	•	•	_____	_____
Day of week:_____	Lunch	•	•	_____	_____
Date: ___/___/___	Dinner	•	•	_____	_____
	Other	•	•	_____	_____

Days before illness onset: 4	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten

Interviewer name:_____
Date of interview: ___/___/___

Day of week:_____

Date: ___/___/___

Breakfast	•	• _____ _____
Lunch	•	• _____ _____ _____
Dinner	•	• _____ _____
Other	•	• _____ _____ _____

Interviewer name:_____
Date of interview: ___/___/___

Days before illness onset: 5

Day of week:_____

Date: ___/___/___

Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
Breakfast	•	•	_____	_____
Lunch	•	•	_____	_____
Dinner	•	•	_____	_____
Other	•	•	_____	_____

Days before illness onset: 6

Day of week:_____

Date: ___/___/___

Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
Breakfast	•	•	_____	_____
Lunch	•	•	_____	_____
Dinner	•	•	_____	_____
Other	•	•	_____	_____

Days before illness onset: 7

Meal	Ate at home	Ate outside of home	Outside location	Foods eaten

Interviewer name:_____
Date of interview: ___/___/___

Day of week:_____

Date: ___/___/___

Breakfast	•	• _____ _____
Lunch	•	• _____ _____ _____
Dinner	•	• _____ _____
Other	•	• _____ _____ _____

Interviewer name:_____
Date of interview: ___/___/___

Appendix: Specific food consumption history:

Please indicate for each of the food items listed below whether you **definitively** ate it, **maybe** ate it, **definitively did not** eat it, and whether it was cooked or uncooked, during the seven days before you became ill. The time period we are talking about is from _____, ___/___/___ to _____, ___/___/___

Check the appropriate box; if "definitely ate" or "maybe ate" fill out remainder of columns.

Food item	definitely	maybe ate	definite NOT	how prepared	brand	store	date bought	date eaten
Dairy								
Milk								
Buttermilk								
Sour cream								
Cottage cheese								
Cheese								
a. shredded								

Interviewer name:_____
Date of interview: ___/___/___

b. processed sliced								
c. block								
d. string								
e. curds								
Ice cream								
Frozen dessert								
Yogurt								
Meat, poultry								
Chicken								
Turkey								
Hamburger								
Hamburger as ingredient								

___What kind of dish?_____

Hamburger: ___raw, ___rare (red in middle), ___medium (pink in middle), ___well done

Other beef								
Pork								
Lamb								

Interviewer name:_____
Date of interview: ___/___/___

Sausage								
Fish								
Shellfish								
Other meat/poultry/fish								

Eggs

Any egg								

fried: ___sunny-side up ___over easy ___fried hard
scrambled: ___scrambled-runny ___scrambled-dry
boiled: ___soft-boiled ___hard-boiled
omelette ___omelette-runny ___omelette-hard

Fruits (fresh, not canned)

Oranges								
Other citrus								
Pears								
Apples								
Other tree fruit								
Strawberries								

Interviewer name:_____
Date of interview: ___/___/___

Other berries								
Grapes								
Bananas								
Mangoes								
Cantaloupe								
Water melon								
Other melon								
Exotic fruit (specify)								

Vegetables (fresh)

Prepackaged salad								
Lettuce								
Iceberg								
Red leaf lettuce								
Romaine lettuce								
Mesclun greens								
Spinach								
Cabbage								

Interviewer name:_____
Date of interview: ___/___/___

Tomatoes								
Cucumbers								
Peppers								
Asparagus								
Celery								
Carrots								
Radishes								
Pea pods								
Egg plants, squash								
Onions								
_Green								
_Other (white, Spanish)								
_Broccoli								
Fresh herbs								
Mushrooms								
Cilantro								

Interviewer name:_____
Date of interview: ___/___/___

Sprouts (e.g. on sandwich)								
__Alfalfa sprouts								
__Bean sprouts								
Peanut butter								
Salsa								
Dips								

Salads

__Green (tossed)								
__Caesar salad								
__Fruit salad								
__Pasta salad								
__Potato salad								
__Cole slaw								
Other Salad								

Beverages

Apple juice or cider								
Orange juice								

Interviewer name:_____
Date of interview: ___/___/___

Other fruit juice								
Iced tea								
Special teas, herbal drinks								

Mr. KINGSTON. The thing that is interesting about it is I could see why there would be some push for uniformity on those things.

Dr. Acheson, you have been great, you have taken it on the chin. You have been a gentleman about it. I wanted to ask you this.

Ms. Kaptur and Mr. Bishop and I are on the Military Committee. We frequently see generals and colonels getting basically fired for something that happened down rank from them, something that they might not have had any control over, but it happened under their watch, and in most cases, it was not a malicious kind of thing but the results were the wrong thing.

In the FDA, what happens from here if somebody has made a colossal mistake, $100 million, maybe a $200 million mistake? Who takes it on that? Who is the general?

Dr. ACHESON. I do not think there is any evidence that FDA made any errors. As we heard earlier, I think when we got the green light, go trace this back through a complex, one up, one back system, small producers, lots of paper, we went back in a month on the tomato side and then in the next month, we went back on the peppers from sick patients to a farm in a foreign country.

I think FDA did an excellent job. I wish it were quicker. Obviously, the preventative controls are going to make it less likely we have to do it in the first place.

I do not think FDA made any errors.

Mr. KINGSTON. I appreciate that answer. Let me ask this then. Who squeezed the trigger on shutting down the tomato industry for the Summer and caused Mr. Murray to lose—what did you say?

Mr. MURRAY. Enough tomatoes to feed 90,000 people for a year.

Mr. KINGSTON. That was $2 million worth?

Mr. MURRAY. No. The $2 million is also what I lost on produced bales.

Mr. KINGSTON. I know you have already told me before this meeting in a private conversation, which I think it is okay to allude to because it just sort of clarifies, Mr. Murray said, you know, FDA was doing their job and I understand that. He was not taking pot shots at the FDA.

Mr. Murray, would you say that it was the FDA's fault? Who is at fault here? In the sense that we see over and over again when there is a breakdown in the military order of things, they seem to—maybe too quickly—they do seem to find some place where the buck stops, somebody who is accountable. Who is accountable?

Mr. MURRAY. When I wrote this, a lot of this, I did not know. It sounds like CDC just took their best guess that it was probably tomatoes. There has been a report out within the last month that there have been many shipments of peppers turned back at the Border because they had Salmonella on them.

I just wonder why anybody did not look at that. Why did they just say tomatoes. Tomatoes are the second most likely consumed vegetable that there is. I guess they just assumed that it is probably tomatoes.

That is like going to the doctor with a pain in your chest and he just takes your heart out. [Laughter.]

Mr. BISHOP. Will the gentleman yield?

Mr. KINGSTON. Yes.

Ms. DELAURO. Will the gentleman yield for one second?

I think it is important because you raise the issue of the Mexican peppers. This is very, very interesting because this is in public documents.

FDA seemed to be ignorant of information it had in its hands about risk with Mexican peppers and did not act on the information earlier. The AP reported that FDA inspectors had repeatedly turned back filthy, disease-ridden shipments of peppers from Mexico in the months before a Salmonella outbreak had sickened 1,400 people, was finally traced to Mexican chiles.

No action was taken. Since January alone, 88 shipments of fresh and dried chiles were turned away. Ten percent were contaminated with Salmonella. In the last year, eight percent of the 158 intercepted shipments of fresh and dried chiles had Salmonella.

Dr. Acheson, you told reporters at the time, and it is AP, that "Peppers were not a cause for concern before they were implicated in this Salmonella outbreak. We have not typically seen problems with peppers."

I did not make this up. I did not make this up. Ten percent of those rejected had Salmonella. It was likely they could have caused this disease.

This is the left hand not knowing what the right hand is doing. Why did we not view this as a problem and something that ought to be looked at?

I do not mean to impinge on your time, Jack. I think this is very relevant to this issue.

Dr. ACHESON. Will you allow me to respond to that?

Ms. DELAURO. Sure. Did you take any action with regard to these Mexican peppers prior to this outbreak?

Dr. ACHESON. Let me explain to you the context of this conversation that we had with the media on this. The question was framed in the context of has FDA seen problems in the past with fresh peppers from Mexico. The answer to that was typically no.

As you pointed out, we have found ten positive Salmonella samples from imported peppers from Mexico. Eight—seven of those are on fresh peppers that were part of the investigation that was initiated following the identification of peppers that were linked to this outbreak.

Of those ten Salmonellas, seven of them were ones we found once we started to seriously look at imported peppers.

Ms. DELAURO. But this goes back—my point was that in January, 88 shipments of fresh and dried chiles were turned away. Ten percent were contaminated with Salmonella.

Dr. ACHESON. No.

Ms. DELAURO. This is a lie?

Dr. ACHESON. No. Ten percent of the total shipments were contaminated with Salmonella, but seven out of those ten were sampled subsequent to the initiation of an assignment linked to this outbreak.

They were fresh and they were ones that we found as we were beginning to ramp up. We needed to be looking at fresh peppers from Mexico, because we had concerns.

Ms. DELAURO. But you had information in January.

Dr. ACHESON. We had information that dried peppers were rejected at the Border because of labeling issues, because of lack of processing issues, some of them were designated—I have a breakdown of them here.

Twenty-nine were detained as a result of sanitation issues. Twenty-nine were refused because of the registration process around the canning issue. Twenty-six were refused because of pesticide residues. Three were refused because of labeling violations. As I said, ten were refused because of Salmonella, and of those ten, seven were ones that came in after we started to intensify our investigation looking for peppers.

The context of that conversation with the media was around have we seen problems with fresh peppers from Mexico before, and the answer was we had not.

You are right. We have had 88 shipments of peppers refused. The vast majority through nothing to do with Salmonella. That is out of a total, in that time frame, of about 150,000 shipments.

Ms. DELAURO. I do not know where they got this number. This is August 18, 2008, Associated Press, that ten percent were contaminated. That is of the 88 shipments. Ten percent were contaminated with Salmonella. In the last year, eight percent of the 158 intercepted shipments of fresh and dried chiles had Salmonella.

That is what is reported. It would seem to me if you have peppers coming in that have Salmonella, dried or fresh, I would say peppers. Light bulb goes off, potential problem. Eighty-eight shipments stopped. Some percentage, Salmonella. Maybe, whoa, this is the cause here, so that you put the pieces together and you come up with something or it may not be, but at least it gives you a road to go down. And we had the information months in advance, back to January.

That seems to me to be quite frankly a dereliction of duty. Jack, I would just say to you, oftentimes it is not the generals that go. My experience recently is it is the guys at the bottom and the gals at the bottom go before the generals go. They are blamed for the problems and not the folks at the top.

In any case, Dr. Acheson, I think we have some information here that says CDC—we can talk to CDC—someone was asleep at the switch here. That is the system. The system is wrong, is broke.

Mr. KINGSTON. Reclaiming my time. I do not know if we want him to have a shot at that. What do you think? Go ahead.

Dr. ACHESON. I was simply going to say that three Salmonella positives prior to this outbreak, out of 150,000 shipments, is what we are talking about. That is not something that FDA would jump all over because we do not have the resources.

Three Salmonella positives all in dried peppers, not fresh, prior to this outbreak. Subsequent to the outbreak, we found seven more because we intensified looking and we continued to maintain that high intensity. We are still looking and we are finding positives, and we are dealing with them as we find them.

Mr. KINGSTON. How many out of those ten—what was the total volume? You found three before, seven after. What was the total volume during that period of time?

Dr. ACHESON. About 120,000/150,000 shipments of peppers, one sort or another. This is not just fresh peppers. This is canned peppers, all kinds of things.

Mr. KINGSTON. Actually, that is a good record. I hate to say it at this meeting, I might get thrown out by members of both parties. That is not bad.

However, I would say that underscores my opening statement that the private sector has been doing a very good job and that I am very hesitant to give the Federal Government more money and more power based on some of the dissatisfaction that we have been hearing today.

For example, following a business model, somebody would have been accountable for this. There does not seem to be one. Maybe Rosa's legislation could move us in that direction. I do not know.

I go back to what Mr. Levi said, have a "no year" funding before we know exactly what the money is we are investing in, and I feel like we should not have already appropriated that $150 million.

Let me yield back.

Ms. DELAURO. Thanks for your indulgence.

I wanted to just—first of all, I will put into the record, if I can—we did have a GAO report that did look at the European Union and looked at several other countries. The data here, the European Union, and I think it is Japan, Canada, thinking about what they have done in terms of food safety.

GAO REPORT—INTERNATIONAL FOOD SAFETY

They look at farm to table. They look at focuses on prevention rather than crisis management. They have created safeguards, separated government bodies to carry out risk assessment activities from those of risk management decisions. They have cooperative arrangements between government veterinarians and public health officials. They have mandatory recall. They have mandatory traceability.

We cannot seem to get there for some reason. At the core of all of these systems is mandatory traceability. It is mandatory recall, and it is the cooperative relationship between the states.

Rather than moving down that line, and I would ask my colleagues here, the FDA has come forward with ten pieces of new authority related to food safety.

What I wanted to try to do, and this is a little bit different, is to ask our panel, Mr. Levi, Mr. Taylor, Mr. Murray, to comment. This is new legislative authority that you have asked for subsequent to this outbreak or prior to the outbreak.

I would also add that in terms of that authority, there is nothing from farm to fork. There is no mandatory traceability. There are no performance, preventive performance standards. I do not know that it addresses these cooperative arrangements, et cetera.

I would like to just read what it is, and I can do it for a few minutes and then come back around if people have burning questions, but I thought it would be interesting to get some commentary, Dr. Acheson, from you on this, and then from our panelists, on whether or not we are moving in the right direction for new authorities or we should be going someplace else and rethinking what new authorities the Agency ought to be given.

I am committed to looking forward and how we can construct an Agency here.

Just so you know, it is pages 21 and 22 of Dr. Acheson's testimony. First out of the box is "Allow the FDA to require preventive controls against intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain."

Is there anything further you want to say about that, Dr. Acheson, before I ask others to comment on it?

Dr. ACHESON. Only so there is clarity about what we are focusing on there. It is focused on food defense.

Ms. DELAURO. Mr. Levi.

Mr. LEVI. I guess the observation I would make is that each of these authorities makes sense. The question is what is the larger context in which they are going to be framed, and that would be part one and part two, if we are thinking about integrating food safety functions, this is only addressing the FDA portion of what happens.

Going back in the time line, if FDA entered the scene at the end of May, the problem started in the middle of April, so we need to make sure that not only the FDA has the authority or this new entity has the authority, going from the very start of an outbreak, whether individually or together. I personally do not have any issues.

Mr. TAYLOR. I have a few. It is not on that first one, Madam Chairwoman. Two broad points. One is on the second item, which is to authorize FDA to issue additional preventive controls for certain high risk foods.

FDA has authority now on a case by case basis to require preventive controls. It has done it for seafood.

This provision as it was formulated in the food protection plan would actually limit FDA's authority, current authority, to issue preventive control regulations because it would require the finding of significant recurring adverse health consequences or death before preventive controls could be put in place.

To me, that is not a preventive strategy. That is a reactive strategy. Most of the legislation that is pending would require preventive controls across the board in food facilities, case by case on the farm for commodities on a risk basis, but in terms of food facilities, processing facilities, it would be a comprehensive requirement.

I think that is frankly better policy. If I could add one more point on that, it picks up on Mr. Kingston's observation about industry responsibility for food safety and the fact that the Government cannot make it safe, industry is responsible, and it is the industry that does produce a by and large safe food supply.

I think there is really a lot of common ground on that principle. In fact, the preventive control legislation that is pending is really all about recognizing and codifying that industry responsibility for food safety.

As Mr. Murray indicated, there are many companies who are using preventive controls today and are applying practices and standards that actually exceed current Government requirements.

The problem is that not everybody does, and in order to have a system that is really fair and a level playing field, and that the

public can have confidence in, I think there is a lot of agreement that we ought to have comprehensive preventive controls.

Really again embracing the industry responsibility for food safety.

Mr. BISHOP. Mandatory controls?

Mr. TAYLOR. Mandatory controls; yes, sir.

Another point at a broad level has to do with imports, which I think are not addressed here strongly enough, and I think we have rightly had some points about that.

FDA's authority today to oversee imports was given to it 70 years ago, in 1938. Its only real legal hook on imports is the ability to inspect product at the port of entry. If it finds a problem, to detain it and keep it from entering the country.

Dr. Acheson's ideas and in the import plan that the administration has are good concepts and good ideas, but they are not backed up with adequate legal authority.

Just as we should require preventive controls for all facilities here in the United States, we need a legal basis for ensuring that foreign producers meet the same standards and have the same preventive controls in place.

I think some of the legislation that is pending would make the importer responsible, the U.S. based legal entity that is bringing the food in, responsible for providing some reasonable assurance that the produce produced overseas has in fact been produced in accordance with U.S. standards and preventive controls and so forth.

Again, this is just codifying and finding a way to capitalize on the industry's responsibility for food safety.

We will never have enough FDA inspectors to inspect all the foreign food facilities. There are three times as many foreign facilities registered to send product here than there are domestic facilities. We need more overseas inspections.

We need to have a mechanism for codifying and enforcing that industry responsibility.

Ms. DELAURO. You said this has to be part of an overarching—can you just explain what you mean by that?

Mr. LEVI. I think as you were thinking about an uniformed safety agency, we have to go to the period before what is now the FDA steps in and look at what authorities CDC may need or what is now a CDC function. It is going to get very confusing about what we are talking about.

What is now a CDC function and also what state and local governments have and what authority they have to conduct these inspections. I think Mr. Kingston's example was these investigations need to be systematized, and it is unfortunately true for lots of surveillance activities, not just for food safety, where we have 50 states and the District of Columbia, and each may have slightly different approaches.

This is an instance where we need to be feeding into the system relatively systematic and consistent information.

That is the sort of going further back in sort of the starting with the initial identification and the capacity. Capacity is like identifying the problem, the capacity is identifying the problem and then do the further inspection.

Ms. DELAURO. Thank you. Mr. Murray.

Mr. MURRAY. I do not have any problems with these at the time. I do not really see why FDA registrations would have to be over two years.

Ms. DELAURO. I have a question about mandatory recall. What is the trigger? Is there a trigger? Is that immediate? Do they have to do a voluntary recall first, Dr. Acheson, or can you move to a mandatory?

Dr. ACHESON. In the current view of the FDA, it would be a situation where a company has refused to do a recall, which is rare but has occurred, or is essentially being unduly slow in initiating a recall.

Ms. DELAURO. It is reliant as it currently is on whether or not—it is not an immediate recall that you can do regardless of what the company has done?

Dr. ACHESON. The concept is we need the authority to require a recall. How that is translated finally into legislative language and what caveats are put around it, I think, would need to be determined as part of the rulemaking process.

The concept is that right now we cannot require anybody to do a recall except in infant formula. We need that tool in our toolbox to be able to require that. Exactly how it would look, to answer your questions, I think it would be part of the deliberative processes, in the rulemaking.

Mr. BISHOP. Would the gentlelady yield on that point?

Ms. DELAURO. Sure.

Mr. BISHOP. If you finger a business or an industry as a potential source of contamination, that is tantamount to recall right there, is it not?

Dr. ACHESON. It depends on what you mean by "tantamount to a recall." The company has to do the recall. We cannot make them do a recall. We can seize product. We cannot require them to recall it.

Mr. FARR. Can states? State health authorities?

Dr. ACHESON. I doubt that a state has the authority to do it.

Mr. BISHOP. All the retailers are going to do it and the wholesalers, too, because nobody wants to assume that liability, once you make the identification. That is what happened to our tomato people.

Dr. ACHESON. The point is the FDA does not currently have authority to require a recall.

Mr. BISHOP. You need it.

Dr. ACHESON. We know. That is what I am saying.

Ms. DELAURO. That is what he is saying.

Mr. FARR. I just had a question. I think these recommendations are moving in the right direction, but I do not see them being isolated at the Federal level. A lot of these facilities that you want to inspect require inspections at the local and state level, some of those inspections are higher than the Federal standards.

It seems to me, and I think what Dr. Levi is talking about, is there needs to be an integration of sort of the best responses that are out there. For example, highly qualified third parties for voluntary food inspections.

FDA-STATE PARTNERSHIPS

I would think you would use the states, if they are doing that now, and authorize it. Set up a plan here that is really integrated back to that kind of incident command system.

Dr. ACHESON. We already use states a lot for inspections. To answer your question, part of the plan here is to build on those state partnerships. The states and the local health authorities are critical in ensuring the safety of the food supply, both on the preventative side as well as the response side. The system does not work without them.

Mr. FARR. Your recommendations here would design an integrated system, not just a federalization of a lot of these——

Dr. ACHESON. The FDA only has authority obviously over the Federal part, the FDA part. Working through partnerships with the states, we had a 50 state meeting in August to begin to explore how can we build those partnerships around outbreak response and recalls, and how do we define roles and responsibilities.

States are key. As part of the new appropriations, we are going to be establishing a series of rapid response teams which again are localized, integrated Federal/state response teams.

I agree with you. Incident command systems are the way to go. One of the lessons learned for us at FDA is to find ways to do that more effectively through ICS.

Mr. BISHOP. Would the gentlelady yield?

Ms. DELAURO. I just would like to make this point, Dr. Acheson. I am hopeful because I am future oriented, but we had a very similar type meeting in 1998, same groups, same cast of characters. 1998. Same question, et cetera.

We are now ten years later. My hope is that I am going to be an optimist that we can move, but ten years is an awful long time to recreate the same event again.

Mr. Taylor.

Mr. TAYLOR. Madam Chair, I think the reason for that, the dominant force among Government agencies is centrifugal force. There are a lot of pressures, there are some pressures that push them to cooperate, but most of the pressures on them are to stick within their own walls and do their own thing and to not operate as part of an integrated system.

If you want an integrated system, if you want a Federal entity to be leading the development of an integrated national food safety system that includes the state and local bowls, you need to legislate that. You need to tell them to do that and create legal accountability for that. It will not happen otherwise.

Ms. DELAURO. It looks like what the European Union has done in some instances in terms of these.

Mr. Kingston wanted to be recognized and then let me go to Mr. BISHOP.

Mr. KINGSTON. Go ahead.

THIRD PARTY CERTIFICATION

Mr. BISHOP. I just wanted to ask with regard to the third party, highly qualified third party volunteer food inspections, you men-

tioned state and local agencies. Are you also contemplating private contractors?

Dr. ACHESON. Absolutely. To a standard that we have confidence in, that you have confidence in and the American consumer has confidence in, utilizing third party inspections to essentially help inform the risk based inspection process that we do, it is essentially we have 200,000 foreign manufacturers that FDA does not get to inspect on a very frequent basis, to say the least. We believe third party inspections could help inform that process. It does not give them a free ride of entry, but we believe there is information there that if it is done right, it could be helpful.

Mr. BISHOP. We would have an industry of third party inspectors that are paid by the Government to do that?

Dr. ACHESON. No. We would not pay those inspectors. This is already going on. There is already a whole certification auditing industry out there.

What I am saying is they are already doing that. Let's make sure that if they are doing it, they——

Mr. BISHOP. They are certified.

Dr. ACHESON. They are doing it to a standard and we can then use that information to help inform our risk based inspection process. We have a pilot underway right now with regard to shrimp, just to explore the feasibility of this, is it viable.

Ms. DELAURO. There will be lots of questions that surround that and that has to be whether we are doing domestic, whether we are doing foreign, what kind of accreditation, who oversees these folks.

Is this one more example of outsourcing of Federal responsibility. There are a myriad of questions around this. We have watched what has happened with contracting out from the military to you pick an area of the Federal Government, the food stamps, it is all contracted out. We have massive corruption and abuse and failure of the system.

Mr. Kingston.

Mr. KINGSTON. Here is the Immigration Service who cannot find illegal aliens and here is UPS that can find any package and move them from California to Washington.

Ms. DELAURO. Not mine. Mine did not arrive on Saturday with all my material for this hearing.

Mr. KINGSTON. Yes, but you know who to blame.

Ms. DELAURO. That was Federal Express.

Mr. KINGSTON. Think about the corner video store can track down any video that my 17 year old has not returned. I would like to see the Government match some of that.

I want to say this is an important point to me. Dr. Acheson. In terms of this recall, you have said FDA has done nothing wrong, but we do agree there has been a $100 million loss, maybe $200 million; correct?

We are saying that may have been the CDC. No heads are rolling. Nobody is in trouble. You have been a good soldier saying it was not your agency. [Laughter.]

Dr. ACHESON. The answer to that is can we all say that it was never tomatoes. Is the data to say it was never tomatoes. We have not found the data at our side of it to say it was, as I think Mr. Bishop pointed out.

That is the problem. Could we go back and say it never was tomatoes, it was a mistake.

Mr. KINGSTON. You also said earlier that you want to move on and look forward, but I could never see you guys saying that to Mr. Murray, "you guys" being the collective Government.

Can you imagine him saying got a little environmental problem, I have cleaned it up, and the EPA says that is okay, Mr. Murray, you have been a great taxpayer, the farm has been in your family 110 years, let's just move on.

The Federal Government never says to anybody move on. They always want—you have to defend yourself, and many times, spend millions of dollars to prove you are innocent.

The Federal Government is going to be very benevolent on itself now, let's just move on, and by the way, we want recall. Frankly, I think this committee would not be making a good judgment to give you guys recall based on this.

RECALL

What would you have recalled and when would you have done it and who would have made that decision?

Dr. ACHESON. Around this outbreak?

Mr. KINGSTON. Yes.

Dr. ACHESON. There was never a recall.

Mr. KINGSTON. No, I am saying if you had the recall authority and you got all of Congress screaming at you, why in the heck are you not exercising it. When would you have pulled the trigger and who would have made the decision? What would you have recalled?

Dr. ACHESON. In the current situation, there never was a recall situation around tomatoes. There was a recall situation around peppers.

Mr. KINGSTON. That is not what I am asking. I am saying hypothetical, if you had the recall authority that you want.

Dr. ACHESON. Okay, I see where you are going.

If we had evidence that a firm has got a product that is in commerce that is making people sick and they are not recalling it, this authority would give us the authority to require them to recall with some penalty if they do not.

That decision and the way it is currently being envisioned by the administration would be taken at a very high level, secretary, deputy secretary, commissioner level. That is the current vision.

Like all of these authorities, these are proposals. They are suggestions. It is up to Congress to essentially go one way or the other. If you have concerns about one part, you want to do something different——

Mr. KINGSTON. Do you think that audits are ever done on a political basis? That the IRS ever audits a firm politically? Do you think all audits are random?

Dr. ACHESON. I do not work for the IRS.

Mr. KINGSTON. I know that. I am just asking you.

Dr. ACHESON. As a personal opinion, consumer, do I think—what are you asking me?

Mr. KINGSTON. Can you get me with a little Government conspiracy here? [Laughter.]

Do you think that when some companies are audited, it could be a little politically motivated?

Dr. ACHESON. It sounds like you have an inside track that I do not. I have no idea.

Mr. KINGSTON. I am curious. Frankly, it is something that I think from time to time all of our constituents accuse of us.

What about immigration raids on farmers or on plants?

Mr. Murray, do you ever think that is done on a targeted basis? You are a really big plant, you do not get raided, but if you are medium sized, you might get raided? What do you think? Anybody hear anything about that?

Mr. MURRAY. I would not.

Mr. KINGSTON. Good answer.

Mr. BISHOP. Great answer.

Mr. KINGSTON. Do you think that any president, Republican or Democrat, might at some point use a recall power?

Dr. ACHESON. I hope not.

Mr. KINGSTON. I would hope not, too. I do know that some inspections of the USDA and many on a state level, I have heard, have been done politically. I am not necessarily saying there is hard evidence. Frankly, if there was hard evidence, this Congress, Democrats and Republicans, would be united on it.

There does seem to be some scary factor, for those of us that feel like a healthy distrust of Government is good for all of us. The more power you have, the more recall. I just cannot see it.

You have a situation right now where you are saying nobody was really at fault, that the FDA did nothing wrong. There is no place where the buck stops, but we have a $100 million disaster result because of this. Nobody is stepping forward and saying you know what, I really was the one to mess up.

Mr. LaHood said you are the only guys that apologized to Mr. Murray, and you are doing that because you are a good sport and I understand. You are doing a good job today.

The reality is if we had an infrastructure where you could say look, here is what went wrong and this is the department that made the mistake and they made the mistake on sound science, not on subjective judgment, then that would make somebody like me feel a lot more comfortable, and I think also the Chairwoman, but my concern falls off, I do not know why just given the present situation, that the FDA reserves any kind of recall power.

Mr. BISHOP. Mr. Kingston, would you yield for a second? In addition to what Mr. Kingston said, would you be willing to couple your recall authority with an indemnification requirement if your recall is inappropriate, so that somebody like Mr. Murray, who was wrongfully injured, could be required by your agency to pay for the mistake—receive compensation for your mistake?

Mr. KINGSTON. Out of your own budget.

Mr. BISHOP. Out of your budget. [Laughter.]

Dr. ACHESON. Congress can enact anything they wish around that. It is not part of our proposal.

Mr. BISHOP. I said would you feel comfortable with that. In other words, you have to shoulder the responsibility for the decisions that you make that go along with that authority that you are requesting.

Dr. ACHESON. I think Mr. Kingston's point and yours is there needs to be accountability, and I am not going to question that.

Ms. DELAURO. Let me just add, the European Union, if you read the GAO report about the European Union countries and you read about the Canadians and Japanese, et cetera, you will find that they do have recall, a mandatory recall authority, and it has been used very, very sparingly. It has hardly been used. It is an arrow in the quiver.

It is as much for prevention as it is—having the authority to move in that direction does not mean that is the first thing that you drop on the table. It is not a preemptive war, if you will.

You always have it there. The data from the GAO and their examination of these countries has said it has not in fact been used very much.

I just have one more question with regard to the authorizations. I do not know how much further my two colleagues will want to go. I wanted to ask some of the funding questions.

INTENTIONAL ADULTERATION

FDA to require preventive controls against intentional adulteration by terrorists or criminals, and additional preventive controls for certain high risk foods.

Why is it limited to "intentional adulteration?" Why not require preventive controls from farm to fork?

That is what my concern is with regard to the authorizations and how far they go and with high risk, what are we talking about there, which high risk foods are eligible, why only certain high risk foods, when you are looking at further authorities that you are looking for.

Dr. ACHESON. The goal here was to try to divide food defense in terms of deliberate versus food safety unintentional. That is what the split is on those two.

We know there are certain areas with regard to somebody doing something deliberate to the food supply, where if they were to do it, they could cause mass casualties. That is the focus of that particular language. That is what we are trying to do there, when we know if somebody were to put a small amount of an agent at one point in the food supply, they could contaminate large numbers of servings with a lethal dose. That is what that is about.

Ms. DELAURO. We do have laws with regard to that at the moment, do we not?

Dr. ACHESON. No. It is against the law, sure. Of course, it is against the law. Let's take a specific example. FDA cannot require that there be a lock on a milk tanker. We know a milk tanker is potentially vulnerable. Many industries do that as a routine because it is smart.

We want to be able when we know there are areas of specific risk to be able to require that. That is where we are trying to go with that.

Ms. DELAURO. Okay. That is understandable. Would you concur, and this goes back to a long time here in terms of the preventive controls from farm to fork that we were trying to talk about earlier, that is an authority, if you will, that ought to be part of this lexicon, you know, added to it as we move forward.

We asked you about mandatory traceability. As far as I can tell from looking at these—which would have been an enormous help in terms of the cutting down the time frame and risk here, but that does not show up in these ten new kinds of authorities.

That is what is of concern to me. I think we need to go further in these areas if we are trying to get to fundamentally changing the system because I go back to my premise that the system is broken and in order to fix the system, you need various kinds of standards and authorities in order to be able to do the job properly.

Why are they not there?

Dr. ACHESON. That list was essentially a significant step forward, to put that out there as a marker of some needs, and we regard that as a start.

You are right, trace back is not in there. That does not mean that we are not saying well, we need to think about that. There is a limit to what you can deal with.

Ms. DELAURO. I will make this point. Trace back. If you take this as a case study, this Salmonella crisis, if we had the trace back capability, it would have saved weeks and weeks and weeks of time. Is that not right?

Mr. BISHOP. And money.

Ms. DELAURO. And money.

Dr. ACHESON. I think it probably would.

Ms. DELAURO. When you are looking at where you want to go in the future, it was the two things that you mentioned.

Dr. ACHESON. Absolutely.

Ms. DELAURO. When I asked you about the authorities and the tools, preventive and the performance standards, prevention and performance standards to deal with it, and traceability. Then we look at the blueprint for the future.

I have not talked about the funding for the future. You have allocated pieces of money for where you want to go. That is real dollars. Are we spending the money properly, which goes back to Mr. Levi's question, if we are not designing the kind of system that will prevent what happened this time from happening again.

Let's not leave it on the table. Let's not leave it for the next time.

Dr. ACHESON. You certainly know my views on the value of a mandatory traceability because we have already discussed that.

I think we have to recognize that what was put out in November as part of the food protection plan was where we were in November 2007. Things change.

We would never have predicted Melamine in pet food, it just was not on anybody's radar screen. That then gets you thinking. We have to stay nimble and we have to have the ability when something crops up that maybe we have not given it sufficient priority, maybe we have not moved in the right direction.

It then triggers okay, let's deal with this. We are not going to get it all figured out ahead of time.

Ms. DELAURO. I would only say this and then I will end this conversation. I understand. Maybe that is all the market internally would bear, to be very honest with you. I cannot answer that question. Only you can answer that question.

I will go back to the traceability initiative that is out there. The industry looked at this. We had the Western Growers here last

year. They said mandatory, enforceable food safety standards. We have to move in that direction. You are killing us. They picked it up.

I am going to leave it at that, this is what the market will bear. I think you understand my point and I think I understand where you are coming from.

Mr. BISHOP. I would like to go back, if Madam Chair will allow me, you gave an example, you said you could not require locks on milk tanks, that you did not have that authority. Why do you not have that authority if you have authority to require the milk tanks to be maintained at a certain temperature?

Dr. ACHESON. We just do not have the authority. Congress has not given it to us.

Mr. BISHOP. You are charged with safety. If security is a part of safety, to make sure that it is not contaminated intentionally, a lock would certainly assure that, inasmuch as keeping it at a certain temperature would ensure the safety of it. What is the difference?

Dr. ACHESON. One is a food defense issue and it is around——

Mr. BISHOP. Both of them are food defense issues.

Dr. ACHESON. No, they are not. Food defense is defined as somebody doing something deliberate. The point is to prevent somebody from doing something deliberate.

I am not an attorney, but I am assured by our attorneys at FDA that we do not have the authority, and that is why we are asking for it. We recognize it as a gap.

Mr. BISHOP. If somebody turns the temperature gauge down on the milk, they contaminate it on purpose. Causes the culture of some toxin to be developed. It is the same principle. I do not understand why your folks would say that, other than they probably just do not like regulations.

Ms. DELAURO. I just have a couple more things. I want to try to wrap this up here by 5:00, in the next ten minutes. Thank you for bearing with us.

I would just like to put on the record something that Mr. Levi said in terms of trying to hold up money to get information. While we tried to do that with the $28 million in food safety from last year, we still do not have a report back as to what the $28 million could be used for and so forth. It is tough to get responses in terms of—I want to spend the money but I want to spend it wisely.

That leads me to just getting really a quick response, because the funding issues—I thank you for that, Dr. Acheson, were laid out on pages two through four in Dr. Acheson's testimony.

FDA PRESENCE IN FIVE COUNTRIES

That is the $14 million FDA presence in five countries, $10 million, et cetera. I do not know if you have any comments about the money, use of it in terms of the direction, future direction, as to where we ought to be going at the FDA.

Twelve million for targeting risk based inspection; better targeting of risk based inspection of imports; the $32 million for inspectors to expand domestic and foreign inspectors; $27 million for improving response capability and reducing the time between detection and containing illnesses.

Any comments? Mr. Taylor.

Mr. TAYLOR. I think each of these pieces is a piece of a risk based approach building up the base, the tools, to do it. I think the point that Dr. Levi was making and I think Dr. Acheson would acknowledge is these pieces are meaningful in the context of a larger going forward strategy.

I guess that is what in this particular statement does not give us. There is some of that in the food protection plan, but for example, the investments in the ability to identify and assess risk, that is important capacity. It has value for food safety when you actually go ahead and identify the risk, when you publicly identify what are the significant hazards in the food supply, so that Government and industry can be accountable for addressing them.

These are building the tool kit and then the question is how the tools actually are used.

I would say the same thing about the inspection increases. I believe there needs to be more inspection resources and more inspections, both domestically and overseas. That resource is well used when it is used to hold the industry accountable for doing its prevention responsibility and meeting certain standards, and we do not have the preventive control standards in place.

Again, I am all for investing in building up this tool kit but then the question is how you use it operationally in a strategy that is based on enforcing the duty to be preventive.

Ms. DELAURO. This is risk based foods versus the facility, et cetera? Should we be looking at risk as it is attached to food groups? What is the work that is being done in that area versus going to a facility——

Mr. TAYLOR. We can take you well beyond 5:00 with this one. A starting point should be what epidemiology, and I come back to epidemiology's role in this again, what epidemiology says are the most significant hazards in the food system, and then we ought to focus on particular foods, particular pathogens in foods.

We know broadly that some foods are more subject to microbial contamination than others, like meat, seafood, dairy products. We also know epidemiologically what are the pathogens that are causing illness, and we ought to be doing the epidemiology to attribute those illnesses to specific foods and then identifying those hazards.

That is how epidemiology can inform the preventive effort. The tools are good. The inputs are necessary. I think these investments are sound, but they have to be aimed at being used in a way that actually contributes to prevention.

Mr. LEVI. The only thing I would add is sort of a question which is how far down the road is this taking us, what does $10 million, just to pick one of these, how much technical assistance is that buying us. What is the level we ideally would need, is this the full payment, is it a down payment, what is the goal.

I think for each of these, that would be a reasonable question to ask, so as you are thinking about 2009, 2010, 2011, there is a least a trajectory down which we could go.

Ms. DELAURO. I have a final question, Dr. Acheson, which has to do with the overseas offices. In June, we were going to start with China, have three offices open by the end of 2008. If you can update us, where are we in terms of getting the offices opening?

The reports were Beijing, Shanghai, Guangzhou; is that correct?

Dr. ACHESON. That is correct.

Ms. DELAURO. The cities have been chosen?

Dr. ACHESON. That is still the plan.

Ms. DELAURO. What is the status? How many staff people? How many Chinese nationals? Is the paperwork done? Where are we in terms of opening these offices?

Dr. ACHESON. The director is hired. He is going over there, I believe, in October, to set up.

Ms. DELAURO. In these three cities?

Dr. ACHESON. He will be based in Beijing. The applications for staffing this up from within FDA because we want experienced FDA personnel there has just recently closed. I believe there were over 80 applicants to staff this.

Ms. DELAURO. Still talking just about Beijing?

Dr. ACHESON. No, about China.

Ms. DELAURO. About China in general; okay.

Dr. ACHESON. The goal as I currently understand it is there would be probably eight to nine U.S. FDA type personnel and five or so Chinese nationals.

Ms. DELAURO. In every office?

Dr. ACHESON. No, total China would be 13, spread around between the three cities. I do not actually know how many in each.

Ms. DELAURO. Has China approved the necessary paperwork such as visas and all that?

Dr. ACHESON. Yes. We are good to go. That was one of the hold up's.

Ms. DELAURO. I understand that. My understanding, and correct me if I am wrong, they were looking for reciprocity with having——

Dr. ACHESON. There were some concerns around that, but we are through that.

Ms. DELAURO. We are through that?

Dr. ACHESON. We are through that. It was not approving individual visas. It was approving the concept of setting this up.

Ms. DELAURO. Restrictions? Will there be restrictions on travel by staff of these offices within China and access to facilities?

Dr. ACHESON. I do not know, but I will get back to you with an answer for that. I do not know.

We do not anticipate problems gaining access to facilities that we want to inspect. The Memoranda of Agreement with the State Food and Drug Administration (SFDA) and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) both require that each country facilitate the inspections of establishments by the other country. The Agreements also acknowledge that inspections may be conducted with or without providing advance notice to the establishment to be inspected.

ACCESS TO FACILITIES IN CHINA

Ms. DELAURO. Secretary Leavitt has said that he did not view the offices as being just an inspection group. What does that mean? Will these folks do inspections?

Dr. ACHESON. Yes. Part of what they will do is inspections. It is clearly not realistic to expect 13 people to inspect thousands of firms in China. That is not what this is all about.

Ms. DELAURO. Can you get to us when you are getting us some information on kind of the scope, the job description, what is it that we are asking these people to do there?

Dr. ACHESON. At a high level, part of it is inspection, part of it is being there when things go wrong, as we are just right now experiencing in another situation with infant formula.

There is no way that we could staff up China to the point where we would be out inspecting every firm, to Mr. Bishop's point.

Ms. DELAURO. I understand that. I want to know what is their job description, what are we asking them to do?

Dr. ACHESON. We have a job description. We will get you a copy of the job description. A high level. It is about building the relationships, understanding what is going on there and essentially establishing a presence so that when things go wrong, we are in a better place to respond.

[The information follows:]

FDA Country Director
Foreign Duty Station
GS-301-14/15

Introduction:

This position is located in the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the incumbent is responsible managing FDA programs and activities that are operated in foreign countries.

The primary mission of the FDA is protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. Annually, consumers spend nearly $1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA-regulated products.

The primary purpose of this position is to serve as the FDA Country Director (India) responsible for fully representing FDA in the overall planning, organization, administration and coordination of all FDA activities throughout the country/regional area of assignment.

Major Duties and Responsibilities:

The FDA Country Director (India) provides assistance and leadership in directing the FDA presence and responsibilities in the area that includes information exchange, technical training, collaboration with counterpart agencies, and foreign audits and inspections. The Representative is responsible for maintaining regular and consistent communication with FDA, Office of International Programs (OIP) staff and referring policy issues to OIP for guidance and consultation.

The FDA Country Director (India) will do the following:

- Serves as the agency focal point for foreign officials in the assigned area, including foreign embassy personnel in the U.S., and U.S. embassy personnel in the foreign country.

- Serves as the agency expert in the assigned area, with a working knowledge of the culture, society, people, language and current public health issues.

- Represents FDA in discussions and negotiations with high-level foreign government representatives. This could include representing and speaking on behalf of the Commissioner, Deputy Commissioners, Associate and Assistant Commissioners or other agency leadership. Articulates, explains, and defends the agency's policies,

guidances, rules, regulations, and international goals intelligently and accurately; and understands their importance to, and implications for, people and institutions having differing interests and responsibilities. Builds, maintains, and enhances effective working relationships with foreign government officials. Provides leadership and guidance to FDA officials in their dealings with foreign officials. Maintains positive working relationships with foreign policymakers during deliberations and negotiations on subjects of great sensitivity and controversy.

- Serves as an agency expert in working with senior, policy-level officials and technical specialists at other U.S. regulatory agencies, such as the U. S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service and the USDA's Food Safety and Inspection Service, which work in areas that impact on FDA. Works closely with senior, policy-level officials and technical experts in other U.S. agencies such as the Department of State, the United States Trade Representative (USTR), and the USDA's Foreign Agriculture Service toward the conception, development and implementation of agreements with foreign countries.

- Advises the Assistant Commissioner for International Programs (ACIP) in developing evaluating, and negotiating positions and proposals for the solution of complex national issues; articulates FDA positions in a persuasive manner; provides authoritative and direct assistance to officials in other federal agencies; and maintains good working relationships while working out substantive disagreements with officials of other countries and agencies.

- Oversees the effectiveness of administration of FDA agreements with foreign representatives in the area. Develops and maintains strong liaison and close contacts with officials in the host country's Ministry of Health and other relevant Ministries.

- Keeps informed on new developments in his/her assigned area. Periodically procures copies of supplementary legislation, new documents and other material and prepares appropriate reports for use both locally in making determinations in specific cases for transmittal to Headquarters.

- Exercises leadership skills necessary to lead and/or coordinate FDA efforts in complex new policy and program areas involving multiple Centers and product areas to develop, evaluate, and gain agency consensus on important new policies, concepts, strategies, negotiating positions, procedures, and other courses of action. Through persuasion and leadership, ensures consistency among the Centers in both the development and implementation of new policies.

FACTOR LEVEL DESCRIPTIONS

FACTOR 1. KNOWLEDGE REQUIRED

The incumbent must possess:

- Expert knowledge of FDA programs and international public health policy issues: Comprehensive knowledge of FDA implementing legislation, rules, regulations, policies, regulatory programs, and administrative processes; knowledge of international public health policy issues, including trade agreements and agreements with multilateral organizations, and the ability to apply the principles of those agreements or the work of those organizations to situations involving FDA-regulated products. Knowledge of the programs, organizations, activities, and relationships to assess the political and institutional environment in which decisions are made and implemented. Ability to apply broad knowledge of international policy issues, and comprehensive knowledge of legal, regulatory, and technical matters pertaining to these issues to assist policymakers in considering policy proposals during the decision making process.

- Expert knowledge of the specific geographic region specified: Comprehensive knowledge of the region, people, culture, society, and the public health challenges facing that region as well as FDA's history of working with that region.

- Knowledge of the principles and practice of scientific research and public health. Broad knowledge of countries of the Asia Pacific Region, including perspective on their historical relationship in health, scientific social welfare and family policy with the United States. Knowledge of global public-policy priorities and programs of other U.S. Government Departments and agencies, such as the USAID; the U.S. Departments of State, Commerce, Energy, Interior, and Defense; the Environmental Protection Agency; the National Science Foundation; and others.

- Project management and leadership skills: Ability to gauge the effort of the most complex and important matters, to select what needs to be done and by whom, how to proceed, and to recognize impact in terms of risks involved, necessary trade-offs, the scheduling of time of various participants, and the cost both to the agency and all other participants; ability to accomplish work through others at all necessary levels within the agency and in other federal and international organizations to achieve appropriate and timely support.

- Policy analysis skills: Ability to analyze the most complex and sensitive regulatory issues involving numerous variables to identify and prove root causes and anticipate ancillary problems; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory and scientific specialists, regulated industry, and involved State, local and foreign governments, and other Federal agencies.

- Negotiating skills: Negotiating skills sufficient to achieve consensus on agency and inter-agency positions on the most complex and sensitive issues; resolve differing points of view between various organizations; and, in dealing with representatives of foreign governments, achieve solutions that satisfy the foreign government while meeting FDA's negotiating goals.

- Judgment: Ability to exercise judgment in the most complex and sensitive subjects in all phases of analysis, ranging from sorting out the most pertinent issues when dealing with voluminous amounts of information to ensuring that the many facets of a policy issue are explored, to sifting evidence and developing feasible options or alternative proposals and anticipating policy consequences.

- Communication skills: Ability to communicate in a highly effective manner in writing and in person-to-person contacts; ability to deal effectively with others in a leadership capacity and command respect.

- Demonstrated experience in participation in U.S. Government delegations to international meetings where applicant articulated and presented ideas and policies effectively to a range of audiences, including representatives of countries from all parts of the world, including Ministers of Health, diplomats, as well as public- and private-sector scientists and experts from developed and developing countries, and high-ranking officials of multilateral organizations.

- Skill in working under pressure: Ability to work effectively and highly independently under the pressure of very tight time frames and to meet deadlines with quality work.

FACTOR 2. SUPERVISION RECEIVED

The ACIP provides direction in terms of broadly defined missions and goals. The incumbent is responsible for initiating, planning, designing, and carrying out projects, studies, and other work, consulting with the Staff Director. Assignments may originate out of the activities of the incumbent, who negotiates the scope and objectives of projects subject only to resource and time constraints with the approval of the ACIP. Any recommendations for new projects and alteration of objectives are usually evaluated only for such considerations as availability of funds and other resources and consistency with broad agency goals. Results of work are considered as technically authoritative and normally accepted without significant change.

FACTOR 3. GUIDELINES

In order to have a comprehensive knowledge of FDA implementing legislation, rules, regulations, policies, regulatory programs, and administrative processes, the FDA Country Director (India) must have an understanding of the context in which FDA operates internationally, a variety of guidelines are used. They include: Food and Drug Law, FDA Compliance Policy Guides (ORA's guidance to inspectors), Code of Federal

Regulations, Title 21, FDA Regulatory Procedures Manual, and Consumer Protection Law. Several international agreements are also used as informative guides, which include: GATT, SPS (Sanitary and Phytosanitary) Agreement, TBT (Technical Barriers to Trade) Agreements, NAFTA, and Canada- U.S. Free Trade Agreement. Information is not always located in the available resources and there are times when regulations and policies are developed through the Federal Register notice process. Because of the potential effect on FDA, on other Federal agencies, on State, local and foreign governments, and on regulated industries, considerable judgment is required in the selection, evaluation, and modification of agency program operations, and agency regulatory and technical policies, procedures, and methods.

FACTOR 4. COMPLEXITY

Assignments consist of the selection and resolution of problems that involve the highest degree of complexity and require the highest degree of judgment. The regulatory problems are of the highest public interest, involve (separately or in combination) other Federal agencies, State, local, and/or foreign governments, and international organizations, and in most instances have not been addressed in the past, or have been addressed previously without success. The incumbent's projects are highly significant and usually have high international visibility. They will require interaction with officials of foreign government agencies, with U.S. agencies involved in international issues, and international organizations in the United Nations system (if responsibility includes this area), and, therefore, are of utmost sensitivity and require diplomacy. Projects will often involve one or more of the following complications: (1) controversial issues, i.e., disagreements on program requirements, policy positions, or operating procedures; (2) strong interest on the part of FDA stakeholders (e.g. consumers, Congress and industry); or (3) last minute changes requiring extensive coordination. Problems often lack definition at the beginning of assignments and projects. Alternatives must be developed and problems solved, the solutions becoming standards and policy for agency program operations, participating Federal agencies and governments, and regulated industries.

FACTOR 5. SCOPE AND EFFECT

Work involves planning and conducting projects on behalf of the agency and providing authoritative information and analyses to tackle problems of national and international scope and impact. Findings and conclusions are of the greatest significance in altering and modifying agency regulatory concepts on a long term and continuing basis and often influence the programs of other Federal agencies, State, local, and foreign governments, and regulated industry. Decisions are frequently questioned and challenged, and therefore must be based on the soundest scientific, regulatory, technical, and legal grounds to be ultimately accepted. The international policies that FDA develops have important implications for industry and consumers and for many aspects of FDA's activities. The U.S. has traditionally been looked up to as a world leader in health and safety regulation and the concepts and policies that FDA develops can be expected to have a significant impact on other countries' policies and, therefore, global public health. The nature of the work, and the level at which it is executed, has a significant impact on and draws from

the various programs of the Agency involved with the safety and efficacy of imported and exported products, and requires application of a highly intensive and specialized knowledge of the field. The projects themselves may have potentially significant economic effects on industry and include complex technical issues related to the assurance of product safety, quality, and efficacy.

FACTOR 6. PERSONAL CONTACTS

Contacts are with other agency officials at the policymaking level and senior staff, and with high ranking officials outside the agency, including key officials and top professionals of other Federal agencies, State, local, and foreign governments, international organizations, private industry, trade organizations and consumer groups.

FACTOR 7. PURPOSE OF CONTACTS

Contacts are made in order to present agency requirements, discuss controversial technical points and regulatory requirements and policies, to identify emerging problems, and to justify, defend, negotiate, and settle regulatory and technical matters of international significance. Contacts are often with those of widely differing viewpoints, goals, and objectives. The incumbent uses tact, diplomacy, negotiating skills, and technical expertise in agency regulatory programs, policy, and regulations in order to obtain an acceptable point of view or develop suitable alternatives.

FACTOR 8. PHYSICAL DEMANDS

The work is usually sedentary and may require some walking or travel to meetings and conferences away from the normal work site including lengthy air travel and work in different time zones. The duty station may be demanding, in that the incumbent may be deployed in a "hardship post" as determined by the U.S. Department of State. International and in-country travel may expose the incumbent to additional hazards.

FACTOR 9. WORK ENVIRONMENT

The position involves working in a foreign country where living, working, and travel conditions and public health procedures may be inadequate. The incumbent will generally work in an office setting.

FDA Country Associate Director (China)
Foreign Duty Station
GS-301-14/15

Introduction:

This position is located in the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the incumbent is responsible managing FDA programs and activities that are operated in foreign countries.

The primary mission of the FDA is protecting the public health by assuring the safety, efficacy, and quality of human and veterinary drugs, human biological products and medical devices, and the safety of our nation's food supply (including animal feeds and pet foods), cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The primary purpose of this position is to serve as an FDA program expert in a foreign country, responsible for fully representing FDA and assisting the Country Director in the overall planning, organization, administration, implementation and coordination of all FDA activities throughout the country/regional area of assignment. The incumbent's expertise should be specific to foods, medical devices, or drugs).

Participating fully with the Director, the FDA Country Associate Director (China) is responsible for representing FDA in the overall planning, organization, administration and coordination of all FDA activities throughout the country/regional area of assignment.

Major Duties and Responsibilities:

The FDA Country Associate Director (China) participates fully with the Director in providing assistance and leadership in directing the FDA presence and responsibilities in the area that includes information exchange, technical training, collaboration with counterpart agencies, and foreign audits and inspections. The Representative is responsible for maintaining regular and consistent communication with FDA, Office of International Programs (OIP) staff and referring policy issues to OIP for guidance and consultation.

The Associate Director applies knowledge of administrative and program management principles and skills in carrying out the mission of the FDA foreign office in association with the Director, as well as using them to address and solve unusual and often precedent setting problems associated with the FDA's foreign office program segment (s). Seeks and develops the most cost effective and fiscally responsible methods to conduct this program segment(s) and to solve problems.

The FDA Country Associate Director (China) will do the following:

- Participating fully with the Director, the Associate Director serves as the agency focal point for foreign officials in the assigned area, including foreign embassy personnel in the U.S., and U.S. embassy personnel in the foreign country.

- Sharing fully with the Director, the Associate Director serves as the agency expert in the assigned area, with a working knowledge of the culture, society, people, language and current public health issues.

- As directed by the Director, the Associate Director represents FDA in discussions and negotiations with high-level foreign government representatives. This could include representing and speaking on behalf of the Commissioner, Deputy Commissioners, Associate and Assistant Commissioners or other agency leadership. Articulates, explains, and defends the agency's policies, guidances, rules, regulations, and international goals intelligently and accurately; and understands their importance to, and implications for, people and institutions having differing interests and responsibilities. Builds, maintains, and enhances effective working relationships with foreign government officials. Provides leadership and guidance to FDA officials in their dealings with foreign officials. Maintains positive working relationships with foreign policymakers during deliberations and negotiations on subjects of great sensitivity and controversy.

- In consultation with the Director, the Associate Director serves as an agency expert in working with senior, policy-level officials and technical specialists at other U.S. regulatory agencies, such as the U. S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service and the USDA's Food Safety and Inspection Service, which work in areas that impact on FDA. Works closely with senior, policy-level officials and technical experts in other U.S. agencies such as the Department of State, the United States Trade Representative (USTR), and the USDA's Foreign Agriculture Service toward the conception, development and implementation of agreements with foreign countries.

- As directed by the Director, the Associate Director advises the Associate Commissioner for International Programs (ACIP) in developing evaluating, and negotiating positions and proposals for the solution of complex national issues; articulates FDA positions in a persuasive manner; provides authoritative and direct assistance to officials in other federal agencies; and maintains good working relationships while working out substantive disagreements with officials of other countries and agencies.

- The Deputy\Associate Director, in conjunction with the Director, oversees the effectiveness of administration of FDA agreements with foreign representatives in the area. Develops and maintains strong liaison and close contacts with officials in the host country's Ministry of Health and other relevant Ministries.

- Keeps informed on new developments in his/her assigned area. Periodically procures copies of supplementary legislation, new documents and other material and prepares appropriate reports for use both locally in making determinations in specific cases for transmittal to Headquarters.

- Exercises leadership skills necessary to lead and/or coordinate FDA efforts in complex new policy and program areas involving multiple Centers and product areas to develop, evaluate, and gain agency consensus on important new policies, concepts, strategies, negotiating positions, procedures, and other courses of action. Through persuasion and leadership, ensures consistency among the Centers in both the development and implementation of new policies.

FACTOR LEVEL DESCRIPTIONS

FACTOR 1. KNOWLEDGE REQUIRED

The incumbent must possess:

- Expert knowledge of FDA programs and international public health policy issues: Comprehensive knowledge of FDA implementing legislation, rules, regulations, policies, regulatory programs, and administrative processes; knowledge of international public health policy issues, including trade agreements and agreements with multilateral organizations, and the ability to apply the principles of those agreements or the work of those organizations to situations involving FDA-regulated products. Knowledge of the programs, organizations, activities, and relationships to assess the political and institutional environment in which decisions are made and implemented. Ability to apply broad knowledge of international policy issues, and comprehensive knowledge of legal, regulatory, and technical matters pertaining to these issues to assist policymakers in considering policy proposals during the decision making process.

- Expert knowledge of the specific geographic region specified: Comprehensive knowledge of the region, people, culture, society, and the public health challenges facing that region as well as FDA's history of working with that region.

- Knowledge of the principles and practice of scientific research and public health. Broad knowledge of countries of the Asia Pacific Region, including perspective on their historical relationship in health, scientific social welfare and family policy with the United States. Knowledge of global public-policy priorities and programs of other U.S. Government Departments and agencies, such as the USAID; the U.S. Departments of State, Commerce, Energy, Interior, and Defense; the Environmental Protection Agency; the National Science Foundation; and others.

- Project management and leadership skills: Ability to gauge the effort of the most complex and important matters, to select what needs to be done and by whom, how to proceed, and to recognize impact in terms of risks involved, necessary trade-offs, the

scheduling of time of various participants, and the cost both to the agency and all other participants; ability to accomplish work through others at all necessary levels within the agency and in other federal and international organizations to achieve appropriate and timely support.

- Policy analysis skills: Ability to analyze the most complex and sensitive regulatory issues involving numerous variables to identify and prove root causes and anticipate ancillary problems; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory and scientific specialists, regulated industry, and involved State, local and foreign governments, and other Federal agencies.

- Negotiating skills: Negotiating skills sufficient to achieve consensus on agency and inter-agency positions on the most complex and sensitive issues; resolve differing points of view between various organizations; and, in dealing with representatives of foreign governments, achieve solutions that satisfy the foreign government while meeting FDA's negotiating goals.

- Judgment: Ability to exercise judgment in the most complex and sensitive subjects in all phases of analysis, ranging from sorting out the most pertinent issues when dealing with voluminous amounts of information to ensuring that the many facets of a policy issue are explored, to sifting evidence and developing feasible options or alternative proposals and anticipating policy consequences.

- Communication skills: Ability to communicate in a highly effective manner in writing and in person-to-person contacts; ability to deal effectively with others in a leadership capacity and command respect.

- International Experience: Demonstrated experience in participation in U.S. Government delegations to international meetings where applicant articulated and presented ideas and policies effectively to a range of audiences, including representatives of countries from all parts of the world, including Ministers of Health, diplomats, as well as public- and private-sector scientists and experts from developed and developing countries, and high-ranking officials of multilateral organizations.

- Skill in working under pressure: Ability to work effectively and highly independently under the pressure of very tight time frames and to meet deadlines with quality work.

FACTOR 2. SUPERVISION RECEIVED

The Associate Director reports to the Director, who provided broad administrative and policy guidance. In the absence of the Director, the incumbent reports to the ACIP, who provides direction in terms of broadly defined missions and goals. The incumbent is responsible for initiating, planning, designing, and carrying out projects, studies, and other work, consulting with the Director. Assignments may originate out of the activities of the incumbent, who negotiates the scope and objectives of projects subject only to

resource and time constraints with the approval of the Director and/or ACIP. Any recommendations for new projects and alteration of objectives are usually evaluated only for such considerations as availability of funds and other resources and consistency with broad agency goals. Results of work are considered as technically authoritative and normally accepted without significant change.

FACTOR 3. GUIDELINES

In order to have a comprehensive knowledge of FDA implementing legislation, rules, regulations, policies, regulatory programs, and administrative processes, the FDA Country Associate Director (China) must have an understanding of the context in which FDA operates internationally, a variety of guidelines are used. They include: Food and Drug Law, FDA Compliance Policy Guides (ORA's guidance to inspectors), Code of Federal Regulations, Title 21, FDA Regulatory Procedures Manual, and Consumer Protection Law. Several international agreements are also used as informative guides, which include: GATT (General Agreement on Tariffs and Trade), SPS (Sanitary and Phytosanitary) Agreement, TBT (Technical Barriers to Trade) Agreements. Information is not always located in the available resources and there are times when regulations and policies are developed through the Federal Register notice process. Because of the potential effect on FDA, on other Federal agencies, on State, local and foreign governments, and on regulated industries, considerable judgment is required in the selection, evaluation, and modification of agency program operations, and agency regulatory and technical policies, procedures, and methods.

FACTOR 4. COMPLEXITY

Assignments consist of the selection and resolution of problems that involve the highest degree of complexity and require the highest degree of judgment. The regulatory problems are of the highest public interest, involve (separately or in combination) other Federal agencies, State, local, and/or foreign governments, and international organizations, and in most instances have not been addressed in the past, or have been addressed previously without success. The incumbent's projects are highly significant and usually have high international visibility. They will require interaction with officials of foreign government agencies, with U.S. agencies involved in international issues, and international organizations in the United Nations system (if responsibility includes this area), and, therefore, are of utmost sensitivity and require diplomacy. Projects will often involve one or more of the following complications: (1) controversial issues, i.e., disagreements on program requirements, policy positions, or operating procedures; (2) strong interest on the part of FDA stakeholders (e.g. consumers, Congress and industry); or (3) last minute changes requiring extensive coordination. Problems often lack definition at the beginning of assignments and projects. Alternatives must be developed and problems solved, the solutions becoming standards and policy for agency program operations, participating Federal agencies and governments, and regulated industries.

FACTOR 5. SCOPE AND EFFECT

Work involves planning and conducting projects on behalf of the agency and providing authoritative information and analyses to tackle problems of national and international scope and impact. Findings and conclusions are of the greatest significance in altering and modifying agency regulatory concepts on a long term and continuing basis and often influence the programs of other Federal agencies, State, local, and foreign governments, and regulated industry. Decisions are frequently questioned and challenged, and therefore must be based on the soundest scientific, regulatory, technical, and legal grounds to be ultimately accepted. The international policies that FDA develops have important implications for industry and consumers and for many aspects of FDA's activities. The U.S. has traditionally been looked up to as a world leader in health and safety regulation and the concepts and policies that FDA develops can be expected to have a significant impact on other countries' policies and, therefore, global public health. The nature of the work, and the level at which it is executed, has a significant impact on and draws from the various programs of the Agency involved with the safety and efficacy of imported and exported products, and requires application of a highly intensive and specialized knowledge of the field. The projects themselves may have potentially significant economic effects on industry and include complex technical issues related to the assurance of product safety, quality, and efficacy.

FACTOR 6. PERSONAL CONTACTS

Contacts are with other agency officials at the policymaking level and senior staff, and with high ranking officials outside the agency, including key officials and top professionals of other Federal agencies, State, local, and foreign governments, international organizations, private industry, trade organizations and consumer groups.

FACTOR 7. PURPOSE OF CONTACTS

Contacts are made in order to present agency requirements, discuss controversial technical points and regulatory requirements and policies, to identify emerging problems, and to justify, defend, negotiate, and settle regulatory and technical matters of international significance. Contacts are often with those of widely differing viewpoints, goals, and objectives. The incumbent uses tact, diplomacy, negotiating skills, and technical expertise in agency regulatory programs, policy, and regulations in order to obtain an acceptable point of view or develop suitable alternatives.

FACTOR 8. PHYSICAL DEMANDS

The work is usually sedentary and may require some walking or travel to meetings and conferences away from the normal work site including lengthy air travel and work in different time zones. The duty station may be demanding, in that the incumbent may be deployed in a "hardship post" as determined by the U.S. Department of State. International and in-country travel may expose the incumbent to additional hazards.

FACTOR 9. WORK ENVIRONMENT

The position involves working in a foreign country where living, working, and travel conditions and public health procedures may be inadequate. The incumbent will generally work in an office setting.

International Program and Policy Analyst PD
Foreign Duty Station
GS-301-13/14

Introduction

This position is located in the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the incumbent is responsible implementing and managing FDA programs and activities that are conducted in foreign countries.

The primary mission of the FDA is protecting the public health by assuring the safety, efficacy, and quality of human and veterinary drugs, human biological products and medical devices, and the safety of our nation's food supply (including animal feeds and pet foods), cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The primary purpose of this position is to serve as an FDA program expert in a foreign country responsible for fully representing FDA and assisting the FDA Country Director in the overall planning, organization, administration, implementation and coordination of all FDA activities throughout the country/regional area of assignment.

While the general duties and responsibilities of an FDA International Program and Policy Analyst are well established, this PD is specific to a foreign country duty station. Upon returning to FDA at the end of a given foreign duty station rotation, the incumbent would revert to a PD specific to a domestic duty station.

Duties

The incumbent serves as an international policy and program staff member with responsibility for a broad range of projects at his/her duty station in a foreign country:

I. Policy Analysis

- Serves as an agency specialist on FDA-regulated products (specific to either food, medical devices, or drugs) with an important impact on international policy direction and the agency's long-term public-health goals. Works with the FDA Country Director at the foreign country duty station and other senior policy staff at FDA's Headquarters to provide in-country input into the development of agency policies and national and international standards, procedures, and guidance.

- Follows the in-country news and developments within the foreign government's public health regulatory infrastructure to monitor activities and identify

international trends and positions affecting FDA. Represents FDA and U.S. Government policy and advocates for adoption as required.

- Conducts analysis of foreign country programs and issues with a view towards their impact on FDA programs and activities.

- Attends meetings or forums, such as regular or special meetings of international organizations, international consortia, or other in-country meetings likely affecting FDA's international policy or likely to contribute to the objective of effective oversight on, and compliance of FDA-regulated products.

- Provides advice and guidance to the FDA Country Director and handles specific policy issues as they arise.

- Supports the Country Director, in providing input to FDA Headquarters, in deciding policy and procedures for bilateral (and multilateral) agreements including Free Trade Agreements (FTAs). Provides staff support to the Country Director in the identification of international policy issues. May play a supporting role in negotiations with foreign countries on FTAs.

- Participates directly with the Country Director in the planning and execution of activities relevant to international organizations and foreign regulatory agencies in-country. This could include:

    a. the development of international standards, guidelines, etc.; review of regulations, guidelines, etc. with international impact proposed by FDA, other agencies, and international organizations; and reviews on FDA's behalf proposals submitted to other U.S. agencies (e.g., USDA, Environmental Protection Agency, Department of Commerce, USTR and referred to FDA by these agencies.)

    b. the development of workshops, conferences with or for FDA's foreign regulatory counterparts, regulated industry, academia, or other stakeholders

    c. ad hoc meeting or exchanges on FDA-related matters

II. PROGRAM AND REPRESENTATION ACTIVITIES:

- Serves as an FDA program expert in the area of (drugs, medical devices, or foods) and under the leadership of the Country Director, provides information or technical training to FDA's foreign regulatory counterparts, regulated industry, academia, or other stakeholders in-country.

- At the direction of the Country Director, may represent FDA in discussions and negotiations with high-level foreign government representatives as appropriate. Articulates, explains, and defends the agency's policies and international goals intelligently and accurately; and understands their importance to, and implications for, people and institutions having differing interests and responsibilities. Maintains effective working relationships with foreign policymakers during deliberations and negotiations on subjects of great sensitivity and controversy.

- At the request and direction of FDA Headquarters and with concurrence of the Country Director, works with international standard-setting organizations such as Codex Alimentarius and the International Organization for Standardization. May be called upon to represent FDA in meetings of these organizations, provides technical expertise for the development of international standards (with a special emphasis on standards related to equivalence) and plays a key role in planning and carrying out strategies to achieve U.S. goals in international standard-setting organizations.

- As appropriate, represents the Country Director or Deputy Country Director, at conferences and meetings concerning international policy issues within the Department of Health and Human Services, with other U.S. government agencies, foreign government agencies, and international organizations. Explains program or project goals, seeks to persuade others to support FDA positions, and coordinates and completes projects.

- Other duties as assigned by the Country Director.

III. LEADERSHIP RESPONSIBILITIES:

- Develops and exercises leadership skills necessary to lead and/or coordinate FDA efforts in complex new policy and program areas involving multiple Centers and product areas in the foreign duty station.

- Leads or represents the agency on task forces, planning groups, or special study groups within the U.S. Embassy or in the foreign country.

FACTOR LEVEL DESCRIPTIONS

FACTOR 1. KNOWLEDGE AND SKILLS REQUIRED

In order to function on behalf of the Agency as staff responsible for managing critical international issues, problems, and actions related to the supply of FDA-regulated products to the nation and the world, the incumbent must possess:

- Knowledge of FDA programs: Expert knowledge of FDA implementing legislation, rules, regulations, policies regulatory programs, and administrative processes; Knowledge of the programs, organizations, activities, and relationships to assess the political and institutional environment in which decisions are made and implemented.

- Knowledge of the international regulatory arena: General and working knowledge of foreign regulatory systems; ability to apply broad knowledge of international policy issues, and comprehensive knowledge of legal, regulatory, and technical matters pertaining to these issues to assist policymakers in considering policy proposals during the decision making process.

- Project management and leadership skills: Ability to gauge the effort at hand, to select what needs to be done and by whom, how to proceed, and to recognize impact in terms of risks involved, necessary trade-offs, the scheduling of time of various participants, and the cost both to the agency and all other participants; ability to accomplish work through others at all necessary levels within the agency and in other federal and international organizations to achieve appropriate and timely support.

- Policy analysis skills: Ability to analyze complex and sensitive regulatory issues involving numerous variables. Identify and prove root causes and anticipate ancillary problems; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory and scientific specialists, regulated industry, and involved State, local and foreign governments, and other Federal agencies.

- Negotiating skills: Negotiating skills sufficient to achieve consensus on agency and inter-agency positions; achieve consensus within an international setting with multiple interests: resolve differing points of view between various organizations; and, in dealing with representatives of foreign governments, achieve compromises that satisfy the foreign government while meeting FDA's program goals.

- Judgment: Ability to exercise judgment in all phases of analysis, ranging from sorting out the most important problems when dealing with voluminous amounts of information to ensuring that the many facets of a policy issue are explored, to sifting evidence and developing feasible options or alternative proposals and anticipating policy consequences.

- Communication and Diplomacy skills: Ability to communicate in a highly effective manner in writing and in person-to-person contacts; ability to deal effectively with others in a leadership capacity; understanding of and ability to effectively work in an environment guided by diplomacy and protocol. The incumbent not only represents FDA abroad, but represents the United States government. The ability to successfully work in a foreign environment, with the utmost diplomacy and professionalism is paramount.

- Skill in working under pressure: Ability to work effectively and highly independently under the pressure of very tight time frames and to meet deadlines.

FACTOR 2. LANGUAGE SKILLS

Knowledge of and Proficiency in Mandarin Chinese is highly desirable. The incumbent must be willing to complete Chinese language training as offered by the U.S. Department of State Foreign Service Institute or a commensurate program.

FACTOR 3. SUPERVISORY CONTROLS

The incumbent directly reports to the FDA Country Director, and as all foreign service staff, ultimately is under the direction of the U.S. Ambassador or Chief of Mission. The incumbent will also have a link to his/her given program (the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Food Safety and Applied Nutrition) in order to stay apprised of any program issues, updates, policies, or procedures.

The incumbent is responsible for planning, and carrying out projects, studies, and other work, consulting with the Country Director. Assignments may originate out of the activities of the incumbent, who negotiates the scope and objectives of projects subject only to resource and time constraints. Results of work should be at a level that is accepted without significant change. Any recommendations for new projects and alteration of objectives are usually evaluated only for such considerations as availability of funds and other resources and consistency with broad agency goals. The incumbent is expected to have excellent time management skills, work relatively independent and require limited supervision by the Country Director.

FACTOR 4. GUIDELINES

In order to have a comprehensive knowledge of FDA implementing legislation, rules, regulations, policies, regulatory programs, and administrative processes a variety of guidelines are used. Specific to an area of program expertise (drugs, medical devices, or foods), they could include: Food and Drug Law, FDA Compliance Policy Guides (ORA's guidance to inspectors), CFR 21 -Food and Drugs, CFSAN Food Safety Manual, FDA Regulatory Procedures Manual, and Consumer Protection Law.

Several international agreements are also used as informative guides, which include: GATT (General Agreement on Tariffs and Trade), SPS (Sanitary and Phytosanitary) Agreement, TBT (Technical Barriers to Trade) Agreements, information is not always located in the available resources and there are times when regulations and policies are developed through the Federal Register notice process particularly in the equivalence area of the international food and drug regulatory field. Because of the potential effect on FDA, on other Federal agencies, on State, local and foreign governments, and on regulated industries, considerable judgment is required in the selection, evaluation, and

modification of agency program operations, and agency regulatory and technical policies, procedures, and methods.

FACTOR 5. COMPLEXITY

Assignments consist of the selection and resolution of problems that involve complex public health issues and require the highest degree of public policy judgment. The regulatory problems are of extraordinary public interest, involve (separately or in combination) other Federal agencies, State, local, and/or foreign governments, and international organizations, and in most instances have not been addressed in the past, or have been attempted previously without success. The incumbent's projects could have high international visibility. They will require interaction with foreign government agencies and with U.S. agencies involved in international issues, and therefore are of utmost sensitivity. Projects will often involve one or more of the following complications: (1) controversial issues, i.e., disagreements on program requirements, policy positions, or operating procedures; (2) strong public interest; or, (3) last minute changes requiring extensive coordination. Problems often lack definition at the beginning of assignments and projects. Alternatives must be developed and problems solved, the solutions becoming standards and policy for agency program operations, participating Federal agencies and governments, and regulated industries.

FACTOR 6. SCOPE AND EFFECT

Work involves planning and conducting projects on behalf of the agency and providing authoritative information and analyses to tackle problems of national and international scope and impact. Findings and conclusions are of considerable significance in altering and modifying agency regulatory concepts on a long term and continuing basis and often influence the programs of other Federal agencies, State, local, and foreign governments, and regulated industry. Decisions are frequently questioned and challenged, and therefore must be based on the soundest regulatory, technical, and legal grounds to be ultimately accepted. The international policies that FDA develops have important implications for industry and consumers and for many aspects of FDA's activities, including the monitoring of imported products and how other nations will treat products imported from the U.S. The U.S. has traditionally been looked up to as a world leader in health and safety regulation and the concepts and policies that FDA develops can be expected to have a significant impact on other countries' policies. The nature of the work, and the level at which it is executed, has a significant impact on and draws from the various programs of the Agency involved with the safety and efficacy of imported and exported products, and requires application of a highly intensive and specialized knowledge of the field. The projects themselves may have potentially significant economic effects on industry and include complex technical issues related to the assurance of product safety efficacy and quality.

FACTOR 6. PERSONAL CONTACTS

Contacts are with other agency officials, U.S. government officials, and officials of foreign governments, international organizations, industry and consumers.

FACTOR 7. PURPOSE OF CONTACTS

Contacts are made in order to present agency requirements, discuss controversial technical points and regulatory requirements and policies, to identify emerging problems, and to justify, defend, negotiate, and settle regulatory and technical matters of international significance. Contacts are often with those of widely differing viewpoints, goals, and objectives. The incumbent uses tact, diplomacy, negotiating skills, and technical expertise in agency regulatory programs, policy, and regulations in order to obtain an acceptable point of view or develop suitable alternatives.

FACTOR 8. PHYSICAL DEMANDS

This is a foreign duty post and may present hardships. The work is usually sedentary and may require some walking or travel to meetings and conferences away from the normal work site and in different time zones.

FACTOR 9. WORK ENVIRONMENT

This is a foreign duty post and may present hardships, including conference calls with the the agency during late evening or early morning hours to accommodate the time zone differences. The work is primarily performed in office settings that require normal safety precautions.

CONSUMER SAFETY OFFICER
Foreign Investigator
GS-696-13/14

INTRODUCTION

The incumbent of this position is considered a Senior Level Consumer Safety Officer (CSO) in the Office of the Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA) as well as an active member of the foreign inspection cadre. The incumbent serves as a primary investigational/inspectional resource for the FDA in the area of foreign inspections of the manufacturers of the products regulated by the FDA. The incumbent of this position will be stationed outside the United States for a period of two years with an option to extend a third year. A portion of the assignment may be within the United States for training or other activities in preparation for deployment to the foreign duty assignment.

MAJOR DUTIES

The incumbent serves as a Senior Level CSO and is a field resource in conducting foreign inspection/investigations of the commodities regulated by the FDA. The incumbent carries out foreign inspectional or investigational assignments and at least 75% of his/her operational time is dedicated to international inspectional or investigational assignments, in one or more of the major functional areas: (1) drugs, (2) foods, (3) medical devices and radiological health products, (4) biologics (5) animal feed and drug products, (6) bioresearch involving human subjects or (7) such other major functional areas of topical concern and of comparable scope, as may be designated. The individual is also recognized for special competence in one or more of the major functional areas. While in foreign countries the incumbent, in consultation with other Agency officials, represents the Agency's point of view and the person is recognized as a government official conducting business abroad. He/she assumes primary responsibility in any of the major areas for carrying out the following duties and responsibilities requisite for uniform inspectional approach to compliance activities and national programs by the nationwide field service of the Food and Drug Administration. Specifically:

1. Serves as the lead investigator in foreign investigation/inspection assignments. Is viewed as the focal point within FDA to whom headquarters and field service may turn for authoritative guidance and consultation regarding inspectional and investigational methods and procedures necessary to accomplish compliance objectives in their major functional area and country of assignment. Makes recommendations that may affect the status or decision of the Agency as to the status of domestic or foreign products or to permit the entry of the inspected product.

2. Provides a focal point within FDA to whom foreign manufacturers may turn for authoritative guidance and consultation regarding inspectional activities and how to comply with GMPs or other regulatory requirements, and investigation methods and procedures necessary to accomplish compliance objectives.

3. Develops and implements formal training programs for Agency personnel, industry representatives, foreign governments and local officials, and provides technical expertise to industry representatives. Conducts on-the-job training for CSOs and other employees and other training for investigators, supervisors, compliance officers, district or regional personnel, other FDA personnel and industry regarding technical and scientific matters, inspectional/investigational issues, policies, and laws.

4. Serves as an operational focal point to facilitate the establishment of an auditing and certification program within the host country.

5. Works directly with the local or foreign national government to communicate standards, and conduct public health systems evaluations.

6. Conducts audits that consist of follow-up inspections, and system audits designed to evaluate the effectiveness of the foreign government's regulatory oversight and certification process for ensuring that exported products meet FDA standards.

7. Promotes confidence in the foreign government's regulatory system and provides periodic feedback to internal and external Agency customers.

8. Gathers information on the regulated industry preventive controls and industry practice.

9. Other duties as assigned (e.g. collaborations efforts, capacity building efforts, etc.

Factor I Knowledge required by the position.

The incumbent must have a thorough knowledge of the FDA regulations, statutes and compliance policy guidelines, practices, and/or procedures as well as international inspection and technical support programs. He/she must also know the administrative elements involved in the program. Knowledge of inspectional data and analytical evidence and/or scientific technical data required in order to provide technical support to the investigators, review of reports and accomplishments of the assigned investigators and make final conclusions as to violative conditions found.

Ability to analyze the most complex and sensitive regulatory issues involving numerous variables to identify and identify root causes and anticipate ancillary problems; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory and scientific specialists, regulated industry, and involved foreign governments, and other Federal agencies.

Ability to communicate in a highly effective manner in writing and in person-to-person contacts; ability to deal effectively with others in a leadership capacity and command respect.

As a headquarters/field authority on inspectional/investigational techniques in any of the major functional areas listed above, the incumbent must have knowledge of these techniques in order to provide a focal point within the FDA for the headquarters and field service for authoritative guidance and consultation; be able to select appropriate methods for inclusion in nation-wide manual issuance systems; to conduct research to develop improved inspectional techniques for coping with advances in manufacturing technology and bulk distribution practices.

Desirable:

1. Comprehensive knowledge of the region, people, culture, society, and the public health challenges facing that region as well as FDA's history of working with that region.
2. Proficiency with the language of the country in which the incumbent is stationed.
3. Prior experience, or demonstrated understanding of working in a position requiring diplomacy and working in an environment driven by protocol.

Factor II Supervisory Controls

As a Senior Level Consumer Safety Officer the incumbent receives administrative supervision only and is given great latitude in carrying out assignments subject only to broad program direction and policy guidelines from Division of Field Investigations, Office of Regulatory Affairs. Independently designs, and carries out program work within the framework of applicable laws and regulations. Any review of work is focused on such matters as fulfillment of program objectives.

The incumbent 1) receives supervision pertaining to investigative-related activities from FDA Headquarters, Division of Field Investigations; 2) receives administrative supervision from and coordinates assignments with the FDA Country Director assigned to the area; and 3) ultimately works under the direction of the U.S. Ambassador or Deputy Chief Mission in charge of the U.S. Embassy or U.S. Mission. The incumbent's performance evaluation will be led by FDA Headquarters Division of Field Investigations with significant input from the FDA Country Director.

Factor III Guidelines

The guidelines include the Food, Drug and Cosmetic Act, applicable regulations and compliance policy guidelines as well as cooperating federal, state, local, and foreign regulatory agencies. Also included are the Foreign Travel Reports and the General Administration Manual. There are times when these guidelines are not clear or do not address a specific concern and the incumbent must make a determination. The incumbent also selects appropriate methods for inclusion in nation-wide manual issuance systems. Conducts the research to develop improved inspectional technique for coping with advances in manufacturing technology and bulk distribution practices.

Factor IV Complexity

The work involves a variety of independent assignments with varying duties, many of which are complex in nature. The regulatory problems are of the highest public interest, involve (separately or in combination) other Federal agencies, foreign governments, and international organizations, and in most instances have not been addressed in the past, or have been addressed previously without success. In assessing the potential for regulatory follow-up to the most complex cases involving products destined for export to the US, is often required to intensively analyze the facts of the case, as well as the regulatory, scientific, and political issues impacting on the case.
The incumbent may be involved in developing new regulations, programs, and policies, and may be required to draw upon expertise in various scientific and regulatory disciplines. In developing regulatory approaches to new areas of concern, the incumbent is often required to identify and secure appropriate authorities and resources from various sources, including those of cooperating international agencies, and must determine the appropriate course of action in unprecedented situations, based upon past experience and a thorough understanding of the involved industry, the regulatory goals, and the legal, logistical, and scientific limitations.

Factor V Scope and Effect

Through the development of programs and guidelines, the incumbent has significant impact on the objectives, goals, activities, programs, and resources of the regulated international industries.

Through the conduct of training activities, the incumbent has significant impact on the accuracy, reliability, and acceptability of the regulated industry as well as the FDA.

Through the advisory role in the management of the most complex and sensitive cases, the incumbent has significant impact on the accuracy, reliability, and acceptability of the Agency' regulatory actions internationally.

The expert's work involves problems in the imported FDA regulated product area, which has an extremely high visibility and sensitivity to Congressional, consumer, and international interest. The work has a high degree of importance to the FDA's regulatory mission, involving a significant degree of the nation's FDA regulated products supply.

Factor VI Personal Contacts

Contacts are mainly with agency officials and scientists from our foreign regulatory counterparts as well as at the headquarters level, and personnel in private industry, e.g., Regulatory Affairs Officers, QA/QC managers, Production personnel, academia). In addition, contact will require the incumbent to interact with individuals of different cultures and regulatory meetings may involve participants that speak languages other than English. The incumbent will establish and maintain contacts at the local, regional, and/or national level of the host government, embassies, as well as industry and consumers.

Factor VII Purpose of Contacts

The contacts with FDA personnel serve to: provide technical, scientific, and policy information and advise through informal discussions, formal briefings, and training sessions; resolve policy issues, develop regulatory strategies, and review, comment on, justify, enlist support for, and secure resources for regulatory activities.

The governmental contacts outside the FDA serve to: provide technical, scientific, and policy information and advice through informal discussions or formal briefings, resolve often widely divergent viewpoints on policy issues; accumulate and assess information concerning capabilities and effectiveness of international regulatory programs. Contacts also include making arrangements for international travel, such as obtaining passports and visas, and obtaining technical assistance for field and headquarters units.

Factor VIII Physical Demands

Foreign and domestic travel requires ability to carry luggage and equipment, i.e., computers, portable printers and reference material through airports and train stations.

The temporary duty station may be demanding, in that the incumbent may be deployed in a "hardship post" as determined by the U.S. Department of State. International and in-country travel may expose the incumbent to additional hazards.

In addition, candidates for this position may be exposed to the following:

- Work long tours of duty (e.g. > 8 hours) and unscheduled hours - exposure to all various extremes of weather and noise;
- the need to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel and climb
- handling of lab equipment and sampling instruments
- Flexibility: Be able to adjust to unforeseeable scheduling demands, flight delays, cancelled flights, and agency priorities ;
- International travel during a single trip may include multiple sites, multiple international locations, for more than three weeks at a time.
- working in foreign countries where English is not the primary language, and
- Travel by air is required.

Factor IX Work Environment

The position involves working in a foreign country where living, working, and travel conditions and public health procedures may be inadequate. The incumbent will generally work in an office setting.
The work involves moderate risks or discomforts that requires special safety precautions, e.g. working around moving parts, carts, or machines; exposure to contagious diseases or irritant chemicals, and working at great heights under extreme outdoor weather conditions. During inspections there is potential for exposure to hazards involved in a manufacturing, setting, analytical or research laboratory. The use of safety glasses, safety gloves and safety shoes is often required. Work is demanding, and requires intense efforts to meet multiple demands and numerous deadlines, while producing high-quality work.

Ms. DELAURO. What gives me pause on this is the fact that this infant formula issue in China has essentially to do with their regulatory process.

Dr. ACHESON. Right.

Ms. DELAURO. We continue to move stuff back and forth. We have had it for a very long time, evidence, that their regulatory process is seriously at fault.

Babies are dying in China as a result of their lax regulatory process.

We continue to have this back and forth, products coming in overwhelmingly relying on a very faulty regulatory process. I do not know where that gets addressed or how it gets addressed, but it has to be addressed if we are going to have to deal with the safety here of product coming from China.

What other countries are you planning to open offices in and when?

Dr. ACHESON. India. The director has been appointed for India. I think he is going to take up station later this year. I believe there are nine people that are going to be in India.

South and Central America. I do not know that the actual sites have been chosen for those yet specifically. The Middle East, which the current thinking was Jordan, and then within Europe, which is obviously a slightly different circumstance, within EFSA, within essentially the regulatory—I think it is potentially one person in Brussels. There are going to be three in Europe. The EMA was the other one in Europe.

Mr. DELAURO. Mr. Kingston? No? Okay.

Thank you all very, very much. We have been here since 2:00. It is 5:00. I appreciate your patience. I appreciate your commitment and your willingness to answer the questions and to be candid about it.

My hope is that we can really and truly not move backward but move forward in trying to design an infrastructure and an agency that one, protects the public health, and also I use the word "protection" because I am not afraid of the word "protection," but protects the industry and protects the public health.

I think that is where we need to go. I think it is going to require some time to do, but I think we have to have everybody at the table with all the cards on the table and not be afraid to mix it up with one another, so we can come out with a product here that puts the public—gives the public—renews the public's confidence in our food safety system.

I do not think anyone would disagree that the public has real confidence problems today, no matter what we want to say, and certainly a response to making sure that industry has the ability to grow and to thrive, have economic security. Thank you all very, very much. This hearing is concluded.

THURSDAY, MARCH 6, 2008.

FOOD SAFETY AND INSPECTION SERVICE

WITNESSES

DR. RICHARD A. RAYMOND, UNDER SECRETARY FOR FOOD SAFETY
ALFRED V. ALMANZA, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE
SCOTT STEELE, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

Ms. DELAURO. Dr. Raymond, I would like to welcome you this morning and thank you very, very much for being here; also to welcome Mr. Almanza. Good to see you, and of course our steady guest here is Scott Steele. So I want to apologize, Dr. Raymond, for not being able to meet prior to today's hearing, but I serve on the budget committee and with them all day until about 12:30, 12:45 a.m. just remarking of the 2009 budget.

I do not have to remind anyone of this agency's mission or how important it is. On this subcommittee we have an obligation to make sure the Food Safety and Inspection Service is well-prepared and well-supported to carry out its regulatory responsibility and protect our nation's food supply.

We all share a common goal, that is to create an effective food safety system that focuses on prevention, not just reaction, ensures the public health, and makes the most effective use of limited resources. These are rather basic and guiding principles of reform, but for too long they have been undermined by inadequate authority, outdated oversight laws, and by regard for private interest that compromises the public—

This past year has been an eventful one for FSIS. The meat recall involving Topps Meat Company in September included a then-record 22 million pounds of beef. When Topps closed its doors the following month, it was a stark reminder that every recall carries not only—health consequences, but significant economic implications for businesses and workers as well. Last year we also learned that the Food Safety and Inspection Service was underestimating the prevalence of E. coli O157:H7 in our nation's meat supply. The Food Safety and Inspection Service was not analyzing all of the regulatory samples taken for raw ground beef to test for the presence of the E. coli bacteria.

The agency had allowed companies with their own testing programs to divert ground beef that tested positive for E. coli O157H7. And the Food Safety and Inspection Service inspection personnel were allowed to discard samples that tested positive from the same lot of meat, preventing it from being sent to a food safety and inspection service laboratory for further analysis.

Fortunately, the agency modified the policy, but we still have serious questions as to why it ever happened in the first place. The end of 2007 also saw the Office of Inspector General release an

audit report, confirming the subcommittee's concern that the Food Safety and Inspection Service lacks coherent data to support the move forward a risk-based inspection system for poultry processing plant.

I'm glad that the Food Safety and Inspection Service has agreed with the Office of Inspector General's recommendations on key steps that it must take before proceeding with its risk-based system.

But simply acknowledging those recommendations is not enough to earn the green light. The Food Safety and Inspection Service must actually address the problems identified in the report before moving forward. The Office of Inspector General emphasized this important distinction as well, criticizing Food Safety and Inspection Service for failing to achieve its proper commitments to the Office of Inspector General.

The Food Safety and Inspection Service is clearly not ready to implement risk-based inspection; yet it appears to be moving forward with a so-called public health-based inspection system. Essentially a risk-based inspection system for poultry slaughtering plant, it has a new title, but the concerns remain the same.

If the Food Safety and Inspection Service is not ready to implement risk-based inspections for processing plants, it certainly is not prepared to go forward with risk-based inspections for slaughtering facilities. The labor implications of these facilities faster lines—are problematic, but the food safety implications are even more—

Of additional concerns about relying on company inspectors in place of USDA inspectors, and I hope to address all of those questions with you today and to discuss your plans for the months and the years ahead.

To be sure this agency has not been starved for resources, in 2007 it was funded at $29 million above the budget request. For fiscal year 2008 it was spared across-the-board cuts and funded at the full request. And I'm happy to say, working with you, that we did that specifically because we did not want you to have the full request that we believe and you believe was important for you to carry out your—

Unfortunately news on food safety hasn't improved since—the Humane Society uncovered horrific practices—Hallmark Westland—plants—California were downed cattle were forced to answer that they could pass federal inspection. As we all know, the slaughtering of downer cows—present a higher risk of E. coli contamination, and it violates the law with regard to downer cows.

This investigation led to the recall of more than 140 million pounds of meat, setting a new record for the largest recall in U.S. history. Perhaps the most disturbing is the fact that this Hallmark Westland plant was the second-largest meat supplier to the national school lunch program. Thirty-seven million pounds of the recalled meat were originally estimated to have gone to the program.

Next week the subcommittee will be hearing from the Department of Agriculture's Food and Nutrition Service, and I intend to focus specifically on the school lunch aspects of the recall.

I might—here that I think what the Humane Society investigation pointed up what might be regarded as a perfect storm. We were there looking at some real fault lines, in my view, within the

agency, and that is the inhumane slaughtering—the violation of the downer cow rule, the potential contamination of beef that goes to a school lunch program. It has uncovered a myriad of problems that I think point to the very real problems in our food safety system and in the food system safety as they exist at the Food Safety and Inspection Service.

I should note that I'm troubled that your testimony this morning while addressing some topic like BSE in great depth fails to seriously address some of our most urgent concerns like the dramatic Hallmark Westland failures or the larger questions of E. coli threats. There's something seriously wrong with our system when it is the disease outbreaks that are catching the failures at these plants, and not the Food Safety and Inspection Service. That is your responsibility. It's our responsibility in terms of oversight, but it's your responsibility, and it is not the Humane Society's responsibility or the disease outbreak that is what is catching failure at these plants.

Dr. Raymond, I thank you again for being here. I look forward to our discussion, so that we confront these very tough issues, strengthen Food Safety and Inspection Service's ability to meet its regulatory responsibilities and together to meet our commitment to the American people. And I thank you.

And with that let me yield to Mrs. Emerson. Mr. Kingston? Is Mr. Kingston coming at all today? I don't believe Mr. Kingston will be here today.

SPEAKER. He is coming.

Ms. DELAURO. Okay, but is he here for opening remarks? Ms. Emerson will proceed with opening——

Ms. EMERSON. I just would like to thank you, Dr. Raymond, Mr. Almanza, and Mr. Steele, for being here. I know that we will have a very interesting and hopefully very productive meeting today. With that, Madam Chair, I think I'll just save any remarks and/or questions until Dr. Raymond has finished his testimony.

Ms. DELAURO. Thank you, Dr. Raymond, and you know, please proceed with your testimony, and you know the entire testimony will be made a part of the record, so you summarize in the fashion you care to.

OPENING STATEMENT

Dr. RAYMOND. Right. Thank you, Madam Chairwoman, and Ranking Member Kingston and members of the Subcommittee, I am pleased to appear before you today. I would like to thank you and other members of the Subcommittee for your ongoing efforts to provide FSIS with the resources to improve the safety of meat, poultry, and processing products.

I would first like to address the ongoing investigation of the Hallmark Westland Meat Packing Company in Chino, California. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory disabled cattle in that facility. As soon as we learned of the problems at Hallmark Westland, we did take immediate steps to determine if the allegations made public by the Humane Society of the United States were accurate. The FDA's Office of Inspector General is leading the investigation at this time with support from FSIS and AMS.

At the conclusion of the investigation, the Secretary announced last week that we will be implementing a series of interim actions to verify and thoroughly analyze humane handling activities at all Federally inspected slaughter establishments.

The Federal Government has an interlocking system of controls to protect against BSE. The FDA's ruminant-to-ruminant feed ban, which began in 1997, is the most significant step that the Federal Government has taken to protect animal health.

The single most important thing we can do to protect human health regarding BSE exposure is the removal from the food supply of specified risk materials, or SRMs, those tissues that, according to the available scientific evidence, could be infective in a cow with BSE. According to the Harvard Risk Assessment, the SRM removal alone reduces the risk to consumers of BSE by 99 percent.

The USDA has conducted targeted BSE surveillance testing since 1990, which has detected only two animals with the disease out of over 759,000 high-risk animals tested to date, and both of those animals were born prior to initiation of the feed ban and neither entered the food supply.

The rule that prohibits non-ambulatory cattle from entering in the food supply is another one of the multiple measures that are in place to protect us. Because of these measures, we can be confident of the safety of our beef supply in regards to BSE.

I'd now like to highlight some efforts that we have made to protect human health from other foodborne pathogens. Based on the Centers for Disease Control and Prevention's annual Food Net data report, we know that we are making some progress towards the Healthy People 2010 goals regarding the incidence of foodborne illness. However, we also know that we still have work to do to further reduce the foodborne illnesses.

Following an increase in positive product test results and recalls for E. coli O157:H7, which I'll just refer to as E. coli from now on, last fall the FSIS announced several new ongoing actions to further protect the public against the risk of E. coli, which includes expanded testing.

It is important to keep things in perspective, however. Although we ended 2007 with 21 recalls due to E. coli, which is an increase, and the percentage of E. coli-positive samples from 2007, which was 0.24 percent, while being slightly higher than the 0.17 levels that we saw in 2004–2006, is still well below the percentage of positives that we saw in 2001, when we announced our new guidelines, which at that time was 0.87. And I think the graph does illustrate there is a definite increase, we acknowledge it, but is still better than it had been at the start of this decade.

FSIS also collects and analyzes samples of raw meat and poultry product for Salmonella. Because of the increase in Salmonella-positive product tests that we were seeing early in this decade, FSIS did announce an 11-point risk-based strategy for Salmonella reduction in raw products in February 2006.

We can easily see the positive results in this risk-based strategy already. The percentage of plants that fall into the best-performing category has increased dramatically from 35 percent to 74 percent over that two-year period of time. On March 28, 2008, this agency will begin posting on its Web site the completed verification test re-

sults from establishments with Salmonella rates in the other two categories, beginning with young chicken slaughter establishments.

In addition to strengthening our policies to reduce foodborne pathogens, FSIS has been proactively building its data infrastructure for the last few years, based on internal FSIS assessments and also audits by the Office of Inspector General. We were pleased that the OIG agreed that our responses to all 35 of its recommendations from the December 2007 OIG audit addressed their concerns. We acknowledge the need identified by OIG in this audit for FSIS to have an integrated system and an infrastructure in place to support a robust risk-based inspection system that we do need to further improve the safety of the food products that we regulate.

FSIS has already initiated or completed a number of actions, and we have milestones to measure our successes in this area.

Because our employees are on the front lines, enforcing our food safety and food defense policies and monitoring establishment controls of foodborne pathogens, they do remain our greatest asset. When FSIS received its final appropriation from Congress last year, including the budget increase of $27.4 million that we requested to help reduce vacancy rates and meet increased demand for front-line personnel, an aggressive effort was already underway to hire a significant number of new inspectors.

I'm pleased to let you know that on October 27 of 2007, FSIS did achieve the goal of an additional 184 in-plant front-line personnel, including food inspectors and consumer safety inspectors, which the President had requested the budget increase.

As of February 16, 2008, our vacancy rate in slaughter establishments is now at 4.25 percent, our vacancy rate in processing plants is 2.23 percent, and our total overall vacancy rate in front-line inspection is 7.4 percent today.

Because our workforce is so important, FSIS is requesting $952 million for fiscal year 2009, an increase of $22 million above the fiscal year 2008 level. This appropriation request includes funding for an increase in pay and benefit costs, an increase for costs of the State meat and poultry inspection programs, and an increase to support Federal responsibilities added due to the takeover of the New Mexico State Inspection Program.

The appropriation of the full amount requested is paramount because of the importance of FSIS's mission, that is, protecting the public's health. If we are not appropriated the full amount of our request, the salary and benefit cost for FSIS's statutorily mandated workforce will have to be fulfilled using the budget of other FSIS initiatives and programs.

The Administration also proposes legislation to provide the USDA with the authority to collect new user fees, including a licensing fee and a performance fee.

Madam Chairwoman, Ranking Member Kingston, Mrs. Emerson, and members of the Subcommittee, thank you for the opportunity to testify today, and Mr. Almanza and I will be very happy to try and answer all of your questions as best we can.

[The information follows:]

Dr. Richard Raymond, Under Secretary for Food Safety, United States Department of Agriculture

Dr. Richard Raymond was appointed as Under Secretary for Food Safety on July 18, 2005. In this position, Dr. Raymond is responsible for overseeing the policies and programs of the Food Safety and Inspection Service (FSIS), and he chairs the U.S. Codex Steering Committee, which provides guidance to U.S. delegations to the Codex Alimentarius Commission.

Dr. Raymond has extensive experience in developing and implementing policies and programs designed to improve public health. Prior to joining USDA, Dr. Raymond served as the director of the Nebraska Department of Health and Human Services Regulation & Licensure division where he oversaw regulatory programs involving health care and environmental issues and was also Nebraska's Chief Medical Officer since January 1999.

While serving as Nebraska's Chief Medical Officer, Dr. Raymond directed a large number of public health programs including disease prevention and health promotion. He also developed several anti-bioterrorism initiatives and a statewide health care alert system. He also played an integral role in developing multi-county health districts to provide a public health system that included all of Nebraska's 93 counties.

Dr. Raymond served as president of the Association of State and Territorial Health Officials (ASTHO) and was a member of the association's Preparedness Committee for three years.

A life-long resident of Nebraska, Dr. Raymond practiced medicine in rural Nebraska for 17 years. Dr. Raymond then established and directed a community-based Family Practice Residency for Clarkson Medical Center, served as president of the Nebraska Medical Association, chaired Nebraska Governor Mike Johanns' Blue Ribbon Panel on Infant Mortality and served on numerous state committees related to public health.

Dr. Raymond attended Hastings College and earned his medical degree from the University of Nebraska Medical Center.

For release only by the
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Appropriations

FOOD SAFETY AND INSPECTION SERVICE

Statement of
Dr. Richard Raymond, Under Secretary for Food Safety
Before the
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Introduction

Madam Chairwoman, Ranking Member Kingston, and Members of the Subcommittee, I am pleased to appear before you today to discuss the status of the Food Safety and Inspection Service's (FSIS) programs and the fiscal year (FY) 2009 budget request for food safety within the U.S. Department of Agriculture (USDA). I am Dr. Richard Raymond, Under Secretary for Food Safety. With me today is Al Almanza, Administrator of FSIS.

I look forward to working with the Subcommittee on our common commitment to public health and food safety. I would like to thank you and the other members of the Subcommittee for your ongoing efforts to provide FSIS with the resources to protect meat, poultry, and processed egg products. These funds are helping to move our public health agenda forward.

Who We Are

FSIS is the public health regulatory agency within the USDA. We are responsible for ensuring that the Nation's commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome, and accurately labeled and packaged, whether those products are domestic or imported. FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, the Humane Methods of Slaughter Act, and the regulations that implement these laws. The Humane Methods of Slaughter Act requires that all livestock be handled and slaughtered in a humane manner.

FSIS program personnel form the backbone of FSIS' public health infrastructure in establishments, laboratories, and import houses throughout the country. In FY 2007, the agency employed over 9,000 personnel, including approximately 7,800 full-time in-plant and other front-line personnel protecting the public health in approximately 6,200 Federally-inspected establishments nationwide. The high volume and the high-risk nature of the products FSIS inspects demands an in-plant inspection presence, which is not only required by law, but is necessary to protect consumers.

During FY 2007, FSIS inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the processing of over 48 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 4.3 billion pounds of processed egg products. They also inspected at U.S. borders 3.9 billion pounds of imported meat and poultry products. In

addition, FSIS personnel conducted more than nine million procedures to verify that establishments met food safety and wholesomeness requirements. .In addition, FSIS personnel conducted more than nine million procedures to verify that establishments met food safety and wholesomeness requirements.

In support of in-plant personnel in Federally-inspected establishments, FSIS employs a number of other field personnel, such as laboratory technicians and investigators. The program investigators conduct surveillance, investigations, and other oversight activities at food warehouses, distribution centers, retail stores, and other businesses operating in commerce that store, handle, distribute, transport, and sell meat, poultry, and egg products to the consuming public. These in-commerce businesses do not operate under grants of inspection and are not inspected on a daily basis by FSIS. However, the agency's oversight of FSIS-regulated products moving in consumer distribution channels is vital to the public health.

Our Workforce

Our employees are our greatest asset. We are only as strong as that committed workforce. Just as they are committed to keeping the Nation's food supply safe, *we* are committed to them. When FSIS received its final appropriation from Congress last year, an aggressive effort was already underway to hire a significant number of new inspectors. As of October 19, 2007, FSIS had hired more than 600 new in-plant personnel and, as a result, achieved a net gain of approximately 160 in-plant personnel. On October 27, 2007, FSIS achieved a net gain of 194 in-plant personnel, surpassing the goal of 184 for

which the President had requested the budget increase. By December 22, 2007, we had achieved a net gain of more than 220 in-plant personnel, or food inspectors and consumer safety inspectors.

FSIS has employed the aggressive use of existing and new staffing authorities to fill mission-critical positions, especially for in-plant and other frontline positions, where 85 percent of FSIS employees are located. A comprehensive human capital strategy was developed to improve hiring and retention efforts, to better match resources to needs, and to develop new skills sets needed by the workforce. As a testament to those efforts, the agency received a Presidential Quality Award for Management Excellence for its dedication, hard work, and outstanding leadership in advancing the President's Management Agenda through the strategic management of human capital. FSIS received one of six awards given to Federal agencies for excellence in quality and productivity – the first for USDA.

Current Concerns Regarding Humane Handling of Livestock

Before I go any further, I would like to address the ongoing investigation of the Hallmark/Westland Meat Packing Company (Hallmark/Westland) in Chino, California. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory disabled cattle in that facility.

I want to further assure you that, as soon as we learned of the problems at Hallmark/Westland, we took immediate steps to determine if the allegations made public

by the Humane Society of the United States (HSUS) were accurate. Secretary Edward Schafer called on USDA's Office of Inspector General (OIG) to work with FSIS and USDA's Agricultural Marketing Service (AMS) to conduct a thorough investigation into this matter.

In addition, USDA's Food and Nutrition Service placed an administrative hold on all Hallmark/Westland Meat Packing Company products that were in or destined for Federal food and nutrition programs, pending further information from the investigation. An administrative hold prevents program operators from using the product until further notification from USDA.

As soon as FSIS determined that humane handling regulations were violated, FSIS issued a Notice of Suspension to Hallmark/Westland, although the establishment voluntarily stopped slaughter operations as soon as the investigation began. Additionally, immediately upon receiving conclusive evidence that non-ambulatory animals were allowed into the food supply, FSIS worked with the company to initiate a voluntary recall.

Timeline of USDA Actions

On January 30, 2008, USDA learned about the original HSUS video regarding violations through the media. On the same day, USDA indefinitely suspended Hallmark/Westland as a supplier to Federal nutrition programs. Hallmark/Westland was not permitted to produce or deliver any products under contract, and, under the suspension, no further

contracts could be awarded to the company. In addition, USDA placed an administrative hold on all Hallmark/Westland products we identified that were in, or destined for, Federal nutrition programs as of October 1, 2006. The October 1, 2006, date for the start of the initial hold period was chosen to capture the Hallmark/Westland product that was in the Federal nutrition program supply chain.

On February 1, 2008, Hallmark/Westland voluntarily stopped slaughter operations. As a result of FSIS findings, FSIS suspended inspection at the plant on February 4, 2008. This action was based on FSIS findings that the establishment failed to prevent the inhumane handling of animals intended for slaughter at the facility, as required by FSIS regulations and the Humane Methods of Slaughter Act.

Our evidence demonstrates that, over the past two years, this plant did not always notify the FSIS public health veterinarian when cattle became non-ambulatory after passing ante-mortem (prior to slaughter) inspection, as is required by FSIS regulations. It is important to note that certain cattle, while ambulatory when they pass ante-mortem inspection, later become non-ambulatory from an acute injury or another circumstance. If such a situation occurs, FSIS regulations require the public health veterinarian to inspect the animal again before the animal is permitted to go to slaughter. This failure by Hallmark/Westland led to the company's February 17, 2008, voluntary recall of 143 million pounds of fresh and frozen beef products produced at the establishment since February 1, 2006.

On February 17, 2008, FSIS amended the suspension to reflect the fact that Hallmark/Westland had allowed cattle that had become non-ambulatory after passing ante-mortem inspection to be slaughtered without further inspection by FSIS personnel. This suspension will remain in effect and the establishment will be unable to operate until corrective actions are submitted in writing and verified through a full review by FSIS. Slaughter operations will not resume at Hallmark/Westland until the company complies fully with FSIS regulations.

While it is extremely unlikely that these animals pose a risk to human health, the recall action was deemed necessary because the establishment did not comply with FSIS regulations. The recall was designated Class II because of the remote probability that the recalled beef products would cause adverse health effects, if consumed.

As is the case for all recalls, FSIS is conducting effectiveness checks to verify that customers have received notice of the Hallmark/Westland Meat Packing Company recall and are making every effort to retrieve and destroy the recalled product or return it to the establishment. FSIS personnel are in the process of verifying that Hallmark/Westland has been diligent and successful in notifying its consignees of the need to retrieve and control recalled product, and that the consignees have responded appropriately.

Safeguarding Against BSE

I am aware that this situation has raised questions about the risk of bovine spongiform encephalopathy (BSE). I would like to take this opportunity to give you a brief summary of the safeguards against BSE that we have in place to protect our food supply.

Since the discovery of the first case of BSE in Great Britain in 1986, we have learned a tremendous amount about this disease. That knowledge has greatly informed USDA's regulatory systems and response efforts. It has also given us the opportunity to examine our own cattle herd, which is why we know that the risk of BSE in the United States is extremely low.

As noted earlier, non-ambulatory cattle are excluded from the food supply as part of the Federal government's interlocking system of controls to protect the food supply from BSE. These BSE security measures include the ban on non-ambulatory cattle, but that is simply one of the multiple measures in place.

We have learned that the single most important thing we can do to protect human health regarding BSE is the removal from the food supply of specified risk materials (SRMs)—those tissues that, according to the available scientific evidence, could be infective in a cow with BSE. FSIS requires that all specified risk materials (SRMs), including the brain and spinal cord, are removed from carcasses so that they do not enter the food supply. Slaughter facilities cannot operate without the continuous presence of FSIS inspection personnel to ensure safe and wholesome product, and the safeguards include the removal

and segregation of SRMs. FSIS line inspectors are stationed at key points along the production line where they are able to directly observe certain SRM removal activities. Other off-line inspection personnel verify additional plant SRM removal, segregation and disposal. According to the 2005 Harvard Risk Assessment, SRM removal alone reduces the risk to consumers of BSE by ninety-nine percent.

The ruminant-to-ruminant feed ban is another significant step that the Federal government has taken to prevent the spread of BSE and bring about its eradication in the animal population. In 1997, the Food and Drug Administration (FDA) implemented a mandatory feed ban that prohibits feeding ruminant protein to other ruminants. The feed ban is a vital measure to prevent the transmission of BSE to cattle.

Moreover, BSE testing is best used as a surveillance tool. By testing animals that show possible clinical signs of the disease, we can document the effectiveness of our security measures.

USDA's Animal and Plant Health Inspection Service has conducted targeted BSE surveillance testing since 1990, including an enhanced surveillance effort that was initiated after an imported cow tested positive for the disease in December 2003. The goal of the enhanced effort, which began in June 2004, was to test as many animals in the targeted population as possible over a 24-month period. This intensive effort detected only two animals with the disease, out of over 759,000 animals tested. Both of those animals were born prior to initiation of the FDA feed ban and neither entered the food

supply. This testing confirms an extremely low prevalence of the disease in the United States.

Because of the strong systems the United States has put in place, we can be confident of the safety of our beef supply and that the spread of BSE has been prevented in this Nation.

Further Actions

The investigation led by OIG with support from FSIS and USDA's AMS is ongoing. Once the investigation has concluded, we will have additional information to determine the actions for FSIS oversight, inspection and enforcement that may be required. However, we are not waiting for the completion of the investigation to act. USDA is already taking a number of steps to strengthen our inspection system.

USDA will continue to provide the public with an update of our actions at www.usda.gov/actions.

Enhancing Our Use of Data

As most of you know, FSIS has been actively strengthening its public health data infrastructure as part of its ongoing effort to improve food safety and food defense. The agency has been building its data infrastructure for the last few years based on internal FSIS assessments. More recently, several audits by USDA's OIG identified a number of areas within the agency's data system and infrastructure that required strengthening. We

have been using the results of these audits to strengthen our efforts and bolster our infrastructure. We were pleased that OIG agreed that our responses to all 35 of its recommendations from the December 2007 OIG audit address their concerns. Your active involvement and commitment to public health, Madam Chairwoman, made this possible.

We acknowledge the need identified by OIG in this audit for FSIS to have an integrated system and infrastructure in place to support a comprehensive, timely, and reliable data-driven inspection system. FSIS has already initiated or completed a number of actions, and we have milestones to measure our success.

An integrated strategic approach is needed to build a reliable infrastructure that can evolve as the agency's needs change. FSIS is finalizing its strategic plan for fiscal years 2008 through 2013 and once completed will release it publicly and share it with the Subcommittee. Our plan emphasizes the importance of the agency's work to continue to build its infrastructure over the next five years. The other key element to building a quality public health infrastructure is data that is readily accessible to key decision-makers and front-line personnel. Of course, the quality of public health data is only as good as the infrastructure that surrounds it. By using tools that regularly mine and aggregate the data, the agency will be able to better use its resources to interpret and act on indicators to better protect public health.

FSIS has made numerous efforts to improve the agency's collection and analysis of data, such as AssuranceNet, a Web-based system of management controls that pull inspection and laboratory data from the agency's data warehouse. More recently, our improvements include forming the Data Analysis and Integration Group (DAIG) and the Data Coordinating Committee (DCC). The DAIG is a staff dedicated to conducting data analysis and ensuring that agency data analyses are consistent, of high quality, and relevant to the agency's mission and business processes, and fully integrated into ongoing decision-making. The DCC has members from each agency program office who serve as liaisons between the DAIG and the program offices. More specifically, DCC members coordinate the analysis of data that goes on around the agency to ensure that data is not duplicated, that data is used efficiently, and that analysis done in one part of the agency is available to inform the work done in other parts of the agency. We are also creating analysis plans for directives and notices, conducting peer reviews and soliciting input from stakeholders, and developing a consistent set of tools for conducting data analysis.

We have also provided broadband computer connections in the field so that most inspection personnel are linked to a near real-time data communications infrastructure. This improved access is vital for agency personnel who are collecting data in the field, because it will allow them to spend more of their time on inspection activities.

To be successful, public health decisions must be based on data. The agency has made great progress in the collection, analysis and response to data, including using data to predict problems before they occur. All of this effort is directed to better protect public

health. Based on a case study of the Topps recall and the multi-State outbreak of *E. coli* O157:H7 presented to the National Advisory Committee on Meat and Poultry Inspection on February 5, 2008, we know that our planned system based on public health and risk could provide: 1) improved inspector understanding of *E. coli* O157:H7 hazards and controls; 2) automated monitoring of inspection results and built-in alerts of anomalies (e.g., changes in establishments' HACCP plans and lack of inspection activity); and 3) identification of vulnerabilities in the overall food safety system (e.g., new verification questions for inspectors would better verify plants' implementation of process controls). By examining our approach and ensuring that we have a strong system and infrastructure in place to make best use of and assess the data, we will be even better at what we do.

Public Health Information System

FSIS is currently making improvements to focus inspection time on public health risks, which will be one key component of the Public Health Information System (PHIS). This Web-based system will make it easier for inspectors in the field to report on the results of their inspection activities, and will allow the agency to analyze the data more quickly and identify trends or problems sooner. This will, in turn, decrease the time needed to respond to incidents. Better use of technology will improve our ability to collect, analyze, and predict likely outcomes, allowing agency employees to better protect public health, address humane handling concerns, and ensure food defense. Moreover, PHIS will affect all parts of the agency, including import, export, in-commerce, and laboratory activities. Deployment of this system is scheduled for late FY 2009.

As part of the continued evolution of our inspection program, FSIS is currently planning a public health-based slaughter inspection system for young chickens and is discussing how a similar approach could be used for inspection in processing and other slaughter establishments. On February 5-6, 2008, FSIS hosted a meeting for the National Advisory Committee on Meat and Poultry Inspection to seek the Committee's input on public health-based slaughter inspection. The goal of this approach to inspection, which is science-based and data-driven, is to focus our resources where they can best ensure that establishment controls protect the public health.

Food Safety Assessments

In response to recommendations in the 2003 and 2004 OIG audits, FSIS implemented a more comprehensive system to verify establishments' Hazard Analysis and Critical Control Point (HACCP) plans using food safety assessments. During these food safety assessments, specially trained personnel conduct in-depth reviews of the designs of establishments' HACCP or food safety plans. OIG agrees with FSIS that food safety assessments are a fundamental building block for assessing establishment risk. Food safety assessments are also a key component in building FSIS' public health data infrastructure.

One significant recommendation from the more recent December 2007 OIG audit directed FSIS to complete food safety assessments in all plants using an objective scoring mechanism to help determine the level of inspection needed. Our effort to do this for all plants is well underway.

Efforts to Fight Foodborne Pathogens

Based on Centers for Disease Control and Prevention's (CDC) annual FoodNet data report, we are making some progress toward meeting the Healthy People 2010 goals regarding the incidence of foodborne illness. However, we know we still have work to do to further reduce foodborne illness.

FSIS' verification sampling is a critical method the agency uses to collect data and is a good example of how we have taken a more risk-based approach. Under the agency's verification sampling program, FSIS samples meat, poultry and processed egg products and analyzes them for the presence of microbial pathogens. However, the agency has paid particular attention to *E. coli* O157:H7 in raw ground beef and *Salmonella* in raw meat and poultry products through the *E. coli* initiative announced last fall and its ongoing *Salmonella* strategy.

The new, ongoing actions we have undertaken to protect the public against the risk of *E. coli* O157:H7 include expanded testing. By March 2007, FSIS had already begun testing trim, the primary component in ground beef, in addition to ground beef itself. However, as a result of an increase in *E. coli* O157:H7-positive samples, the subsequent increase in the number of *E. coli* O157:H7-related recalls, and the increase in human illnesses linked to these recalls, FSIS implemented a number of initiatives to combat *E. coli* O157:H7.

In July 2007, after an unusual number of *E. coli* O157:H7 positives the month before, FSIS substantially increased the number of raw ground beef samples scheduled for July

from 1,100 to 1,943 – an increase greater than 75 percent. After seeing nothing unusual in the positive sample rate in July, FSIS began scheduling samples for every raw ground beef establishment once per month (i.e., approximately 1,350 samples per month).

On October 26, 2007, FSIS inspection program personnel began testing additional components of ground beef. By testing earlier in the production chain, FSIS minimizes the likelihood that this contaminated source material will be used in ground beef that is available to consumers. FSIS began requiring countries whose beef is imported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the agency has begun verification sampling of trim at ports of entry to supplement the agency's sampling of ground product at ports of entry. We will be analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs.

Other key initiatives targeted to Federally-inspected plants that produce raw beef products include verifying control of *E. coli* O157:H7, the creation and use of a new checklist for verifying control, targeted sampling for *E. coli* O157:H7 at slaughter and grinding facilities based on production volume and pathogen controls, follow up sampling of 16 samples and conducting food safety assessments for plants with a Federal or State positive *E. coli* O157:H7 test result, and refinement of the agency's *E. coli* O157:H7 test method to provide a more sensitive test that will detect *E. coli* O157:H7 at even lower concentrations. All of these policy changes mean that FSIS will be better able

to identify an emerging problem as early as possible and will be able to prevent contaminated product from entering commerce.

The agency is completing a more in-depth analysis of the data captured in responses to questions, filled out by FSIS inspection program personnel, about reassessment of HACCP plans related to *E. coli* O157:H7. Our preliminary data, completed in November 2007, shows that almost 96 percent of all beef slaughter and processing establishments reassessed their HACCP plans. We are analyzing these responses, and we anticipate that the analysis will lead to new policies, directives, or possibly rules and regulations.

In the wake of these progressive *E. coli* O157:H7-related policy changes, FSIS determined that steps were also needed to ensure that inspection program personnel and the industry fully understand the nature of the challenge presented by *E. coli* O157:H7. We are developing a strong, ongoing strategy to evaluate the success of our training program. Through the In-Plant Performance System, AssuranceNet management controls, and reports from district analysts, the agency is ensuring that inspection program personnel are doing their jobs correctly, are held accountable, and have appropriate workloads and supervision.

As with any policy or program change, FSIS is making sure that we educate and receive feedback from our public health partners and stakeholders regarding our *E. coli* initiatives. For example, on October 17, 2007, FSIS, FDA, and CDC hosted a public meeting regarding *E. coli* serotypes other than O157:H7 that are related to foodborne

illness. In October and November, 2007, FSIS targeted outreach and training sessions around the country for small and very small raw beef processors. On January 23, 2008, FSIS participated in a meeting with the American Meat Institute Foundation and the National Meat Association about *E. coli* O157:H7 surveillance and prevention.

We will continue to work to identify the cause of the recent increase in *E. coli* O157:H7 illnesses and recalls, and to find a permanent, workable solution to the issue. Thus, we are planning a public meeting for April 2008, focused on a discussion with representatives from science, academia, industry, consumer groups and government, about the increase in illnesses and recalls attributed to *E. coli* O157:H7. This meeting will provide updates on FSIS initiatives and build a foundation for establishing solutions to address the challenges posed by this pathogen.

In mid-May, FSIS will hold a meeting with its State and local public health partners, including FDA, CDC, industry and consumer groups, about how to improve the effectiveness and efficiency of outbreak investigations and recalls conducted by FSIS in collaboration with these partners. Every *E. coli* O157:H7-related recall last year showed me something that we can improve, and I hope that these meetings will get everyone to start thinking about how to improve the coordination, accuracy, and timeliness of communication and food safety activities, specifically outbreak investigations and recalls.

Another important step in that direction is USDA's announcement on February 5, 2008, that the Department agreed to grant a conditional license to Bioniche for its *E. coli*

O157:H7 Cattle Vaccine. This is the world's first vaccine that may be used as an on-farm intervention to reduce the amount of *E. coli* O157:H7 shed by cattle.

It is important to keep things in perspective. Although last year we observed a rise in *E. coli* O157:H7-positive samples and recalls, because of new policy implementation and closer oversight and by working with industry, USDA has made tremendous progress in controlling *E. coli* O157:H7 overall. In fact, between 2002 and 2006, FSIS testing shows the percentage of samples testing positive for *E. coli* O157:H7 declined by 78.3 percent. During this time there was also a reduction in illnesses attributed to *E. coli* O157:H7. There was a slight increase in 2006, but several of those illnesses were attributed to food outbreaks that were not related to meat products.

FSIS instructed plants to reassess their food safety plans in 2002. As a result of industry's hard work and commitment to making safer products, we saw the rates of positive samples decrease in 2002, 2003 and 2004, remaining at 0.17 percent for 2005 and 2006. To put that percentage into perspective, out of 12,000 samples taken in 2006, only 20 were positive for *E. coli* O157:H7.

Although we ended 2007 with 21 recalls due to *E. coli* O157:H7, the percentage of *E. coli* O157:H7 positive samples for 2007 – 0.23 – was still well below the percentage of positives during the 2000 – 2003 timeframe.

At the same time as we have been searching for the cause of the observed rise in *E. coli* O157:H7-positive samples and related recalls, we have also been exploring how we can improve the recall process to better protect the public. FSIS published a proposed rule on March 7, 2006, which would allow FSIS to make available to the public lists of retail establishments, such as grocery stores, that have likely received products that are subject to a recall. The rule is in the final stages of the rulemaking process. This is something that I strongly believe in and have been pushing for since I arrived at USDA. Making retail information available to the public will help consumers to better identify recalled product that may already be in their pantry or freezer, thus preventing foodborne illness and saving lives. Making retail information available to the public may further increase the effectiveness of our recalls as it may prompt consumers that shop at the listed retail outlets to examine the labels of those products stored in their pantry or freezer sooner. It is important that recalled products are returned or destroyed as quickly as possible to minimize potential foodborne illness.

We have already made great strides in improving the recall process. For example, FSIS now takes into account a broader, more complete range of evidence when evaluating whether to seek a recall or take regulatory action. In other words, we now look to epidemiological evidence, as well as test results, to identify the source of human illnesses related to foodborne pathogens. Two recalls in the fall of 2007 resulted from this new policy. In these cases, FSIS acted upon epidemiological evidence that linked illness to opened, FSIS-inspected product found in consumers' freezers, where previously, we believed the agency needed a test result from an intact or unopened package because of

the possibility of cross-contamination. Also in the fall of 2007, through an extensive epidemiological and traceback investigation, we were able to pinpoint the source of the multi-state outbreak of *E. coli* O157:H7 infections linked to the Topps Meat Company, which led to the second largest beef recall ever.

As another part of the agency's verification sampling program, FSIS collects and analyzes samples of raw meat and poultry product for *Salmonella*. In response to this continued foodborne threat, in February 2006, FSIS announced an 11-point, risk-based strategy for *Salmonella* reduction in raw products. The initiative included targeting resources at establishments with higher levels of *Salmonella* and changed the reporting and utilization of FSIS' *Salmonella* verification data test results.

We can easily see the positive results of this risk-based strategy. If we compare the plant categories based on broiler carcasses analyzed for *Salmonella* in 2006 to 2007, we see that the percentage of plants in Category 1, or those with sampling results amounting to half or less than half of the current standards, increased dramatically, from 49 percent to 74 percent. Likewise, the percentage of plants in Category 3 decreased significantly from 10 percent to two percent. Essentially, the percentage of young broiler carcasses that tested positive for *Salmonella* decreased by 50 percent – from 16 percent to 8 percent.

Earlier this year, FSIS announced further changes in its *Salmonella* policy to continue driving down the incidence of *Salmonella* in poultry. On March 28, 2008, the agency will begin posting on its Web site completed verification test results from establishments

performing in Category 2 or 3, beginning with young chicken slaughter establishments. The agency will also offer specific waivers to Category 1 establishments. With these waivers, those establishments with the lowest *Salmonella* rates will be able to test new procedures, equipment, or processing techniques that will facilitate improvements in the ongoing control of *Salmonella*.

Coordination with Public Health Partners

In conjunction with CDC, FDA, and epidemiologists and public health laboratories in several States, FSIS continues to build upon existing data in the Foodborne Diseases Active Surveillance Network, or FoodNet, which conducts active surveillance of foodborne diseases, case-control studies to identify risk factors for acquiring foodborne illness, and surveys to assess medical and laboratory practices related to foodborne illness diagnoses. FoodNet data are also used to evaluate progress toward meeting CDC's Healthy People 2010 national objectives for foodborne infections.

A sister system of FoodNet is PulseNet, a collaborative national computer network of public health laboratories that link seemingly sporadic illnesses together and enable public health officials to more quickly identify and respond to multi-State illness outbreaks. In fact, through the use of PulseNet, we are able to identify seemingly unrelated foodborne illnesses as actual outbreaks more quickly. Prior to PulseNet, many of these outbreaks would not have been recognized as outbreaks. These two systems allow agencies to collaborate and bring their specialized knowledge together to better protect public health.

FSIS also takes every opportunity to diversify and improve the data submitted to CDC's PulseNet. On August 30, 2007, FSIS and the Agricultural Research Service (ARS) signed a memorandum of agreement in order to share data on *Salmonella*. Specifically, the cooperative agreement served to set requirements related to the submission of *Salmonella* strains and carcasses from the FSIS/Pathogen Reduction, HACCP Verification, Baseline, and other programs to ARS for testing. ARS tests include Pulsed-Field Gel Electrophoresis, which helps to determine the so-called DNA fingerprint of a pathogen; antimicrobial susceptibility tests; and other laboratory sub-typing procedures.

We rely on the efforts of our partners to help us in our mission to protect public health. FSIS works in collaboration with its sister agencies on multi-jurisdictional food safety issues, whether those agencies are Federal, State, or local entities.

Small and Very Small Plant Outreach

We are committed to making the foods we regulate the safest they can be, wherever they are produced, whether in large or very small plants, or in urban or rural plants. We are also committed to providing the owners and operators of small and very small plants access to the information and tools they need in order to meet our regulatory requirements. I have taken this charge very seriously in my tenure at USDA.

We have increased the type and amount of resources, technical assistance, and guidance documents available to this important segment of industry. We have taken new directions in communicating with these plant owners and operators, through a Web page

dedicated to small and very small plants, a monthly newsletter, information sessions, Net meetings, and a new feature on the FSIS Web site called "askFSIS," designed to answer technical and policy questions regarding inspection and public health regulations 24 hours per day, seven days per week. Visitors can also ask new questions, which are reviewed and answered quickly, then categorized and posted on the agency's Web site.

Ensuring that industry, particularly small and very small plant owners and operators, have access to the same training provided to our inspection program personnel is another important feature of our outreach and training strategy.

I will be announcing an organizational change later this week, which will strengthen the agency's approach and ensure that outreach to small and very small plants continues to be a top agency priority for the future Under Secretaries for Food Safety.

Outreach to At-Risk and Underserved Populations

Many of the agency's ongoing education efforts continue to focus on at-risk and underserved populations. Infants and young children, pregnant women, older adults, and people with weakened immune systems caused by cancer treatment, diabetes, AIDS, and bone marrow and organ transplants are at greatest risk for foodborne illness. That is why FSIS is following up on the conference we held in fall 2006 on reaching more vulnerable at-risk populations.

We are reaching out to at-risk populations through brochures and fact sheets written with this audience in mind. We are also planning more formal efforts to follow up on the findings from the conference and to translate those findings into concrete actions that we and our public health partners can take to better reach and serve the at risk population. In addition, FSIS is dedicated to reaching the emergent Spanish-speaking population in the United States. The *En Español* section of FSIS' Web site includes news releases, fact sheets, and food defense and emergency response materials that have been translated into Spanish.

Through the Partnership for Food Safety Education, FSIS continues to reach out to consumers. The Partnership for Food Safety Education was formed in 1997 as a public-private coalition dedicated to educating the public about safe food handling to reduce foodborne illness. Through its Fight BAC!™ Campaign, FSIS educates consumers about four simple steps they can take to fight foodborne bacteria and reduce the risk of foodborne illness: CLEAN, SEPARATE, COOK, AND CHILL. In addition, we launched a *Be Food Safe* Campaign, an updated public education effort based on those important food safety messages, in cooperation with the Partnership for Food Safety Education, FDA, and CDC, because research shows that Americans are aware of food safety, but they need more information to achieve and maintain safe food handling behaviors. As a measure of our success, FSIS recently celebrated the 10th anniversary of the Partnership for Food Safety Education, which included a salute to the role that State and community organizations play in creating and disseminating unique programs based on the four core safe food handling messages.

Food Defense

To further ensure the safety of domestic, imported, and exported products, the agency engages in active surveillance through a series of food defense verification procedures performed daily in all FSIS-regulated facilities. With a strong food safety verification system in place, FSIS has been focusing on fortifying existing programs with a greater emphasis on food defense and improving internal and external lines of communication, including the integration of food defense data into the larger public health data infrastructure.

FSIS conducts food defense activities both in-plant and in commerce to ensure the safety of domestic, imported and exported product. A field force of approximately 100 investigators conduct food safety and food defense surveillance at food warehouses, distribution centers, retail stores and other types of facilities throughout the United States to determine whether meat, poultry, or egg products distributed in interstate commerce are safe, secure, wholesome, and not adulterated or misbranded.

How FSIS Ensures the Safety of Imports

FSIS uses a comprehensive system to ensure that imported meat, poultry, and processed egg products are safe and secure. The three-part system includes a thorough analysis of each country's food laws and inspection systems to determine initial equivalence; on-site audits of each country's food safety system to verify that the system is implemented in accordance with what is in writing, and then to ensure equivalence is maintained; and port-of-entry inspection on all FSIS-regulated meat, poultry, and processed egg products coming into the United States, with a few exceptions. The amount of FSIS-regulated

meat and poultry imports has remained approximately the same over the past five years, hovering around four billion pounds of meat and poultry from 29 of the now 34 eligible countries, approved through rulemaking.

In addition to the initial re-inspection of product entering the United States, FSIS performs intensive random re-inspection on approximately 10 percent of the shipments of meat and poultry products. These re-inspection tasks include product examinations, microbiological analysis for pathogens, and/or a test for chemical residues.

Approximately five percent of shipments of imported meat and poultry products receive microbiological and chemical verification testing. This system is enhanced by FSIS' Import Surveillance Liaison Officers, who conduct a broad range of surveillance activities at import facilities and in commerce, and serve as liaisons to improve coordination with other agencies like U.S. Customs and Border Protection.

Access to the U.S. Customs and Border Protection's Automated Commercial Environment (ACE) database has provided FSIS a more targeted approach to identifying and controlling ineligible entries of FSIS-regulated product closer to the entry point, rather than after its release into commerce. In FY 2005, prior to FSIS' use of the ACE system, the amount of ineligible product removed from commerce that did not pass through import houses was a little over 36,000 pounds. In FY 2006, this amount increased to 1.6 million pounds, and in FY 2007, 2.1 million pounds was identified, destroyed, or redirected to FSIS for re-inspection.

Interagency Working Group on Import Safety

Recently, I represented USDA in the Interagency Working Group on Import Safety, helping to determine which aspects of the U.S. food safety system can be strengthened. The President formed this Working Group to conduct an across-the-board review of import safety by U.S. importers, and by Federal, State, and local governments. It was also given the task of providing recommendations to the President that will help to further improve the safety of imported products.

In September 2007, the Working Group issued a strategic framework for doing more to ensure the safety of imported products. This framework outlines a risk-based approach that includes the principles of prevention, intervention, and response. The framework supports USDA's long-standing approach to evaluating and verifying the ability of foreign food safety systems to meet food safety requirements for meat, poultry, and processed egg products exported to the United States.

On November 6, 2007, the Working Group released an implementation action plan containing 14 recommendations and 50 action steps. The Working Group provided specific short- and long-term recommendations for import safety improvements and reflected stakeholder input received through several outreach activities, as well as from a public meeting that was held on October 1, 2007, at USDA headquarters here in Washington. The Administration is working toward implementation of the Working Group's recommendations. Progress is being measured by each action step.

FY 2009 Budget Request

I appreciate having the opportunity to share many of accomplishments and priorities with you. Now, I would like to offer an overview of the FY 2009 budget request for FSIS.

In FY 2009, FSIS is requesting $952 million, an increase of $22 million above the FY 2008 level.

FSIS has a statutory obligation to provide inspection of meat, poultry and egg products. An increase for the FSIS inspection program is requested to maintain our high standards for the safety and wholesomeness of meat, poultry and egg products and our continued efforts to ensure effective inspection and policy implementation. This appropriation request includes funding for an increase in pay and benefit costs, which make up approximately 80 percent of FSIS' budget; an increase for the costs of the State Meat and Poultry Inspection Programs; and an increase to support Federal responsibilities added due to the takeover of the New Mexico State program. The appropriation of the full amount requested is paramount because of the importance of FSIS' mission: public health.

The Administration's budget submission assumes that the cost of inspection services for Federal meat, poultry, and processed egg products will continue to be paid with Federal funds in FY 2009. The Administration also proposes legislation to provide USDA with the authority to collect new user fees, including a licensing fee and a performance fee. The collection of these new user fees, which we estimate would amount to $96 million

during FY 2009, would be available for spending in FY 2010. A total of about $92 million in licensing fees would be collected from establishments based on their inspection services. An additional $4 million in performance fees would be collected from establishments that require additional inspection activities for performance failures such as retesting, recalls, or inspection activities linked to an outbreak.

Continued Evolution of Inspection and Use of Risk

As you know, because of my medical background and passion for public health, I have pursued the issue of how best to use risk in inspection. It has been a healthy debate. I believe this open and frank debate on risk needs to be expanded to include all foods.

We need to continue to pursue these looming questions: Where is the risk greatest and where do inspection and other resources belong? Not all food products are equal from a risk standpoint. I am encouraging all food safety partners to join together and assess all foods and ensure that we are getting the best return for the Federal investment in food safety for the American public.

Higher risk products and processes would appear to warrant a higher level of effort to ensure measures are in place and put into action to control pathogens, lowering the likelihood of foodborne illness. While inspection may be critical for some plants and products, a system of audits may be acceptable for products with less inherent risk, or processes with less risk or hazards, where established methods have proven effective to control pathogens.

We need to develop a uniform, consistent process to determine when and where inspection is warranted, based on the inherent risk of the product and a plant's demonstrated control of that risk, and when and where audits are sufficient. I hope that we will collectively ask the tough questions and come up with answers for a new approach to inspection based on public health and risk.

Conclusion

FSIS is committed to improving its approach to inspection to focus on public health and risk. By relying on data and determining the most effective use of our resources, we will have an ever stronger food safety inspection system that protects public health. We thank Congress and the OIG for assuring that this system will be the very best that it can be. We can all be proud to have a part in its creation and refinement.

We are committed to continuing open and transparent communications with our public health and food safety partners. FSIS will continue to engage the scientific community, public health experts, our food safety partners, Congress, industry, consumer groups, and all interested parties in our efforts to identify science-based solutions to public health issues to ensure positive public health outcomes. Our continued progress in reducing the incidence of foodborne pathogens and human illnesses demonstrates that we can save lives with sensible science-based policies. Communication is a two-way process, and the agency demonstrates flexibility by responding to stakeholder input, which includes the very important oversight role of our food safety partners here on Capitol Hill.

As a medical doctor and a public health professional, I believe that what all of us with a stake in food safety must accomplish is protecting people, especially those most vulnerable to a foodborne illness – the very young, the elderly, the immune-compromised and pregnant women.

Madam Chairwoman, Ranking Member Kingston, and Members of the Subcommittee, thank you for the opportunity to testify before you today. I am happy to respond to any of your questions.

For release only by the
House Committee on
Appropriations

FOOD SAFETY AND INSPECTION SERVICE

Statement of
Alfred V. Almanza, Administrator,
Before the
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Madame Chairwoman, Ranking Member Kingston, and members of the Subcommittee, I am pleased to have this opportunity to discuss the U.S. Department of Agriculture's (USDA) fiscal year (FY) 2009 budget request for the Food Safety and Inspection Service (FSIS), and to discuss the various initiatives that FSIS is undertaking to meet the latest challenges in food safety and food defense.

First, let me take this opportunity to thank all of you for providing FSIS with the resources necessary to ensure that meat, poultry, and processed egg products distributed in commerce for use as human food are safe, secure, wholesome, and accurately labeled. This is part of our mutual charge: protecting the American public and those who consume American products. Everyone here today shares the same goal of promoting and ensuring public health. I look forward to discussing the ways in which FSIS is working to achieve this important mission.

FSIS is the public health regulatory agency in USDA charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, the Humane Methods of Slaughter Act, and the regulations that implement these laws. The Humane Methods of Slaughter Act requires that all livestock be handled and slaughtered in a humane manner.

At FSIS, our policies are rooted in science and based on data. Through science-based initiatives and efforts to continue to strengthen our infrastructure, FSIS has made progress in reducing the incidence of foodborne illness and in deterring adulterated food from reaching the consumer.

FSIS' workforce is the frontline of public health. In FY 2007, the agency employed over 9,000 personnel, including about 7,800 full-time in-plant and other front-line inspection personnel protecting the public health in approximately 6,200 Federally-inspected establishments nationwide. In addition, FSIS has 134 program investigators and other in-commerce personnel to provide surveillance and investigation of product from the time that it leaves the plant until it reaches the consumer. The high volume and the high-risk nature of the products FSIS inspects demands an in-plant inspection presence, which is not only required by law, but is necessary to protect consumers.

During FY 2007, FSIS inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the

processing of over 48 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 4.3 billion pounds of processed egg products. They also inspected at U.S. borders 3.9 billion pounds of imported meat and poultry products. In addition, FSIS personnel conducted more than nine million procedures to verify that establishments met food safety and wholesomeness requirements.

FSIS also has a small expert cadre of program investigators nationwide who conduct food safety, food defense, and outbreak investigations across all in commerce meat, poultry and egg product facilities. These individuals are responsible for all FSIS enforcement actions, working closely with our Office of the Inspector General (OIG), State, local and other government agencies to ensure swift and effective action. The work of these personnel as well as our laboratory technicians, import inspectors and others is paramount to the success of our mission and the protection of consumers.

I am proud to report that in recognition of FSIS' success in managing personnel, on December 3, 2007, FSIS received the 2007 Presidential Quality Award for Management Excellence. FSIS was honored for its dedication, hard work and outstanding leadership in advancing the President's Management Agenda through the strategic management of human capital. More specifically, the award recognizes the agency's many initiatives in human capital productivity, including the ability to recruit and hire the veterinarians, food inspectors, scientists and other employees that are the backbone of the FSIS public health and inspection program. FSIS received one of only six awards given to Federal agencies

for excellence in quality and productivity. This was the first time an agency within the USDA received such an award.

Current Concerns Regarding Humane Handling of Livestock

Before I go any further, I would like to address the ongoing investigation of the Hallmark/Westland Meat Packing Company (Hallmark/Westland) in Chino, California. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory disabled cattle in that facility.

I want to further assure you that, as soon as we learned of the problems at Hallmark/Westland, we took immediate steps to determine if the allegations made public by the Humane Society of the United States (HSUS) were accurate. Secretary Edward Schafer called on USDA's OIG to work with FSIS and USDA's Agricultural Marketing Service (AMS) to conduct a thorough investigation into this matter.

In addition, USDA's Food and Nutrition Service placed an administrative hold on all Hallmark/Westland Meat Packing Company products that were in or destined for Federal food and nutrition programs, pending further information from the investigation. An administrative hold prevents program operators from using the product until further notification from USDA.

As soon as FSIS determined that humane handling regulations were violated, FSIS issued a Notice of Suspension to Hallmark/Westland, although the establishment voluntarily

stopped slaughter operations as soon as the investigation began. Additionally, immediately upon receiving conclusive evidence that non-ambulatory animals were allowed into the food supply, FSIS worked with the company to initiate a voluntary recall.

Timeline of USDA Actions

On January 30, 2008, USDA learned about the original HSUS video regarding violations through the media. On the same day, USDA indefinitely suspended Hallmark/Westland as a supplier to Federal nutrition programs. Hallmark/Westland was not permitted to produce or deliver any products under contract, and, under the suspension, no further contracts could be awarded to the company. In addition, USDA placed an administrative hold on all Hallmark/Westland products we identified that were in, or destined for, Federal nutrition programs as of October 1, 2006. The October 1, 2006, date for the start of the initial hold period was chosen to capture the Hallmark/Westland product that was in the Federal nutrition program supply chain.

On February 1, 2008, Hallmark/Westland voluntarily stopped slaughter operations. As a result of FSIS findings, FSIS suspended inspection at the plant on February 4, 2008. This action was based on FSIS findings that the establishment failed to prevent the inhumane handling of animals intended for slaughter at the facility, as required by FSIS regulations and the Humane Methods of Slaughter Act.

Our evidence demonstrates that, over the past two years, this plant did not always notify the FSIS public health veterinarian when cattle became non-ambulatory after passing ante-mortem (prior to slaughter) inspection, as is required by FSIS regulations. It is important to note that certain cattle, while ambulatory when they pass ante-mortem inspection, later become non-ambulatory from an acute injury or another circumstance. If such a situation occurs, FSIS regulations require the public health veterinarian to inspect the animal again before the animal is permitted to go to slaughter. This failure by Hallmark/Westland led to the company's February 17, 2008, voluntary recall of 143 million pounds of fresh and frozen beef products produced at the establishment since February 1, 2006.

On February 17, 2008, FSIS amended the suspension to reflect the fact that Hallmark/Westland had allowed cattle that had become non-ambulatory after passing ante-mortem inspection to be slaughtered without further inspection by FSIS personnel. This suspension will remain in effect and the establishment will be unable to operate until corrective actions are submitted in writing and verified through a full review by FSIS. Slaughter operations will not resume at Hallmark/Westland until the company complies fully with FSIS regulations.

While it is extremely unlikely that these animals pose a risk to human health, the recall action was deemed necessary because the establishment did not comply with FSIS regulations. The recall was designated Class II because of the remote probability that the recalled beef products would cause adverse health effects, if consumed.

As is the case for all recalls, FSIS is conducting effectiveness checks to verify that customers have received notice of the Hallmark/Westland Meat Packing Company recall and are making every effort to retrieve and destroy the recalled product or return it to the establishment. FSIS personnel are in the process of verifying that Hallmark/Westland has been diligent and successful in notifying its consignees of the need to retrieve and control recalled product, and that the consignees have responded appropriately.

Safeguarding Against BSE

I am aware that this situation has raised questions about the risk of bovine spongiform encephalopathy (BSE). I would like to take this opportunity to give you a brief summary of the safeguards against BSE that we have in place to protect our food supply.

Since the discovery of the first case of BSE in Great Britain in 1986, we have learned a tremendous amount about this disease. That knowledge has greatly informed USDA's regulatory systems and response efforts. It has also given us the opportunity to examine our own cattle herd, which is why we know that the risk of BSE in the United States is extremely low.

As noted earlier, non-ambulatory cattle are excluded from the food supply as part of the Federal government's interlocking system of controls to protect the food supply from BSE. These BSE security measures include the ban on non-ambulatory cattle, but that is simply one of the multiple measures in place.

We have learned that the single most important thing we can do to protect human health regarding BSE is the removal from the food supply of specified risk materials (SRMs)—those tissues that, according to the available scientific evidence, could be infective in a cow with BSE. FSIS requires that all SRMs, including the brain and spinal cord, are removed from carcasses so that they do not enter the food supply. Slaughter facilities cannot operate without the continuous presence of FSIS inspection personnel to ensure safe and wholesome product, and the safeguards include the removal and segregation of SRMs. FSIS line inspectors are stationed at key points along the production line where they are able to directly observe certain SRM removal activities. Other off-line inspection personnel verify additional plant SRM removal, segregation and disposal. According to the 2005 Harvard Risk Assessment, SRM removal alone reduces the risk to consumers of BSE by ninety-nine percent.

The ruminant-to-ruminant feed ban is another significant step that the Federal government has taken to prevent the spread of BSE and bring about its eradication in the animal population. In 1997, the Food and Drug Administration (FDA) implemented a mandatory feed ban that prohibits feeding ruminant protein to other ruminants. The feed ban is a vital measure to prevent the transmission of BSE to cattle.

Moreover, BSE testing is best used as a surveillance tool. By testing animals that show possible clinical signs of the disease, we can document the effectiveness of our security measures.

USDA's Animal and Plant Health Inspection Service has conducted targeted BSE surveillance testing since 1990, including an enhanced surveillance effort that was initiated after an imported cow tested positive for the disease in December 2003. The goal of the enhanced effort, which began in June 2004, was to test as many animals in the targeted population as possible over a 24-month period. This intensive effort detected only two animals with the disease, out of over 759,000 animals tested. Both of those animals were born prior to initiation of the FDA feed ban and neither entered the food supply. This testing confirms an extremely low prevalence of the disease in the United States.

Because of the strong systems the United States has put in place, we can be confident of the safety of our beef supply and that the spread of BSE has been prevented in this Nation.

Further Actions

The investigation led by OIG with support from FSIS and USDA's AMS is ongoing. Once the investigation has concluded, we will have additional information to determine the actions for FSIS oversight, inspection and enforcement that may be required. However, we are not waiting for the completion of the investigation to act. USDA is already taking a number of steps to strengthen our inspection system.

USDA will continue to provide the public with an update of our actions at www.usda.gov/actions.

Public Health Data Infrastructure

Data is fundamental for FSIS. All of our decisions hinge on the availability of data and the science from which it derives. Both internal FSIS assessments of its informational technology needs and audits by the USDA's OIG have identified several areas within the FSIS public health data infrastructure that require strengthening. As a result of these findings, FSIS has been actively strengthening the way that it collects and analyzes data and bolstering its infrastructure.

For example, we made available much of the agency's inspection-related data through a data warehouse to provide easier and quicker access to data for analysis across agency databases and to improve decision-making. We have been using AssuranceNet, a Web-based management control system that pulls inspection data from the data warehouse, since FY 2006 for inspection operations in the field and are committed to expanding this system to all agency programs in the future.

FSIS' goal is to provide broadband connectivity in the field so that most inspection personnel are linked to a near real time communications infrastructure. We currently have enabled over 2,300 connections as of February 1, 2008, so that inspection personnel are linked to a near real-time data communications infrastructure. This improved access is vital for the agency personnel who are collecting the data out in the field and will allow them to spend more of their time on inspection activities.

To build on our past efforts, this past year we formed the Data Analysis and Integration Group (DAIG) and the Data Coordinating Committee (DCC). The DAIG is a staff dedicated to conducting data analysis and ensuring that agency data analyses are consistent, of high quality, and relevant to the agency's mission and business processes. The DCC has members from each agency program office and serves as a coordinating body to ensure that there is no duplication of analytical effort and to keep all parts of the agency abreast of the data analytical work that is being done. We are also creating analysis plans for directives and notices, conducting peer reviews and soliciting input from stakeholders, and developing a consistent set of tools for conducting data analysis.

Moving forward, FSIS is working to enhance its system for inspection to make it more public health based and risk based. The goal of this system is to focus our resources where they can better ensure that food safety systems are under control. This system will be science-based and data-driven; focusing our inspection resources where they can best accomplish our most important charge: protecting the public.

This enhanced inspection system will rely on a Web-based Public Health Information System, which is currently in development. This system will make the collection of data and reporting easier and quicker for inspectors in the field. It will allow the agency to analyze data more quickly and to identify trends sooner. This is vital for our public health mission because it will decrease the time needed to respond to incidents and improve FSIS' ability to collect, analyze, and predict likely outcomes, which will in turn allow agency employees to better protect public health.

As part of the enhanced system, the agency is also developing a poultry slaughter inspection system that is public-health based. This effort will focus on establishments that slaughter young chickens, or broilers. Our goal in both of these initiatives is to better protect public health and diminish the incidence of foodborne illness.

As a public health agency, FSIS needs systems that can provide information in a way that allows data sharing, data mining, data reporting, and data analysis throughout the agency, with Federal partners, and, in appropriate circumstances, the public. These new initiatives will give us better tools to lower the chance that our consumers will contract a foodborne illness by reducing the prevalence of dangerous pathogens in the meat and poultry supply.

We are committed to working with all of our food safety and public health partners to use the data that is available and seek more data to be able to attribute illnesses to specific foods. To cite one important example, we held a public meeting in April 2007 with our stakeholders and partners and engaged them in a discussion about the importance of foodborne illness attribution data, how this data is being developed, and how it is being used. Because we believe attribution is important in public health decision making, we are pioneering the use of attribution data in our evolving public heath risk-based approach to inspection.

Food Safety Assessments

In response to recommendations in the 2003 and 2004 OIG audits, FSIS implemented a more comprehensive system to verify establishments' Hazard Analysis and Critical Control Point (HACCP) plans using food safety assessments. During these food safety assessments, specially trained personnel conduct in-depth reviews of the designs of establishments' HACCP or food safety plans. OIG agrees with FSIS that food safety assessments are a fundamental building block for assessing establishment risk. Food safety assessments are also a key component in building FSIS' public health data infrastructure.

One significant recommendation from the more recent December 2007 OIG audit directed FSIS to complete food safety assessments in all plants using an objective scoring mechanism to help determine the level of inspection needed. Our effort to do this for all plants is well underway.

Addressing Gaps in Our Current Infrastructure and System

FSIS performs a key role in addressing the complex public health and food defense issues associated with the handling of meat, poultry, and processed egg products in-commerce. Responsibilities include surveillance of the transportation, storage, and distribution of inspected products for intentional and some non-intentional chemical, biological, and physical abuse of inspected products; conducting investigations to detect, prosecute, and deter criminal violations; and performing food defense activities including assessment and emergency response. These in-commerce activities include surveillance review

activities which investigators conducted at approximately 11,841 in-commerce locations. These activities focused on verifying that meat, poultry, and processed egg products that were transported, distributed, and stored in-commerce were safe, secure, and accurately labeled.

As we have been working to ensure we have necessary data, we have also been identifying and addressing gaps in our current infrastructure and system. One area where we have focused attention and resources has been our in-commerce surveillance activities. Last year we issued a series of directives for employees outlining the standard investigative and surveillance practices and procedures to be followed. Later this spring, we will be automating data from all our food safety and food defense surveillance activities in commerce, including retail, wholesale, transportation and distribution.

Pathogen Reduction Initiatives and Successes

FSIS is dedicated to public health, a dynamic, ever-changing field. There is always more that can – and will – be done to fight foodborne pathogens. However, FSIS' scientific policies have made a measurable, positive impact on public health.

Over the past year we focused most of our efforts on *E. coli* O157:H7 and *Salmonella.*

I will first address *E. coli* O157:H7. The month of June 2007 brought an increase in the number of *E. coli* O157:H7-positive samples collected by FSIS, and this fall brought an increased number of recalls and illnesses. As a result, FSIS implemented several risk

management initiatives, including increasing the number of raw ground beef samples that were taken and implementing trim testing ahead of schedule.

As part of our continuing fight against *E. coli* O157:H7, FSIS has begun testing all materials that are used as components in raw ground beef, whether the raw ground beef is domestic or imported; conducting food safety assessments at establishments that have positive test results for *E. coli* O157:H7, performing targeted sampling for *E. coli* O157:H7 at slaughter and grinding facilities; using a more sensitive enrichment broth for *E. coli* O157:H7 sampling; and meeting with stakeholders and experts to determine what additional steps can be taken to combat *E. coli* O157:H7.

One significant step we took was creating a checklist to better assess how establishments are controlling the risk of *E. coli* O157:H7. FSIS inspection personnel have completed these checklists in nearly 2,500 beef establishments, both suppliers and grinders, to evaluate control measures.

The agency is completing a more in-depth analysis of the data captured in responses to questions, filled out by FSIS inspection program personnel, about reassessment of HACCP plans related to *E. coli* O157:H7. Our preliminary data, completed in November 2007, shows that almost 96 percent of all beef slaughter and processing establishments reassessed their HACCP plans. We are analyzing these responses, and we anticipate that the analysis will lead to new policies, directives, or possibly rules and regulations.

FSIS has also been aggressively combating *Salmonella*. Each year an estimated 1.4 million people in the United States develop foodborne illness from *Salmonella*. In February 2006, FSIS announced an initiative to reduce the presence of *Salmonella* in raw meat and poultry products. The initiative concentrated resources at establishments with higher levels of *Salmonella* and changed the reporting and utilization of FSIS *Salmonella* verification test results.

Earlier this year, FSIS announced further changes in its *Salmonella* policy to continue driving down the incidence of *Salmonella* in raw meat and poultry products. On March 28, 2008, the agency will begin posting on its Web site completed verification test results from establishments performing in Category 2 or 3, beginning with young chicken slaughter establishments. The agency will also offer specific waivers to Category 1 establishments, or those with sampling results at or less than half of the current standards. With these waivers, those establishments with the lowest *Salmonella* rates will be able to test new procedures, equipment, or processing techniques that will facilitate improvements in the ongoing control of *Salmonella*.

The agency will conduct targeted sampling based on available data regardless of the relative risk posed by a given product, randomly scheduling sample sets at Category 1 establishments.

Our Federal partners also play important roles in our efforts to better control *Salmonella*. In August 2007, FSIS and Agricultural Research Service (ARS) finalized a cooperative

agreement to strengthen their data-sharing relationship. The agreement ensures that identifying information on *Salmonella* isolates Pulsed-Field Gel Electrophoresis patterns that FSIS collects are compared against information about isolates associated with human illness in PulseNet, a database maintained by the Centers for Disease Control and Prevention (CDC) . Under the agreement, FSIS will be able to routinely access this data for all isolates maintained by ARS, instead of sending a request for isolates of special interest. The data would also be available in a timeframe rapid enough for data to be relevant to in-plant and public health investigations. These changes are expected to play a significant role in providing valuable attribution data by identifying whether products regulated by FSIS contributed to reported human illnesses.

We can easily see the positive results of this risk-based strategy. If we compare the plant categories based on broiler carcasses analyzed for *Salmonella* in 2006 to 2007, we see that the percentage of plants in Category 1, or those with sampling results amounting to half or less than half of the current standards, increased dramatically, from 49 percent to 74 percent. Likewise, the percentage of plants in Category 3 decreased significantly from 10 percent to two percent. Essentially, the percentage of young broiler carcasses that tested positive for *Salmonella* decreased by 50 percent – from 16 percent to 8 percent.

Significant concerns have been raised by stakeholders about the lack of information on how much FSIS-regulated products have contributed to human illness caused by *Salmonella* and other pathogens. FSIS has taken a number of initial steps to be able to better provide such information and intends to take more steps in the near future. This

includes the revised steps the agency is taking to collect and evaluate *Salmonella*-related data associated with FSIS regulated raw products to better ensure public health. FSIS is developing a pilot program around the best proactive use of this comparison data with CDC PulseNet data and is exploring broad options to help ensure public health in conjunction with our public health partners.

Over the next few years, FSIS will conduct a series of recurring, nationwide baseline studies. These baseline studies are designed to provide FSIS and the regulated industry with data concerning the prevalence of selected foodborne pathogens and microorganisms that serve as indicators of process control. This data will enable the agency and industry to target interventions that effectively reduce the presence of foodborne pathogens found in FSIS-regulated products. In addition, these baseline studies will provide essential data for future risk assessments and permit the evaluation of trends over time.

FSIS began a nationwide baseline study on June 25, 2007, designed to estimate the prevalence and quantitative level of *Salmonella* and *Campylobacter* on broiler carcasses. Ultimately, the microbiological data obtained from this baseline study will be used in the development of risk assessments, risk-based sampling programs, performance standards and regulatory policy decisions. We will complete testing for the baseline by the end of August 2008.

FSIS has also instituted more targeted sampling for *Listeria monocytogenes* (*Lm*). This program, in its fourth year, is based on the *Listeria* risk assessment and the *Listeria* regulation. Food safety assessments are conducted for targeted plants and in addition to product samples, samples are taken of the environment in the plant as well as food contact surfaces. We are also in the initial stages of looking at the virulence of the *Lm* serotypes we find through our testing program. Because the percentage of regulatory samples of meat the poultry products that tested positive for *Lm* has fallen by almost 80 percent since 1998, we are now looking at what measure we should be using to report *Lm* performance. We are committed to continuing to demonstrate improvement and are considering tightening or lowering the *Lm* performance measure.

Ensuring the Safety of Imported Food

Another important role for FSIS is ensuring the safety of imported meat, poultry and processed egg products. First we establish the initial equivalence of the meat, poultry, or processed egg inspection system of a country wishing to export to the United States. We then verify continuing equivalence of the foreign system through audits and re-inspection of foreign meat, poultry, or processed egg products imported into the United States; 34 countries have achieved equivalence. However, only 29 of these 34 eligible countries are currently sending products to the United States.

FSIS engages in three types of foreign inspection systems equivalence evaluations: initial equivalence determinations, individual sanitary measure determinations, and ongoing verification activities. Equivalence is the foundation for our system of imports. It

recognizes that an exporting country can employ different sanitary measures to address food safety hazards if the country can objectively demonstrate that their measures provide the same level of public health protection as the measures used by the importing country.

As part of the ongoing equivalence process, FSIS must determine whether foreign countries' inspection systems are maintaining equivalence and in cases where these countries fail to meet U.S. requirements, initiate additional actions. FSIS conducts on-site audits to determine whether a country is maintaining an equivalent inspection system or whether further measures are warranted to protect U.S. public health.

FSIS performs re-inspection of all shipments of meat, poultry, and egg products, with few exceptions, exported to the United States from eligible foreign countries. The shipments are reviewed and verified for compliance with FSIS regulatory requirements including product eligibility, certification by the foreign inspection system, condition of product and labeling verification. Re-inspection of product is then subject to statistically-based random sampling and intended to verify the effectiveness of the foreign inspection system.

FSIS also performs random re-inspection on approximately 10 percent of shipments of meat, poultry, and egg products. These re-inspection tasks include product examinations, microbiological analysis for pathogens, or a test for chemical residues. Approximately 5 percent of shipments of imported meat and poultry products receive microbiological and

chemical testing. Acceptable products are marked as "inspected and passed" and released into commerce. Non-compliant products are rejected, marked as "Refused Entry," and either destroyed or returned to the originating country. More intensive re-inspection is automatically applied to future shipments of product from the foreign establishment when product fails re-inspection.

Once the imported product enters the country, FSIS' field force of program investigators provide ongoing surveillance of product in commerce to protect the public from illegally imported and smuggled meat, poultry and egg products from reaching their tables.

Ensuring the Safety of State Inspected Product

FSIS also conducts comprehensive reviews of all State meat and poultry programs to ensure "at least equal to" programs are operating and can be maintained. We follow a review manual that follows a two-part methodology for State reviews; annual self-assessments by the state and FSIS on-site reviews. On August 13, 2007, all State-inspected establishments and custom exempt operations within the New Mexico meat and poultry inspection program officially transferred to Federal inspection and jurisdiction.

Training

Training has been and continues to be a top priority for FSIS. It is the foundation of our public health successes and a key element in our strategy to reduce the incidence of foodborne illness.

FSIS can only achieve its public health, food safety, and food defense missions with a well-prepared workforce. Through scientific and technical training that reflects the agency's science-based approach to food safety and food defense, we can accomplish this. FSIS has made a number of improvements in employee training, thereby increasing workforce capability and advancing our public health goals.

FSIS has made substantial progress in improving its workforce training program. Some key milestones demonstrating improvement include establishing a new curriculum based on food safety and public health; implementing training as a condition of employment; launching a comprehensive management, leadership and development program based on the Office of Personnel Management's competencies to meet the goals of the President's Management Agenda and the need for succession planning; introducing a regular process to provide training that coincides with the issuance of key agency policies; building capacity for follow up training and education through distance learning; achieving greater flexibility with training contracts; establishing regional training bringing courses closer the worksite; and evaluating the effectiveness of training through pre and post testing.

While we have made improvements, I believe more must be done. An increased focus on science-based policies requires more training and continual updates as policies change. The lessons learned from recalls this past year raised questions about the support field employees were getting to implement the knowledge they gained in training when they returned to duty.

We intend to conduct a comprehensive assessment of the effectiveness of the FSIS training program and to identify how FSIS can continue to enhance and improve its training programs.

Food Defense and Emergency Response

FSIS has a strong infrastructure in place to protect the food supply from intentional and unintentional threats and to coordinate all agency activities to prevent, respond to, and recover from any attack on the food supply and handle large-scale food emergencies.

Growth in the agency's food safety and food defense responsibilities is reflected not merely in the volume of product inspected and shipped, but also dramatically in the need to cover complex public health issues associated with the handling of meat, poultry, and egg products outside of the federally inspected establishments.

These responsibilities include surveillance of the transportation, storage, and distribution of domestic and imported products for intentional and non-intentional chemical, biological, and physical contamination of products; conducting investigations to detect and control non-compliant products, developing evidence to prosecute and thereby, deter criminal violations; performing food defense activities such as assessment, developing partnerships with other Federal, State and local health, agriculture, and law enforcement officials and emergency response; supporting and following-up on recalls; conducting illness outbreak and consumer complaint investigations; and auditing and reviewing of State and foreign inspection programs. These efforts resulted in detaining almost 16

million pounds of adulterated or mislabeled domestic or illegally imported meat, poultry, or egg products; and approximately 400 regulatory enforcement actions against owners of meat, poultry, and egg product facilities.

Today, FSIS conducts food defense activities both in-plant and in commerce to ensure the safety of domestic, imported and exported product. A field force of approximately 100 investigators conduct food safety and food defense surveillance at food warehouses, distribution centers, retail stores and other types of facilities throughout the United States to determine whether meat, poultry or egg products distributed in commerce are safe, secure, wholesome and not adulterated or misbranded.

The agency has developed specific procedures on monitoring and sampling to be taken depending on the threat level as determined by the Department of Homeland Security (DHS). Over 1.4 million food defense verification procedures were conducted in FY 2007. The testing is based on vulnerability or risk-based assessments for selected domestic and imported food products, which allows the agency to rank food products and potential contaminating agents in order of highest concern.

FSIS has created and distributed model food security plans that FSIS-inspected meat, poultry and processed egg products facilities and import establishments can use to develop and implement a Food Defense Plan. These plans identify the types of preventive steps that establishments might take to minimize food security risks for products under their control. A simplified version of guidance on food defense plans was

developed this past year in consultation with industry trade groups, which provides an easy three-step process which will result in a completed food defense plan. The agency continues to encourage industry to develop food defense plans.

This past year the agency began final user testing of an automated Non-Routine Incident Management System that can quickly notify key agency emergency responders about emergency incidents while tracking and sharing those responses with those managing the incident.

The agency's enhanced Consumer Complaint Monitoring System, a national surveillance system that monitors food-related consumer complaints that will eventually be incorporated into the Public Health Information System, will further assist in the agency's efforts to track potential attacks on the food supply.

To further strengthen food safety and defense, FSIS is launching a new automated In-Commerce System which will work in tandem with the Public Health Inspection System to provide a farm-to-table database. The In-Commerce System will house all available data on in-commerce facilities, facilitate ongoing collection of in-commerce data, data exchange with other data bases vital to our mission, and provide risk-based reports for users to better focus resources on identified food safety and defense weaknesses in commerce.

FSIS has also taken a lead role in the development of the Food Emergency Response Network (FERN), a joint effort of national, State, and local laboratories to provide ongoing surveillance and monitoring of food and to promptly respond to a foodborne illness outbreak or intentional contamination that targets the Nation's food supply. Additionally, FSIS has cooperative agreements with a total of 21 State labs geographically located across the country. The FERN laboratories will eventually be proficient to screen for the same threat agents as Federal labs, some with capability to do confirmation testing. FSIS primarily focuses on microbiological agents with our partners at FDA focusing on chemical and radiological agents.

I mentioned that FERN is a joint effort with our sister agencies at the national, State, and local levels. Yet another example of inter-agency coordination and collaboration by FSIS is participation in the integrated consortium of lab networks developed by the Department of Homeland Security. This consortium ensures coordination among Federal and State partners focused on both food and agriculture. The consortium ensures consistency of methods development, reporting of lab results and the sharing of lab results among all Federal and State partners.

Outreach to Small and Very Small Plants

All plants, including small and very small plants, must have well-designed and effective HACCP plans. HACCP is the regulatory standard that all plants are required to comply with to protect public health, and it provides the foundation for the FSIS strategic, data-driven inspection program.

For FSIS to ensure public health protection through food safety, it not only needs to verify that small and very small plants, establishments that comprise over 90 percent of the plants under FSIS' jurisdiction, are producing safe food but to reach out to those plants to make sure that they fully understand their responsibilities and how to achieve them. Thus, for our small and very small plants, we launched a targeted Web page and launched a monthly publication called *Small Plant News* which includes articles with up-to-date technical information and guidance, resource materials, and FSIS rules and regulations as well as the most common questions asked and answers that apply to establishments' operational practices. All of this is in addition to outreach visits, net meetings, information sessions, and numerous regulatory education sessions.

As one of our outreach efforts to stakeholders, including small and very small plants, we launched askFSIS in 2007. askFSIS is a Web-based feature designed to help answer technical and policy questions regarding inspection and public health regulations 24 hours a day. The new interactive feature provides answers on technical issues in more depth than the standard list of "frequently asked questions" available through FSIS' Web site. It allows visitors to seek answers on topics such as exporting, labeling and inspection-related policies, programs and procedures, as well as submit new questions to be added to the system. This new Web-based tool has received high customer satisfaction marks from our stakeholders, and the system already has nearly 800 questions and answers.

We will soon be announcing an organizational change that will send a strong signal to agency employees and small and very small plant owners and operators indicating just how seriously we take our outreach mission.

Consumer Education

FSIS also has an obligation and responsibility to provide food safety education for consumers.

Our *Be Food Safe* Campaign is an updated public education effort based on the Clean, Separate, Cook, and Chill messages developed as part of the national Fight BAC!® campaign. FSIS developed the *Be Food Safe* campaign in cooperation with the Partnership for Food Safety Education, the FDA, and CDC and Prevention because research shows that Americans are aware of food safety, but they need more information to achieve and maintain safe food handling behaviors. The *Be Food Safe* campaign, which is grounded in social marketing, behavior change, and risk communications theories, is designed to provide educators with the tools to inform consumers about foodborne illness and raise the level of awareness of the dangers associated with improper handling and undercooking of food. The campaign centers around a simple yet vital message: Clean, Separate, Cook, and Chill.

be FoodSafe: The FSIS Magazine, focuses on food safety behavior trends, emerging science and research, inspection issues (domestic and international), and education

programs for food workers, consumers, and caregivers. Currently, *be FoodSafe: The FSIS Magazine* has nearly 20,000 online subscribers.

A prominent feature on FSIS' Web site is the virtual representative, "Ask Karen." "Ask Karen," the only government-sponsored virtual representative in the world. Consumers may ask questions of the automated representative, 24 hours a day, seven days a week, 365 days a year, through an extensive database of frequently updated questions and answers, and receive responses about safely storing, preparing, and handling meat, poultry, and processed egg products.

We also staff the USDA Meat and Poultry Hotline, responding to an average 81,000 telephone calls annually on the safe storage, preparation, and handling of meat, poultry, and processed egg products.

Those at highest risk for foodborne illness, infants and young children, pregnant women, older adults, and people with weakened immune systems caused by cancer treatment, diabetes, AIDS, and bone marrow and organ transplants, have been the focus of the majority of our efforts. FSIS held a conference late in 2006 focused on how to reach the more vulnerable at-risk population. This year we will be taking the findings from the conference and in conjunction with our public health and medical partners, we will develop and implement strategies on how to best to reach those most at risk for foodborne illness. We also unveiled a series of brochures and fact sheets at the conference providing vital food safety information for this most vulnerable population.

We continue to improve our outreach to specialized groups. FSIS continues to translate food safety education documents into Spanish and continues its outreach to the Hispanic community by providing food safety education materials for planned activities. The Spanish language brochure, *"Todo Cuenta Cuando Se Trata de Cuidar s Su Familia" (Everything Counts When Looking After Your Family)* was selected for a 2007 National Association of Government Communicators' Blue Pencil Award in the category brochures/booklets. The *En Español* section of FSIS' Web site includes news releases, fact sheets, and food defense and emergency response materials that have been translated into Spanish. The agency also continues to distribute the flyer, "Listeriosis and Pregnancy: What is Your Risk? Safe Food Handling for a Healthy Pregnancy," in English and Spanish to obstetricians and gynecologists nationwide. FSIS prepares food safety materials for the visually impaired in large print and Braille cards and is currently translating food safety information into Arabic, Chinese, Hmong, Japanese, Korean, Tagalog (Filipino), Thai, and Vietnamese.

Cooperation and Collaboration with Stakeholders

FSIS promotes stakeholder understanding, input and support of the agency's public health and food defense mission through a variety of ongoing outreach efforts such as public meetings and scientific symposia conducted every year with industry, academia, scientific, our State, local and Federal partners and consumer communities on various agency priorities. FSIS also conducts separate monthly meetings with industry associations and consumer representatives. The FSIS askKaren and the USDA Meat and Poultry Hotline are an on-going means of two-way communication.

Communication with Employees

FSIS employees are also a vital stakeholder group in the agency's outreach efforts. As a former District Manager, I know first-hand how important it is for headquarters staff to communicate with our employees in the field including plants, field offices, laboratories, and alternative workplaces. I am committed to seeking input from all employees across the Nation. We will continue to work with our entire workforce on future initiatives that will improve the safety and defense of our country's food supply.

FY 2009 Budget Request

I appreciate having the opportunity to present some of FSIS' biggest accomplishments and priorities to you. Now, I would like to offer an overview of the FY 2009 budget request for FSIS.

In FY 2009, FSIS is requesting $952 million, an increase of $22 million above the FY 2008 level.

FSIS has a statutory obligation to provide inspection of meat, poultry and egg products. An increase for the FSIS inspection program is requested to maintain our high standards for the safety and wholesomeness of meat, poultry and egg products and our continued efforts to ensure effective inspection and policy implementation. This appropriation request includes funding an increase in pay and benefit costs, which make up approximately 80 percent of FSIS' budget; an increase for the costs of the State Meat and Poultry Inspection Programs; and an increase to support Federal responsibilities added

due to the takeover of the New Mexico State program. The appropriation of the full amount requested is of paramount importance because of the importance of FSIS' mission: public health.

The Administration's budget submission assumes that the cost of inspection services for Federal meat, poultry, and processed egg products will continue to be paid with Federal funds. The Administration also proposes legislation to provide USDA with the authority to collect new user fees, including a licensing fee and a performance fee. The collection of these new user fees, which we estimate would amount to $96 million during FY 2009, would be available for spending in FY 2010. A total of about $92 million in licensing fees would be collected from establishments based on their inspection services. An additional $4 million in performance fees would be collected from establishments that require additional inspection activities for performance failures such as retesting, recalls, or inspection activities linked to an outbreak.

Conclusion

Madam Chairwoman, thank you again for providing me with the opportunity to submit testimony regarding the steps that FSIS is taking to continue serving the public health and ensuring food defense. I look forward to working with you and the Subcommittee to continue to improve our food safety system to meet the growing challenges and opportunities of tomorrow.

FOODBORNE ILLNESS DATA

Ms. DELAURO. Thank you very much.

Do you want move first because you have to——

Ms. EMERSON. Madam Chair, I'll let you go on and go first, and then I'll just pick up right afterwards.

Ms. DELAURO. Thank you.

Dr. Raymond, in your testimony before this committee last year, the numerous speeches including your presentation at the USDA Agricultural Outlook Conference recently and again in your testimony today you claimed that USDA FSIS, the Food Safety and Inspection Service, is making great progress in reducing foodborne illness, and we have the charts, and the charts that are up there. There is little data to back up that assertion, and I wonder why you keep making it.

First you continue to cite the regulation verification data for Salmonella and E. coli collected by the agency as though the numbers reflect a reduction in the national prevalence of these two pathogens in FSIS-regulated foods. I have a chart here as well, in which we're looking at the increases. I didn't get it blown up here, but we're looking at increases in whether it's Campylobacter, E. coli, Salmonella, or Listeria monocytogen.

You've been told by the Office of Inspector General and the National Advisory Committee for Microbiological Criteria for Food that the regulatory verification data do not represent a national sample. They reflect only what is happening in a particular plant on the day that it was tested. The reductions in positive tests for E. coli, O157:H7, may show only that the companies tested had no E. coli on that day of testing. It's less appropriate to use Salmonella verification data as reflecting improvements in public health protection.

First, these are only reflective of what is happening in one plant on the day that it was tested. The data have no national significance. Second, the Salmonella performance standard is not a public health standard. It was established based on an industry standard a decade ago; it represents only what the top half of companies were able to achieve then. It is entirely possible that every company in the country could pass the Salmonella test and Salmonellosis cases from USDA-regulated products would not decline.

Let me just ask you this. Do you understand that the verification data do not reflect the prevalence of the pathogens in the meat supply?

Dr. RAYMOND. We've made changes in the way we collect that data to try to make it more representative. For instance, we used to sample for Salmonella at the very start of the first shift in plants, and we recognize with input at the Safe Food Coalition that that probably is not a representative sample. And so we do samplings throughout the day to make it more representative.

Ms. DELAURO. But I'm saying is we posit information and data here is if it gives the public the sense that we're moving in a direction, and a very positive direction, when in fact that's not the case. I think honesty, quite frankly, requires that you stop suggesting that the numbers reflect a national prevalence or reductions in the national prevalence of Salmonella and E. coli. Quite frankly, I

would like your commitment here this morning that you're not going to misuse these data to support the national changes in the inspection system.

Can you just answer us "yes" or "no" about whether we have representative samples here that lead us to what appear to be erroneous conclusions about reducing foodborne illness?

Dr. RAYMOND. Well, Madam Chair, two years ago when we started the initiative, we had approximately 17 percent of chicken carcasses positive for Salmonella, and last year it was 7.4 percent.

Ms. DELAURO. Can you answer "yes" or "no," Dr. Raymond?—dealing with information—what's the answer to his question? This is data that is being—you've been told by the OIG. You've been told by the National Advisory Committee for Microbiological Criteria for Food that the regulatory verification data do not represent a national standard. I didn't make this up. I am neither this National Advisory Committee, nor am I the Inspector General. Now they say it is not representative, isn't a national sample.

Dr. RAYMOND. We do believe that trends over time do show, the data over time do show trends in prevalence in the products that we test.

Ms. DELAURO. I probably should have blown this chart up or enter this chart into the record, which demonstrates that in fact while early on between 2001 and 2005 we were looking at minor reductions, but in every measure here we are looking and going further forward in terms of the cases of foodborne illness.

So, again, honesty requires. We're not going to address this problem and deal with what you talked about in terms of prevention versus reaction unless we know what our set of circumstances is. And—appear to me that not we, but that you, that the agency is burying its head in the sand and not really focused in on the dimension of the problem and then how we work together in order to be able to address it—sure that we reducing foodborne illness in this nation, and not increasing it.

HALLMARK/WESTLAND RECALL

Ms. EMERSON. Thank you, Madam Chair.

Dr. Raymond, first let me ask you with regard to the Hallmark incident, is there a quantifiable level of BSE risk that USDA has been able to measure for the Hallmark meat which improperly entered the food supply?

Dr. RAYMOND. An analysis that we just recently completed and had peer reviewed, showed that if this plant had allowed every downer cow that presented—let me take the most conservative viewpoint here—if every downer cow that was at that plant—and by the way, 5 percent of animals at that plant were condemned—and if all of those had been allowed to enter the food supply, because of all the other measures in place that we have, the risk would have increased by 0.13 percent. And I must point out that we don't have a quantifiable baseline risk, but it is extremely small because of the interlocking steps that we have to prevent BSE from entering the food supply.

Ms. EMERSON. Okay.

The information regarding the downer animals entering the food supply obviously as you mentioned came to light after undercover

work by the Humane Society. Does USDA utilize similar investigative techniques? And if you don't, do you think you should consider it?

Dr. RAYMOND. We do use some—undercover perhaps is the right way to describe it—some observation of pens when the plant is not aware that we are observing them. For instance, it could be from off-premise instead of just on-premise. Whether we should do more of that is a question that we will consider, once this investigation is complete as to how we can better do our job.

Ms. EMERSON. Can you outline for us the time lines for when the video was taken when USDA learned of it and steps leading up to the recall and effectiveness checks? Do you believe that the video was released in timely fashion, and also—I've got another follow-up to that. So go ahead.

Dr. RAYMOND. I believe the video was obtained over about a six-week period of time, probably all of October and maybe half of November, and I believe we became aware of it on—Al, correct me if I'm wrong—I think it's January 31? January 31 is when we became aware of the video. Thirtieth. I've been corrected, January 30.

Ms. EMERSON. Can you estimate how many pounds of food were produced between the film's production in October and its release to the agency? Do you know?

Dr. RAYMOND. Well, that would be over a four-month period of time, which would be one-third of a year, and we know over the two years it was 143 million pounds produced over two years. I guess we divided by six, it would be approximately 270,000 pounds. Yeah, that would be about right. No, it would be about 220,000 pounds. I'm sorry.

Ms. EMERSON. Okay. You know, I think it was at least clear to Hallmark or their employees when the improper handling of animals was possible without being detected by USDA. Tell all of us, if you would, how you all plan to address this glaring concern.

Dr. RAYMOND. Well, as you know, and as I said, the OIG is conducting and leading an investigation right now with our support, and once that investigation is done, we will sit down and have serious conversations about what the investigation shows and what we need to do differently.

Ms. EMERSON. Do you anticipate that study taking several months, several weeks, or is it just impossible to know?

Dr. RAYMOND. You know, I cannot predict how long the OIG will take in its investigation, and we will move as quickly as we can once that is done.

Ms. EMERSON. In the meantime, though, are you taking more precaution?

Dr. RAYMOND. Yes. We have taken, instituted several steps, beginning with the 19 slaughter plants that do supply products to the school food supply system. Following that, we'll focus on old cow plants and veal plants, and then from there to the rest of the slaughter plants, over a 60-day period of time. This includes increased time doing humane handling, and surveillance activities. It would include some increased undercover surveillance activities.

Al, help me out. What else? There are several points I'm forgetting.

Mr. ALMANZA. Utilizing other departmental—parts of the agency, APHIS, and packers and stockyards and some of those other——

Ms. EMERSON. Their personnel to assist so that you——

Mr. ALMANZA. Yes.

INTERSTATE SHIPMENT

Ms. EMERSON. Okay.

Let me just switch subjects really quick. Last year, Dr. Raymond, our colleague, Sam Farr, raised the issue of interoperability, increased coordination between state inspectors and FSIS, and this question unfortunately was dismissed on the basis of, one, Federal law prohibits interstate shipment of meat produced, state inspected at facilities. And two, I think you all said it was FSIS's intention to bring common sense to bring common sense to federal inspections through risk-based inspection.

On the other hand, FDA has kind of taken this whole idea and run with it, and have proposed standards for manufactured food regulatory program, which would allow them to coordinate and utilize state inspectors, so FDA can focus its limited resources elsewhere.

Both the Senate and House versions of the Farm bill contained provisions that allow expanded interstate shipments of state-inspected meat. So my question would be: Has FSIS revisited the agency's relationship with potential state partners, and what is your all's current position?

Dr. RAYMOND. We don't have a position on interstate shipment at this time on the Farm Bill. We have provided technical assistance to both the Senate and the House—both from a fiscal standpoint and also from an FTE standpoint. And either one of those versions or a compromise of the two would require more increased cooperation between FSIS and State inspection programs and perhaps increase supervision, depending on which model was used.

Ms. EMERSON. And would that be helpful?

Dr. RAYMOND. Again, we don't have a position on those subjects. We will certainly follow whatever is passed.

Ms. EMERSON. Well, let me just say, though, Dr. Raymond, that you know I know you're on the science side, but USDA doesn't generally hesitate to make drastic proposals for the Farm bill, I have to say, and certainly USDA has been to think outside the box on occasion when it has wanted to.

Anyway, let me thank you very much, and Madame Chair, thank you.

Ms. DELAURO. Mr. Hinchey.

INSPECTION PERSONNEL VACANCIES

Mr. HINCHEY. Thank you very much, Madame Chairman. Under Secretary, thank you. Nice to be here with you again, and you know talk about a subject that is really important to the health and safety of people of our country. And I think that based on the information that I have and the interaction that we've had over the last few years, it seems to me that you try to do a good job. But it's not always easy to do.

One of the issues that you have to deal with is the number of inspectors that you have around the country to look at these food

production facilities, and to make sure that the food that is being sold is safe, it's not going to have adverse consequence.

I understand the number of inspectors now is down by about 10 percent, is that right?

Dr. RAYMOND. The number of inspectors today compared to a year ago is actually up, Mr. Hinchey, by 100.

Mr. HINCHEY. I'm not talking about compared to a year ago.

Dr. RAYMOND. Okay.

Mr. HINCHEY. The number of inspectors that are supposed to be in your agency I understand is about 8,000. And you have now something in the neighborhood of 7,300, or something like that. So, based on those numbers, the number of inspectors is down from where it ought to be by about 10 percent. Is that correct?

Dr. RAYMOND. The numbers right now today are 7.4 percent. They were 10 percent, and we've been able to bring those numbers down somewhat.

Mr. HINCHEY. Oh, so it's a little over 9 percent, then? Not by 10 percent?

Dr. RAYMOND. 7.4 percent is the overall vacancy right now of our front-line inspection workforce.

Mr. HINCHEY. 7.4 percent?

Dr. RAYMOND. Yes. 3

Mr. HINCHEY. But you have less than 7,400 inspectors. Or do you? Well, how many inspectors do you have? You're supposed to have 8,000. How many do you have?

Dr. RAYMOND. As of the first pay period, the first week in January we had 7,310 inspectors in the establishment.

Mr. HINCHEY. 7,300? Okay.

Dr. RAYMOND. Yes, sir.

Mr. HINCHEY. That's what thought originally. So you're down about 10 percent, close to 10 percent. And the question arises, you know, what is the quality of inspection that is being administered since we don't have enough inspectors? Why is it that we don't have the full number?

Dr. RAYMOND. There are several reasons, and probably the biggest one is that we just have trouble recruiting for some geographical areas in the country. We have been very aggressive in offering signing bonuses and moving expenses, et cetera, trying to fill those vacancies. But it is difficult in some parts of the country to find——

Mr. HINCHEY. Well, I would encourage you to be more aggressive in that regard, because I think that this is very, very important. And if we don't have enough inspectors out there, then this job is not going to get done.

Ms. DELAURO. Will the gentleman yield for a second? It's my understanding, and just for verification, that in the Alameda District, which is where Hallmark Westland is, that the vacancy rate in that area was at about 11 percent.

Mr. HINCHEY. Okay. The vacancy varies. It varies sometimes up as high as 11 or 12 percent, down in some areas by less. But across the country, the vacancy rate is somewhere in the neighborhood of 9, close to 10 percent.

There's a request in the budget from the president to increase the amount of funding by $22 billion. [CLERK'S NOTE—The Depart-

ment subsequently clarified the number is $22 million] I would just say that we've got to focus more on this issue of the number of inspectors, because the inspections aren't being done. They're not being carried out properly.

Last month, for example, we saw that the largest beef recall in U.S. history took place at the end of February, and you know I think it's pretty shocking for the American people to see that kind of thing happening. They expect that their government is going to be doing everything it can to protect their health and safety.

RETAIL DISTRIBUTION LISTS

Now to your credit, as I understand, going back a couple of years, to 2006, you recommended that whenever there is a beef recall, people should know where that food that was being recalled was sold from. Am I right about that?

Dr. RAYMOND. Yes, sir.

Mr. HINCHEY. But that hasn't happened. In spite of the fact that you made that recommendation, which is to your credit that you did so, that hasn't happened. So in the case of this beef recall, the largest recall of food in the history of the United States of America, people across the country who are subject to exposure to that adverse food weren't able to learn from where they bought it. I would like you to tell us the names of the retail establishments that that food was sold from. And to the best of your ability, give us an indication as to how many people actually purchased that food from those specific retail stores. Now can you do some of that right now?

Dr. RAYMOND. Congressman, I can tell you there is nearly 10,000 retail establishments, and I cannot give you each individual——

Ms. DELAURO. What was the number? I'm sorry?

Dr. RAYMOND. Just short of 10,000 retail establishments.

Mr. HINCHEY. There are 10,000 retail establishments?

Dr. RAYMOND. Nearly 10,000.

Mr. HINCHEY. Some fraction of that 10,000 was engaged in the sale of this beef product, which was recalled, and I assume recalled because of the work that you do in your operation, because you were responsible for that recall, and I congratulate you on that. But I think that you are confronting some adverse circumstances in the context of the overall situation in which you work, in spite of the fact that I've cited two examples of how you as the Under Secretary for Food Safety Inspection, have done those two very important things in recent years, nevertheless the effect of what you are trying to do is not where it ought to be.

So there are 10,000 retail stores, a fraction of those 10,000 was responsible for selling this adverse food that was recalled. I would like you to tell us where those retail stores were, what the names of those retail stores were, and where those retail stores obtain the product that they sold which was recalled; and to whatever extent you can, also tell us to what extent they knew that the product that they were buying was under the quality that it should be, and that it might in fact be recalled. Can you do that?

Dr. RAYMOND. First of all, if I might, I'd like to clarify. It's 10,000 consignees, not 10,000 retail stores. I assume that means consignees could have several retail stores.

Mr. HINCHEY. Okay.

Dr. RAYMOND. So it's more than 10,000. I'm sorry for that misstatement.

Mr. HINCHEY. So, 10,000 retail companies——

Dr. RAYMOND. Consignees, yes.

Mr. HINCHEY. Yeah. So they're companies, and they may have a number of outlets, which many of them do.

Dr. RAYMOND. That would be correct.

And to answer your last question, no, of course they had no idea they were buying meat that had not been produced under full compliance with our regulations at the time.

Mr. HINCHEY. How quickly can you provide us with the information that I just asked for?

Dr. RAYMOND. I'm not sure that I can at this point in time, because it's considered proprietary.

Mr. HINCHEY. Now, wait a minute. I'm going to strongly object to that.

Dr. RAYMOND. Okay.

Mr. HINCHEY. And I don't want you to say that. This is not proprietary information. This is information that is directly engaged in the health and safety of the American people, for which we have a responsibility, along with you, to protect.

Dr. RAYMOND. Yes.

Mr. HINCHEY. And if we have stores that are selling bad products, we need to know about it. So if we can't get this information from you by the first of next week, then we're going to start pressing you very hard in whatever way we can in order to obtain that information.

So I hope that you will provide it to us by Monday or Tuesday of next week.

Dr. RAYMOND. I will check with legal counsel and do what I can, sir. I do agree with you. That's why we're pushing to get this rule, retail rule.

[The information follows:]

On April 4, 2008, FSIS sent separate letters to House Agriculture Appropriations Subcommittee Chairwoman Rosa DeLauro (D–CT) and Ranking Member Jack Kingston (R–GA) providing them with a list of consignees who received meat from the Hallmark/Westland Meat Packing Company.

Mr. HINCHEY. I thank you very much.

RETAIL RULE

Ms. DELAURO. I will make a comment on that. I tell you, I wrote to Secretary Schafer. What's the date? Two weeks ago. Two weeks ago. Asked for a list of the retail outlets. I also asked for the list of schools that was—to date, no reply, no reply. And to your credit, Dr. Raymond, as my colleague Mr. Hinchey has pointed out, you are for making public these retail outlets. This is a rule, as I understand it, that was proposed on March 7, 2006. Tomorrow will be two years. Two years. The public comment closed down? We don't have a list. We can't get this rule out. Who is holding up the rule? Tell us.

Dr. RAYMOND. The rule——

Ms. DELAURO. If it's not you, we don't want to continue badgering you. We will go and move to deal with OMB, or whomever else is involved in this effort.

Dr. RAYMOND. And I know you're not going to like this answer, but it is in the very final stages of clearance.

Ms. DELAURO. This agency is in its final stages, Dr. Raymond, and on this issue you have been forthright. But we can't for two years produce a rule that says let's get a list of where the contaminated product was sent? The list of schools? That's unacceptable, Dr. Raymond.

And if you find it unacceptable, you should then work with us. And I don't know what our—you're going to check with your legal counsel. I don't know what our legal possibilities are.

And then, you know, that may be the direction that we have to go, to tell an agency, or an OMB, or a USDA that this is unacceptable. Is it OMB? Who's sitting on it? Tell us. Where is it? On whose desk does this lie? In what office or cubby does this rule lie? And where is it being discussed?

Dr. RAYMOND. We're in discussions with OMB at this time.

Ms. DELAURO. So, it's at OMB?

Dr. RAYMOND. It has not been formally sent to OMB yet. We're having informal discussions with OMB at this time.

Ms. DELAURO. Is it in your office? Is it USDA? Somebody has to know where this stuff is.

Dr. RAYMOND. It is at the USDA.

Ms. DELAURO. The USDA?

Mr. STEELE. Yes.

Ms. DELAURO. Yes, Mr. Steele.

Mr. STEELE. Are trying to work out—OMB before we actually send it over there. So when we get it over there—but we had some informal comments coming back from them, which we're going to try to build into the final rule before we submit it back to them, so we don't have this back and forth. We'd rather get it all done, wrapped up before we send it over there, so we don't have a long delay after it's submitted.

Ms. DELAURO. Thank you for the clarification, but I make my point. Two years. Two years tomorrow. And that really is not acceptable. It's not acceptable——

Mr. HINCHEY. Everybody out the door.

FOODBORNE ILLNESS DATA

Ms. DELAURO. Yeah. Let's go.

Well, let me just pick up on a couple questions for my last round, and then I'll move to Mr.—and I don't know what time—but I wanted to go back if I might—but I'm going to get the charts, our charts—bone up. This is infection rates for E. coli, which in fact—2001 were pretty high, came down. But again——

Dr. RAYMOND. Yes.

Ms. DELAURO. Moving back up again, and with Listeria, you know, up and down, and now really again on the rise. So my question to you, Dr. Raymond, is with regard to—and I really do want a yes or no answer—do you understand that the verification data do not reflect the prevalence of the pathogen?

Dr. RAYMOND. Yes, I do, Madam Chairwoman.

Ms. DELAURO. Thank you very much.

Mr. Hinchey.

Mr. HINCHEY. Well, I think that a very important subject has been raised here, and as we pointed out, we very much respect the work that you specifically have done, your operation, Dr. Raymond. And none of this is personal toward you because it seems to me, based on all the information that I have, that you've approached this in the right way. In fact, there's an article recently that says that there's a February 14 letter in which you urged Secretary Schafer to quickly approve a 2006 proposal, your 2006 proposal, that would make public the list of the supermarkets involved in the recall.

So obviously this is something that the most important office in the government of the United States which oversees the issue of food safety and carries out inspections in order to provide that food safety to the highest level, understands the need to provide the safety of the purchasers by letting them know the stores from which they purchased agricultural products, food products, and in the particular case that we mentioned here, beef products that were recalled. The largest recall in the history of the country.

So I'm just basing my assumption, which I'm about to state, on the interaction that we've had here, and that assumption is that you're being impeded, you're being impeded by the Secretary of Agriculture. And the Secretary of Agriculture is probably to some extent being impeded by the Office of Management and Budget. And the Office of Management and Budget is probably to a major extent being given direction by the White House.

So we have a situation here where the highest level of government is acting in a way that is making it less safe for people to walk into a store where they have every reason to believe that what they're going to buy is going to be safe. They get home, feed it their children, the rest of their families, and suffer the consequences of that, which could be illness and substantial illness, and even worse than that, deaths of people.

So this is a very, very critically important issue, which you have attempted to address. And we are now urging to provide us as quickly as possible with this information, have it to us by next week. Because we would like to become even more directly engaged in this activity. People of the United States have got to know this, got to know what's going on. And when they know what's going on, then the impediments that you're confronting from OMB and elsewhere will be alleviated. Because when that information is put out, the response is going to have to be proper and appropriate, very positive.

So this is a critically important issue, and I trust that you will be able to join in and continue what you've been trying to do. But now do it with us. Give us that information. You have the information. I know that. You have that information. So I'm asking you to just give that information to the Congress, so that the Congress can deal with this issue in the appropriate way.

I've just been given this question. I'm going to ask it, even not having read it. [Laughter.]

PLANT SURVEILLANCE

Mr. HINCHEY. What are your thoughts on putting permanent video cameras inside and outside of plants?

Dr. RAYMOND. That's a proposal that many people have asked us to consider, and we will consider it when the investigation is done as we come up with potentially new policies and directives on how we can do a better job of observing animals to make sure——

Mr. HINCHEY. When is that direction going to be done? See, what's going to happen here is that all of the harm that's been done in the context of this administration is just going to drag out over the course of the remaining months of this year. So my fear is that this issue is not going to be addressed until sometime in February or March or April of next year in the context of a new Administration. It will be much wiser and much more responsible to deal with it now, though I hope that you will do everything you can to get these issues moving as—and positively as possible, knowing that you really want to do it—you've done this kind of thing in the past.

Thank you.

RETAIL DISTRIBUTION LISTS

Ms. DELAURO. Thank you. I just would harken back to tie up this conversation. In my opening remarks I said that we all share a common goal, to create an effective food safety system that focuses on prevention, not just reaction.

Dr. RAYMOND. Right.

Ms. DELAURO. Ensures the public health and makes the most effective use of limited resources. These are basic and guiding principles reform. But I think that what we're seeing here, Dr. Raymond, and in some regards I think you concur, but they've long been undermined by inadequate authority, outdated oversight laws, and by a regard for private interest that compromises the public. And that I say directly related—proprietary information. Don't have to belabor that—know what your view is. And we are going to continue to press on this issue with the tools that are available for us, so that we can give people the information that they need. It is their right to know, it is their right to know.

I am going to—we have—coming up. I believe Mr. Farr is back—

HALLMARK/WESTLAND RECALL

Dr. Raymond, with regard to Hallmark, and we'll just get started on Hallmark—you say in your testimony on page 6 that our evidence demonstrates that over the past two years this plant did not always notify the FSIS Public Health Veterinarian when cattle became non-ambulatory antemortem, prior to slaughter inspection, as is required by FSIS regulation. When was this evidence discovered by USDA? After the Humane Society video, or before?

Dr. RAYMOND. After.

Ms. DELAURO. After the video?

Dr. RAYMOND. Yes, ma'am.

Ms. DELAURO. After the video. How was this evidence developed, through what methods was it developed?

Dr. RAYMOND. Through our investigations, interviews of our employees, plant employees, cattle buyers, et cetera.

Ms. DELAURO. How many times over the past two years did the plant notify FSIS—the public health veterinarian in such circumstances? What about before the last two——

Dr. RAYMOND. Our investigations at this time show that this was a practice that occurred very rarely, for that two year period.

Ms. DELAURO. I'm sorry. I—go ahead, please.

Dr. RAYMOND. I said our investigations showed that this was a practice that occurred on rare occasions—going back two years. We have no evidence that it went back further than the two years at this time, and it was very rare——

Ms. DELAURO. What occurred? What occurred at that time?

Dr. RAYMOND. What occurred was an animal would be passed ante-mortem or before slaughter by our Public Health Veterinarian or other specially trained inspectors, that had saw this animal both at rest and in motion, saw no evidence of any chronic diseases or illnesses, and passed it fit for human consumption. And then at some point in time between that inspection and it entering into the slaughter facility the animal went down and refused to get back up. And no one was notified, and it was allowed to go into slaughter.

Ms. DELAURO. Do you have the number of times? Is there a record of notification of when this did happen?

Dr. RAYMOND. Al, can you answer that?

Mr. ALMANZA. Yes, ma'am. There were a number of times that were documented where the Public Health Veterinarian was notified that an animal went down between the pens and the knocking box.

Ms. DELAURO. And the knocking box——

Mr. ALMANZA. It's an alley.

Ms. DELAURO. Yes, sure. No, I, yeah, I've been there.

Mr. ALMANZA. Okay. So have I plenty of times.

Ms. DELAURO. I know.

Mr. ALMANZA. And so we do have documents that demonstrate that that did occur periodically, a couple. I think the last number we got was a couple of times a month where they would actually call.

Ms. DELAURO. Do you have a record of all of the notifications within the last two years?

Mr. ALMANZA. Actually every time it occurs.

Ms. DELAURO. Before——

Mr. ALMANZA. Yes, ma'am. We have a record of it every time he's called back up.

Ms. DELAURO. Okay. Well, I'm going to ask the question, but we have to go to vote and come back, and so we will do that.

Why do we only have this information now, after the Humane Society—did their undercover video? I'm going to leave you with that, and——

Mr. ALMANZA. I've got an answer for you.

[Recess.]

Ms. DELAURO. Hearing will come to order. I'm going to try to finish up on some of the questions we were looking at. Dr. Raymond, and then I'll yield to my colleagues. We're talking about why we

don't have this information until now, after we had an undercover investigation by an outside group, not by the Agency. And then we found out that we have a lot of data here that demonstrates that there have been problems. And people have been notifying the Agency of the problems. And maybe one of the issues that comes up here is about closing this loophole. This is a loophole in the law that says that you have to go this extra step here. And that was dealt with after the fact, after—I think it was Secretary Veneman who came forward and laid it out: cows, and we had the interim and then we came back with this. So maybe this is a mistake. And we can address that issue as well, and we will address that issue as to whether or not it was a mistake. Because I think we do have to go down that road. But tell us why we don't have the information until now, why you're telling us it now, and why didn't we know about this before the fact.

Mr. ALMANZA. Okay. The records—case. I may have—or maybe I misspoke. What I intended to say was that we do have records of when the Public Health that day was called back out. In other words, when ante-mortem was performed and then an animal went down in that alley area. Those are—we have records of that. Obviously we don't have records of when they didn't call us back, otherwise——

Ms. DELAURO. Nobody informed you of that, which then leads us to this loophole issue of what we should do about that. Let me just ask you. Do you think we should shut down that loophole? Yes or no?

Dr. RAYMOND. No.

Ms. DELAURO. We should leave the loophole there. Can you explain why?

Dr. RAYMOND. Yes. I think there are a couple reasons. I can explain why. We have a rule. The rule wasn't followed. And when the rule is not followed, I don't think that's a good reason to change the rule. We enforce the rule, and we take immediate action like we did, and that plant is probably out of business. One offender of the rule should not make 800 other plants change the way they do business. This is an avenue for getting these cattle into slaughter that had passed ante-mortem inspection that were deemed to be healthy; they were fully ambulatory, showed no signs of chronic disease. And if they do break a leg, there's no reason that that meat is now unfit for human consumption.

ENHANCED SURVEILLANCE

Ms. DELAURO. And do we know that this was just in one plant?

Dr. RAYMOND. We do not know that for certain, and that's why we're doing this enhanced surveillance over the next 60 days.

Ms. DELAURO. Is that part of this investigation? You're looking at this as part of the investigation? That you're looking at——

Dr. RAYMOND. Absolutely.

Ms. DELAURO. You're not waiting for the completion of the investigation to act. The FDA is taking a number of steps to strengthen our inspection. You were asked about the investigation. But this piece is included as well as whether or not other plants may have been involved in the same kind of activity. Is that part of the investigation?

Dr. RAYMOND. It's probably not part of the OIG's investigation at this plant. It's part of our increased auditing and surveillance in the next 60 days in all of the slaughter plants.

Ms. DELAURO. So you are doing an investigation in all of the slaughter plants on this particular issue of whether or not this loophole in the law, which allows the potential for a downer cow to go into the food supply, as to whether or not that's happening. What's the nature of that investigation? I mean what are you looking for there?

Dr. RAYMOND. I think I would refer to it as probably enhanced surveillance. We're going to spend up to twice as much time out in the pen area where humane handling is an issue, and humane handling would include a downer cow being dragged into a slaughter facility.

Ms. DELAURO. Do you have any—before Hallmark came to light did federal personnel do any observations on the handling of animals after the veterinarian completed the ante-mortem inspection?

Dr. RAYMOND. Yes. That's done as a routine in all slaughter facilities.

Ms. DELAURO. But did they talk about their observations? Because those reports have suggested that it's relatively easy for a plant employee to "gain the system." Because they know the schedules of the veterinarians and the inspectors. Is that what you're trying to—it sounds like this is part of what you're trying to address with your surveillance activities.

HUMANE HANDLING NONCOMPLIANCE

Dr. RAYMOND. It is part of what we're trying to address. Yes. To see how we can do our job better, but I do feel a need, Madam Chairwoman, to point out to you that last year there were between 600 and 700 noncompliance reports written by our inspectors for inhumane issues that were not egregious enough to pull suspension. And of the 66 plants last year that we did pull inspection, 12 of those were for egregious humane handling errors. Now that's way too many, but we are there. We took action, and we closed 12 plants because of humane handling issues, and wrote over 600 noncompliance reports.

Ms. DELAURO. Can we get access to that information?

Dr. RAYMOND. Absolutely. Absolutely.

Ms. DELAURO. Okay. That would be good to do. Because I—yeah. I mean I applaud that effort. I didn't see anywhere that any place was closed down because of noncompliance in this area, and honestly this is the first time that I have heard that information if that was the case.

Dr. RAYMOND. I could tell you that in 2003 it happened nine times, there was suspended inspection. In 2004, eight times; 2005, 13 times; 2006, 14 times; and then last year, 12 times.

Ms. DELAURO. I suggest to you that we have a problem here with this issue. It continues. It gets worse. Maybe we do need to look at this process and see what it needs to have to strengthen it.

Dr. RAYMOND. As I said, that's way too many times to suspend a plant.

Ms. DELAURO. Yeah. And I think that that's where we have to go in terms of strengthening that. And it may include, though you

disagree at this juncture, closing down that rule, because it's not one plant, obviously. That there are a number of them, by virtue of the information that you have. So that it may be that the rule is a problem, but there may be some other areas where there are problems as well. But we clearly have a flawed system at the moment, which is creating a public health problem. I think we can agree on that.

Dr. RAYMOND. A potential public health problem. Yes. Yes. If I might, for clarification, the plants that we pulled suspension from—that was for egregious inhumane handling issues that were not necessarily reflective of the downer cow thing.

Ms. DELAURO. No. Did not necessarily deal with the downer cow moving into the supply.

Mr. KINGSTON. Thank you, Rosa. I'm going to yield, Mr. Latham, because I've been——

BSE AND NON-AMBULATORY DISABLED CATTLE

Mr. LATHAM. Just kind of on the same subject. What would be the ramifications, as far as food safety, if in fact these downer cows were not brought into the system? And I know we've had a lot of debates over the past several years about not having sick animals or whatever brought into the system. And I'm worried about mad cow disease and things like that. What would happen to those animals if in fact there were no potential market for them?

Dr. RAYMOND. They would probably all go to rendering.

Mr. LATHAM. Rendering? Or would they be buried out on somebody's deal someplace or in the back 40, which then in fact would—we would never know if we had mad cow disease in the system somewhere?

Dr. RAYMOND. I would assume that probably does happen on occasion. And as long as that animal, even if it's dead, has some potential value to the farmer or rancher I think they're going to try to get it to rendering, as long as there's some cash value.

Mr. LATHAM. I mean that's my concern. If you're really concerned about potential diseases that could destroy, obviously confidence in food safety, but also our markets overseas, things like that, if we're not staying on top of the situation the one way that we have to do that is to have those animals brought in to be inspected at the packing mills. Isn't that correct?

Dr. RAYMOND. That's correct.

Mr. LATHAM. Is there any information of what would —any way to quantify how many animals that would not be brought in, or what the potential food safety issues there would be if we did not have inspections at packing houses?

Dr. RAYMOND. I can give you some numbers, Congressman that I think might help. At this particular plant that we're talking about, in the last three years it slaughtered 371,000 head of cattle. In those three years we did condemn 17,000 head; a little over 4 percent were condemned because of inspection. And if we did not have inspection at that plant, that 17,000 cattle go right into the food supply.

Mr. LATHAM. Right. And those 17,000 I would assume are tested for things like Mad Cow. Is that correct?

Dr. RAYMOND. Yes. Yes. Not 100 percent tested for Mad Cow, but those that show certain symptoms of some of the dead—a lot of the condemnations refer to other illnesses.

VETERINARY LOAN REPAYMENT PROGRAM

Mr. LATHAM. One issue, I know, Mr. Kingston and I, we appropriated a couple million dollars over the last few years for veterinary grads to serve in underserved areas, and some of the money basically was not—shifted over to you folks I think to hire more vets and inspections, and not used for the purpose as intended by Congress. I just wonder if you have any knowledge about the loan repayment program or what—is this an ongoing practice, or is there any kind of program actually being done?

Dr. RAYMOND. Yes. There is. And it's—I can apologize, but it took too long to get it going. But the $750,000 that has been given to FSIS to use for loan repayments to encourage veterinarians to come and work for us, $150,000 of that has been obligated to new Public Health Veterinarians that are working for us at this time. We just recently——

Mr. LATHAM. Not necessarily to vet students who are going into private practice in underserved areas. Is that correct?

Dr. RAYMOND. That is correct.

Mr. LATHAM. Which was the intent of the legislation.

Dr. RAYMOND. I don't have the legislation in front of me, so I can't——

Mr. LATHAM. Well, that was what the program was all about. It's to have vets go into areas where they cannot—a lot of vets want to go into small animal practice, things like that today, and their critical need is out in the country, so it's somewhat frustrating I think to several of us that those dollars that we appropriated for a specific purpose are not being used for that purpose.

STATE INSPECTION

You assist states or brought in training, technical assistance, provide states with about 50 percent reimbursement accounts for their functions. Is that—that's what it's been in the past. Is that about the same as what it has been, and can you—is there any change or modernization going on as far your training of the inspection services at the state level?

Dr. RAYMOND. The first part of your question. We are funding up to 50 percent at this time. Two years ago, we were unable to fund up to that level, because of some fiscal issues we had across the whole budget, which Congress fortunately has rectified for us. So we're back up to the 50 percent level. As far as training, we're always looking at new ways to train. And actually, tomorrow we'll be announcing a new reorganization within FSIS that will address training specifically, or elevate the importance of it, and, I think, the visibility of our training and outreach programs.

RECALLS

Mr. LATHAM. Okay. Kind of getting back to where we were before, but you have been working supposedly, or have been, I assume, on plants as far as the recall to make them faster, more effi-

cient in the last year. What changes have you made, or are we doing better as far as faster recalls? Just tell us what the status is.

Dr. RAYMOND. Sure. I'd be glad to. And thank you for that question. It's an area where I have a particular high-degree of interest in, coming from State health.

Mr. LATHAM. Right.

Dr. RAYMOND. I think sometimes recalls, they just take too long to get out in the public's eye and to get that product off the shelves. One of the things that we have initiated this year is to use epidemiological evidence more aggressively. Instead of—I don't know how to phrase this exactly—but instead of everything having to line up perfectly in a row so you know—you know—that that had to be recalled, I would rather err to the side of protecting the public's health, and say, "It sure as heck looks like it came from this plant. We're going to do a recall."

And a couple specific examples would be where if one person is ill, and the PFG for that particular—we'll use E. coli—the PFG, the pattern for that matches the pattern of frozen products in the person's freezer, historically, we would not do a recall, because of the possibility that person took the frozen patty out and contaminated another frozen patty, and they all had E. coli, and I think that—from a public health standpoint and from my position standpoint—I'm saying odds are that was contaminated in the plant, and we're going to do a recall. We did that twice last fall. That's part of the reason for the increased recalls, a very small part. But that's one example. We're not going to wait until we have other people get sick, so we can check 16 different refrigerators.

Mr. LATHAM. Is the system of notifying you of people getting sick—is that any better than what it has been?

Dr. RAYMOND. It's better, but there's a tremendous amount of room for improvement. And because of that, I've actually formed a committee within FSIS, and FDA, and CDC, and our state and local health officers, and our state public health labs and state epidemiologists. We've got representatives from all those organizations putting together a two-day summit that will be held—I don't know if we have an exact date yet—probably May, mid-May. We'll gather state health officials and city and county health officials and state epidemiologists, and representatives of us, and CDC and FDA. And I expect this conference to expose some warts. I want to know what we can do better as a Federal Government, but at the same time I'm going to tell state and locals where you can do better as far as notifying us. That has been an issue.

REPORTING FOODBORNE ILLNESSES

Mr. LATHAM. Something I probably should know, but are the doctors required to report——

Dr. RAYMOND. There are certain communicable diseases that reporting is required, but they do vary state by state. For instance, in your state of Iowa, influenza is a reportable disease. In my state of Nebraska, it's just if it's in a pediatric population is it reportable.

Mr. LATHAM. Okay. I've gone well over five minutes. Thank you, Madame Chairwoman.

Ms. DELAURO. Thank you, gentleman. Congresswoman Kaptur.

SMALL AND VERY SMALL ESTABLISHMENTS

Ms. KAPTUR. Thank you very much, Madam Chair. Welcome, gentlemen. Glad to have you here today. Dr. Raymond, I wanted to link the recent situation with the recall of beef, the largest in U.S. history, to a trend I see in your Agency and invite you out to Ohio to help me deal with a problem I'm going to describe to you here. Let me talk about protecting small producers.

Between 1998 and 2003 there were over 2,200 federally inspected establishments that produced ground beef. 2,200. Then in 2005 your Web site reported there were 1,700 such facilities, so we're moving downward. And then the current version of the Web site, updated in February of 2007, reported there were 1,400. So we're almost halving the number of federally inspected establishments.

Meanwhile, here's a letter I'm going to read—it's very brief—from a constituent of mine in northern Ohio. "Dear Congresswoman Kaptur, I'm a small farmer. We've been producing locally grown food for my family and for the local community. In the last seven years of our operations we've not been allowed by USDA to sell our products, such as fresh milk or dressed poultry or small areas at our farms or in many local stores. In order to be compliant with USDA regulations, we would need over a million dollars of stainless steel facility to butcher just a small number of our poultry and livestock. It is strange that many small operations with all the goodness of fresh, locally produced products, and I might say identifiable origins to the buyer, free of commercial influence of chemicals and hormones have not been able to serve in local communities. I hope you can help change this to accommodate the little farmers to grow local foods that in turn help us decrease the carbon footprints and also prevents such large national crisis of contaminated food product."

In working with our extension service in Ohio over a number of years, we've been trying to help our producers—we are a major corn producing region and soybean producing region—to bring beef to market. And here's what they tell me. And I've asked the secretary, by the way, to come to Ohio as well to work this problem out and meet with our small producers. A constituent writes me, "We as a small family packer must cover the cost of travel per diem and a $68.50/hour labor charge for grading product. This works out to cost exceeding $20 per head at some of our participating locations." You know, there are some who would argue that the destruction of small and family agriculture and smaller producers and the rise of these very large concentrated organizations that don't procure locally and then provide us with contaminated products that get into our school programs, that there's a relationship here. So my question to you is: What can USDA do to make these small producers that we know—we drive by them in our cars when we go to work and go back home, who are accountable locally, they label their product, they want to sell—what can USDA do to help us let them move their product to market without such difficulty. What is going on with the regulatory process that allows these large conglomerates to contaminate the food chain, and these local people not to be able to get to shelf?

Dr. RAYMOND. Congresswoman Kaptur, I would be more than happy to accept your invitation to come to Ohio and meet with those. You duly noted that, right?

Ms. KAPTUR. Thank you.

Dr. RAYMOND. We will be there. We have traveled around the country on the issue of small and very small plant viability. I come from a very small town myself. I believe strongly that rural economic development sometimes can start with a business of four people. We have instituted at FSIS a very aggressive outreach program for small, very small plants to help them comply with approvals, etc. When I came here, we found that they were less vigorous asset plants, because they did have a full-time person for quality assurance and asset. They wrote their asset plans on their kitchen tables at night, as they worked during the day at the plant. And that's one of the stars, I think, or one of the jewels in our crown, of something that we have done very aggressively and very well. And then small or very small plant establishments and their respective organizations have lauded us many times. And tomorrow the announcement we will be making will be talking about creating this new program area within FSIS totally dedicated to outreach and to education and training. Instead of just being something that someone's doing over here, it's going to rise in elevation. Now, that doesn't address all of your issues. But what it does address is those that are under federal inspection, and we help keep them viable, instead of writing so many noncompliance reports that they eventually close their door.

Ms. KAPTUR. But what about all this investment they say have to make? Millions of dollars. I mean these are not large enterprises.

Dr. RAYMOND. I said this addresses those that have already—have made that investment. We want to keep them operating and viable. Your issue is slightly different: Those that haven't made that investment that want to be able to sell locally. I will look into that. I will have to learn a little bit more about that. And I will come up. And we will contact you, and we'll work on that.

Ms. KAPTUR. We can start with the lead extension agent who handles beef marketing for our extension service. Maybe you can call him before you come out, and we'll work on a really good session.

Dr. RAYMOND. We would love to do that.

Ms. KAPTUR. Thank you.

Ms. DELAURO. Mr. Kingston.

HALLMARK/WESTLAND RECALL

Mr. KINGSTON. You had said that on that particular plant, Hallmark, that there were 571,000 slaughters, and there were 17,000 that you had condemned this year?

Dr. RAYMOND. No. 371,000 slaughters over three years, and 17,000 condemned over three years time.

Mr. KINGSTON. Is that a high number or a low number? Average?

Dr. RAYMOND. Compared to the national average—it is higher than the national average. For this particular type of cattle—you've got to remember we're talking dairy cows here too, not fat cattle.

RISK-BASED INSPECTION

Mr. KINGSTON. Would risk-based inspections have been helpful, if that was a plant that had a higher number?

Dr. RAYMOND. The risk-based inspections conversations that we've had in the past have been primarily on processing, and this is a slaughter plant. So if we had done risk-based inspection, it would not have been active in this particular plant, other than maybe in the further processing where they ground the beef.

Mr. KINGSTON. Well, let me just get theoretical then. Had it been process and not slaughter, would RBI have been helpful?

Dr. RAYMOND. In this particular plant, it would not have been. The issues with humane handling and allowing a downer cow to go into the food supply that did get re-inspected—it would not have helped that.

Mr. KINGSTON. Okay. Next question. On—I just—it might get you to go on record of saying anything positive about RBI. Despite my best efforts Dr. Raymond——

Dr. RAYMOND. I'm trying to be honest. RBI I believe strongly in. I still believe——

HUMANE HANDLING AND FOOD SAFETY

Mr. KINGSTON. You can still accomplish both. But, I know you are a very scientific guy. Straight shooter, so I don't want to put words in your mouth, even through I'm trying to help you load your own gun.

In terms of humane violations versus food safety—I want you to talk about that a minute. Sam Johnson, our distinguished colleague, who is a Vietnam POW, he tells a story about having a pet dog in the prison camp, which the Vietnamese decided it was time to eat the pet dog. And they threw it in a hole. And they threw sticks at it, and they tormented the dog for five or six days with the idea that this enhanced the dog meat. Now as inhumane as that is, it probably did not affect the quality of the meat. So there are two different issues I believe in terms of the quality of the meat for food safety and the humane treatment of the animal. And what I want to ask you is—talk to me a little bit about that. In this case I understand that the cow was not really mobile, but there was nothing wrong with the meat. Is that right or wrong? And you can use this as an example, or go broader than that. But I'm trying to figure out where there's a violation for one issue, but doesn't necessarily get into the other.

Dr. RAYMOND. They are for the most part very separate issues. The humane handling was the egregious handling that we saw on film: night after night after night of cattle being prodded with forklifts, et cetera. Most of those—maybe none of those animals ever passed ambulatory examination. They did not go to the food supply for the most part if not 100 percent. They were not ambulatory cattle. The other issue is the cow that was ambulatory and passed inspection and then went down. And I would like to tell you that there was absolutely no health risk to that animal going into the slaughterhouse. But I cannot. I can't load this gun, because we have a regulation that says that animal must be re-inspected by the Public Health Veterinarian, and he or she must determine that

it went down because of an acute injury. And if that had been done, then I would sit here and say, "No. There's absolutely no health risk of that animal entering the food supply." But that step wasn't done.

Mr. KINGSTON. So that's an important thing though. Because what you're saying is if there's a treatment issue, then it's possible that that could lead to a food safety issue. But you really don't know the answer to the second one until you've inspected it because of the first one.

Dr. RAYMOND. That's correct.

Mr. KINGSTON. Okay. And then often when you look into humanitarian issues, cruelty, how often does that lead to an overlap in food safety?

Dr. RAYMOND. I can't give you a number. It obviously can, because inhumane handling causes stressed animals. Stressed animals causes animals to defecate and other things that change in terms of the risk factors. So, besides cruelty to animals, there is a health issue here.

FOREIGN-OWNED ESTABLISHMENT

Mr. KINGSTON. Okay. All right. Another question. Smithfield has been bought out by a Brazilian company. Is that correct? Smithfield Ham? They're a part of the division?

Dr. RAYMOND. Terri says the news report said that. I hadn't seen that news report. I know National is being bought out, but I was unaware of Smithfield.

Mr. KINGSTON. I think it's Smithfield. How big is Smithfield. I don't think it was very, but I'm not sure. Mr. Latham says Smith. Okay. All right. How many of you think it was Smith? Raise your hand. [Laughter.]

But my question is when you have—and this is something that Ms. Kaptur and I are kind of more and more interested in, in terms of the international issue, when you have a large domestic producer like that, and they're bought out internationally, how does that change the food inspection? Because I know that the quick answer is going to be "no," but is that really the same? Because management is different.

Dr. RAYMOND. It does change the inspection a bit. If it is an international buyer or if it is a domestic buyer, whenever there is a change in ownership, we will be doing increased inspections of that plant for a certain time period to make sure that the policies and the regs are being followed and have not changed.

Mr. KINGSTON. Does that include management practices back in Brazil on maybe machine processing or anything like that? What would be some of the differences that you could find?

Dr. RAYMOND. There are lots of differences. The robustness of their own testing, for instance. We will take beef slaughter in this case and how much testing are they doing for E. coli. Did they cut it in half to save money when the new owner took over or did they double it because the new owner believes even more strongly in food safety. It can go either way.

In part of our E. coli initiative that we announced this Fall, we are looking at corporate practices, so this would involve an international buyer also. Instead of just looking at individual plants, we

are going to look at corporate practices because if the corporate practice allows plants to be sloppy, we want to know that.

We will be looking at the buyers of these companies.

Mr. KINGSTON. Is that a growing challenge to you with domestic companies selling?

Dr. RAYMOND. I do not know. Al, do you know if that has increased?

Mr. ALMANZA. No. We do not have any information that is the case.

Mr. KINGSTON. Let me yield back. I wanted to raise that issue.

Ms. DELAURO. Thank you very much. Mr. Bishop.

USER FEES

Mr. BISHOP. Thank you very much, Madam Chairman.

I have a question regarding the President's 2009 budget. The 2009 budget again proposes a series of user fees, including country of origin labeling to help the Agricultural Marketing Service implement country of origin labeling, the Grain Inspection, Packers and Stockyards Administration, $27 million in new fees in 2009 for GIPSA to fund the development, as well as packers, stockyards and other meat and poultry disciplines.

For APHIS, a new fee to help cover the costs associated with the Animal Welfare Act, the Virus Serum Toxin Act and the Plant Protection Act.

I would like to ask you what the impact of these user fees are going to be on the basic consumer as well as on the industry as a whole. It seems to me that it would definitely increase the price of food and the production of food.

It seems to me that the food inspection issue and food safety is such a benefit to all consumers, everybody who eats food, that it ought to be a cost that would be paid for from the general fund rather than an user fee that places the burden of food safety on a small number or small segment of the industry.

It seems to me that food inspection ought to be an important enough function to warrant a direct appropriation rather than nickel and diming off a fee.

Would you comment on that, please?

Dr. RAYMOND. I would be glad to, Congressman.

Part of what we are asking for is a performance fee or a cost recovery fee, depending on how you want to phrase it.

When a plant has a problem and we have to go in and do a food safety assessment or we have to do another Salmonella test or we have to do 16 more E. coli tests because they had a positive E. coli, whatever, if they have done something that put the food supply at greater risk for meat or poultry, and we have to expend extra resources to go in there and make sure this is not rampant throughout the plant or make sure they have corrected whatever it is, we do feel they should pay that fee.

Make that analogous perhaps to our State patrolmen. They are out there to protect us. They are paid with tax dollars. When you get caught speeding, you are going to pay a fine to pay for that extra inspection, that extra time that patrolman took.

We do feel it is fair to ask for recovery for extra costs that we incur so the taxpayer does not have to incur that cost.

Mr. BISHOP. I will grant you that. What about country of origin labeling? It does not seem like that would fall under that category.

Dr. RAYMOND. That would be an AMS issue rather than an FSIS issue, I believe.

Mr. BISHOP. The Grain Inspection, Packers and Stockyards Administration fee?

Dr. RAYMOND. Unless Mr. Steele wants to answer, that was on behalf of USDA, I am going to defer.

Mr. STEELE. Mr. Congressman, there are fees in the budget, user fees, and we have traditionally put fees in over time in the budget. Some of these are new fees, some of them are repeats from last year again.

Mr. BISHOP. Did we fund them last year?

Mr. STEELE. You did not fund them; no.

Mr. BISHOP. You did not get the message though?

Mr. STEELE. Yes, we have a learning curve on that that we have to get over, I guess.

In any case, those fees, we would not collect money until the fiscal year 2010 budget. We would propose them in terms of 2009 as a proposal. It is for you to consider.

Mr. BISHOP. Would it not be more effective and would we not get a much higher product, I should say, a result, if we went on and funded the measures necessary to make America's food safe and save the consuming public from problems with infrastructure and proper investment could be addressed rather than waiting for 2010 to start collecting fees, which will come in on a piecemeal basis?

Would it not be the responsible thing for the Department to go ahead and request that the Congress invest in the food safety infrastructure so that the American public would be safe and have the most innovative processes possible to make sure that our citizens have safe food to eat, rather than doing it on a piecemeal basis, one item at a time, starting in 2010?

Mr. STEELE. I will let Dr. Raymond comment on the food safety part of that. I think those fees would provide some extra services. I do not think they would endanger the safety of the food supply, whether or not we had the fees. They are for re-inspection and other activities that we would like to enhance our ability to inspect in these terms where we have problems at the plants.

The question is we already have user fees in FSIS right now. We already do fund some of the programs through existing user fees. User fees for FSIS is not necessarily a new concept. Congress has approved those fees in the past.

Mr. BISHOP. You are supplementing your budget request. Are you supplementing your income while not requesting adequate funds to really do the job, and we raised the same questions last year, and you come back with these fees.

Why not just ask for enough money to do what needs to be done to make sure food is safe? It is clear that you do not have the infrastructure you need. You do not have all of the things that are necessary to adequately on a periodic basis inspect all of the facilities that need to be inspected.

Why not just tell us what you need? That is what we are here for.

Dr. RAYMOND. Our budget request is telling you what we feel we need, and part of the request would be to replace some of the tax dollars in fiscal year 2010 with the user fees. The amount of money we would be requesting would not change as a total.

Mr. BISHOP. Basically, when you come before us, what you tell us is what OMB has told you to say and not necessarily what you independently or personally might think is needed for the process; is that correct?

Dr. RAYMOND. We submit our budget request. It goes through the Department and gets modified somewhat, up or down, depending on what discussions we have, and then it does go to OMB for their approval; absolutely.

Mr. BISHOP. Your submissions inside the Department are not necessarily passed onto us. We do not have any idea of whether or not what you submitted was in this case, lowered, when it got up to OMB.

Dr. RAYMOND. What we do is submit the President's budget to you, of course.

Mr. BISHOP. I know that. You also inside your department submit something to OMB before the President prepares his budget.

Dr. RAYMOND. Absolutely.

Mr. BISHOP. What I am talking about is that intra-agency preparation, from agency to the executive, OMB.

Ms. DELAURO. Mr. Bishop, just to let you know what this committee did in 2007, we provided all the funds that the budget raised from user fees, $105 million we took from our 302(b) allocation, as well as an additional $29 million on top. This was done on a bipartisan basis.

When you have budgets that come up here, and my colleague, Mr. Bishop, is correct, we know that the user fees have not been authorized, and they continue to come up.

In fact, it casts some doubt on the budget and its accuracy. We have spent our own funds in this committee to address shortfalls.

Mr. Latham.

COUNTRY-OF-ORIGIN LABELING

Mr. LATHAM. Thank you. Maybe just for a point of clarification, the country-of-origin labeling has never even by the advocates been a food safety issue. It's a marketing issue. Is that your understanding?

Dr. RAYMOND. I think there are some people that believe it is a food safety issue.

Mr. LATHAM. It is not under your jurisdiction because it is a marketing issue.

Dr. RAYMOND. Right.

FOOD SAFETY ASSESSMENTS

Mr. LATHAM. The inspections are done no matter what. If you are talking about food safety, that is a different issue.

In the past, you have been criticized for lack of transparency on carrying out the food safety risk assessments. First, maybe explain why do you think that criticism has arisen and what steps have you taken to address the transparency problem.

Dr. RAYMOND. I am sorry. I am not quite sure I understand the question about the food safety assessment.

Mr. LATHAM. There has been a lot of concern by a lot of folks, GAO or whatever, as far as how you actually go through the process as far as transparency, what actually you are doing out there. We have talked about it in past hearings also.

I just wondered if there are any changes as far as an open process.

Dr. RAYMOND. We strive to be as open and transparent as we can, Congressman. Besides the two advisory committees whose meetings are open to the public, we have monthly meetings with industry and we have monthly meetings with the Safe Food Coalition, and oftentimes in the last year and a half, we have had joint meetings with our employees, the Safe Food Coalition and the industry and scientists to discuss proposed changes within our inspection system.

Of course, with the Federal Register and directives and notices and postings, I really do not know how we could be more open and transparent.

FOODBORNE ILLNESS

Mr. LATHAM. Is there any effort—I think the public in some ways is kind of out of the loop—as to how safe our food is maybe compared to other parts of the world or any way to quantify that so the American people know the kind of job you are doing?

Dr. RAYMOND. We have, of course, CDC's report each spring which gives us the overall known rate of foodborne illnesses for the common pathogens. We have to keep in mind that does reflect illnesses from all foods, not just meat, poultry and egg products that we inspect, also from the environment, water and other things that are not regulated.

We have those trends we look at. We have seen positive changes over the first part of this decade. I have said openly at the start of this hearing and other hearings that we seem to have plateaued and in a couple of instances, as the Chairwoman brings up, we actually unfortunately last year saw a slight rise.

To put it in perspective, I tried to look at the rates were for 2007 compared to the rates of 2000, 2001 and 2002, both for product samples and also for foodborne illnesses, and we have shown tremendous improvement that way.

BSE has never been diagnosed in this country by someone eating American beef. I think that is an indication of the interlocking steps we have put in place to protect the American public, and perhaps the headlines are the bad news and the good news does not make the headlines as frequently.

Mr. LATHAM. I just think our story in agriculture is not told enough. We have the most abundant, safest food supply anywhere in the world.

Because when we have the recalls like this, things like that get a great deal of publicity, people get concerned, but the fact of the matter is there are many parts of the world where that would not even have been an issue, unfortunately, I believe.

We do have the safest and most abundant food supply in the world. Would you agree?

Dr. RAYMOND. Yes, I would, sir.

Mr. LATHAM. Thank you. Thank you, Madam Chairwoman.

Ms. DELAURO. I thank the gentleman. People do not get BSE, cows do. The infection rate for E. coli is going up. I talked about Listeria a while ago. There seems to be some real difference between what Dr. Raymond, you talk about with regard to foodborne illnesses, and even what CDC talks about, if you take a look at that. I am not going down that road again.

We have all kinds of documents from CDC, and they really outline the differences between your characterization of the data and CDC's characterization of the data.

SURVEILLANCE/INCREASED INSPECTION ACTIVITIES

One question and then I want to move to the Topps' recall issue. You were talking about the surveillance activities to observe the handling of animals outside the approved hours of operation from vantage points within and adjacent to the official premises.

If you increase the time per shift for these activities, what does this mean for the other responsibilities? Are you proposing to add inspectors to cover the other responsibilities or will those tasks just be done less thoroughly?

You are proposing to add inspectors. How will the 2008 budget or the 2009 request accommodate this?

Dr. RAYMOND. The increased activities that you have described will be going on for the next 60 days. It will not be necessarily going on in all plants at the same time. We will be prioritizing these extra resources.

Some of the resources will be coming from the district office itself, supervisors, deputy district managers, the DVMSs, the humane handling specialists.

Ms. DELAURO. What are "DVMSs?"

Dr. RAYMOND. District Veterinary Medical Specialists. These are the humane handling experts. There is one in each district.

Some of the eyes and ears will be out there watching, as Mr. Almanza already mentioned, will be coming from sister agencies that are in there doing grading, for instance. AMS grades meat. They are also there in these establishments that are producing food for the schools. We will be using those resources also.

TRAINING AND INSPECTION COVERAGE

Ms. DELAURO. All the people that you have talked about, and you know the various categories, we had a question about training, are these folks trained to do the task that they are being asked to perform?

Dr. RAYMOND. Yes.

Ms. DELAURO. AMS graders?

Dr. RAYMOND. The AMS graders will receive that training before they do this task. We will be bringing them on more towards the end of the 60 day period. The ones that are being done today are being done by our own investigators and inspectors.

To answer your concern, and we do have that concern, yes, they will be doing less of other services while they are doing more humane handling observations, and to decrease that impact, we are

working with Under Secretary Knight and his staff to provide a different set of eyes and ears, or an additional set.

Ms. DELAURO. In essence, we are going to look at some other responsibilities that are not going to be covered as well as they might be in order to move to this function?

Dr. RAYMOND. To a degree, that is true; yes.

Ms. DELAURO. You said 60 days. My concern, quite frankly, is how do you sustain this with the other responsibilities that you have? That seems to me to once again be walking down the road where we are going to see what I call the fault lines in the agency, in areas that are not going to be covered thoroughly. I do not know what those are.

You are going to make internal decisions about what you are going to do. Maybe you would share those with us. How you deploy your personnel and what the priorities are, I think, is a big issue, and where do we go with the future of that, do we have enough personnel or do we not have enough personnel to do the kinds of jobs that need to get done to protect public health.

Dr. RAYMOND. I agree——

Ms. DELAURO. You tell me now you have what you need. You do not need anything else and it is not going to impact the 2008 budget or the request for 2009.

Dr. RAYMOND. Based on what our enhanced surveillance reveals to us and based on the investigation, we may come up here and have a conversation with you, Madam Chairwoman, if we do need to make additional requests.

The request at this time is for the current staffing levels, but we may need to have further discussions based on what we find.

HALLMARK/WESTLAND RECALL

Ms. DELAURO. I have another question with Hallmark and the school lunch program. It is a very quick question, if I can. They placed an administrative hold on the Hallmark/Westland Meat Packing Company, on their products that were destined for the food and nutrition programs.

The administrative hold prevents program operators from using the product until further notification from USDA.

I will tell you where I am puzzled. FNS put a hold on the product, but I have a copy of a notice on the State of California website that quotes USDA guidance on this as follows.

It says "Any Hallmark/Westland Meat Packing Company products in Federal food and nutrition programs or its derivatives must be destroyed and cannot be used or reconditioned for human consumption."

Did we have an administrative hold or were we destroying the product? Are we holding it or destroying it? What are we doing with it?

Dr. RAYMOND. I'm getting into Under Secretary Johner's turf just a little bit here, but I think I can answer that question because we worked so closely on this.

We had a hold as of January 30. They were instructed to hold the product at that time pending further investigation, and then as a result of further investigation, when we found out that on rare occasions these down cattle were allowed to go into the slaughter

house after they passed inspection but then went down, that is in violation of their contracts with the school lunch program, and they were instructed then to destroy the product or return it to us. I am not sure exactly what the instruction was.

Ms. DELAURO. I read it carefully. I think your testimony does talk about "hold." That is when you made your decision actually to deal with the recall. You talked to the company.

We continue to go back to the issue of recall and mandatory recall. We are going to get there. I promise you we are going to get there.

That is when you made your decision that in fact this had to be the recalling of the 143 million pounds; is that correct?

Dr. RAYMOND. We were in charge of the decision for recall, yes. Under Secretary Johner or FNS would have been in charge of the destruction of the school lunch program product.

Ms. DELAURO. I actually saw this in the Wall Street Journal on February 26. "As food companies become frustrated with meat recall," it actually has some of them quoted saying they were going to hold the product and so forth.

I do not know what our system is in order to be able to make sure they are doing what we want them to do. They just said—one company said Costco has not yet destroyed the beef it has removed from the shelves, with the hope that the regulators may allow it to be used.

This is taking your decisions into their own hands and kind of doing what they want with it.

Again, I do not know what your system is here, if you can let us know. If you can let us know who has destroyed product, who has not destroyed product. What is our system for finding out whether or not when we say something that it has happened?

Dr. RAYMOND. I am going to have Mr. Almanza help me on this one. To start out, your quote from that Wall Street Journal is correct, where some companies held the product. They pulled and held the product in hopes, as the quote says there, that the regulators would change the recall rules. We have not.

They have been instructed that all product is to be destroyed.

Ms. DELAURO. Do we know if it has been destroyed?

Dr. RAYMOND. That is where I am going to have to ask Al, Mr. Almanza.

Ms. DELAURO. Mr. Almanza, has the product been destroyed in all these places?

Mr. ALMANZA. Some has. The process is that——

Ms. DELAURO. Are they holding it or are they going to destroy it?

Mr. ALMANZA. They are going to destroy it. That is what I was going to explain, the process. What our process is, we go to the consignees, which is the number Dr. Raymond gave you earlier, and we do a percentage of plants, where we go out and do some verification activities to be sure that is what is occurring. It will be somewhere in the number of 200 to 300 locations where we will go and look and be sure that those products have in fact been destroyed.

Ms. DELAURO. What do you think gives this company or other companies the sense that they can say in a very reputable news-

paper, in the press, that they are going to hold the product and not destroy it, hoping that the regulators will let it move? That is pretty audacious.

Dr. RAYMOND. Or wishful thinking, but it did not happen. The regulators said you will pull and destroy all that product. We did not budge.

Ms. DELAURO. Do you have a list of the places where it was destroyed?

Mr. ALMANZA. We are in the process of getting that information; yes, ma'am.

Dr. RAYMOND. If I might, Madam Chair, you realize with nearly 10,000 consignees, it will take us time to confirm that it has all been destroyed. We cannot just do it overnight.

Mr. KINGSTON. If the gentlewoman will yield, in the event that they did not destroy it, do you have a mechanism to determine that, and then if they did not destroy it, is there a penalty?

Dr. RAYMOND. We do not have the authority to assess fines, but we do have the authority to cease and detain that product and destroy it ourselves.

Mr. KINGSTON. If the gentlewoman would yield.

Ms. DELAURO. Please.

Mr. KINGSTON. Then there is no down side in them keeping the product.

Dr. RAYMOND. If I might, I would like to ask the guys behind me that are in charge of the recalls, because there may be penalties. It is a prohibited activity, which leads to criminal——

Mr. KINGSTON. That answers the question.

Ms. DELAURO. We could move on these things a lot quicker and a lot faster with a lot more protection of public health if we had real enforcement authority. That is an issue of putting those authorities in place. I do, but the agency does not have the stomach to put those enforcement rules in place or the penalties in place.

It goes back to what I said at the outset, and that is dealing with an agency that is dealing with an industry, quite frankly, that is compromising our public health.

I am way out of time.

FOODBORNE ILLNESS DATA

Mr. KINGSTON. Dr. Raymond, how many foodborne illnesses are there a year?

Dr. RAYMOND. The CDC estimates 75 million.

Mr. KINGSTON. How many people go to the hospital?

Dr. RAYMOND. The CDC estimates about 500,000.

Mr. KINGSTON. How many die?

Dr. RAYMOND. I believe the number is about 35,000, but I am not certain.

Mr. KINGSTON. That is wrong.

Dr. RAYMOND. Okay.

Mr. KINGSTON. It is about 5,000. I want to make sure Dr. Raymond knows, 260,000 actually go to the hospital. I do not think it is 500,000.

Dr. RAYMOND. The one thing I do know is those numbers have not changed for a long, long, long time. The estimate is an old estimate. It may be a lot less than that.

Ms. DELAURO. We have not re-estimated it.

Dr. RAYMOND. That is right. That is correct.

Mr. KINGSTON. How many people are there in America?

Dr. RAYMOND. 300 million.

Mr. KINGSTON. How many meals a day do they eat?

Dr. RAYMOND. I hope three.

Mr. KINGSTON. Do they eat more? We are a pretty health conscious nation.

Dr. RAYMOND. Some more, some less.

Mr. KINGSTON. How many visitors are there?

Dr. RAYMOND. I do not know that answer.

Mr. KINGSTON. That number could be as high as 50 million a year. I am not sure. If you multiply that, that would be 900 million meals a day.

Mr. STEELE. That is correct; yes.

Mr. KINGSTON. Scott, I am going to have to turn to you because you are the numbers guy. What is that number times 365 days a year?

Mr. STEELE. I do not know. Probably in the billions.

Dr. RAYMOND. If you took the 900 million and rounded it up to a billion, then you would have 365 billion. That would be an easy way to do the math.

Mr. KINGSTON. We are talking 75 million divided by that number; right? This is only a math question.

What is the USDA budget? He has an $8 calculator. [Laughter.]

There are not enough zeroes on there. Here is my question. That number, 75 million divided by the other number, 32 billion or whatever it is, that is going to give you the foodborne illness rate; correct?

Mr. STEELE. I guess it would; yes.

Mr. KINGSTON. You guess? Can we all agree that is right? I do not know any other way to describe it.

Do you agree with that, Dr. Raymond?

Dr. RAYMOND. Yes, I do. Trying to do the math while we talk.

Mr. KINGSTON. I would love to see you do the math. I think I know what it is, but I would love to see how good you are just as an intellectual exercise.

Dr. RAYMOND. 0.0002.

Mr. KINGSTON. Okay. What is the foodborne illness rate for the American public? That is what we are trying to determine; right? You do not know where to put the zero, do you? I have finally stumped the expert.

Dr. RAYMOND. What you are saying is for every meal we eat in this country, there is a chance of 0.0002 of coming down with a foodborne illness. I think that is where you are going.

Mr. KINGSTON. That is a pretty safe food supply, it would appear to me, numerically speaking, without any question; right?

Dr. RAYMOND. Absolutely.

Mr. KINGSTON. In your testimony, do you give any kind of state of the food supply or the safety of the food supply statement? Is the food supply safe?

Dr. RAYMOND. I believe the food supply is safe; yes. I believe that 0.0002 can be made even safer with proper handling and cooking.

Mr. KINGSTON. That number, you would say, has integrity; correct?

Dr. RAYMOND. We did the math pretty fast, but yes, I think it does.

[The information follows:]

The estimated rate of illnesses per meal in the United States can be derived by the following calculations:

Estimate of Foodborne Illness Rate (probability of illness per meal consumed)

300,000,000	population of U.S.[1]
1095	number of meals consumed per person per year[2]
76,000,000	number of annual foodborne illnesses[3]
0.000231355	foodborne illness rate[4]

[1] approximation

[2] 365*3

[3] Mead et al, 1999

[4] =annual foodborn illnesses/(population * number of meals)

- Based on the above calculation, approximately one in four people in the United States is expected to experience foodborne illness each year (76 million cases in 300 million people).

- The above calculation for the U.S. foodborne illness rate is based on a study by the Centers for Disease Control and Prevention (CDC) estimating that foodborne diseases cause approximately 76 million illnesses in the United States per year (Mead et al, 1999). This figure includes estimates for all causes of foodborne illness, known, unknown, infectious, and noninfectious. Of these 76 million illnesses, only 14 million are attributable to known pathogens. The CDC is expected to release updated estimates in 2009 to account for ongoing changes in the food supply, the identification of new foodborne diseases, and the availability of new surveillance data.

- In deriving this estimate, we have assumed that everyone consumes 3 meals per day, every day of the year, and that all foodborne illnesses are associated with the consumption of a "meal." However, this estimate does not account for exposure, serving size, or "snack" food consumed between meals. In addition, illnesses caused by foodborne diseases are not all contracted from food. Foodborne diseases can be contracted via non-food sources, such as petting zoos, drinking water, turtles, human-to-human transmission, and other sources. Therefore, the risk of contracting a foodborne illness from food is actually lower than 0.0002.

Mr. KINGSTON. For the record, I would love for you to follow back up with that math to make sure. I would love to have you send me a letter, just in my own thinking, but the reason is in a country of 300 million people, you are going to have some illnesses, but if you look at that percentage, it is a pretty remarkable percentage.

That being the case, what do you attribute that to?

Dr. RAYMOND. I think there are multiple things to attribute it to. One is the passage of the Federal Meat Inspection Act way back in 1906. Another one is passage of the Poultry Products Inspection Act. One is the Egg Products Inspection Act. They have all directed how we do our business on a day to day basis at FSIS and USDA.

That plus we have moved from an inspection workforce that was organoleptic, they were looking for tainted meat that they could either see or smell, and we changed that focus to looking for things that we cannot see and smell and touch, the pathogens that cause foodborne illnesses, E. coli, Salmonella, Listeria, and we have revamped how we do our inspections on a daily basis, still following the Federal laws and statutes, but bringing more public health into it.

Mr. KINGSTON. Would you also give credit to the private sector for not wanting to poison their own customers?

Dr. RAYMOND. Absolutely. A classic example is with E. coli O157:H7, after the outbreak in Northwest and further studies that were done, and E. coli declared an adulterant, and in 2002, we put out guidelines to help companies understand how they could markedly reduce E. coli, and the numbers we saw dropped that year to the next year to the next year. It was just short of fantastic.

They declared public health not to be competitive, and they have done a terrific job.

Mr. KINGSTON. You did not comment on this.

Dr. RAYMOND. I did not but I have seen it and I know it, and that is one of the reasons we have our E. coli 157 Initiative that we announced this Fall, because we need to address that.

Mr. KINGSTON. Do you have any idea as to why the number went up? Do we have any ideas, Madam Chair?

Dr. RAYMOND. I do. I believe there are multiple factors to that also. One is there was a large spinach outbreak that involved E. coli O157:H7. That number is not all of our product. I cannot tell you what part of that graph is ours for sure and what part is something else. It is shared.

The spinach outbreak did affect those numbers, and the CDC has said that in their report.

I think what has also happened because we saw an increase in our product that we sampled and we saw an increase in recall's from foodborne illnesses attributed to ground beef and tenderized steaks, we know there was an increase to our product, and I believe there are multiple factors even there.

It is what we feed our animals that has changed. Studies have been done that show that does affect the amount of E. coli shedding in these animals. The weather patterns changed in our large beef producing states last year from very dry, almost drought conditions for five years, to very wet conditions last year, and that stresses cattle, and that causes more shedding.

I do not know this but I believe there is research going on to see if this pathogen itself has changed. Maybe the nature of the bug has changed so that the intervention procedures we have in place in our plants are no longer as effective as they used to be.

It is just like Penicillin is no longer as effective against Staphylococcus as it used to be. It may be that we need to change our interventions in the plants.

Mr. KINGSTON. You have some lab types studying that very question?

Dr. RAYMOND. The ARS' Animal Meat Research Center in Nebraska is all over this trying to look at the bug itself to see if the pathogen has changed. They are also doing feeding studies with the animals.

Yes, we have top scientists looking at this along with several of our state institutions.

Mr. KINGSTON. I appreciate that.

Ms. DELAURO. I just might add, this is where we get into all well and good, Dr. Raymond, but not too long ago, and Mr. Kingston, before you were here, where I talked about what the Inspector General and the National Advisory Committee on Microbiological Criteria stated, that what Dr. Raymond speaks about is it does not represent national samples.

As we have to sign affidavits saying that we have no financial interest in a particular earmark or whatever it is, I have no dog in this hunt with the Office of Inspector General or the National Advisory Committee on Microbiological Criteria.

It says that they reflect only what is happening in a particular plant on the day it was tested, and Dr. Raymond, in response to my question, says that the data is not representative.

In the same hearing, we are talking—we say one thing earlier on and another thing later on. The data is a misrepresentation of what is in fact actually occurring in this country in terms of an increase in infection rates for E. coli.

I have to address, Mr. Kingston, your point about 5,000 people dying every single year. Let me see if I can give you a parallel.

September 11, 2001, 3,000 people were killed at the World Trade Center. Got up that morning, went to work, and lo and behold, the Trade Center was attacked and they died.

This nation went to war because of those deaths. I will distinguish between going to war with Afghanistan versus going to war in Iraq. I voted to go to war in Afghanistan. I suspect you did the same thing. I did not vote to go to war in Iraq. I do not remember what you did.

We have 5,000 people every single year dying in this nation from foodborne illness. Do we not believe that in fact, we should go to war against the system that is allowing that to happen.

Those folks who went to the World Trade Center that morning, we could not stop that. We have it within our jurisdiction and the jurisdiction of this committee to stop 5,000 people dying every single year.

Mr. Kingston, if you do not think that ought to be our priority, I can hardly fathom that because I believe you do care about that, but I do believe that this agency has not taken on that responsibility to put in place the mechanisms and the infrastructure to go

to war against 5,000 deaths every single year for foodborne illnesses.

Mr. KINGSTON. Let me reclaim my time for a minute. Number one, as passionate as my friend is, and I certainly agree with her, I do not know how that is relevant because nobody is saying dismiss the 5,000 deaths a year.

My point——

Ms. DELAURO. The point is it was infinitesimal, why should we concern ourselves with it.

Mr. KINGSTON. My point was to underscore the math. Secondly, very relevant, CDC or any health care provider will say that the 5,000, unfortunately, had other illnesses going on, an immune system problem. Very rarely did somebody eat a piece of meat and they were totally healthy and they died from it. That is relevant.

Thirdly, Dr. Raymond has said repeatedly in his testimony that it is still too high and he wants to achieve it.

I do not think anybody is debating that. I am trying to put some perspective in in terms of the numbers.

Ms. DELAURO. One out of four people in this nation get sick with foodborne illness. If that is not a cause for concern, I do not know what is.

Mr. KINGSTON. Where did that number come from?

Ms. DELAURO. 75 million.

Mr. KINGSTON. That does not mean the same people over and over again. I have not seen that number.

Ms. DELAURO. To be quite frank with you, I dismiss your premise because I think 5,000 deaths every year on that basis, we ought to be dealing with this issue, and it is my intention to deal with this issue.

Mr. KINGSTON. Let me say this to my friend. Certainly, we all agree the number is there. My point is to put it in mathematical context and it is interesting, I did not even editorialize on it, but I did detect a little passion on your part.

Ms. DELAURO. Children dying from E. coli, if you had a chance to talk to their parents, you would be passionate about it as well.

Mr. KINGSTON. Are you saying I am not?

Ms. DELAURO. I do not know.

Mr. KINGSTON. I think my friend knows. I have to say unfortunately I have to go to an appointment, so I am going to leave.

I would have to tell you I am disappointed. I would say that. I have been a member of this committee for a while. I do not dismiss that.

I think part of our job is to look at the broad perspective, but at the same time, I would have to say that nobody is saying that is not a real issue, if 5,000 people are dying, but I think we always have to say in reaching the political conclusion and the grand standing what did the 5,000 die of.

There is an immune system issue, and there are still remarkable success stories in the American food supply that I think we should all be pleased about, and underscoring.

Dr. Raymond, as frustrated as he is, is a witness to me and to you, he is a man who always gets back to let us focus on the food safety, let's try to get something done about it.

I cannot build a case for him because he will not let me.

Ms. DELAURO. You did not hear what I said at the outset. I think we have a system where the disease outbreaks are catching the failures at the plants, and it is not the Food Safety and Inspection Service. I want to reverse that.

I want to do everything I can with you and the other members of this subcommittee, with Dr. Raymond, with the agency, to reverse that.

I want FSIS to be able to have the systems in place where we are preventing these incidences and these recalls. That is the goal of the Committee. It is not political. That is where we are.

We have a recall. We have an outbreak. Then we uncover evidence that points out, as I said earlier, the fault lines within the system. Let's correct the fault lines. I believe that we have the capability. I believe we do not have all of the resources but we have some of the resources to address that issue, and we should figure out together how in fact we put this agency on a path to prevention and not reaction.

Ms. Kaptur.

HALLMARK/WESTLAND RECALL

Ms. KAPTUR. Thank you, Madam Chair, very much, and thank you for your passion. America needs that. We need people that care and do not offer excuses and try to make things better.

I wanted to ask Dr. Raymond, with this latest recall, the largest in history, could you just state for the record again how many pounds that was? Am I recalling correctly, 143 million?

Dr. RAYMOND. Yes, you are.

Ms. KAPTUR. Of that, what percent will actually be recovered in hand and destroyed?

Dr. RAYMOND. If historical patterns follow, it will be a very small percentage because it was a recall over a two year period of time, and we do have reason to believe that most of that product has already been consumed.

Ms. KAPTUR. Let me tell you an experience I had in our Toledo Public School System, the largest system I represent, with USDA senior officials a couple of weeks ago.

The meat recall came up during the discussion with food bank directors and school lunch people, and the school officials informed us that they indeed had some of that meat on hold, but did not know what was going to happen to it.

USDA said at that time they would be asked to destroy the food, and the school officials looked at us puzzled, wondering why they did not already know that important point. That is the Toledo School System.

MANDATORY RECALL AUTHORITY

Since USDA lacks mandatory recall authority, could you please explain to the Committee why the agency does not seek that authority?

Evidently, this meat is still out there, but if you are telling us the majority of the meat will not be recovered, it was recalled, so we just say it is out there. USDA cannot provide us with the list of places, 10,000 retail consignments. You do not have a list of that.

I happen to know one of those is the City of Toledo School System.

Here you had a situation where this meat was sitting there, probably in their freezers or something, and they did not know what was going to happen.

Why does not the agency want the mandatory recall authority?

Dr. RAYMOND. Again, I am not sure of the time frame when you were at the schools. There was a hold until an investigation was done. At the time, we had allegations of inhumane handling, and that was it.

The school lunch program felt that was in violation of their contract, so they put it on hold until they had confirmation. Once they had confirmation there were other issues, then they instructed the schools to destroy it.

It should not be misconstrued when I said we probably would get a very small amount of this product back. It is not because it has not been recalled. It is because there was not that much—of the 143 million pounds, there was not that much out there recalled because it was over a two year period of time.

A lot of this is fresh raw ground beef. People buy fresh raw ground beef and they eat it. I did not mean to imply in any way, and I am sorry if I did, that the recall would not be effective. I think the recall would be effective in that product that is out there.

The reason we do not support mandatory recall is because we have never had a company turn us down or refuse to do a recall when we have asked them to do one. The system works well for us.

We do have the statutory authority to cease and detain that product should a company not cooperate with us. We have never had to invoke that policy.

We would really prefer not to see a system that we feel works very well for us changed.

HALLMARK/WESTLAND RECALL

Ms. KAPTUR. Of the 143 million pounds that you said were technically recalled, are you saying 143 million pounds could have been consumed because the recall was over a two year period, so the vast majority was eaten? Am I hearing this right?

Dr. RAYMOND. I did not say 143 million. I will say I believe the vast majority has been eaten; yes. I don't know what the amount would be.

Ms. KAPTUR. Then what good does the recall do?

Dr. RAYMOND. Again, some of this product was put into canned products or frozen products that may have been produced two years ago and is still sitting in a grocery store on the shelves or in the freezer, whatever.

We always do a recall back to the point of where we feel the product was either unfit or adulterated.

Ms. KAPTUR. Can you provide a list for the record of companies that have recalled the meat?

Dr. RAYMOND. As I said earlier, we will check with legal counsel whether we can do that or not. I do not want to make a commitment that I cannot keep.

[The information follows:]

On April 4, 2008, FSIS sent separate letters to House Agriculture Appropriations Subcommittee Chairwoman Rosa DeLauro (D-CT) and Ranking Member Jack Kingston (R-GA) providing them with a list of consignees who received meat from the Hallmark/Westland Meat Packing Company.

Ms. KAPTUR. It should be upsetting to every American who hears that, that the vast majority of what could have been bad out there or was declared bad was consumed; right?

Dr. RAYMOND. We did not declare the meat bad. We did the recall because of regulatory non-compliance with our regs and rules. It was more of a technical recall because the meat was produced without going through the final step of inspection. Therefore, it is declared unfit for consumption, but it was more of a regulatory matter than an adulterated meat matter.

Ms. KAPTUR. You really do not know because you do not know which downed animals were in the food chain; right?

Dr. RAYMOND. We do not know with 100 percent certainty; you are correct.

RETAIL DISTRIBUTION LIST RULE

Ms. KAPTUR. Let me just ask one final question, Madam Chair. On March 6, 2006, FSIS proposed a rule in the Federal Register to permit the agency to list in its recall press releases the names of retail consignees so that consumers could be better informed about the scope of the recall and expedite the recovery of these products that are out there.

We understand that you and perhaps others have endorsed the promulgation of such a rule. What is the status of it and is anything holding it up?

Dr. RAYMOND. The rule, as you know, has gone through the normal process of rule making, which is lengthy, allowing for public input and others, and then we have to respond to all this input and make sure they have all been addressed.

At the current time it is in the final stages of clearance. It is still in the Department, but we are having conversations with the Office of Management and Budget—they have had an informal opportunity to look at it. It has not formally gone to OMB.

What we are trying to do, as we do many times, is work out any differences so that when the final product goes to OMB, it can be signed off on very quickly and become a functioning rule.

Ms. KAPTUR. On record, which industry groups have been opposed to this rule?

Dr. RAYMOND. I do not know the answer to that, Congresswoman. I know during the comment period, I believe we had 19 comments that were opposed to it, but I have not looked at those comments individually myself, but there are people here who have.

Ms. KAPTUR. Would those be able to be provided for the record, Madam Chair?

Dr. RAYMOND. They are on our Web site. They are available to your staff to look them up and get you that answer, if you would like.

Ms. KAPTUR. I would ask the agency to provide those for the record, please.

Dr. RAYMOND. Again, I assume we can do that unless counsel tells me for some reason I cannot. It is on the Web site. I assume we can provide it as part of the record.

[The information follows:]

In response to the proposed rule and public meeting on "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls," FSIS received almost 6,000 comments from consumers, consumer advocacy organizations, industry representatives, Federal and State agencies, and professional organizations. This number includes several comments made by individuals at the public meeting and taken from the transcript of that event. There was strong support for the rule from consumers, consumer advocacy organizations, Federal and State agencies, and professional organizations. Collectively, these individuals and groups filed 26 original, substantive comments and almost 6,000 form letters supporting the rule. FSIS received nine comments opposed to the proposed rule.

The nine organizations that submitted comments opposed to the proposed rule were the American Association of Meat Processors, the National Meat Association, the National Turkey Federation, the American Meat Institute, the National Grocers Association, the Food Products Association, the National Cattlemen's Beef Association, the Small Business Administration, and the National Meat Canners Association.

The 26 substantive comments in favor of the rule, four requests for an extension of the comment period, and the nine comments opposed to the rule are posted on FSIS' Web site. A copy of these 39 comments are being submitted for the record.

[The information follows:]

List of Commenters
Docket Number: 04-006P

View Comments

Cumulative Number of Comments Received	Commenter Name	Commenter Affiliation	FSIS Assigned Comment Sequence Number
1	Aller, Marion F.	Association of Food and Drug Officials (AFDO)	12
2	Berry, Muriel		33
3	Brown, Andrea H.	American Association of Meat Processors (AAMP)	1
4	Bubenzer, Carrie		38
5	Cambridge, Michael J.	State of New York Department of Health	14
6	Consumers Union	Consumers Union	2
7	Corby, Jody	State of New York Department of Agriculture and Markets	10
8	Doop, Mark	American Meat Institute (AMI)	21
9	Dopp, Mark	AMI	16
10	Floyd, Antoinette		34
11	Fong, Phyllis K.	Office of the Inspector General	7
12	Form Letters	Form Letters Received to date Total 5,336	5
13	From Letters	Form Letters Received to date Total 326	4
14	Gatulis, Marion		27
15	Govro, Mike	Oregon Department of Agriculture	13
16	Griswold, Sharon		8
17	Hellermann, Mark		32
18	Henry, Craig; Hontz, Lloyd	Food Products Association (FPA)	24
19	Horton, Mark B.	California , Department of Health Services	17
20	Kelly, Ken	Center for Science in the Public Interest (CSPI)	19
21	Kowalcyk, Barbara; Donley, Nancy; Buck, Patricia	Safe Tables Our Priority (S.T.O.P.)	23
22	Marr, Christy	National Turkey Federation (NTF)	20
23	Maupin, Barbara J.		35
24	McClarren, Gregory R.		29
25	Mucklow, Rosemary; Mastracchio, Ken	Naional Meat Association	18
26	Munsell, John		30
27	Odaashian, Elisa	Consumers Union	6
28	Sachau, B.		36
29	Sachau, B.		37
30	Smith, Catherine		28
31	Sparrowhawk, Larisa		31
32	Sullivan, Thomas M.; Rayford III, Linwood L.	Office of Advocacy: the voice of small business in government	9
33	Wenning, Thomas F.	National Grocers Association (NGA)	3
34	Wenning, Thomas F.	National Grocers Assoication (NGA)	11
35	Wenning, Thomas; Lieberman, Erik	National Grocers Association (NGA)	22
36	Wenonah, Hauter	Consumer Group Food & Watch	26
37	White, Deborah R.	FMI, Food Marketing Institute	15
38	Wilkenson, Leah	National Cattlemen's Beef Association	25

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Andrea H. Brown

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April 21, 2006

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102 Cotton Annex
Washington, DC 20250

RE: Docket No. 04-006P
Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

The American Association of Meat Processors (AAMP) is pleased to submit the following comments on the proposed rule, "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls." Our Association is an international organization whose members include meat and poultry processors, slaughterers, caterers, food service companies, wholesalers, retailers, suppliers, and consultants to the meat and poultry industry. There are 33 state, regional, and provincial associations of meat processors that are also affiliated with AAMP. Majority of our members are small and very small businesses, most of them family-owned and operated.

This proposed rule would make the lists of retail consignees of meat and poultry products that have been voluntarily recalled available to the public if product has been distributed to a retail level. FSIS has proposed to routinely post these retail lists on its website as they are developed by the Agency during the retail verification activities. FSIS believes that by adopting the proposed rule, the efficiency of the recall process would be improved because consumers could easily identify the products that are being recalled. AAMP disagrees and is in opposition of the proposed rule. FSIS currently receives the consignee lists and traces the product forward to the retail level, sharing the relevant facts with other state and federal agencies, while still keeping the information confidential. The Agency already provides adequate information on their website for recall purposes and it is not necessary to allow the public to access these lists. The current process is effective and there is no need for confidential information to be shared with the public.

The major concern AAMP has with FSIS making the retail consignee lists available is that the Agency is releasing confidential and proprietary business information which will negatively affect the firm that is recalling the product. If retail consignee lists are made public, the establishment's customer list is essentially available for competing companies to access. There is a distinct possibility of competitors using the retail consignee information for their own benefit to gain customers who have become affected through the recall process. This type of situation is hardly beneficial to meat and poultry processing establishments, the safety of the food supply, nor the general public. In fact, it may force those who possibly will have recalls out of business because their customers are taken by competitors during a very vulnerable time period.

Page 2 – Comments on Docket No. 04-006P

This proposed rule may also damage relationships between meat and poultry processors and their customers due to the linkage to the recall. No business wants their name publicly associated with a recall, and with the consignee lists available online, competitors may take advantage of the situation.

Publicizing the retail lists will not remove the problem of consumers mistakenly associating all of a manufacturer's products with a recall. Instead, it may heighten their concern over where they are purchasing products, and damage relationships between consumers and retailers who sold the recalled product. The degree of seriousness of recalls continues to be very important, since the word "recall" is typically of great concern to a consumer, especially when related to food they may be feeding their families. Another issue relates to short shelf-life products like ground beef, which is typically already consumed by the time the recall is activated. Publicly available retail consignee lists are certainly not necessary in recalls involving non-food safety issues (i.e., labeling, weight requirements, etc.), nor products with a short shelf-life.

Public interest groups may also use the retail lists for their own agendas instead of strictly for the purpose of improving the recall process. Boycotts, negative publicity, and other means of economic harassment detrimental to the business are all possibilities. This inappropriate utilization of the retail lists could result in serious and unnecessary damage to the reputation of an establishment or its customers.

Making retail consignee lists available to the public may provide limited assistance to the recall process, but not enough to risk negatively affecting meat and poultry processing and retail establishments in this manner. Releasing the confidential and proprietary information in retail consignee lists is wrong, especially when plants already go out of their way to accommodate FSIS during recall verification procedures. AAMP believes this proposed rule may greatly intimidate processors and serves as another attempt to decrease the number of recalls by FSIS. Every establishment has recall protocol within their HACCP plan and their procedures should be adequate to handle any recall situations that may occur. AAMP hopes that the Agency will also take into account how this proposed rule will affect small and very small meat industry establishments, whose business is at stake if they lose their customers. Industry demands that retail consignee lists remain confidential in order to protect the livelihood of meat and poultry processors, both large and small.

Sincerely,

Andrea H. Brown
Director of Legislative and Regulatory Affairs

cc: Steve Krut, AAMP Executive Director
Mark Schad, AAMP President
Jason Jennings, AAMP Meat Inspection Committee Chairman

04-006P-2
04-006P

2

Consumers Union
Comments to United States Department of Agriculture's Food Safety Inspection Service on Docket No. 04-006P, Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls
April 28, 2006

Introduction/Summary

Consumers Union* (CU), the non-profit publisher of Consumer Reports magazine, appreciates the opportunity to comment on Docket No. 04-006P, "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls."

We commend the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) for proposing to inform the public, via publication of a list on the internet, about the names and locations of stores where meat or poultry that have been voluntarily recalled have been sold. As with any recalled product, the consumer has an absolute right to know where such products are sold prior to the recall. As USDA notes, making such information public allows consumers to determine if they have purchased any of the recalled meat or poultry products, so that they can return the product to where they bought it or dispose of it.

While we applaud USDA for proposing this rule, we think USDA's proposal does not go far enough and is vague on certain crucial details. First, USDA should make available the names and locations not only of retail stores (referred to by USDA as "retail consignees") where meat and poultry products are sold, but also of hotels, restaurants and institutions—such as hospitals, nursing homes, schools, etc.—that have received recalled meat and poultry products that are later recalled. Consumers especially need to be notified if recalled meat and poultry products have been delivered to institutions (e.g. hospitals, nursing homes, schools, etc.) and are later recalled. Such places often have populations that cannot fully protect themselves. For example, if a mother knew that meat or poultry products that were later recalled had been delivered to the elementary school attended by her daughter, the mother could contact the school to find out how much recalled product was delivered and whether any of it remained at the school.

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* Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finances; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is derived solely from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports*, with approximately 4.5 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

Secondly, CU believes that consumers should be informed *as soon as possible* about *all* the names and location(s) of the institutions and retail outlets to which any recalled meat and poultry products have been distributed that either sell or serve those products to consumers.

Disclosure Should Include Restaurants, Hotels and Institutions

CU strongly agrees with USDA that it has the authority to make available the distribution lists for recalled meat and poultry products and that making such lists available "would enhance the efficiency of recalls by helping consumers to identify and focus on the products that are recalled."

Consumers overwhelmingly want information on which stores and restaurants have been sent recalled meat or poultry products. In January, 2004 Consumers Union conducted an online survey of a random sample of U.S. adults on meat safety issues. The survey was conducted from January 14-41, 2003 and included 1,085 people. Some 95% of the respondents agreed, of whom 78% strongly agreed, with the statement "In the event of recall, USDA should make public the names of stores/restaurants that sold contaminated meat." Thus, the overwhelming majority of US consumers want to know where contaminated meat has been sent.

We are concerned, however, that FSIS is too restrictive in terms of the places/entities that received recalled meat or poultry products that would be disclosed to the public. At present, FSIS is proposing to make public only the names and addresses, of "retail consignees" that were shipped recalled meat or poultry products. The USDA does not define what it means by "retail consignees," but elsewhere has indicated that it does not include hotels, restaurants and institutional consignees. We note that the proposed rule talks of "the level of product distribution (e.g., wholesale; retail) to which the recall is to extend." We also note that the most recent FSIS Directive on recalls is FSIS Directive 8080.1, Revision 4, 5/24/04—"Recall of Meat and Poultry Products" (at http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf). FSIS Directive 8080.1, Revision 4 refers to four levels to which the "Depth of Recall" extends: 1. Consumer 2. Retail levels—This includes all retail sales of the recalled product. 3 User level—This includes hotels, restaurants, and other food service institutional consignees. 4. Wholesale level. In this Directive, FSIS distinguishes between "retail level" and "user level", with the latter consisting of hotels, restaurants and other food service institutional consignees. It thus appears that hotels, restaurants and institutions like daycare centers, schools, and nursing homes are not covered by the proposed rule.

CU believes that USDA should make available the names and locations not only of grocery stores and supermarkets (referred to by USDA as "retail consignees") to which recalled meat and poultry products were sent, but also of hotels, restaurants and institutions—such as hospitals, nursing homes, schools, etc.—that have received meat and poultry products that are later recalled. Consumers especially need to be notified if recalled meat and poultry products have been delivered to institutions (e.g. hospitals,

nursing homes, schools, etc.), as such places often have populations that cannot fully protect themselves. For example, if a mother knew that meat or poultry products that were later recalled had been delivered to the elementary school attended by her daughter, the mother could contact the school to find out how much recalled product was delivered and whether it had been returned as required and how much may have been served to her child. Also, if one knew that meat or poultry products that were later recalled were sent to a nursing home where one's parents or grandparents were housed, one could contact the nursing home to make sure they are returning or discarding the recalled products.

Posting

FSIS has proposed making the names and addresses of "retail consignees" available to the public by posting it on a website. We support this proposal.

In addition, **FSIS should post the names and locations of retail stores, hotels, restaurants, and all other food service institutional consignees (such as hospitals, nursing homes, schools, day care centers, etc.) that were sent recalled meat or poultry products on the internet.**

According to present FSIS procedure: "FSIS also lists those States to which recalled product was shipped if fewer than 13 States were involved in the recall. If the recall extends to more than 13 States, it is considered to be a nationwide recall." Consumers Union believes that, unless all 50 States are involved in a recall, FSIS should list all the States. If a recall involves, say, 20 States, but the FSIS site refers to a "nationwide recall," a consumer in one of the 30 States *not* involved in the recall may mistakenly believe that recalled product was sent to their State and that could cause them undue concern—they could needlessly worry that they may have purchased/consumed tainted meat. If FSIS had listed all 20 States, then residents of the 30 States not involved in the recall would not have to be concerned. Thus, **FSIS should list all the States, regardless of number, involved in a recall of meat and or poultry products.**

The FSIS proposal is vague as to exactly *when* it would post the names and addresses of the "retail consignees". CU believes that USDA should post on the internet the names and locations of any entity (not including intermediate distributors) that received recalled meat and/or poultry products as soon as the USDA has received this information. (This includes retail stores, restaurants, hotels and other food service institutional consignees.) In the proposed rule, FSIS talks of "recall verification activities," but there is no indication as to *when* in the recall verification process FSIS would make the distribution lists available. Posting the information immediately could actually aid in the recall process. If a recall involved hundreds or thousands of locations, it could potentially take government officials/employees quite a while to contact them all. If consumers had this information, they might contact the locations before overworked employees at USDA and help prevent recalled meat from being sold or served.

Posting information as soon as possible is crucial in order to recover as much of the meat or poultry products involved in a recall as possible. A General Accounting Office study of USDA's food recalls in 2003, found that only 38% of the recalled food was actually recovered; this means that 62% of the recalled food was most likely consumed by consumers (GAO, 2004). In recalls involving large amounts of meat products, the recovery rate can be even lower. The 2002 recall of 18 million pounds of ground beef contaminated with *E. coli* 0157:H7 by a ConAgra plant in Greeley, Colorado, one of the largest recalls in US history, only 17% of the recalled meat—or 3 million pounds—was recovered; thus, some 15 million pounds of recalled neat was consumed by the public (GAO, 2004). Perhaps if there were immediate posting of the names and locations of stores, restaurant, hotels and other institutions, the amount of recovered product would increase.

Another factor that leads to small recovery rates for recalled foods is that the USDA staff has not increased in size while the amount of recalled meat products has dramatically increased. The amount of recalled meat and poultry products has increased from 6 million pounds in 1998 to about 36 million pounds in 2003 (GAO, 2004). Since the size of USDA's staff involved in recalls has not grown, this suggests that the agency can take quite a while to start or finish a recall. In the case of ConAgra's 2002 recall of ground beef for contamination with *E. coli* 0157:H7, the expanded recall of 18 million pounds of beef began on July 18, some 3 months *after* the plant had been testing positive for *E. coli* 0157:H7 (from April 12 through July 11, 2002).

There was also a delay in the mad cow-related recall initiated on December 23, 2003 when USDA announced the first case of BSE in the U.S. This BSE-related recall involved some 38,000 pounds of beef and beef bones that were distributed to seven western states, including California. California's Department of Health Services (DHS) was not notified that any of the recalled meat might have been shipped to California grocery stores, restaurants and other institutions until December 29—almost a week later (Ortiz, 2004). According to USDA spokesman Steve Cohen, "California wasn't notified until December 29. It was around the holidays, and I don't think anybody was in their offices. We tried to reach them" (Ortiz, 2004). California DHS spokeswoman Lea Brooks retorted, "Not only were department staff in their offices over the holidays, the department has a duty officer who is available 24 hours a day, seven days a week." USDA gave California state officials the list of California businesses affected by the recall on December 30, 2003, but there was virtually no more information—such as whether the businesses were cooperating, how much beef had already been sold, how much had been returned. An investigation by California DHS found that the recall was not very effective (Ortiz, 2004). In Alameda County, the Country Health Officer, Dr. Anthony Iton, noted that soup bones involved in the recall had been sold and consumed in five county restaurants before Dr. Iton or any of the restaurant owners were notified (Russell, 2004). If any of the restaurant owners, or one of their customers, had seen this information posted on the FSIS web site around December 23, 2003, then action could have been taken immediately so that any bones that had not already been served at the restaurant could be returned to the distributor.

Given these delays, if FSIS posted information on the internet, alert consumers could help by potentially contacting the locations that received meat and poultry products that have been recalled before overworked employees at USDA contact these locations, thereby minimizing the amount of recalled meat that is inadvertently consumed by the public.

FSIS should post the relevant names and locations of retail stores, hotels, restaurants, and all other food service institutional consignees (such as hospitals, nursing homes, schools, day care centers, etc.) on the internet as soon as FSIS receives this information from the distributor.

References

GAO. 2004. Food Safety. USDA and FDA Need to Better Assure Prompt and Complete Recalls of Potentially Unsafe Food. GAO-05-51. Washington, D.C. At www.gao.gov/new.items/d0551.pdf

Ortiz, J. 2004. State hit a wall on beef recall. *Sacramento Bee*, May 10, 2004. At www.sacbee.com/content/business/story/9245790p-10170952c.html

Russell, S. 2004. Mad cow censoring gets legislator's goat. *San Francisco Chronicle*, February 25, 2004, pg. A15. At //sfgate.com/cgi-bin/article.cgi?file=c/a/2004/02/25/BAG0O57QT91.DTL

NGA

National Grocers Association

April 27, 2006

3

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street SW
Room 102 Cotton Annex
1400 Independence Avenue, SW
Washington, DC 20250

04-006P-3
04-006P
Thomas F. Wenning

RE: Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Docket No. 04-006P

Dear Sir or Madam:

The National Grocers Association (N.G.A.) is requesting an extension of the comment period for the proposed rule issued by the Food Safety and Inspection Service (FSIS) on the Availability of Lists of Retail Consignees During Meat or Poultry Recalls, 71. Fed. Reg. 11326 (March 7, 2006), for a period of sixty days following the publication of the transcript of the public meeting held by FSIS on April 24, 2006. N.G.A. appreciated the opportunity to participate in the meeting. The comment period is currently set to close on May 8, 2006. N.G.A. is the national trade association that represents exclusively the interests of independent community-focused grocery retailers and wholesalers. N.G.A. retail and wholesale members accounted for approximately $200 billion of U.S. grocery sales last year. N.G.A. intends to submit detailed comments in response to the proposed rule. The current comment period does not provide enough time to comprehensively address issues raised at the public meeting. Granting this extension will provide all interested parties with adequate time to incorporate the issues discussed at the public meeting into their comments.

We thank FSIS for considering this request.

Sincerely,

Thomas F. Wenning
Senior Vice President and General Counsel

1005 N. Glebe Road, Suite 250 • Arlington, VA 22201-5758 • (703) 516-0700 • FAX: (703) 516-0115
E-mail: info@NationalGrocers.org • Website: http://www.NationalGrocers.org

04-006P-4
04-006P
As of 5/3/06 form letters received
Total 326

4

FSIS RegulationsComments

From: A Bonvouloir [RA3ajw@sbcglobal.net]
Sent: Thursday, March 30, 2006 6:03 PM
To: FSIS RegulationsComments
Subject: Re: [Docket No. 04-006P]

I am in full support of your proposal to publicize the list of retail stores where voluntarily recalled meat and poultry products have been sold. As many people don't remember the particular brand and batch of meat they purchased, they are unaware of the food safety risk, and continue to purchase or consume the recalled product. The retail information for recalled meat is very important to consumers, who are at risk for food-borne illnesses like E.coli and Salmonella. This rule change is a common sense solution, which will enable consumers to better protect themselvea from adulterated or misbranded products.

Please continue forth with the planned rule change. The lack of public availability of this information has left many consumers- and their families- at risk for food-borne illness.

Sincerely,

A Bonvouloir
PO Box 70185
Sunnyvale, CA 94086

04-006P-5
04-006P
As of 5/4/06 form letters received
Total 4,888

5

From: Dan Karney [dk424@comcast.net]
Sent: Monday, May 01, 2006 9:04 AM
To: FSIS RegulationsComments
Subject: FSIS: docket #04-006P--End meat recall secrecy!

May 1, 2006

Public Comment USDA

Dear USDA,

I'm writing in support of the proposed rule requiring the U.S. Department of Agriculture to make public the names of grocery stores who have received tainted meat and poultry products.

Under the proposed regulation, "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls" (Docket No. 04-006P), the Food Safety and Inspection Service (FSIS) will be required to make available to the public the names and locations of the grocery stores who have received tainted meat and poultry products.

The proposed regulation is a positive step forward and will ensure consumers have access to important information about the health and safety of the meat and poultry they purchase that is currently not available. It will help me to know if I might have bought a recalled product and might have it in my refrigerator.

In addition, however, I feel strongly that the federal government should also make available information about contaminated meat or poultry products that have been sent to hotels, restaurants and
institutions, such as public schools and nursing homes. If tainted meat or poultry products have been sent to the school my children attend, or to the nursing home my parents are in, I would like to know that information, so that I can contact the school or home and make sure they are returning or discarding the recalled meat or poultry products.

In addition, I feel strongly that FSIS should post the relevant names and locations on the internet as soon as they receive it from the distributor. The earlier I know about a meat recall, the earlier that I can take action to protect myself and my family.

Even though the new proposal is a good first step, however, USDA still needs the legal authority to require companies to recall tainted foods. Currently, the agency has to rely on the meat industry's voluntary compliance with recall requests from USDA.

I commend FSIS for proposing this rule. The American public has too much at stake for this rule, with the suggested modifications, not to be considered and adopted at the earliest possible date.

Sincerely,

Mr. Dan Karney
424 Lynetree Dr
West Chester, PA 19380-1709

04-006P-6
04-006P
Elisa Odabashian

6

FSIS RegulationsComments

From: odabel@consumer.org
Sent: Thursday, May 04, 2006 10:34 PM
To: FSIS RegulationsComments
Subject: Addendum to Consumers Union's Comments on Docket No. 04-006P, Ava ilability of Lists of Retail Consignees During Meat or Poultry Product Re calls

Consumers Union, the nonprofit publisher of Consumer Reports magazine, has already submitted comments to FSIS on Docket No. 04-006P, "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls." This email communication is an addendum to those comments, as we now have the results of a recent statewide poll of Californians on the issue of meat recalls and retailer secrecy, and wanted FSIS to have the benefit of knowing public opinion in California on the topic.

Consumers Union engaged the services of the Field Research Corporation to conduct a random sample survey of Californians on meat recalls. Founded in 1945 by Mervin Field, Field Research Corporation is one of the largest public opinion research organizations in the Western U.S.. The Field survey is an independent, non-partisan, public policy survey of Californians. The survey results are based on four questions added to a statewide survey of California adults and was conducted by means of telephone interviews with a random sample of 1,000 California adults in English and Spanish on February 12-16, 2006.

Sampling was conducted by means of random digit dialing, which selects telephone exchanges within all area codes serving California in proportion to population. From each exchange a random sample of telephone numbers was created by adding random digits to the telephone exchange selected, permitting access to both listed and unlisted telephones. After the completion of interviewing, the overall sample of adults interviewed was weighted slightly to estimates of the state's adult population. According to statistical theory, results from the overall adult sample would have a sampling error of +/- 3.2 percentage points at the 95% confidence level. Results from subgroups would have somewhat larger sampling error ranges. There are other possible sources of error in any survey in addition to sampling variability. Different results could occur because of differences in question wording, sampling, sequencing or through omissions or errors in interviewing or data processing. Extensive efforts were made to minimize potential errors.

The four questions from the survey of California adults about contaminated beef and poultry products were developed by Consumers Union and Field Research Corporation jointly. Following are the questions and overall
results:

1) Have you seen, read or heard about any situations in the past few years where contaminated beef or poultry products were recalled? Results: Yes, Have Heard = 65%; No, Have Not = 32%; Don't Know = 27%.

2) If you were to hear of a recall of contaminated beef or poultry products from stores or restaurants in your city or town, how concerned would you be--very concerned, somewhat concerned, not too concerned, or not at all concerned? Results: Very Concerned = 59%; Somewhat Concerned = 30%; Not Too Concerned = 7%; Not At All Concerned = 3%; No Opinion = 1%.

3) Current U.S. Department of Agriculture rules permit beef and poultry manufacturers to operate under a voluntary recall system when unacceptable levels of contaminants are found in their products. Do you favor voluntary company recalls of contaminated beef and poultry or mandatory recalls with penalties for not complying? Results: Voluntary Recalls = 11%; Mandatory Recalls = 84%; No Opinion = 5%.

4) To encourage beef and poultry manufacturers to come forward to recall their products under the current voluntary system, the California Department of Health Services and the USDA have agreed not to release the names of the stores and restaurants where tainted beef or poultry have been shipped and sold. Do you think the California Department of Health Services should keep confidential the names of retailers involved in a meat recall or do you think the department should be allowed to make the names of those stores and

restaurants public? Results: Keep Confidential = 15%; Make Public = 80%; No Opinion = 5%.

These results show overwhelming support among Californians for USDA to release the names of retail stores and restaurants that receive USDA-recalled beef and poultry. We hope you will take these survey results into consideration.

Sincerely,

Elisa Odabashian
Senior Policy Analyst
Consumers Union

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington D.C. 20250

APR 2 0 2006

04-006P-7
04-006P
Phyllis K. Fung

7

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street SW.
Room 102 Cotton Annex
Washington, D.C. 20250

Subject: Proposed Rule – Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls, Docket Number 04-006P

Dear Docket Clerk:

The Office of Inspector General has reviewed the proposed rule, and we generally concur with the action proposed. Consumer groups and others have long advocated the public release of information on where recalled products have been distributed. However, we did note some needed clarification and provide the following comment.

Page 11326 of the preamble indicates that when a recalled product has been distributed to the retail level, the Food Safety and Inspection Service (FSIS) will make a list available of the retail consignees on its website. FSIS will post the list of retail consignees as they are developed by the agency during its recall verification activities. Further on the same page of the preamble it states that " * * * if products are recalled to the retail level, FSIS requests that the firm conducting the recall provide FSIS with a list of the consignees to whom the recalled meat or poultry products were distributed." The proposed rule in Section 390.10(a) states that the list of disclosed retail consignees are those FSIS compiled to verify the removal of recalled product. For clarity, this section of the regulation should explain that FSIS uses a statistical sampling plan to identify a sample of consignees to verify the effectiveness of the recall. The regulations need to make it clear that FSIS only verifies a sample of consignees, and therefore, the list provided will only include some of the retail consignees.

Sincerely,

Phyllis K. Fong
Inspector General

cc:
Barbara Masters, Administrator, Food Safety and Inspection Service

04-006P-8
04-006P
Sharon Griswold

8

from: Sharon Griswold [mailto:scgris@bellsouth.net]
Sent: Monday, April 17, 2006 4:14 PM
To: Williams, Charles
Cc: justin_clay@chambliss.senate.gov; Safe Tables
Subject: Docket#2006-0009 04-006P Retail Postings during Meat/Poultry Recalls

Hi Chuck - Thank you for your time this afternoon. As I mentioned I'm very pleased to read about the proposed rule change on posting retail outlets that received recalled meat/poultry. However, as we discussed, your information is not reaching consumers. The majority of Americans don't even know about the USDA FSIS website, let alone the fact that a lot of Americans don't even have a computer.

As you know, when grocery stores receive recall notices they quietly pull the products off their shelves. What about the consumers that have these recalled products in our pantries, refrigerators and freezers? For example, there was a huge listeria Class 1 recall on Armour Lunch Makers #052-2005. Over 2.8 million pounds of product were recalled that had been distributed nationwide. Based on the recall information, most of the products weigh 2.6 ounces - could that mean that over 16 million units of this products was recalled? Not sure the numbers are correct, but the key is...WE NEVER HEARD ABOUT THE RECALL!!

The best way to reach consumers is to post all recall notices at the front entrance to grocery/drug stores. This is public information that you are posting on your website. The grocery stores also have the information, so why not close the loop and really include the consumers?

Please consider this addition to the Proposed Rule on Availability of Retail Lists During Recalls. Through the combination of web postings, media announcements and grocery/drug store postings, I believe we can save a lot more Americans from unnecessary illness and potentially fatal situations.

Thank you

Sharon Griswold
Atlanta, GA
(770) 331-2668

SBA Office of Advocacy
www.sba.gov/advo

Advocacy: the voice of small business in government

May 4, 2006

Docket No. 04-006P
FSIS Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, D.C. 20250

Re: Docket No. 04-006P – Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Dear Sir/Madam:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1]

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring Federal agencies to implement policies protecting small businesses when writing new rules and regulations.[2] Executive Order 13272 instructs Advocacy to provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.[3] Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[4]

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).
[2] Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).
[3] E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.
[4] Id. at § 3(c), 67 Fed. Reg. at 53,461.

On March 7, 2006, the Food Safety and Inspection Service (FSIS) published a proposed rule in the *Federal Register* titled, "Availability of Lists of Retail Consignees during Meat and Poultry Product Recalls."[3] The proposed rule seeks to amend the federal meat and poultry products inspection regulations to provide that the Agency will make available to the public lists of the retail consignees of meat and poultry products that have been voluntarily recalled by a federally inspected meat or poultry products establishment if the product has been distributed to the retail level. This proposed change in the inspection regulations will change FSIS' practice that distribution lists obtained during recalls are confidential business information, exempt from release under the Freedom of Information Act (FOIA).[6]

FSIS is proposing this action because it believes that the efficiency of recalls will be improved if there is more information available as to where products that have been recalled were sold. FSIS is responding to suggestions by some states and consumer groups that product recalls will be enhanced by the disclosure of retail lists.[7]

FSIS' Certification of No Impact is Insufficient under the RFA

On page 11327 of the *Federal Register* notice, FSIS certified that the rule will not have a significant economic impact on a substantial number of small entities, and consequently FSIS did not prepare an Initial Regulatory Flexibility Analysis (IRFA) pursuant to §605(b) of the RFA.

Section 605(b) of the RFA requires that any agency certification of no impact be accompanied with a statement providing the factual basis for such certification. Advocacy believes that FSIS failed to provide the public with an adequate factual basis for its conclusion that the rule will have no significant impact on a substantial number of small entities. As such, the transparency of the rule would benefit greatly from either statements justifying the reasons for the certification or the completion of an IRFA.

Advocacy suggests that FSIS should consider completing an IRFA. The rule's preamble states that the regulation was reviewed under Executive Order 12866 and was determined to be significant. If the rule is deemed significant under the criterion of EO 12866 then the resultant economic analysis would be useful under the small entity analysis requirements of the RFA. Further, on page 11327, FSIS states that, "although the benefits of the proposed action are not quantified, it is reasonable to conclude that they are equal to or exceed the costs of the rule, because the costs are expected to be minimal."

[3] 71 Fed. Reg. 11326 (March, 7, 2006).
[6] 5 U.S.C. 552(b)(4).
[7] 71 Fed. Reg. 11327 (March 7, 2006).

The RFA requires an agency to perform a detailed IRFA when it is unsure of the ability to certify that the rule will not have a significant economic impact on a substantial number of small entities.[8] Advocacy researched the number of small meat and poultry producers, wholesale distributors of meat and poultry products, and grocery retailers likely to be affected by this regulation using the U.S. Small Business Administration (SBA) size standards.[9]

NAICS Code	Industry Title	# Firms
Producers (<500 employees):		
311611	Animal slaughtering (except poultry)	1,712
311612	Meat processing from carcasses	1,184
311613	Rendering & meat byproduct processing	102
311615	Poultry processing	266
3117	Seafood product preparation & packaging	638
Wholesale Distributors (<100 employees.)		
42444	Poultry & poultry products	121
42446	Fish & seafood	270
42447	Meat & meat products	379
Grocery retailers (<$25 million for supermarkets and convenient stores and <$6.5 million for meat and fish markets):[10]		
44511	Supermarkets	34,638
44512	Convenience stores	25,410
44521	Meat markets	5,024
44522	Fish markets	1,968

Clearly, a significant number of small entities exist in the business sectors that this rule will affect. The transparency of this regulation would markedly improve with some discussion of how the regulated stakeholders will be affected. The Office of Advocacy believes that the proposal does not meet the analytical requirements of the RFA if it moves forward without the opportunity for the public to comment on a detailed IRFA.

The stakeholders have a right to determine if the costs of amending an already effective regulatory scheme are reasonable when balanced against benefits that cannot be quantified. If, after the IRFA is completed, FSIS concludes no significant economic impact exists for small entities, a certification can be included in the final rule.

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[8] 5 U.S.C. §601.

[9] The appropriate SBA size standard for each affected industry is shown in the parentheses.

[10] Note: For grocery retailers Advocacy was not able to determine the precise number of affected entities by the size standard because we do not have accurate data on receipts per firm. Instead, Advocacy used an employment size standard of <20 employees to determine the number of affected firms. This is a conservative estimate because the receipt size for smalls would support more than 20 employees. However, because the vast majority of all firms in these industries have <20 employees anyway, adding greater precision would not likely change the number of affected entities significantly.

Meat and Poultry Industry Representatives Approached Advocacy Because They Disagree with FSIS' Certification of No Impact

On page 11327 FSIS concludes that, "This action would not impose a monetary cost on establishments conducting a recall, and the information proposed to be released would not result in any competitive harm to affected establishments." The statement is in direct conflict with the position espoused by stakeholders to Advocacy. Industry representatives believe that the rule will in fact have a substantial economic impact on small meat and poultry producers, small wholesale distributors and small grocery retail stores. Stakeholders believe that FSIS should make its current data on the efficacy of recalls available for public comment before taking steps to change existing effective procedures. Some of the reasons cited by industry in support of their position that this rule will have a significant economic impact on small entities include:

1. This rule is in direct opposition to the conclusion FSIS reached in 2002 during the last regulatory amendment to 9 CFR 390.9 on this issue. At that time FSIS concluded that the type of disclosure being contemplated in the current rule could have an adverse affect on recall efficacy.

2. Current recall procedures provide all necessary product identifying characteristics to allow consumers to check products, regardless of where the product was purchased. Industry contends that consumers currently check the product in their possession against the identifying characteristics of the recall to determine if the product is subject to recall.

3. The proposed rule does not take into account store-to-store transfer of product, which increases the paperwork burden on the regulated entities.

4. FSIS concluded in 2002 that if the agency distributed confidential commercial information to the public, firms would be unwilling to voluntarily share this information with the agency. The agency should analyze how the possible loss of confidential information might impact regulated stakeholders.

5. Most retailers sell numerous meat and poultry products so that the retail name will not serve to differentiate product. This will lead to increases in products returned to the retail establishment, even product that is not subject to the recall.

6. Industry believes that it will take FSIS too long (several days to weeks) to get accurate recall information on its website for public use, thereby eliminating the benefit of the rule and possibly weakening the current recall process.

Conclusion

In conclusion, Advocacy commends FSIS for holding the public hearing on April 24, 2006. It was evident from that hearing (based on the positions advocated by those persons in support of, and against, this regulation) that this rule will benefit greatly from additional economic analysis and from the preparation of an IRFA. The information gleaned from such an analysis would add to the transparency of the rule and would allow stakeholders the ability to comment on the costs and benefits of the regulation.

Thank you for your attention to the above matters. If you have any questions about this correspondence, please do not hesitate to contact Linwood Rayford at (202) 401-6880.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Advocacy

Cc: Donald Arbuckle, Acting Administrator
Office of Information and Regulatory Affairs

06-006P-10
06-006P
Jody Corby

10

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE AND MARKETS
10B Airline Drive
Albany, NY 12235
1-800-554-4501

May 5, 2006

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102 Cotton Annex
Washington, DC 20250

RE: Docket Number 04-006P
Proposed 9 CFR Part 390.10
Availability of Lists of Retail Consignees
During Meat or Poultry Recalls

The New York State Department of Agriculture and Markets [NYSAM] is pleased to offer our comments to the US Department of Agriculture; Food Safety and Inspection Service (FSIS) in relation to a proposal to amend federal meat and poultry products inspection regulations to allow FSIS to make available to the public lists of retail consignees of meat and poultry products voluntarily recalled from federally inspected plants. Our specific comments are as follows:

1) We believe the responsibility for release of a firms distribution records during a recall rests with the particular firm and not necessarily with FSIS. NYSAM routinely requests these records from federally inspected plants that voluntarily recall their products and we have generally been provided with the distribution information for New York.

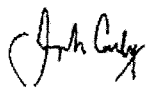
2) The FSIS requirement that state agencies sign a Memorandum of Understanding [MOU] with FSIS before distribution information is shared does not provide a timely release of information which is critical during any recall but particularly those designated as Class I. Furthermore, our inability to then share this important information with our State Health Department and local health agencies is of significant concern, since those agencies are integral partners in protecting the public.

3) The definition for the term "retail" can be interpreted in various ways. For the purposes of this proposal does FSIS consider retail to include restaurants and institutions? Institutions such as hospitals, schools, and prisons where many of our most vulnerable citizens exist should be included in that definition for the purpose of notification..

4) Limiting distribution information to the final retail consignee will create an unnecessary hurdle for state and local public health agencies to overcome in order to obtain timely distribution information.

NYSAM has coordinated over 1300 food recalls in the past three years. We work with all recalling firms to script press releases, notify retailers, and provide timely distribution lists for other government agencies. We believe that key elements to an effective recall involve prompt action by the recalling firm, quick response by regulatory agencies when necessary, and the complete sharing of distribution information to assure the recall is complete and seamless.

Sincerely,



Joseph Corby
Director
Food Safety and Inspection

06-006P-11
06-006P
Thomas F. Wenning

11

National Grocers Association

May 5, 2006

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street SW
Room 102 Cotton Annex
1400 Independence Avenue, SW
Washington, DC 20250

RE: Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Docket No. 04-006P

Dear Sir or Madam:

On April 27, 2006, the National Grocers Association (N.G.A.) requested an extension of the comment period for the proposed rule issued by the Food Safety and Inspection Service (FSIS) on the Availability of Lists of Retail Consignees During Meat or Poultry Recalls, 71. Fed. Reg. 11326 (March 7, 2006), for a period of sixty days following the publication of the transcript of the public meeting held by FSIS on April 24, 2006. Based on representations made at the public meeting, N.G.A. is of the understanding that FSIS intends to extend the comment period past the current closing date of May 8, 2006. However, FSIS has yet to formally indicate such an extension. N.G.A. intends to submit detailed comments and considering the comments are presently due on Monday, we would appreciate an indication today whether or not an extension will be granted. Granting an extension would allow N.G.A., and other interested parties to prepare comments with the benefit of reviewing the transcript of the public meeting.

The current comment period does not provide enough time to comprehensively address issues raised at the public meeting. Granting the above referenced extension will provide all interested parties with adequate time to incorporate the issues discussed at the public meeting into their comments. We would greatly appreciate it if FSIS could give an indication today whether or not an extension will be granted.

We thank FSIS for its consideration.

Sincerely,

Thomas F. Wenning

Thomas F. Wenning
Senior Vice President and General Counsel

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May 8, 2006

04-006P-12
04-006P
Marion F. Aller

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102 Cotton Annex
Washington, DC 20250

RE: Docket Number 04-006P
Proposed 9 CFR Part 390.10

The Association of Food & Drug Officials (AFDO) is a non-profit professional organization representing federal, state, and local regulatory officials as members, with industry representatives participating as associate members. AFDO develops and promotes uniform laws, regulations, and guidelines that have resulted in more efficient and effective regulations along with enhanced cooperation and communication. AFDO has been a leader in many regulatory initiatives and has taken an active role in attempting to integrate resources at all government levels that are applied to food safety in this country. One of our more prominent efforts in recent years has been associated with recalls and how they can be best achieved by industry and monitored by government.

AFDO supports the USDA/FSIS proposal to amend federal meat and poultry inspection regulations to enable them to make available to the public lists of retail consignees of meat and poultry products that have been voluntarily recalled by federally inspected meat or poultry establishments if product has been distributed to the retail level.

AFDO agrees the efficiency of recalls can be improved by informing the public of the retail consignees that are known to be carrying the recalled product(s), provided the information is accurate and provided in a timely manner.

In terms of accuracy, however, "Retail Consignee" needs clarification. Does the term include hotel, restaurants and institutions that serve the product directly to the public or only retail markets and grocery stores? Clearly, the institutions are locations where many of our most vulnerable populations are being fed such as schools, nursing homes, and hospitals. Any delays in identifying distribution to these locations would be unacceptable, in our view.

The timeliness of accurate information is of great concern because most recalls only receive a limited amount of press. Much of the retail consignee information will be gathered as part of sub-recalls being conducted by primary distributors. If the general public is told of the recall via the press and goes to the USDA/FSIS web-site and does not see the store they shop in listed it could work to hinder the recall process. Possible solutions may be highly visible disclaimer statements involving the recall, i.e. "Known Retail Consignees to Date", "Retail Information Will Be Posted By (date)". Another solution is to allow consumers to sign up for e-mail alerts to meat and poultry products being recalled in their state.

AFDO appreciates the opportunity to comment on the proposed regulation. We further hope the successful implementation of the proposed regulation leads USDA/FSIS to reconsider distribution lists as confidential proprietary information. While AFDO would agree the dollar value and amount of product sold to a particular consumer is confidential, we do not agree the customers name should be kept confidential.

Sincerely,

Marion F. Aller

Marion F. Aller, President
Association of Food and Drug Officials

cc: Board of Directors

04-006P-13
04-006P
Mike Govro

13

From: Mike Govro [mgovro@oda.state.or.us]
Sent: Monday, May 08, 2006 11:19 AM
To: FSIS RegulationsComments
Subject: Comments on FSIS Retail Distribution FR Notice

The Oregon Department of Agriculture offers the following comments on the proposal concerning Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls;

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 390

[Docket No. 04-006P]
[FDMS Docket Number FSIS-2005-0028]
RIN 0583-AD10

Availability of Lists of Retail Consignees During Meat or Poultry
Product Recalls

AGENCY: Food Safety and Inspection Service, USDA.

The Oregon Department of Agriculture supports the FSIS proposal to amend the federal meat and poultry products inspection regulations to provide that the Agency will make available to the public lists of the retail consignees of meat and poultry products that have been voluntarily recalled by a federally inspected meat or poultry products establishment if product has been distributed to the retail level.

We believe that making lists of retail consignees available will make FSIS recalls more efficient and effective. Improving information dissemination will facilitate quicker removal of affected products from retail channels and recovery from consumers. By making distribution information more readily available, FSIS will more easily be able to utilize the assistance of State partners who are more familiar with retail operations.

While FSIS's system of recall notification is effective for products that retain their package identity through retail sale, the system is not effective for products such as ground beef that are shipped in bulk from the wholesale plant and packaged at retail. As a State that was directly involved with the first United States BSE case, we spoke to many consumers who did not know if product they had or had consumed was involved in the recall. The current notification system only requires a store that sold recalled product to provide the information on a placard, severely limiting the number of people who will receive the information. This proposal will improve consumers' abilities to determine whether or not product in their possession is being recalled. It will also assure that affected retailers are fully involved in the recall process and guard against failure in the notification system from the distributor to the retailer. In a contamination incident where risk is high, it will be imperative that consumers be able to determine quickly and accurately if product in their posession is safe. This is important from a public health standpoint as well as a public relations standpoint.

This proposal will have two additional benefits. First, it will improve States' abilities to respond more quickly and accurately to public inquiries about recalls, effectively multiplying FSIS efforts to communicate with the public. Second, it will promote consumer confidence in the nation's food supply and the regulatory systems designed to assure its safety. Not surprisingly, the public believes that these systems are in place to protect them, and that they have a right to know when they have been sold food that may be unsafe. This rule change will help more consumers get more specific recall information more quickly, and that will be correctly viewed as a benefit to the consumer.

We urge FSIS to implement this rule change.

Michael Govro
Assistant Administrator
Food Safety Division
Oregon Department of Agriculture
503-986-4726

STATE OF NEW YORK
DEPARTMENT OF HEALTH

14

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

May 8, 2006

04-006P-14
04-006P
Michael J. Cambridge

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102 Cotton Annex
Washington, DC 20250

Re: Docket Number 04-006P,
Proposed 9 CFP 390.10

Dear Docket Clerk:

While the proposed 9 CFR Part 390.10, Availability of Lists of Retail Consignees during Meat or Poultry Recalls, is a positive step forward in ensuring that the public is informed and protected during a recall, the fact that only final retail consignees will be identified may hinder efforts to protect public health.

The USDA policy that considers distribution lists confidential proprietary information and the proposed Section 390.10 excluding all facilities other than the final retail consignee from being made public, hinders our foodborne illness investigations and public health protection efforts. In order for State agencies to work with local health departments to ensure that as much recalled product as possible is returned, State agencies and local health departments must be made aware of all establishments that have produced and received the recalled product. This includes restaurants and institutions such as hospitals and prisons. Since the Freedom of Information Law in New York State would allow the names of all establishments involved in a recall to be made public, New York State agencies are deemed ineligible to obtain the names of these establishments from the USDA. Our sister agency, the New York State Department of Agriculture and Markets, has conducted numerous recalls and it is our understanding that they have generally been required to obtain distribution lists from the companies involved instead of the USDA. This duplication of efforts hinders investigations and jeopardizes the health of the public.

Difficulty obtaining the lists of all establishments involved in voluntary recalls would be of significant concern during an avian influenza outbreak. As 9 CFR 390 is written, the New York State Department of Health would be unable to obtain names and locations of the poultry farms where workers contracted the illness and the distributors that may have received infected poultry.

There is also some concern over the wording of subdivision (b) of the proposed Section 390.10. As written, it is unclear whether the location of the consignee that will be posted on the USDA web page will be the actual individual store that received the product or a business office address. We are requesting that the regulation be clarified to state that the term "location" refers to the address of the specific establishment that received the product.

The opportunity to comment on the proposed regulation is appreciated. The New York State Department of Health believes that complete disclosure of all facilities involved in a voluntary recall is vital to protecting the health of the public. If you would like to discuss this further, please contact Barbara Gerzonich at (518) 402-7600.

Sincerely,

Michael J. Cambridge
Director
Bureau of Community Environmental Health
and Food Protection

en
cc: Mr. Tramontano
Dr. Morse
Mr. Svenson
Mr. Bills/Ms. Jones Rafferty
Mr. Sackett
Ms. Gerzonich
Ms. Linehan-OGA

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15

655 15TH STREET, N.W., SEVENTH FLOOR
WASHINGTON, D.C. 20005-5701
TELEPHONE: 202/452-8444
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E-MAIL: FMI@FMI.ORG
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April 27, 2006

04-006P-15
04-006P
Deborah R. White

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102, Cotton Annex
Washington, DC 20250

Re: Request for Extension of Comment Period for Proposed Rule To Publish Lists of Retail Consignees During Meat or Poultry Product Recalls; Docket No. 04-006P

Dear Sir or Madam,

Pursuant to the request made by the Food Marketing Institute[1] (FMI) and others at the April 24, 2006 public meeting, the purpose of this letter is to provide a written request to the docket asking the Food Safety and Inspection Service (FSIS) to extend the comment period on the referenced proposal regarding the Agency's intention to publish the retail consignee lists that the Agency may obtain during a meat or poultry recall. 71 Fed. Reg. 11326 (March 7, 2006). Currently, the comment period closes on May 8, 2006. However, significant information was presented at the April 24 meeting from both FSIS and the public that must be considered in the preparation of our comments.

Accordingly, we respectfully request that FSIS post the transcript of the public meeting on the Agency's website as quickly as possible and extend the comment period for the proposed regulation for 60 days after the transcript has been made available. Our members must have access to the information presented at the public meeting in order to formulate their comments on the proposal.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

We appreciate your consideration of our request and look forward to your reply.

Sincerely,

Deborah R. White
Vice President &
Associate General Counsel

AMERICAN MEAT INSTITUTE

16

April 28, 2006

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102, Cotton Annex
Washington, DC 20250

04-006P-16
04-006P
Mark Dopp

Re: Request for Extension of Comment Period for Proposed Rule To Publish Lists of Retail Consignees During Meat or Poultry Product Recalls; Docket No. 04-006P; 71 *Fed. Reg.* 11326 (March 7, 2006).

Dear Sir or Madam:

Pursuant to the requests made by the American Meat Institute (AMI) and others at the April 24, 2006, public meeting concerning the above-referenced proposal, AMI requests that the Food Safety and Inspection Service (FSIS) extend the comment period for that proposal. Currently, the comment period closes on May 8, 2006. However, significant information was presented by FSIS and the public at the April 24 meeting, which needs to be considered as AMI prepares its comments.

Because not all interested person were able to attend the public meeting and because access to the information presented may be helpful in formulating comments, we respectfully request that FSIS post the transcript of the public meeting on the agency's website as quickly as possible and extend the comment period such that comments will be due 60 days after the transcript has been made available. We appreciate your consideration of our request and look forward to your prompt reply.

Sincerely,

Mark Dopp
Senior Vice President &
General Counsel

1150 Connecticut Ave, NW • 12th floor • Washington, DC 20036 • (202) 587-4200 • fax: (202) 587-4300 • www.meatami.com

State of California—Health and Human Services Agency
Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

17

MAY 5 - 2006

04-006P-17
04-006P
Mark B. Horton

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street
S.W., Room 102 Cotton Annex
Washington, D.C. 20250

Dear Sir or Madam:

The California Department of Health Services (CDHS) submits the following comments in regard to the proposed rule on the availability of lists of retail consignees during meat or poultry product recalls, 9 Code of Federal Regulations Part 390, Docket No. 04-006P.

CDHS strongly supports the concept of unrestricted sharing of distribution information of recalled meat and poultry products with state and local public health agencies and with consumers. This information is critical for state and local public health agencies to ensure that consumers are protected from contaminated meat and poultry products. CDHS has previously submitted letters to the Food Safety and Inspection Service (FSIS) to this effect.

CDHS noted that the proposed rule specified no time frame as to when the distribution lists are to be disseminated to the public. In recall situations, time is of the essence; any delay in providing information to the public can potentially cause additional illnesses, injuries, or deaths. If retail distribution lists were provided to the public several weeks to several months after the initial recall notification, the public would have likely consumed much of the contaminated product before ever realizing they have adulterated food. Furthermore, the consumer may not remember where they purchased the product several weeks earlier, leading to additional accidental exposures to contaminated products. If there was a bioterrorism event in which a meat or poultry product was contaminated with a toxicological agent, any delay in providing distribution information could also delay appropriate response efforts.

1501 Capitol Avenue, Suite 6001, MS 0028 P.O. Box 997413 Sacramento, CA 95899-7413
(916) 440-7400 (916) 440-7404 FAX Internet address: www.dhs.ca.gov

It is CDHS' view that this proposed rule should be amended to require a specific time frame in which the public is to be notified of the distribution of recalled meat and poultry products. This recommendation was made in the U.S. Government Accountability Office's report, "Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food," on October 2004.

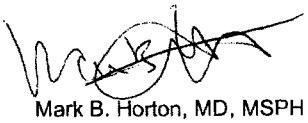
Under the proposed rule, there are no requirements for FSIS to identify the names of intermediate distributors, such as food service or institutional distributors. CDHS disagrees with FSIS that providing this information to the public is not warranted. Food service distributors and institutional distributors should be included because some of these firms may deal directly with the final consumer. There are multiple levels of wholesalers, brokers, distributors, processors, and retailers before a food reaches consumers. Limiting the notification to only retail consignees may leave out distributors or wholesalers who occasionally sell directly to consumers as well. At a minimum, lists of intermediate distributors should be promptly provided to state and local public health agencies without the existing FSIS constraints requiring this information to be withheld from local agencies, consumers, and the media.

CDHS believes that additional information should be provided for each consignee, including amounts of recalled product, dates shipped, or dates received. Local and state agencies may need to prioritize notification efforts and recall effectiveness checks to those locations that received the largest amount of product and/or those most likely to still have product on hand.

Additionally, CDHS believes that the results of recall effectiveness checks should be posted. CDHS has previously requested the results of recall effectiveness checks from FSIS involving product distributed to California; however, no results were ever provided. Consumers and state and local agencies should have access to a timely summary of the assessment of the effectiveness of a recall.

Thank you for the opportunity to comment on such an important proposal.

Sincerely,



Mark B. Horton, MD, MSPH
State Public Health Officer

04-006P-18
04-006P
Rosemary Mucklow
Ken Mastracchio

NATIONAL MEAT ASSOCIATION
1970 Broadway, Suite 825, Oakland, CA 94612
Ph. (510) 763-1533 or (202) 667-2108 Fax (510) 763-1533
staff@nmaonline.org http://www.namonline.org

May 5, 2006

16

Docket Clerk
U.S. Department of Agriculture
Food Safety Inspection Service
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250

Re: Docket No. 04-006F
Federal Register Tuesday, March 7, 2006
Vol. 71, No. 44
Pages 11326-11328

Gentlemen:

On behalf of National Meat Association (NMA) members we respectfully submit the following comments in response to the Food Safety Inspection Service request regarding the *Federal Register* Proposed Rule entitled, "Availability of Lists of Retail consignees During Meat or Poultry Product Recalls".

NMA, organized in 1946, represents the interest of meat packers and processors throughout the United States. Our general membership, which consists of over 300, has always supported efforts to improve the effectiveness of recalls and to provide consumers with all information necessary to identify and remove potentially dangerous product from their refrigerator and pantries. Unfortunately, FSIS has not presented any evidence that the release of confidential retail customer lists will achieve these objectives, or that the potential value of this information would outweigh the competitive harm that will be caused to the industry by its release. Indeed, rather than making recalls more efficient, it is highly likely that the release of this information will cause more confusion and uncertainty with consumers, lead consumers to focus less on important product identification information and more on potentially incorrect and misleading information, and result in consumers returning more product that is not covered by the recall.

When there is a recall of potentially dangerous product, the main objective of both industry and the agency is to provide consumers with timely and reliable information so that they can identify affected product and dispose of it prior to consumption. This objective has been achieved through the immediate dissemination of product identification information in Agency press releases and Recall Notification Reports provided to localities in which the product was sold. The agency has acknowledged in its proposed rule and other public records that this method has been effective.

Docket Clerk
U.S. Department of Agriculture
Food Safety Inspection Service
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Washington, DC 20250

Publishing a list of retail consignees on FSIS' website weeks or sometimes months after a recall would not aid consumers in identifying and disposing of affected product. First, posting information on a web-site for consumers presupposes the consumers will know to check a web-site for this information and that consumers either purchase all their items from only one location or keep sales receipts of all purchases to afford them the ability to trace back products to a specific point of purchase. Second, even if consumers know to check the agency's website or know where they purchased specific product, releasing a list of retail customers could distract consumers from the most important information available to them, the product identification information. In fact, it is conceivable that some consumers will wait until the retail consignee list comes out before deciding to check their refrigerators or pantries. If a consumer later forgets to check the website or the retail consignee list is inaccurate, the consumer could eat potentially hazardous product. Third, the agency assumes that all information on its website will be accurate and complete. According to the proposal, the agency will post the names of retail consignees on its website as the agency collects this information pursuant to its recall effectiveness checks. Unfortunately, it is not uncommon for the agency to have incomplete or inaccurate lists of retail consignees from their effectiveness checks. Intermediate distribution records could be incomplete or affected products could find their way to other retail customers that are not identified on distributor records. The failure to include a particular retail consignee on the agency's website or the failure to post the name of a particular retail consignee on the website in a timely manner could cause a false sense of security, resulting in a person consuming potentially hazardous product.

Faced with these real concerns, the agency does not provide any evidence that its proposal would benefit public safety, and does not provide any explanation whatsoever for changing its position that retail consignees constitutes confidential commercial information. On April 24, 2002 FSIS published a final rule, which enabled FSIS to share confidential lists with State and other federal agencies for the purpose of aiding in the recall verification process by enlisting their assistance in recall effectiveness checks. However, FSIS has long recognized that this distribution list information is confidential commercial information valuable to a firm and to its competitors and was protected from mandatory public disclosure by exemption 4 of the FOIA (5U.S.C. 552(b)(4). Therefore, FSIS does not release distributor lists to States or other federal agencies unless they agree to keep the information confidential.

FSIS does not offer any explanation of how information once regarded as confidential commercial information and protected from mandatory public by exemption 4 of the FOIA is no longer valuable to the firm or its competitors. On the contrary the publication

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of this information would be extremely advantageous to a firm's competitors. A competitor would have the ability to identify specific retail locations where products have been removed and then offer their products as an immediate substitute thus placing firms undergoing a voluntary recall at risk of losing their customer base. The proposed change could be devastatingly destructive, especially to small firms who would be subjected to competitive piracy by web-smart larger firms accessing their most important business asset-their customer list.

In consideration of the aforementioned comments, we request that the proposed rule be abandoned. In the alternative, we request that it be reissued for review and comment under the condition that it also include an Economic Impact study assessing the potential for serious economic loss due a competitors accessing confidential customer information. In addition, we request that FSIS present supporting evidence that would substantiate claims of how publicizing confidential customer information lists will expedite recalls beyond present day capabilities.

The NMA appreciates this opportunity to comment on Food Safety and Inspection Service proposed rule to make available a list of retail consignees during meat and poultry recalls. NMA hopes that you will give our comments due consideration.

Sincerely,

Rosemary Mucklow
Executive Director
National Meat Association

Ken Mastracchio
Assoicate Director
National Meat Association

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04-006P
04-006P-19
Ken Kelly

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

June 11, 2006

U.S. Department of Agriculture
Food Safety and Inspection Service
Docket Clerk
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, DC 20250

RE: Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls Docket No. FSIS-2005-0028

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the United States Department of Agriculture's (USDA) proposed rule on the availability of lists of retail consignees during meat or poultry product recalls. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Summary

USDA's Food Safety Inspection Service (FSIS) is responsible for ensuring that meat and poultry products are safe, wholesome and accurately labeled. The Federal Meat Inspection Act and the Poultry Products Inspection Act require federal inspection of meat and poultry prepared for distribution in commerce for use in human food. Because USDA lacks mandatory recall authority, when a product is believed to be adulterated or misbranded, USDA will request that the firm that introduced the products into commerce

recall them. USDA assists this process by issuing a press release that includes a description of the food being recalled, the reason for the recall, the name of the producing establishment, and the recall classification. However, this information is not always sufficient to tell consumers if meat they have already purchased is part of a recall.

Currently, USDA has a policy of not providing consumers with critical information on where potentially contaminated meat or poultry was distributed and sold during a recall. This policy protects the industry at the expense of public health and effectively acts as a gag order on state public health officials.

This policy has impacted numerous states. In the summer of 2002, public health officials in Colorado and California were barred from obtaining ConAgra's distribution lists from USDA, even though the Denver plant distributed widely in those states.[1] On December 23, 2003, FSIS announced a voluntary recall of 10,410 pounds of raw beef that may have been exposed to tissues containing the infectious agent that causes mad cow disease. This meat was distributed to several states, including California. However, the California Department of Health was barred from disclosing where the tainted meat was distributed and sold to consumers.[2] On April 24, 2006 at the public meeting on this proposed rule, Under Secretary for Food Safety, Dr. Richard Raymond admitted that he was barred from getting retail consignee lists as Director of the Nebraska Health Department. Whether it's California, Colorado or Nebraska, consumers deserve to have as much information as possible to protect them selves and their families from the risks associated with contaminated meat and poultry.

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[1] David Migoya, "Colorado unable to obtain list of where recalled meat sold," *Denver Post*, (Aug. 4, 2002).
[2] Marjie Lundstrom, "Government secrecy agreement over tainted meat unacceptable," *Pasadena Star-News* (January 22, 2004).

USDA requires states to sign a memorandum of understanding prohibiting them from disclosing retail consignee lists to third parties in order to receive information on where tainted meat or poultry was sold in their state for verification purposes. In the past, USDA has contended that retail consignee lists is protected under the Freedom of Information Act (FOIA) "business records" exception. However, this interpretation applies the FOIA business records exemption too broadly.[3] In fact, retail consignee lists have been released under FOIA[4] when it was determined that their disclosure would not cause "substantial competitive harm." Since recalls are limited in their depth and scope, it is questionable whether the release of the names of specific recipients of specific product at a specific time would be of any use to competitors. The Department has also claimed that this policy is appropriate because otherwise companies would not share this information under the voluntary recall policy. From a consumer perspective, however, this approach seems counter-intuitive, as the public may urgently need to know if the meat in their refrigerator or freezer came from the implicated product. A compelling public health interest should take precedent over a companies business records during a meat or poultry recall.

Now USDA has decided to change their policy on sharing retail consignee lists. In the March 7, 2006, *Federal Register* notice, FSIS stated that it has the authority to disclose consignee lists that are compiled during meat and poultry recalls. Furthermore, the Agency has concluded that is appropriate to disclose these lists in order to enhance

[3] Specifically, exemption 4 of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4).
[4] *Greenberg v. FDA*, 803 F.2d 1213, (D.C. Cir. 1986); *Ivanhoe Citrus Assn. v. Handley*, 612 F. Supp. 1560, 1566 (D.D.C. 1985); *Braintree Elec. Light Dept. v. Dept. Of Energy*, 494 F. Supp. 287, 290 (D.D.C. 1980).

the efficiency of recalls. CSPI supports FSIS's change in position. This information will not only assist with the efficiency of recalls but also help protect public health.

I. Disclosing retail store names during meat and poultry product recalls will increase consumer protection.

The proposed rule will improve the recall verification process while also empowering consumers during these recalls. The list of retail consignees that sell recalled meat or poultry is very useful to both consumers and retailers. Typically, during a recall, consumers return more and different types of products than are actually necessary. Disclosing specific retail consignees will increase consumer's ability to identify the specific products subject to a recall. If consumers know the name of a retail consignee that sold recalled meat or poultry, they can simply go their refrigerator and look for the specific package. This will improve the recall process by enabling consumers to return the product to the retail outlet in question while also helping to prevent foodborne illnesses.

The meat industry contends that this information would give consumers a false sense of security. On the contrary, the proposed rule would give consumers additional information that will enable them to protect their families and reduce the potential health risks associated with a recall. Naming retail stores will also act as an extra incentive to retailers to remove potentially contaminated meat or poultry from commerce as soon as possible to avoid the potential economic impact.

Although the proposed rule is a welcome change in policy, USDA should consider improving it by including some additional elements. The proposed rule states

that FSIS will post the retail consignee lists on its website. But this is not adequate for consumer notification. We recommend the following:

- The retail consignee lists should be published in all recall materials like press releases (updated as necessary) and notification of recall reports either in the form of a web link or the list in its entirety when possible.
- The retail consignee list should be "prominently" displayed on FSIS's website along with the usual recall information published by the Agency.
- The retail consignee list should identify the retail consignee by the physical location where the contaminated product is sold.

II. Publishing of a retail consignee during a meat or poultry recall will benefit consumers even where some names are delayed.

At present, FSIS has not committed to a time frame for publishing the list of retail consignees during a recall. We urge the agency to publish the names as soon as they become available. Many in the meat industry argue that partial information is worse than no information. However, consumer ignorance is not a deterrent to foodborne disease. Denying consumer partial information simply because complete information is not yet available would be like not recalling any meat, because products other than that being recalled might be contaminated. From a public health perspective, it just doesn't make sense. Removing any amount of contaminated product from a consumer's home might prevent an illness or save a life. And every illness or death from food weakens consumer confidence in the food supply and government food safety programs.

Clearly having a timely and complete list of retail consignees is preferable when dealing with a recall. But given the long time that meat or poultry is kept in the

refrigerator or freezer, all information regarding retailers is very valuable to consumers. FSIS should post the names of the retail consignees that sell recalled meat or poultry as soon as they become available from the district offices.

III. FSIS should publish retailers as soon as they become known.

If FSIS is unable to find all of the retail consignees of a meat or poultry product subject to a recall, it should publish a list of those consignees whose information it was able to obtain. The information should be posted on FSIS's website along with a disclaimer explaining that the retail list may not be complete. The Agency should continue to update the information as the retailers become known and tell consumers to continue to check the FSIS website and other sources of recall information. The disclaimer should make it clear that the retail lists are a supplement and not a substitute for the traditional information that FSIS distributes during a recall.

IV. FSIS should modify the definition of "retail consignee" to include restaurants for the purposes of this rule.

Lastly, the current proposed rule applies only to retail consignees as defined by FSIS Directive 8080.1 Revision 4. It does not apply to food service establishments like restaurants and institutions.[5] Every day millions of families around the country go out to restaurants for breakfast, lunch or dinner. They eat at schools, hospitals and nursing homes. They purchase and consume meat and poultry served by these establishments. As a result, consumers are put at risk if these establishments received tainted meat or poultry. Food service establishments are an important link in the recall verification chain and

[5] Food Safety Inspection Service Directive 8080.1 Revision 4 defines "user level" as hotels, restaurants, and other food service institutional consignees.

including them in the definition of retail consignees would provide consumers greater protection from the risks associated with tainted meat or poultry.

Conclusion

Consumers rely on the USDA to ensure that the food they purchase and consume is safe. They deserve to know where potentially contaminated meat is distributed and sold. The proposed rule on the availability of lists of retail consignees during meat and poultry products recalls should be adopted promptly with the improvements mentioned above. This information would strengthen the recall process while also providing additional protection to consumers.

Respectfully submitted,

Ken Kelly
Staff Attorney, Food Safety Program

Turkey

June 9, 2006

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Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
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Washington, DC 20250

04-006P-20
04-006P
Christy Marr

Re: Docket No. 04-006P Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Dear Sir or Madam:

The National Turkey Federation (NTF) appreciates the opportunity to submit comments to the above-mentioned proposed rule. NTF represented nearly 100 percent of all turkey processors, growers, and allied industries. NTF is an advocate for all segments of the U.S. turkey industry, providing services and conducting activities, which increase demand for its members' products and protect and enhance the ability to effectively and profitably provide wholesome, high quality, nutritious turkey products. It is the only association representing the turkey industry exclusively.

The turkey industry shares the belief with the agency that information provided to the consuming public is vital during a meat or poultry product recall. Therefore, the industry voluntarily provides all necessary information in the unfortunate event of a product recall. This information allows for clear and concise identification of the recalled product to help ensure consumers return the implicated product.

The agency's proposed rule does not provide additional clarity to the recall process. It is our opinion that the proposed actions would have a deleterious effect on the recall process and create confusion with consumers by causing them to focus less on the clear and concise product identification information and more on information that has the potential to be incorrect, misleading and not timely. All three of these factors are absolutely critical when food safety recalls are being implemented.

Added Confusion

During a product recall, accurate information is provided as quickly as possible by the recalling establishment to the agency. FSIS then publishes a press release and a Recall Notification Report (RNR) containing the relevant information. A critical piece of information FSIS allows on the press release is the name and contact of a company official. This direct link to the company allows consumers, state regulators or other interested parties alike to contact the company directly if there is confusion or other information is needed. In addition, the press release has more commonly included copies of labels in a format readily available to consumers and other interested parties in a format that can be shown on a computer or printed for reference as needed. Both the press release and the RNR contain the vital information that allows the consumer to properly identify the implicated product to be returned or destroyed.

The FSIS proposed rule to compile and publish a list of retail outlets where the product was available for purchase will only add confusion to the situation and could hamper the effects of a recall. As FSIS indicated in the preamble to the proposed rule as well as other public records, the current system is effective. The information provided is the single most important information available that ensures timely and accurate identification of implicated product. In both the press release and the RNR, the agency instructs (along with the pictorial information of the label) consumers to check the product by matching production coding, such as lot identification and establishment number. The agency's proposed rule to develop and publish a list of retail establishments that sold the implicated product "at some later date" can only add confusion and possibly dilute the importance of the product identification information provided if any consumer delays responding to the recall notification waiting to see the list for their corner grocery store.

By providing additional information that will not be timely, complete or worse yet is inaccurate as a result of the fact finding process, the proposed rule will serve not to improve the recall process; rather, it will serve to be counterproductive and could increase the returns of product not implicated in the recall, contrary to the agency's thoughts detailed in the proposal. Additionally, it is not understood how the agency intends to provide the list of retail establishments, either once a complete list is tabulated or on a continuous basis, both of which have some inherent problems.

If the agency intends to provide the list of retail outlets once compilation is complete, there would be little value to such lists. The proposed rule indicates that the agency will compile the list as it conducts its recall effectiveness checks, which take several days to weeks to complete. Should the agency decide to post the retail outlets under this scenario, there seems to be little to no value to public health.

Posting this list on the FSIS website also assumes customers will know to check this site for information.

Should the agency provide the list of retail establishments as it compiles the list during the recall effectiveness check, there is ample room for erroneous information to be provided to the consumer. In this scenario, the information tabulated may omit retail establishments that in fact sold the implicated product, therefore, misleading the consumer if their store is not on the list. Once a consumer reviews the list and determines the retail establishment they shop at is not present, it is highly unlikely they will continue to check the list for updates which could occur even months later. Moreover, if the consumer doesn't see the retail establishment on the list, it is highly likely that they will not even look at any products in their possession.

In addition, release of data with a high likelihood of error and that may also be of little value to the consumer due to the lack of timeliness does not meet the general information quality guidelines USDA-FSIS is to apply pursuant to the Data Quality Act.

Lack of supporting data

The agency argues that the current system is effective. However, it suggests that there is a need, based on speculation from consumer groups and States, to provide the proposed information to further enhance the recall's effectiveness. There is no supporting information to justify the claims outlined in the proposal. If information exists to validate the claim that having the retail distribution list would have a significant impact on public health, the agency should provide such information.

We support any improvement in the recall process that will have a measurable, positive effect on public health. Therefore, the agency should provide any quantifiable information it may currently retain that supports the proposed rule. Without such information, we cannot envision the proposed rule will have a positive effect on public health.

Confidentiality

The information that is being sought through the proposed rule is considered commercial, confidential information by the industry. The agency has previously argued similarly. Now, the agency is suggesting that such information can no longer be classified as such and is no longer valuable to a particular company or a company's competitors. This is not the case.

With the retail list, a competitor would be able to immediately offer its products to that retailer to replace those removed – putting the recalling firm at immediate risk of losing its entire customer base. Without substantial legal arguments in the proposed rule, the agency should provide clarification as to how it determined such information is not afforded the protection previously granted by the agency[1].

Summary

The National Turkey Federation, again, agrees that providing accurate and concise information to the consumer in a timely manner mitigates potential exposure to recalled product. However, for the reasons listed above, we feel that the proposed rule will have a negative effect rather than the positive effect the agency discusses in the proposal. We, therefore, request the agency to abandon the proposed rule as written.

In the alternative, we request the agency reissue the rule for review and comment as long as this would include (1) an Economic Impact study assessing the potential for economic loss from competitors accessing confidential commercial information; (2) provide quantifiable supporting documentation to support how publishing confidential customer lists would increase the effectiveness of recalls beyond today's capabilities as well as significantly increasing the public's health; and (3) address how the released information complies with the USDA-FSIS Quality of Information Guidelines.

Respectfully submitted,

Michael Rybolt, Ph.D.
Manager, Scientific and Regulatory Affairs

[1] *Federal Register* 67:79: 20009-20013

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June 9, 2006

Docket No. 04-006P
FSIS Docket Clerk
U.S. Department of Agriculture,
Food Safety and Inspection Service
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, D.C. 20250

04-006P-21
04-006P
Mark Dopp

Re: Docket No. 04-006P – Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Dear Sir/Madam:

The American Meat Institute (AMI or the Institute) submits the following comments regarding the above-referenced proposed rule. AMI represents the interests of packers and processors of beef, pork, lamb, veal, and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products, and 70 percent of the turkey products in the United States. The Institute provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

It is important that relevant information be communicated to consumers in the most effective manner possible in the event of a recall. The above-referenced proposal published by the Food Safety and Inspection Service (FSIS or the agency), however, will not accomplish that objective. Indeed, as the agency articulated less than four years ago when it last amended this regulation, the very type of disclosure contemplated in this proposed rule could have an adverse effect on recall efficacy, and concurrently on public health. For that reason alone, and for the other reasons articulated in the comments provided below, this proposal should be withdrawn. AMI, however, would be pleased to work with the agency to identify ways to enhance recall efficiencies.

Adoption of the Proposal will Hamper the Currently Effective Recall Procedures and Adversely Affect Public Health.

As the preamble to the proposed rule provides, and as agency officials acknowledged at the public meeting they held on this issue, current recall procedures provide all necessary product identifying characteristics to allow consumers to determine if they possess a meat or poultry product subject to recall, regardless of where the product was purchased.[1] Indeed, Phil Derfler, FSIS Assistant Administrator for the Office of Policy, Program and Employee Development said, "FSIS considers its recall process to be effective. The Agency believes that the measures it has put in place are effective in communicating to the public that a firm has decided to recall product."[2] Existing agency procedures encourage consumers to do the single most important thing to avoid consuming a product subject to recall: check the product in their possession against the identifying characteristics to determine if that product is subject to recall.

[1] 71 *Fed. Reg.* 11327 (March 7, 2006)

[2] Philip Derfler, FSIS Assistant Administrator, OPPDE, April 24, 2006, Transcript of Public Meeting on Proposed Rule on the Availability of Lists of Retail Consignees During Meat and Poultry Recalls (Transcript), p. 22. In the same meeting Undersecretary for Food Safety Dr. Richard Raymond said "I think the current recall system that is in place at FSIS is a strong one." Transcript at 5.

The very questions raised by this proposal were contemplated and rejected by the agency just a few years ago. In that regard, in 2002 FSIS amended the regulations at issue here and in doing so considered and rejected the concepts inherent in this proposed rule.[3] Specifically, in the preamble to the final rule, FSIS concluded that dissemination of this information to the public would be harmful to the public health, saying:

> Distribution information is confidential commercial information that is valuable to a firm and to its competitors. FSIS recognized that if it made the information regularly available to the public, firms would be unwilling to voluntarily share this information with the Agency. The Agency's ability to verify that recalls were proceeding effectively would be significantly hampered as a result, and the public health would consequently suffer.[4]

Significantly, nowhere in the current proposal does FSIS explain why it apparently has reversed its conclusion such that now disclosing this type of information will not significantly hamper the agency's "ability to verify recalls were proceeding effectively" nor, as it previously concluded that "the public health would consequently suffer."[5]

Rather than provide substantive reasons to support the proposal, the agency offers general comments in the preamble that some state officials have asserted that they could better protect public health by using retail consignee information, without the limitations imposed by the current regulations, 9 CFR 390.9(a)(1).[6] Nowhere in the preamble or in the available administrative record is there anything to substantiate this assertion made by these anonymous state officials. Indeed, the agency does not provide a shred of information or any details to support these assertions (*e.g.*, number of states offering such a view, the rationale provided by the state officials to support their assertion that overcomes the earlier FSIS conclusion, measurements used to predict improvements in public health, examples illustrating the assertions, *etc.*).

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[3] See Final Rule, Sharing Recall Distribution Lists with State and Other Federal government Agencies, 67 *Fed. Reg.* 20009 (April 24, 2002).
[4] *Id.* at 20010.
[5] *Id.*
[6] 71 *Fed. Reg.* 11327 (March 7, 2006).

The agency also states that "consumer groups believe that making the retail distribution information readily available will materially improve the effectiveness of recalls."[7] Again, neither in the preamble to the proposal nor in the publicly available docket does FSIS provide anything other than the opinion of these groups to substantiate these assertions. In that regard, there is no rationale articulated, nor is there any supporting data or examples of inefficiencies related to the absence of the retail data that support the conclusion that the proposed change would "materially improve" recall effectiveness. Adoption of the proposed changes in the absence of articulated reasons, with some form of support for those reasons, particularly given the agency's previous conclusions, suggests that promulgating a final rule incorporating the proposed language would be arbitrary and capricious and in violation of the Administrative Procedure Act (APA).

The Proposed Rule Likely Would Mislead Consumers.

The proposal could adversely affect public health in another way, with dire consequences. The agency apparently has not considered the possible negative consequences of the proposed action. For example, current recall procedures provide the necessary product identifying characteristics so that consumers can check products, regardless of where a product was purchased. The agency suggests that if retail consignees are identified consumers would "focus on the products that are recalled." However, it seems far more likely that the proposal will encourage people to check the product only if they remember visiting a retailer identified in the message.[8]

[7] *Id.*

[8] Unfortunately, the proposed rule does not appear to take into account the intricate nature of the food distribution system. For example, the proposal does not consider store-to-store transfers or other movement of products after they reach their initial retail destination.

In that regard, adoption of the proposal could inadvertently provide consumers with a false sense of security, which could place them at greater risk. If the agency implements the proposal as FSIS has indicated, with an initial retail consignee list posted on a website and then amended and updated over time as more information is gathered by FSIS, such an approach presents the following very real possibility. A consumer becomes aware of a recall involving a product, checks the FSIS website on that day or perhaps the day after, does not find the store where he or she shopped because the list is not complete, and uses the product subject to recall relying on an incomplete posting.

FSIS officials asked during the public meeting if this problem can be resolved by incorporating a noticeable disclaimer on the website advising that the information is incomplete.[9] Posting such a disclaimer will force consumers to check repeatedly the website to determine whether the store or stores at which they shop will ever be posted. Indeed, how will the consumer ever know, in a timely manner, if the store where they purchased the product will ever be posted, and what could be the impact if the consumer uses the product after checking the website once, twice, three times, or more, only to use it and have the store listed the next day?

In the alternative, if FSIS posts the list only after all retail stores are identified through the FSIS effectiveness checks, that process certainly will take a considerable period of time, often weeks according to FSIS Assistant Administrator Derfler. That model results in a list being posted well after the press release is issued and having no value.[10]

[9] See Transcript at 25-26.
[10] See Transcript at 20, 25.

Moreover, the agency's website posting can be accurate and complete only if FSIS officials visit every intermediate distribution entity at all levels between the producing company and the retail entities – a practice not currently followed by the agency. To extend those effectiveness checks to cover every entity would significantly increase the resources that FSIS must expend, an expenditure that seems to have at best very marginal, if any, benefits given the admitted efficacy of the current program. In short, failure by FSIS to fulfill those tasks will lead to an incomplete list, possibly leaving some consumers to believe, wrongly, that the product they purchased is not subject to recall. In any scenario, the proposed rule creates the possibility that consumers will be confused or misled, thereby adversely affecting the public health.

The Proposal Violates the Freedom of Information Act.

FSIS states in the preamble to the proposal that "it has authority to make available lists the Agency has compiled during recalls of the retail consignees of meat and poultry products that have been recalled."[11] The proposal, however, provides no rationale for this conclusion nor is there any explanation in the preamble or the available administrative record regarding why FSIS reversed its longstanding legal position that this type of information is confidential commercial information.[12]

Indeed, the agency's assertion is a clear deviation from the longstanding and relatively recently affirmed agency position that such information is confidential commercial information, as defined by the Freedom of Information Act, and is exempt from disclosure under that Act.[13] Indeed, at the April 24, 2006, public hearing regarding this proposal, Undersecretary for Food Safety Richard Raymond acknowledged that the very type of information the agency seeks to publish on the website is confidential commercial information.[14]

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[11] 71 *Fed. Reg.* at 11327

[12] 67 *Fed. Reg.* at 20010.

[13] *Id.*

[14] Transcript at 7.

In addition, in the preamble to the 2002 final rule amending 9 CFR 390.9 FSIS stated that the new subsection "would enable FSIS to share with State agencies and other Federal agencies certain confidential commercial information, specifically, distribution lists from the firm recalling a meat or poultry product, which are protected from mandatory public disclosure by exemption 4 of the FOIA (5 U.S.C. 552(b)(4))."[15] In so saying the agency unequivocally acknowledged the confidential nature of this type of information and established a detailed process that states and other federal agencies would have to satisfy to be provided the information at issue.

That FSIS has considered the very type of information considered for release here to be confidential is evidenced again and again in agency correspondence. Indeed, the administrative record in this docket is replete with letters and other communication to consumers, members of Congress, and state officials emphasizing that distribution lists "are part of an establishments' confidential commercial information."[16]

The agency seeks to sidestep its longstanding position through its assertion that the list of retail consignees of recalled meat and poultry products and states is based on a list compiled by FSIS, with the agency's subsequent conclusion that such information will not be "customer lists of any company." Simply put, this position is a disingenuous fig leaf because the agency cannot glean the information it proposes to disseminate to the public from any source other than the recalling company and its customers.

In short, the legal shell game engaged in by the agency to try to justify publishing confidential commercial information violates the APA, which also requires FSIS to explain why it is deviating from long held agency policy. That the agency has such an obligation is even more pressing when, less than four years ago, the agency reiterated that such information is confidential commercial information when it amended the very regulation at issue here. In this case, however, the available administrative record and the preamble provide no such explanation or legal rationale.

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[15] 67 *Fed. Reg.* at 20010 (April 24, 2002).

[16] Letter from Philip S. Derfler, Assistant Administrator, FSIS to Reverend Lloyd Cresci, December 17, 2004. See also, "FSIS has traditionally treated consignee identities and distribution lists obtained during recalls as confidential business information." Letter from Philip S. Derfler to Jennifer M. Lyons, May 19, 2005; Letter from Philip S. Derfler to Dr. Michael Jacobsen, Enter for Science in the Public Interest (October 29, 2004); Letter for Philip S. Derfler to the Honorable Russell D. Feingold (July 21, 2005).

June 9, 2006

The Proposal Would Violate the Data Quality Act.

The Data Quality Act (DQA) requires that federal agencies promulgating regulations do so in a manner such that the quality of the data is not compromised, is timely, and is of sufficient quality.[17] In this case the proposal achieves none of those objectives.

If the proposal becomes final, the agency could implement the rule in the two ways discussed above. Either the list of consignees could be published *en toto* when finally compiled or it could be published in an incomplete form when the first information becomes available to FSIS, and subsequently supplemented. Either approach is inconsistent with the DQA. In the first scenario, publishing the complete list would not be timely. As FSIS officials admitted at the public meeting, it can and likely will take weeks in most recalls for the agency to compile the list.[18] No colorable argument can be put forth by FSIS contending that, in the case of recalls involving the public health, publication of the list weeks after the recall has been initiated by the relevant company would be timely has utility.[19]

On the other hand, the agency could follow an approach suggested at the public meeting, *i.e.*, that the list will be published with information gathered relatively soon after the recall is initiated and then supplemented as the agency conducts its effectiveness checks. In that circumstance FSIS officials acknowledged that the information initially posted and even supplemented thereafter likely will be incomplete, and again in violation of the DQA.[20] Following either approach, the agency cannot overcome the requirements imposed by the DQA with respect to this ill-conceived proposal.

The Proposal Would Result in More, not Less, Product Being Returned.

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[17] 44. U.S.C. 3504(d)(1) and 3516; Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000)

[18] See Transcript at 20, 25.

[19] See USDA Quality of Information Guidelines "Use reasonably reliable and reasonably timely data and information (e.g., collected data such as from surveys, compiled information, and/or expert opinion). http://www.ocio.usda.gov/qi_guide/regulatory.html. (Visited June 6, 2006).

[20] See Transcript at 20, 25.

Contrary to the preamble's assertion, publishing the list of retail consignees will almost certainly increase the likelihood that many products beyond the scope of the recall will be returned to retail establishments. The very mention of the retail venue stands to trump the product codes and will result in mass concern -- and mass return, particularly in light of the almost certain delay in time between the publication of the press release and the compilation of the complete retail consignee list.

Imagine, for example, a federal agency announcing a tire recall with the statement "Super Tough Radial Tires, code 555-XYZ sold at Sears, Midas and Costco stores are being recalled." Or imagine FDA recalling Acme Aspirin Tablets ABC-999 sold at CVS, Walgreens, and Rite Aid Drug Stores. The mention of the retail venue stands to trump the product codes and will result in mass concern -- and mass return.

When recalls become larger and needlessly involve consumers who do not own recalled product, consumers may become immune to recalls and tune out important information. Common sense says that information that can affect health should be specific, relevant, and meaningful, yet the agency is proposing a program that could shift consumer focus to less-specific considerations. This approach likely would result in circumstances in which consumers return a product to a store when the product has NOT been recalled.

Moreover, as with other elements in the proposal, the agency's conclusion is flawed in that it provides no rationale or information to explain how publishing retail consignee information will help make clear "that other, similar products are not being recalled," because the retail consignee list has nothing to do with the product, except where it was sold. Certainly, virtually all retailers will sell numerous meat and poultry products such that the retail name will not serve in any way to differentiate products, as asserted in the proposed rule. In short, to justify the proposed change, FSIS needs to provide a rational explanation supporting its conclusion rather simply making the self-serving conclusion that such a publication would help in product identification and recall efficacy.

<u>No Federal Agency with Recall Authority Publishes Retail Information of the Nature Proposed.</u>

Finally, the agency seeks to break new ground with this proposal in that, although a number of other federal agencies either have mandatory recall authority or are involved in recalls of products, none of them follow the process suggested in the proposal. For example, the Consumer Product Safety Commission (CPSC), which has mandatory recall authority in at least some circumstances, does not list each retail entity that sold a product subject to recall.[21] Nor does the Food and Drug Administration, the other federal agency with jurisdiction over food products.[22] Indeed, none of the federal agencies involved in recalls, including CPSC, FDA, the Environmental Protection Agency, the National Highway Traffic Safety Administration, and the United States Coast Guard provide the type of retail consignee information that FSIS proposes to publish.

That all other agencies with an active role in the recall of defective products from the marketplace do not engage in the behavior proposed suggests that the publishing of retail consignees is a bad idea, because it is against the law, because it will harm consumers by providing inaccurate or incomplete information, or because it will adversely affect the efficacy of recalls, or for all three reasons. FSIS should not seek to lead the way in promoting suspect or bad public policy.

For the foregoing reasons this proposal should be withdrawn. AMI appreciates the opportunity to submit these comments and would be happy to

[21] See http://www.cpsc.gov/cpscpub/prerel/prerel.html

[22] See http://www.fda.gov/opacom/7alerts.html and see www.fda.gov/opacom/Enforce.html (Visited June 6, 2006).

June 9, 2006

work with FSIS to find ways that will improve the efficacy of recalls involving meat and poultry products.

Respectfully Submitted,

Mark Dopp
Senior Vice President & General Counsel
American Meat Institute

cc: J. Patrick Boyle
Skip Seward
Lynn Morrissette
Jim Hodges
Susan Backus

NGA

National Grocers Association

June 9, 2006

04-006P-22
04-006P
Thomas Wenning
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Food Safety and Inspection Service
300 12th Street SW
Room 102 Cotton Annex
1400 Independence Avenue, SW
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RE: Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Docket No. 04-006P

Dear Sir or Madam:

The National Grocers Association (N.G.A.) welcomes this opportunity to comment on the Proposed Rule issued by the Food Safety and Inspection Service (FSIS or the Agency) to amend the federal meat and poultry products inspection regulations to provide that the Agency will make available to the public lists of the retail consignees of meat and poultry products that have been voluntarily recalled by a federally inspected meat or poultry products establishment if product has been distributed at the retail level. 71 Fed. Reg. 11326 (March 7, 2006) (the "Proposed Rule"). N.G.A. appreciates the openness of FSIS in holding a public meeting on April 24, 2006 to discuss the Proposed Rule (the "Public Meeting").

N.G.A. is the national trade association that represents exclusively the interests of independent community-focused grocery retailers and wholesalers. An independent, community-focused retailer is a privately owned or controlled food retail company operating in a variety of formats. Most independent operators are serviced by wholesale distributors, while others may be partially or fully self-distributing. A few are publicly traded, but with controlling shares held by the family and others are employee owned. Independents are the true entrepreneurs of the grocery industry and dedicated to their customers, associates, and communities. N.G.A. members include retail and wholesale

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grocers and their state associations, as well as manufacturers and service suppliers. N.G.A. retail and wholesale members accounted for $200 billion of U.S. grocery sales last year.

N.G.A. believes that nothing could be more important than the health and safety of consumers. N.G.A. is committed to working with FSIS to create the most effective recall procedures possible. Timely and accurate FSIS communications with consumers in the event of product recalls are critical. FSIS states it is proposing this action because it believes that the efficiency of recalls will be improved if there is more information available as to where products that have been recalled were sold. By providing consumers more information about the locations where recalled products have been sold, FSIS believes that consumers will be more likely to identify and return such products to those locations or to dispose of them.

N.G.A. does not believe that the Proposed Rule in making public the lists of retail consignees with recalled meat and poultry will improve the efficiency of the current recall procedures. Rather, we believe the Proposed Rule will inhibit the efficiency of the current recall procedures. In 2002 the Agency considered making such information public but ultimately decided it would not enhance the efficiency as discussed further in these comments. For this reason and others, we urge FSIS reconsider implementing this rule.

N.G.A. has five major concerns with the Proposed Rule:

1. The Proposed Rule will inhibit the efficiency of current recall procedures.

2. FSIS has not sufficiently justified its authority to make available to the public lists the Agency has compiled during recalls of the retail consignees of meat and poultry products subject to recall.

3. FSIS has failed to show that the Proposed Rule will not have a significant economic impact on small entities as is required by the Regulatory Flexibility Act. An Initial Regulatory Flexibility Analysis should be completed.

4. The distribution of this information to the public is not necessary for the proper performance of the functions of the Agency and as such OMB should deny approval of the Proposed Rule under the Paperwork Reduction Act.

5. The distribution of this information contradicts the principals articulated in USDA's Quality of Information guidelines pursuant to the Information Quality Act.

1. The Proposed Rule will inhibit the efficiency of current recall procedures.

Current FSIS recall procedures work and provide consumers with an optimal level of information. Through its press releases and Recall Notification Reports, FSIS provides the public with information about meat and poultry recalls. This information includes: A description of the food being recalled, any identifying codes, the reason for the recall, the name of the producing establishment, the level of product distribution (e.g., wholesale; retail) to which the recall is to extend, and the appropriate contact persons for FSIS and the recalling company. FSIS also lists those states to which recalled product was shipped if fewer than 13 states were involved in the recall. If the recall extends to more than 13 states, it is considered to be a nationwide recall. In addition, FSIS sends recall information to several media and constituent list-servers. As stated in the Proposed Rule, "the current process is effective . . . ." Id. at 11327. The recall information provided to consumers is optimal because it encourages consumers to check the product itself. It gives consumers the information required to identify the product and determine if it is subject to recall. Recall procedures should encourage consumers to check the product itself and not provide additional unnecessary—or inaccurate—information. The information the Agency is proposing to distribute will be extraneous, untimely and inaccurate.

In establishing an optimal recall procedure, the Agency must create a procedure that encourages consumers to check the lot number or code on the package to the greatest extent possible. If the lists of retail consignees of recalled product are published consumers are likely to focus on the retail name moreso than the identifying codes. Consequently, much more product may be returned to stores than was actually recalled. It is important to consider this fact when evaluating the efficiency of recall procedures.

The Proposed Rule states:

> FSIS has concluded that making information identifying the retail consignees available to the public will improve the efficiency of recalls by helping consumers to identify and focus on the products that are recalled. In addition, making this retail consignee information available will, we believe, help make clear that other, similar products are not being recalled, and that there is no such reason to be concerned about such similar products. The Agency's experience with recalls over time has shown that in many recalls, much more product is returned than has actually been recalled. Often products are returned that were not produced by the recalling company or that were produced at different times or locations than the recalled product. Id.

N.G.A. disagrees. Rather than reducing returns of non-recalled product, providing consumers with the lists of potential retail locations will lead to more returns of product that has not been recalled—exactly the result FSIS is intending to avoid. Greater levels of return of non-recalled product will increase costs for grocers in terms of both consuming staff time and acceptance of non-recalled product. FSIS has provided no data in support of its conclusion that making such information public will improve recall efficiency.

Under the current system, when a recall is initiated the recalling firm notifies its consignees and FSIS. When wholesalers or self-distributing retailers receive the notice, they promptly send it out to all possible retail locations where the product could have been distributed which invariably includes more retail outlets than have actually received the recalled product. Upon receiving the notice at the individual store level, employees will check the shelves to see if the product is displayed, and remove it accordingly. FSIS concurrently conducts effectiveness checks to verify that the recall action is being conducted in an effective manner and provides the public with the information necessary to identify the product. As stated in the Proposed Rule, "the current process is effective . . . ." Id. N.G.A. believes the current process works and that implementing the Proposed Rule will reduce efficiency.

The Proposed Procedures Will Hamper Efficiency

For the below listed reasons, making available to the public lists of the retail consignees of meat and poultry products that have been voluntarily recalled will hamper recall efficiency:

A. Inaccuracy

The grocery distribution system operates in such a way that N.G.A. believes the information FSIS is proposing to distribute to the public will be of little use as it will not accurately reflect individual retail locations which have received recalled product. FSIS requests from firms conducting recalls that they provide the Agency with a list of consignees to whom the recalled products were distributed. FSIS also obtains lists from the consignees of all entities to which they distributed the product. N.G.A. does not believe FSIS will be able to accurately pinpoint individual retail outlets which received recalled product based on this information. The lists most certainly will be incomplete as FSIS does not conduct verification activities for all potential retail consignees in larger recalls—nor does it possess the capabilities to do so. FSIS's current effectiveness check procedures are based on statistical sampling. According to the FSIS Directive 8080.1, Revision 4 (May 24, 2004), statistical sampling is done to verify effectiveness. In the case of larger Class I recalls involving an illness or outbreak (the most serious category) only a very small proportion of consignees are checked. For recalls involving 35,001 to 500,000 retail consignees, only 800

effectiveness checks are made. For recalls involving 500,001 retail consignees or more, only 1,250 checks are conducted—less than 0.2%.

During the Public Meeting, Assistant Administrator of the Office of Policy, Program and Employee Development of FSIS, Philip Derfler posed the question, "Does the possibility of incomplete lists undercut the usefulness of the list?" Transcript at 26.

N.G.A. believes the answer to this question is yes. We are concerned that consumers will get the impression that recalled product was not carried at a retail outlet if the store was not included on the list and consequently not concern themselves with checking the information on the product itself—something the current procedures encourage them to do. Under current procedures, USDA lists the states in which the recalled product was shipped if fewer than 13 states were involved—otherwise the recall is considered national. This the optimal level of distribution information to be given to the public as it can be disseminated with reasonable degree of certainty and encourages consumers to check the product package itself.

Giving consumers inaccurate or overly general information will almost certainly increase the likelihood that many more products beyond those being recalled will be returned to the retail establishment. Consumers will focus on the retail venue rather than the product codes and this will result in needless mass return. A comment made during the Public Meeting, by Patricia Buck of Safe Tables Our Priorities (STOP) supports this contention: "The current system baffles consumers with long lists of case/lot numbers to which they do not have easy access and creates an unnecessary barrier." Transcript at 33. This statement implies consumers would simply focus on the retail establishment without checking the product itself. Finding a lot number is a simple as examining the product itself—the most important step for consumers to take to determine if they possess recalled product. Additionally consumers may not distinguish between different retail locations sharing the same banner and may assume all stores with the same banner received recalled product.

The current recall FSIS recall procedures provide consumers with precisely the information they need to accurately identify the product itself and ascertain if it is subject to recall.

B. Untimeliness

It will likely take FSIS a substantial amount of time to trace product to particular retail locations. In the latest FSIS directive, the recommended timeframe for reporting verification activities for Class I recalls is within 13 days following the initiation of a recall. FSIS Directive 8080.1, Revision 4. As stated previously, FSIS will not likely be able to ascertain with any degree of precision which particular retail outlets are carrying recalled product. By the time the

information is made public—expected to be several weeks from the initiation of the recall—most product will be off of the shelf. As the lists of retail consignees of recalled product are not likely to be compiled in a timely fashion, the information will be of little use to consumers.

As Mr. Derfler stated in during the Public Meeting, in the Proposed Rule, "FSIS proposed to make publicly available on its website, the list of names and locations of the retail consignees of the recalled meat or poultry products that the Agency's EIAOs compile in the trace forwards that they conduct." Transcript at 23. He also stated that "The process of tracing the product forward to retail is, as I've said, very time consuming, often taking weeks to complete." Transcript at 20.

Mr. Derfler continued: "FSIS is not committing to a particular time frame for posting consignee lists. Under the proposal, the Agency will post them as soon as they are compiled, which, as I stated, could be weeks after the recall is announced." Transcript at 25.

Releasing such information to the public weeks after the initiation of a recall will not improve the efficiency of current recall procedures.

C. Consumer Apathy and Accessibility Concerns

When recalls become larger and needlessly involve consumers who do not own recalled product, consumers may become apathetic to recalls and ignore notices. The information provided should be specific and relevant and limited to that which identifies the product—without needlessly confusing consumers. If consumers attempt to return product that was not recalled, they may become discouraged and no longer heed recall notices.

Additionally USDA should consider that many Americans do not have access to the Internet or are not sufficiently computer literate to navigate federal government websites. Patricia Buck emphasized this point during the public meeting: "expecting consumers or journalists to go to the FSIS website to find the list of retail providers associated with the recall is not user friendly . . . the majority of consumers either do not own a computer or they are not familiar with finding specific information on the Internet." Transcript at 34-35.

The means by which FSIS is proposing to distribute the information will not be accessible to all consumers. As the information FSIS is proposing to distribute will likely lead consumers to return product that is not being recalled, they may become apathetic to recall notices.

2. FSIS has not sufficiently justified its authority to make available to the public lists the Agency has compiled during recalls of the retail consignees of meat and poultry products subject to recall.

FSIS states in the Proposed Rule that "it has authority to make available lists the Agency has compiled during recalls of the retail consignees of meat and poultry products that have been recalled." 71 Fed. Reg. 11326. The proposal, however, provides no rationale for its conclusion regarding such authority, nor how publishing such lists will enhance recall efficiency.

Indeed, the agency's assertion is a clear deviation from the longstanding and relatively recently affirmed agency position that such information is confidential commercial information, as defined by the Freedom of Information Act (5 U.S.C. § 552), and is exempt from disclosure under that Act: "distribution lists . . . are protected from mandatory public disclosure by exemption 4 of the FOIA." 67 Fed. Reg. 20010 (April 24, 2002). Furthermore, as FSIS stated in 2002, making public such information would hamper recall effectiveness.

> Distribution information is confidential commercial information that is valuable to a firm and to its competitors. FSIS recognized that if it made the information regularly available to the public, firms would be unwilling to voluntarily share this information with the Agency. The Agency's ability to verify that recalls were proceeding effectively would be significantly hampered as a result, and the public health would consequently suffer. Id.

The retail name will not serve in any way to differentiate products, as asserted in the Proposed Rule. The current FSIS recall procedures provide consumers with precisely the information they need to accurately identify the product itself and ascertain if it is subject to recall. In order to justify the Agency's change in the position that distributions lists are confidential commercial information, FSIS needs to provide a rational explanation supporting its conclusion rather than stating an unsupported assertion that such a publication would help in product identification and recall efficiency.

3. FSIS has failed to show that the Proposed Rule will not have a significant economic impact on small entities as is required by the Regulatory Flexibility Act. An Initial Regulatory Flexibility Analysis should be completed.

N.G.A. has a substantial number of small business members that would face a significant economic impact by the Proposed Rule—in terms of accepting non-recalled product returns and increased time spent by employees in dealing with unnecessarily returned product. Many N.G.A. members meet the criterion for small business size standards set by the U.S. Small Business Administration

which is currently $25 million in average annual receipts. In fact, there are over 34,600 supermarkets in the U.S. that fit this criterion. Thus, N.G.A. believes that an Initial Regulatory Flexibility Analysis (IRFA) is required.

The Proposed Rule states:

> If consumers use such information and are better able to identify and return recalled meat and poultry products to the stores where they purchased them, the recall process will be more timely and effective. Although the benefits of the proposed action are not quantified, it is reasonable to conclude that they are equal to or exceed the costs of the rule, because costs are expected to be minimal . . . The Agency has concluded that the rule will not have a significant economic impact on a substantial number of small entities. Consequently an initial regulatory flexibility analysis is not required. 71 Fed. Reg. 11327, 11328.

This conclusion is not reasonable. The information FSIS is proposing to distribute to the public will inhibit recall efficiency as it will provide consumers with extraneous, inaccurate and irrelevant information which would lead to more non-recalled product being returned than under existing recall guidelines. Retailers generally accept products customers wish to return in good faith, even if they are not subject to recall.

Furthermore, the Regulatory Flexibility Act requires that any agency certification of no impact be accompanied with a statement providing the factual basis for such certification. 5 U.S.C. § 605(b). FSIS has failed to provide an adequate factual basis for its conclusion that the rule will have no significant impact on a substantial number of small entities.

The Office of Advocacy at the U.S. Small Business Department has also contacted FSIS and suggested that the Agency should consider completing an IRFA. N.G.A. agrees.

4. The distribution of this information to the public is not necessary for the proper performance of the functions of the Agency and as such OMB should deny approval of the Proposed Rule under the Paperwork Reduction Act.

The distribution of the lists of retail consignees of recalled meat and poultry constitutes "collection of information" under the Paperwork Reduction Act ("PRA"). "Collection of information" is defined as "requiring disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for . . . (i) . . . identical reporting or recordkeeping requirements imposed on, ten or more persons . . . " 44 U.S.C. § 3502.

Under 44 U.S.C. § 3508:

> Before approving a proposed collection of information, the Director [of the Office of Management and Budget] shall determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility . . . . To the extent, if any, that the Director determines that the collection of information by an agency is unnecessary for any reason, the agency may not engage in the collection of information.

The collection of this information is unnecessary—and as such, the Director of OMB should deny FSIS's request to collect it. This information is not necessary for the proper performance of the functions of the Agency—the current recall procedures provide an optimal level of information to the consumer. It does not have practical utility. As stated earlier it will hamper recall efficiency by providing a discrete group of consumers with inaccurate, untimely and extraneous information, therefore, OMB should deny approval of FSIS's request to collect information.

5. N.G.A. believes the distribution is noncompliant with USDA's Quality of Information Guidelines pursuant to the Information Quality Act

The Information Quality Act ("IQA") (44 U.S.C. 3504(d)(1) and 3516) requires that federal agencies (a) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by the agency and (b) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a).

Under the quality of information guidelines USDA is to follow in developing and reviewing regulatory information and disseminating it to the public, the agency will:

"Use reasonably reliable and reasonably timely data and information." http://www.ocio.usda.gov/qi_guide/regulatory.html (visited May 4, 2006).

For the reasons listed under section 1 of these comments, the information will not be reasonably reliable or timely.

N.G.A. also has concerns that USDA's administrative mechanisms allowing for correction of information under the IQA will not permit retailers to correct information in a timely enough manner as to mitigate economic damage suffered from inaccurate data distributed to the public. Under USDA's IQA guidelines, a

request for correction of information will be responded to "normally within 60 calendar days of receipt." http://www.ocio.usda.gov/qi_guide/corrections.html (visited May 4, 2006). If FSIS makes a mistake by identifying the wrong retail outlets that have received recalled product, the retailers impacted by the mistake should have an opportunity to correct it as soon as possible.

Conclusion

N.G.A. and its members believe that nothing could be more important than the health and safety of consumers and we are committed to working with FSIS to create the most effective recall procedures possible. N.G.A. appreciates this opportunity to comment on the Proposed Rule. Current recall procedures work and provide consumers with an optimal level of information—precisely the information they need to accurately identify the product itself and ascertain if it is subject to recall. The Proposed Rule will inhibit rather than improve the efficiency of current recall procedures by providing consumers with inaccurate, untimely and extraneous information. FSIS should justify its authority to implement the Proposed Rule as it marks a clear deviation from the Agency's longstanding position. An IRFA should be conducted for the Proposed Rule as it will have a significant impact on a substantial number of small entities. As the Proposed Rule hampers, rather than helps recall efficiency OMB should deny the Agency's request to distribute this information under the PRA since it is not necessary for the proper performance of the functions of the Agency. The Proposed Rule also contravenes USDA's quality of information guidelines. N.G.A. urges FSIS to reconsider implementing the Proposed Rule.

Sincerely,

Thomas F. Wenning
Senior Vice President and General Counsel

Erik R. Lieberman
Director of Governmental Affairs

S.T.O.P. – Safe Tables Our Priority
Working Together To Make Safe Food A Reality

June 8, 2006

04-006P-23
04-006P
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Docket Clerk
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Re: Docket Number FSIS-2005-0028
Availability of Lists of Retail Consignees During Meat and Poultry Product Recalls

S.T.O.P.—Safe Tables Our Priority appreciates this opportunity to comment on the above notice. S.T.O.P. is a national, not-for-profit, volunteer health organization dedicated to preventing suffering, illness and death due to foodborne illness by advocating sound public policy, increasing awareness and education, and providing victim assistance. S.T.O.P. was founded in 1993 in the aftermath of the Jack-In-The-Box *E. coli* O157:H7 epidemic from ground beef in California and the Pacific Northwest.

Background

While the newest foodborne disease surveillance data is encouraging, foodborne illness continues to be a serious public health issue, and with deadly new strains of pathogens emerging, it is imperative that FSIS take a more proactive role in protecting public health. According to Centers for Disease Control and Prevention (CDC) estimates, each year 76 million people in the United States suffer a foodborne illness; 350,000 are hospitalized and 5,000 die. While everyone is at risk, the most vulnerable populations to develop serious complications due to foodborne illness are children, seniors, pregnant and postpartum women and individuals with a compromised immune system. Furthermore, the cost of foodborne illness is very high. According to USDA's Economic Research Service (ERS)[1], "Foodborne illnesses account for about 1 of every 100 U.S. hospitalizations and 1 of every 500 U.S. deaths." In fact, the ERS estimates that, each year in the United States, five foodborne illnesses – *Camploybacter, Salmonella, E. coli* O157:H7, *Listeria monocytogenes* and *Toxoplasma gondii* - cause $6.9 billion in medical costs, lost productivity and premature deaths[2]. These estimates do not include many other foodborne illnesses, such as, Norwalk virus - the leading cause of foodborne disease in the United States - botulism, shigella, foodborne staph, and parasites. Nor does it reflect any of the hidden costs that victims and their families suffer: the cost of traveling to receive medical care, time lost from work caring for sick children, lost leisure time, and pain and suffering.

Further, the acute stage of foodborne disease can be only the start of the problem. The Food and Drug Administration (FDA) estimates 2 to 3 percent of foodborne illness victims develop

[1] Buzby, Frezen, and Rasco. Food and Rural Economics Division, Economic Research Service, USDA. Agricultural Economic Report No. 799: *Product Liability and Microbial Foodborne Illness.*
[2] Buzby. Food and Rural Economics Division, Economic Research Service, USDA. *Children and Microbial Foodborne Illness.* Food Review, Vol 24, Issue 2.

secondary long-term medical problems[3] – that is an estimated 1.5 million lingering health problems per year. *Salmonella* is one of the leading predictors for reactive arthritis, a painful, chronic and potentially debilitating condition that causes joint inflammation. *Camplyobacter* is believed to be a leading cause of Guillian-Barre Syndrome, an autoimmune reaction that causes paralysis and kills between five and ten percent of its victims. *E. coli* O157:H7 and other foodborne diseases are almost the exclusive cause of HUS, the relentless condition characterized by cascading organ failure. HUS can cause its victims, most of them young children, to have seizures, strokes and heart attacks and many HUS patients require spleenectomies, chemotherapy, repeated blood transfusions, and even intestinal reconstruction. One-third of HUS survivors will suffer life-long medical problems such as high blood pressure, diabetes, kidney failure and brain damage. In fact, HUS caused by *E. coli* O157:H7 is the leading cause of acute kidney failure in children in the United States.

Proposed Change to Recall Notification Procedures

S.T.O.P. strongly supports FSIS's proposal to publicly identify retail establishments that have received meat and poultry products that have voluntarily been recalled by a federally inspected meat or poultry establishment. For the past 13 years, S.T.O.P. has maintained that supplying the public with more specific information regarding the distribution of recalled meat and poultry products would help consumers identify and avoid consuming potentially harmful products. We commend the agency for protecting public health by taking action to provide this information.

Consumers want and need more information in order to make informed decisions about the food that they consume or serve to their families. The current recall system baffles consumers with long lists of "case/lot numbers," *to which they do not have easy access*, and creates difficulty in identifying which meat and poultry products may be of concern. While current recall announcements usually identify the states that may have received recalled product, consumers may assume that, since local retailers were not identified, the recalled product was not distributed in their local area but elsewhere in the state. Publicly providing the names of retailers implicated in a recall would let consumers readily know if they had shopped at an establishment that had received contaminated product and whether or not they needed to be concerned and check the products in their freezer or refrigerator.

Further, if an individual suffering foodborne illness symptoms knew they had shopped at a retail establishment of concern, they might more readily seek prompt medical attention. Likewise, public health and medical officials might more readily identify a foodborne illness case and its associated pathogen if they knew a patient had shopped at an establishment that had received recalled product.

While supportive of the proposal, S.T.O.P. urges the agency to strengthen the proposed rule by including the following policies:

1. **FSIS should expand the definition of "retail consignees" to include "user" level establishments such as hotels, restaurants and other food service institutional providers.**

   S.T.O.P. recognizes that the recall procedure must follow specific guidelines to maintain orderliness and to minimize the economic impact for establishments that are not involved in the recall. On the other hand, S.T.O.P. is very concerned that consumers are currently not receiving the information that they need to avoid consuming recalled and potentially harmful products.

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[3] Frezen. Economic Research Service, USDA. *The Economics of Food, Farming, National Resources and Rural America,* www.ers.usda.gov

Currently, FSIS is proposing to limit the list of consignees to the retail level as defined in Directive 8080.1, which does not include hotels, restaurants and institutional food service providers. This leaves out a vast number of establishments that consumers frequent and can easily identify. Furthermore, there have been numerous foodborne illness outbreaks associated with these type of establishments, which demonstrates the necessity of including this group of establishments to be identified in the event of a recall.

Exempting "user" level food service providers from the definition of "retail consignees" ignores the fact that a huge portion of Americans eat in restaurants, hotels and other institutional food service settings on a regular basis. Furthermore, expecting consumers to purposefully ask individual retail food service providers if any of their products were part of a meat or poultry recall is unrealistic and assumes that all retail food service employees will have timely access to this information. S.T.O.P. urges FSIS to extend the scope of its proposed recall directive to include the "user" level because S.T.O.P. believes that the Agency should issue its recall information to the level where people buy the food that they consume.

2. **In addition to posting the list of retail and user consignees on USDA's website, FSIS should also list them in all press releases pertaining to the recall.**

   Most consumers will learn of a recall through local media reports. Journalists frequently work on tight deadlines, necessitating them to work with information that is readily available. It is, thereby, imperative that FSIS provide the names of the retail and user consignees in their press releases so that journalists can include them in their reports to the public. Since local media outlets would readily report information regarding local retail establishments that are implicated in a recall, it is far more likely that consumers will learn of the recall if FSIS makes the effort to include the list of retail consignees in all of its press statements.

   Putting the onus on consumers or journalists to go to FSIS' website in order to find the list of retail outlets associated with a recall is burdensome and contrary to the goal of providing important public health information in the most expeditious manner. The majority of consumers either do not own a computer or they are not familiar with finding specific information on the internet. Very few consumers would be able to readily find the recall information; some consumers would not even know to look on USDA's website to see if their local store or food service provider received contaminated product. By identifying retail and user consignees of meat and poultry products involved in a recall only via FSIS' website and not within the press release itself, the Agency is unintentionally depriving millions of consumers from receiving information that could deeply impact on their health and their lives. S.T.O.P. strongly urges FSIS to use multiple press releases in its effort to keep the public informed of the details of a recall.

On May 22, 2006, FSIS held a public meeting in Washington, DC to obtain feedback on this proposed change in recall notification procedures. In addition to the points above, several questions/concerns were raised during the meeting that S.T.O.P. would like to address.

1. **Should the Agency be concerned that the lists of retail consignees will not be timely and/or complete?**

   FSIS should seek to provide a complete list of retail consignees involved in a recall in as timely a manner as possible. Any delay in notifying the public of this important

information will increase the risk of foodborne illness. Since distribution lists are currently considered proprietary information, the Agency must develop its own list by conducting an intensive product tracing procedure, which could be avoided if food producers were willing to disclose their distribution lists. Currently, distribution lists, which companies are required by law to maintain, cannot be used to protect public health.

FSIS should make an effort to inform consumers that the recall lists will be incomplete for some time as the Agency conducts their product trace-forward. The Agency might want to consider supplying a projected completion date for retail lists associated with a particular recall. Further, the Agency should provide an explanation for the delay, so that consumers will better understand why these lists are not complete in a timely manner and why it is important for consumers to check product codes, even if their local retailers are not listed as having received recalled product.

S.T.O.P. commends the Agency for taking this step in protecting public health. Ideally, complete lists of retail providers would be made available to the public in a timely and efficient manner; however, some information is better than no information. The Agency should consider providing an incentive for establishments to voluntarily provide FSIS with its distribution lists, so that the Agency would not have to expend its valuable and limited resources developing its own distribution record for a particular recalled product. One such incentive could be for FSIS to state in public notices that the establishment offered timely and complete distribution information to the Agency in an effort to protect public health. FSIS should also keep an accurate accounting of the resources the Agency has expended on developing the distribution list for each recall, along with the amount of product that was retrieved. By doing this, stakeholders will be able to assess the effectiveness of current recall procedures and have an estimate of the cost of implementing a recall, both to taxpayers and the food producers/providers.

S.T.O.P. hopes that, as this recall directive is implemented and consumers become more aware of recall procedures, the Agency and industry will work together to provide this important public health information in a more timely and efficient manner.

2. **Should the Agency continue to post pictures of recall product?**

When possible, FSIS should continue to provide pictures of recalled product and post these pictures along with their public notices so that consumers can better understand which product is being recalled. In addition, FSIS should encourage retail and user level establishments to post a visual display of the recalled product in a prominent area. Visual displays of recalled products will provide yet another mechanism that will help consumers identify and avoid consuming potentially harmful products.

3. **How can the Agency improve product tracing?**

S.T.O.P. has long advocated for the implementation of an effective product tracing system that will enable a timely product trace-forward as well as a timely product trace-backward. Americans want clean, wholesome food that is traceable to its source and accountable for its safety. All governmental food inspection programs are financed by the public's taxes for their protection. Taxpayers expect swift and sure action on the part of governmental agencies to remove defective products from commerce whenever it is identified. When the prevention system fails and food that

carries deadly pathogens enters commerce, it is critical to quickly trace that defective product. Information and accountability are essential to a successful system of food safety.

Many food products, particularly meat and poultry as well as fresh seafood and produce, are not labeled to identify the producers or processors of the product. "Anonymous" food interferes with effective trace forward in recalls and trace back in cases of foodborne illnesses and outbreaks. *All food products should be labeled with a brand name, farm of origin, and subsequent processing information.* This type of labeling would facilitate more accurate and effective recalls and would improve product recovery. In addition, food producers would benefit in the long run. When recalled food cannot be easily identified, a whole class of foods can be implicated. Clear product identification would limit the negative consequences of a recall to those establishments that are identified as responsible for allowing contaminated food to enter the marketplace.

Product tracing for food products is eminently reasonable and doable. Indeed, it is being done already in other jurisdictions. For example, the UK has adopted a nation-wide bovine tracking system. Closer to home, a Colorado-based meat company has implemented a bar code system that tracks food products from the individual animal to the final product. FDA requires origin labels on mulluscan shellfish to identify the harvester, date of harvest, and location of harvest.

Stronger accountability increases the likelihood that establishments will take precautions to avoid recalls. The irresponsible advantage that food producers have enjoyed to skirt this accountability must be eliminated. There is nothing "proprietary" about safely slaughtering animals, harvesting crops or packaging and distributing raw and/or fresh food products. Accountability is a goal that Americans demand on many levels and in many areas. Food producers should not be excluded from this aspect of market scrutiny.

Conclusion

S.T.O.P. believes that FSIS is initiating this change in recall notification to increase consumer awareness about recalled products with the goal to prevent suffering, illness and death due to foodborne illness. Market forces are an important incentive in building a better food safety network. Unfortunately, under the current system, those forces cannot work because consumers are not adequately informed about the distribution of recalled products. This new recall directive would provide that information and enable consumers to make informed food purchasing decisions for themselves and their loved ones. By posting the food retail establishments associated with a recall, the retail establishments involved will feel economic pressure to change their production or purchasing practices. As a result, this directive will provide a strong incentive to food producers and providers to maintain and improve the quality and safety of their products. Ultimately, this directive will negatively impact only those food producers and providers that fail to produce a safe, wholesome product.

FSIS' mandate as a public health agency includes the responsibility for ensuring the safety of the United States commercial supply of meat, poultry and egg products. S.T.O.P. believes FSIS' proposed changes to its recall notification process will further this mission by providing consumers with vital information that they can use to protect themselves and their loved ones by helping them avoid potentially contaminated meat and poultry products. S.T.O.P., therefore, strongly supports the proposed rule. However, as noted above, we believe public health could be further protected by fully identifying all retail establishments that might have received

contaminated product, and by publishing the names of those establishments in USDA's recall press releases. Thank you again for the opportunity to provide comments.

Respectfully submitted,

Barbara Kowalcyk
President, Safe Tables Our Priority

Nancy Donley
Immediate Past President, Safe Tables Our Priority

Patricia Buck
Volunteer, Safe Tables Our Priority

04-006P-24
04-006P
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June 12, 2006
Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW.
Room 102 Cotton Annex
Washington, DC 20250

[Docket No. 04-006P] Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls; March 7, 2006; 71 *FR* 11326

Dear Sir or Madam:

The Food Products Association (FPA) is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

FPA appreciates the opportunity to comment on this proposed rulemaking that the Agency believes will improve efficiency of recalls and reduce the amount of non-implicated product that is typically returned during recalls. FPA supports effective policies and procedures that enable consumers to promptly identify and return, rather than consume, potentially hazardous product in their possession. Unfortunately, for a variety of reasons discussed herein, we do not believe the proposed regulation will improve the efficiency of product recalls. In fact, we are concerned that in some cases the posting of untimely or incomplete information could have quite the opposite effect by giving consumers a false impression that a product was not sold by their grocery store, when it actually was.

Highlights of FPA Comments

- FPA supports effective policies and procedures that provide timely information to the public that enables consumers to promptly identify and return or destroy implicated product in their possession.
- However, for a number of very important reasons, this proposal to post the name and location of retail consignees seems to be inadequately considered and highly unlikely to achieve its stated objectives.
- FSIS acknowledges that current recall procedures are effective. We concur, since in virtually all cases, all the information needed by consumers to identify and to properly dispose of recalled product in their possession is contained in the widely disseminated FSIS press release that announces a recall to the public and is posted on the FSIS website.
- Regardless of where inspected meat or poultry products might have been purchased, if a consumer has a product of the specified container size that bears the particular brand name, establishment number and production or lot code specified in an FSIS press release, he or she will know that this is the product being recalled and will be able to take appropriate actions immediately.
- Key problems with the proposal include the fact that the information on retail stores will not be timely and the lists will frequently include numerous consignees that did not receive the product being recalled.
- The proposal's most severe flaw is that an untimely or incomplete consignee list would be worse than no list at all if it causes or contributes to a consumer's failure to identify potentially hazardous product in his or her possession.
- Included in our comments are two alternatives to the FSIS proposal that we believe are worthy of consideration as enhancements to an already effective recall system. Neither would require a change in the current FSIS recall regulations.

Detailed FPA Comments

The Agency claims that posting the name and location of retail consignees will improve the efficiency of recalls by making consumers more likely to identify and return or dispose of meat and poultry products being recalled by an FSIS-inspected establishment. However, this proposal seems inadequately considered and the Agency provides little or no rationale for its beliefs.

When there is a need to recall potentially hazardous product from the marketplace, it is critical to provide consumers with timely information they need to identify any implicated product in their possession so that it will not be consumed. FPA supports effective policies and procedures that help accomplish this important goal. Unfortunately, the FSIS proposal would not enhance consumers' ability to identify and return recalled product in most instances. While it may seem intuitive that making more information available to consumers would be better, closer review of how this proposal would work strongly suggests otherwise.

Information consumers need to identify recalled product

FSIS acknowledges in the preamble to the proposal that current recall procedures are effective. We concur. In the vast majority of cases, all the information needed by consumers to identify and to properly dispose of recalled product in their possession is contained in the FSIS press release posted on the FSIS website at the start of a recall. This information (typically including the product name, container size, establishment number, and manufacturer's code) is available when a recall is announced and is very widely distributed on radio, TV and in the newspapers, as well as on the FSIS website, where photos of recalled product labels are being included more and more frequently. Regardless of where a consumer shops, no further information is required to readily identify potentially hazardous product in his or her possession.

If knowledge that FSIS will post a list of retail consignees on its website leads any consumer to wait until the list is posted before they check their pantry for products being recalled, this new Agency policy will send the wrong message to consumers and will be counterproductive. The message should continue to be for consumers to act promptly on the information provided in the initial press releases, not to wait for the posting of retail store information.

Lack of timeliness of retail consignee information

The consignee list to be posted would be compiled by FSIS staff from information provided to the Agency at the various steps in the distribution chain. Unfortunately in most cases, this information will not be timely. The Agency develops its list of consignees from information collected during verification activities associated with recall effectiveness checks. According to the current Agency document on Effectiveness Checks (Attachment 3 to FSIS Directive 8080.1, Revision 4, dated May 2, 2004), it is recommended that Agency personnel begin their verification activities within 3 working days of the initiation of a Class I recall. The document suggests that these verification activities "should be substantially completed" within 10 working days after that. At one point, we understood from communications with Agency personnel that the consignee lists would not be posted on the FSIS website until the lists were complete. Based on information provided at the recent public meeting, we realize this may no longer be the Agency intent. Nevertheless, using this FSIS document as our guide for a hypothetical Class I recall initiated, for example, on Friday, April 21, the recommendations would be satisfied if the verification activities were "substantially complete" by May 10. For a Class II recall, the satisfactory date for substantial completion would be May 17. Clearly, information posted weeks or even several days after a recall is initiated would not be timely. It is therefore of limited or no value relevant to prompt identification and disposition of potentially hazardous recalled product by consumers.

Incomplete or Inaccurate Lists and the Potential for Harm

For a variety of reasons, the posted consignee list is very likely to be incomplete or inaccurate at least on occasion. This could result from simple oversight resulting in a failure to include a specific store on an intermediary's distribution list. It could result from the inability of FSIS to visit and collect consignee information from all interim distributors in a massive recall situation. Other rarer, but equally real, circumstances by which stores selling product that is subsequently recalled would not appear on the FSIS consignee list include product purchased at a discount warehouse or club store for resale at a smaller retail outlet or product initially shipped to one store, but subsequently transferred to another store. This could also occur when product is routed through a salvage operation, a food bank, or as a result of product diversion.

In any event, a worst case scenario should this proposal be finalized is that a consumer who checks the incomplete or inaccurate retail consignee list posted on the Agency website could be misled into thinking a store omitted from the list in error did not carry the recalled product and therefore it would not be in his or her possession. The unfortunate result could be consumption of a potentially hazardous product and injury or illness for the consumer. The same result could occur if the family member that follows up on a recall announcement is unaware that another family member visited and purchased product now being recalled from a store that is on the list, because the family normally shops at a retail food store that does not appear on the list. In FPA's years of experience with recalls, consumers are frequently unable to recall the specific store where they purchased an individual product. This has never been more true than today with so many retail food outlets from which to choose and is yet another reason why posting consignee lists for product recalls could have unintended detrimental consequences.

It bears repeating that regardless of the accuracy of or the availability of a posted consignee list, in virtually all cases the press release provides consumers with the information they need to identify and dispose of recalled product regardless of its store of origin. When this information is available, the point of purchase is irrelevant!

Return of non-implicated product

The preamble to the proposed rule suggests that consumers armed with knowledge of the specific retail stores that sold recalled product would be less likely to return products not implicated in the recall. For a variety of reasons, we believe the proposal would actually lead to more non-implicated product being returned rather than less.

While the chance of omitting some stores from the posted consignee list is unacceptably high, the probability of including stores that did not receive the recalled product is even higher. This is because distributors generally track distribution by product, not by product code. Thus, in the absence of detailed knowledge about which consignees received the specific codes of product being recalled, distributors err on the side of caution and forward recall notices to any consignee that might have received the product. All such consignees are included on the distribution lists provided to FSIS during Agency effectiveness checks. In turn, the Agency proposes to compile

similar distribution lists from multiple sources into the consignee list to be posted. This means that, especially in larger scale recalls, many, perhaps very many, of the retail consignees posted on the FSIS website would not have actually received the product being recalled.

It seems likely that a consumer seeing his or her local store on the posted FSIS list will be more likely to return product not associated with the implicated code. Perceived knowledge that the recalled product was sold at their local grocery store is very likely to lead some consumers to ignore the product identification information provided in the press release and return different codes of the same product, similar products manufactured by other establishments, and even other totally different products in an industry segment. All these well documented and frequently occurring situations are more likely to be exacerbated than reduced should this proposal be finalized.

Disclaimer not a solution

At the public meeting on April 24, the following questions were posed by an Agency official:

- Does this possibility of incomplete lists undercut the usefulness of the list?
- Is there some type of disclaimer or other information that the Agency could provide with a list that explains the purpose of the list and makes clear that the list should not be consider definitive?

The mere fact that USDA is even considering the need for a disclaimer reinforces our position that the information will be both incomplete and inaccurate. We believe the answer to the first question is unequivocally "yes."

In regard to the second question, a disclaimer would definitely be required if the Agency decides to proceed with this ill-advised approach. However, it is our view that use of a disclaimer that fully acknowledges the problems we have identified above regarding incompleteness and lack of timeliness, as well as inclusion on the list of stores that did not carry the product being recalled, would accurately portray the list itself as unworthy of consumer confidence in making decisions about recalled product. Consequently, disclaimers are not a remedy for the incurable ailments afflicting the consignee list proposal.

Confidentiality of information

Finalization of this proposal would very likely result in the posting of confidential commercial business information. The Agency has provided no explanation why simply compiling multiple distribution lists into a single list would negate the confidential nature of the information. FSIS has always considered the names of retail consignees to be confidential commercial information, yet no explanation is provided in the proposed rule as to why this information is no longer considered as such. We believe the failure to provide an adequate explanation for this change is arbitrary and capricious.

Alternatives to this rulemaking

During initial discussions, some members expressed a desire for FPA to support this proposal, if it could enhance the recall process and better protect public health. Upon in-depth consideration of the proposal's elements, FPA members unanimously concluded that the proposal not only could not achieve its stated objectives, but quite likely would be detrimental to our currently effective recall system; and therefore should be opposed.

An effective and efficient recall system is in the best interest of all parties – consumers, industry and governmental entities. That is why we attempted to identify alternatives to the proposal that could improve, rather than compromise, the current recall system. Our conclusion is that there is no systemic problem with the current recall process that needs to be corrected so long as suitable product identification information for consumers is included in the initial FSIS press release announcing a voluntary meat or poultry product recall.

Consumer Education. To heighten awareness, one related action the Agency might consider undertaking is to provide additional consumer education materials that encourage consumers to focus on available product identification information and not on the point of purchase of the product. Inclusion of an informational piece on the FSIS recall website and as appropriate in certain recall press releases about the need to promptly check pantries and refrigerators and with details about how to identify product that is being recalled could be useful. Information about the frequent availability of photos of the recalled product labels on the FSIS website could also be promoted.

That piece could explain how the scope of a product recall is determined. It could review how the EST number identifies the specific establishment where the product was manufactured. It could explain that different container sizes of the same product are typically run on different production lines and for that reason other container sizes may not be implicated in the recall. It could emphasize the importance of other product coding, which at a minimum identifies the date on which product was manufactured and in some cases even permanently records the minute of production. In many cases, FSIS working with the company can pinpoint the timeframe during which a problem occurred. The FSIS press release will spell out the range of production codes that are being recalled. Typically, that range includes a margin of safety on either side of the identified problem. Consumers can rest assured that only those products with the specific codes in the press release are being recalled; other products bearing codes that are similar, but different, are not implicated and can be safely consumed.

The intent of such an educational piece would be to remind and to encourage consumers to promptly check for recalled product and to help give consumers confidence that they can readily distinguish product being recalled from similar looking product which is not subject to recall. It should also note that most food retailers are happy to answer consumer questions about whether or not product in their customer's possession is subject to recall.

Limited voluntary disclosure. Finally, in our consideration of possible enhancements to our already effective recall system, the one situation that might warrant further consideration is the relatively rare situation in which potentially hazardous product being recalled does not otherwise bear adequate information to allow its identification and proper disposition by consumers.

The recall linked to the first case of BSE identified in the US at the end of 2003 has been cited by some States and consumer groups as a prime example of why information on consignees should be made available to the public. Indeed, the FSIS press release issued, in an abundance of caution, on December 23, 2003 did not contain any information that would allow consumers to determine whether or not they had that product in their possession. Fortunately, there is no known BSE-related health risk associated with product from which specified risk materials have been removed and thus it is reasonable to question whether a recall was warranted in that case. Thus, in our opinion the lack of information for consumers in that specific recall in no way justifies the current FSIS proposal.

However, had that recall involved a significant public health threat, it would have been helpful if consumers could have been provided with some additional information to help them identify the potentially hazardous product. We conclude that this situation, which could result from a recall of beef that was ground at retail sue to the presence of *E. coli* O157:H7 or of chicken salad that was repackaged at retail for *Listeria monocytogenes*, for example, is one area worthy of further discussion by interested parties. Unlike the vast majority of meat and poultry recalls, recalled product that was prepared at retail bears no USDA establishment number and only a generic store label, distinguishable from similar product prepared at other stores in a chain only by the location of the store.

We do not believe that rulemaking would be required to address this particular issue. Even though industry maintains as a legal matter that distribution lists are confidential commercial information, recalling entities (for public health and for product liability considerations) would likely be willing to cede a limited waiver of their confidentiality privileges in order to voluntarily provide certain additional information, if that information is essential to consumer identification of product being recalled. We would be happy to work with the Agency to explore whether or not this possibility has merit for addressing this rare situation in which additional information may be needed by consumers to identify recalled product.

Summary

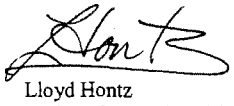
For the reasons presented, FPA strongly believes that this proposed rule would not only fail to achieve its stated objectives, but would also risk being harmfully counterproductive, if it misleads any consumer to believe he or she did not purchase recalled product due to the omission of their local store from the posted consignee list. Since we believe the serious problems with timeliness and omission are inherent and cannot be corrected, we urge the Agency to abandon this proposal.

We stand ready to work with the Agency on alternative means to further enhance the effectiveness of our recall system, such as by providing additional consumer education and/or by further discussion of a means for assuring that consumers have the means to identify recalled product in their possession, even in the rare event that it does not bear an establishment number and other production coding information that is already included in the vast majority of recall press releases.

We thank you for this opportunity to comment on this important issue.

Respectfully,

Dr. Craig Henry, PhD
Senior Vice President, Scientific and Regulatory Affairs
and Chief Science Officer



Lloyd Hontz
Senior Director, Food Inspection Issues
Food Safety Programs

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Leah Wilkenson

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June 9, 2006

Docket Clerk
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250

Re: Docket No. 04-006P "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls."

Dear Docket Clerk:

On behalf of the National Cattlemen's Beef Association (NCBA) I want to express our appreciation for the opportunity to comment on the Food Safety and Inspection Service (FSIS) Docket No. 04-006P "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls." Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

Providing consumers with the safest beef possible is a top priority for the U.S. beef industry. In the event of a recall, consumers must receive appropriate information in a timely manner to determine if they possess the recalled product. This is one mechanism in place to ensure the safety of beef consumers. NCBA concurs with FSIS when it states in this proposed rule that the current recall measures are effective.

FSIS currently provides the appropriate information for a consumer to identify the product. This information includes:

- a description of the food being recalled,
- identifying codes for the product,
- name of the production establishment,
- level of distribution of the product,
- and in most cases even a picture of the product label.

In this proposed rule, FSIS is proposing to publish on their website, the list of retail consignees of a recalled product. NCBA understands the agency's intent in providing this information, but NCBA questions if this enhances the consumer's ability to identify recalled product.

We believe the practical limitations of this proposal will not enhance consumers' ability to identify recalled product. FSIS will gather the list of retail consignees during the trace forward part of the recall investigation. This verification process, according to FSIS Directive 8080.1, Attachment 3 (dated May 4, 2004), should start within three days of an initiation of a Class I recall and be substantially completed within ten days. This means, at best, it will take the agency at least one week to publish the list of retail establishments and in most cases much longer.

NCBA questions how effective this will be for consumers who hear about the recall in their state but then must wait seven days to check a website to see if their store received the recalled product. In most cases, by the time the retail consignees are published, the product will be past its shelf life and therefore not usable to the consumer.

NCBA believes that consumers will continue to use the current information provided to them via FSIS press releases rather than hold the product in their refrigerator until FSIS releases the retail consignees.

In the public meeting on April 24, 2006, FSIS asked several questions on incomplete lists and how this might impact the effectiveness of the rule. If FSIS posts incomplete information it will very likely lead consumers who do not see their store listed to believe that their product is safe. However, to wait until the list is complete will significantly delay the release of the information making it not useful at all. If FSIS decides to post the information in an incomplete form, a disclaimer will need to be provided that is very clear and displayed in a manner that the consumer cannot ignore.

NCBA would like to work with FSIS to find the most effective measures to further increase the effectiveness of the recall process. At this time, we do not believe that this proposal will increase that effectiveness and in fact, may actually cause more harm.

Sincerely,

Leah Wilkinson

Leah Wilkinson
Director, Food Policy

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June 8, 2006

04-006P-26
04-006P
Wenonah Hauter

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
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Room 102 Cotton Annex
Washington, DC 20250

Re: Docket Number 04-006P

Dear Sir or Madam:

On behalf of the consumer group Food & Water Watch, I welcome this opportunity to comment on the proposed rule entitled, "Availability of Lists of Retail Consignees During Meat or Poultry
Product Recalls" which was originally published in the March 7, 2006 Federal Register (71 FR 11326-11328).

I commend the Food Safety and Inspection Service (FSIS) for taking this important first step towards providing more complete information to consumers when meat and poultry products under the Agency's jurisdiction are subject to recall. While we would much prefer that the names of the retail consignees also appear in the Agency's press releases, the fact that the names of retailers will be listed on the Agency's website will provide consumers and media outlets valuable information that could expedite the recovery of recalled product.

At the present time, Agency recall notices provide establishment numbers, product codes, and when possible, pictures of products. Apart from the photographs, this is not information that is readily useful for consumers. Consumers are not accustomed to looking for product codes or establishment numbers on product labels. Consequently, they often do not return recalled product because they do not know what to look for to determine if they have purchased it.

Some industry representatives have claimed that under the current system retailers often accept more product returned by consumers than was initially targeted in the recall. There is no concrete evidence that this occurs on a regular basis. The only instances that we are

aware of where this occurred involved recalls of beef products from cattle infected with bovine spongiform encephalopathy (BSE), or beef products that had been improperly imported from countries that had cases of BSE.[1]

Furthermore, the Agency has recently resumed reporting the amount of product subject to recall that is actually recovered. The rate of recovery for 2005 and 2006 show a range of zero to 86.2 percent. For those large recalls involving quantities of 50,000 pounds or more, the Agency reported a rate of recovery of 2.5 to 12.8 percent.[2] That is unacceptable, and leads us to believe that most consumers were not aware that they were in possession of product that was subject to a recall since the information provided in recall notices was so sketchy. Had the recall notices contained the names of the retailers that sold the product, we believe that more product would have been returned in these recalls.

Some industry representatives also contend that the Agency recall notices might provide incomplete information in recall notices if it is later discovered that not all retail consignees were initially identified. These industry representatives argue that consumers might be lulled into a false sense of security if the supermarket where they purchased a product is not listed on the Agency's website, but is later to be discovered as a retailer of a recalled product. We disagree, because nothing would prevent the Agency from issuing a second or third recall notice should it be discovered that there was incomplete information in the initial notice. In fact, the Agency has already done that when the scope of a recall has needed to be enlarged. For example, the 2002 recalls involving ConAgra and Wampler products necessitated the issuance of two recall notices when it became apparent that the scope of those recalls had to be broadened.[3] The Agency took similar action recently in the recall for Chicken Lunch Makers.[4] There is precedent for the Agency to release more than one recall notice for the same product, so these industry concerns seem to be baseless.

While the Agency should be commended for proposing this rule, we believe that the list of consignees should be broadened to cover such entities as restaurants so that consumers are fully aware of the scope of food recalls. Most consumers frequently eat away from home, so listing as many retailers as possible – whether grocery stores or restaurants – in recall

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[1] http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/recalls/prelease/pr067-2003.htm and
http://www.fsis.usda.gov/News_&_Events/Recall_028_2004_Release/index.asp

[2] http://www.fsis.usda.gov/Fsis_Recalls/Quantity_Recovered/index.asp

[3] http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/recalls/prelease/pr055-2002a.htm ;
http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/recalls/prelease/pr055-2002.htm ;
http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/recalls/prelease/pr090-2002a.htm ;
http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/recalls/prelease/pr090-2002.htm

[4] See http://www.fsis.usda.gov/Fsis_Recalls/RNR_052_2005/index.asp

notices would provide valuable information to consumers, and assist the Agency with any traceback activities.

Should you have any questions regarding our comments, please feel free to contact me at (202) 797-6550.

Sincerely,

Wenonah Hauter
Executive Director
Food & Water Watch
1400 16th St. NW
Suite 225
Washington, DC 20036
(202) 797-6550
www.foodandwaterwatch.org

04-006P-27
04-006P
Marion Gatulis

27

From: Marion Gatulis [mailto:Maalishwalsh@comcast.net]
Sent: Saturday, August 05, 2006 1:17 AM
To: FSIS RegulationsComments
Subject: Docket Number 04-006P

I am writing to comment on the proposed rule entitled "Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls" (Docket # 04-006P). I support the proposal to list retail consignees to the agency's Web site when meat and poultry products are recalled, and I commend the agency for taking this important step to provide information that could expedite the recovery of recalled product.

The information currently provided in the recall process is not necessarily useful for consumers to determine if they have purchased the product in question. If consumers were not sure if they had purchased the recalled product, being able to check the agency's Web site to find out which stores carried it could help consumers determine whether or not they had.

Ultimately, I would like the USDA to include in their press releases about recalls the retail locations, including restaurants, that purchased recalled product. But the proposed rule to post retail consignees on the agency's Web site is an important first step.

Sincerely,

Marion Gatulis
52 West Street
Foxboro, MA 02035

28

From: Catherine Smith [catherine.smith60@verizon.net]
Sent: Tuesday, March 07, 2006 9:02 AM
To: FSIS RegulationsComments
Subject: retail list rule

04-006P-28
04-006P
Catherine Smith

FSIS Rule Would Make Retail Lists Available During Recalls

Congressional and Public Affairs
(202) 720-9113
Steven Cohen

As a consumer, I am very much in favor of making lists of retailers publicly available in the event of a recall. This information will be very helpful to consumers, most of whom either never hear about recalls, or hear about recalls at a level of distribution which is useless to them. Considering that many recalls are never completed, this information will help consumers protect themselves.

Catherine R. Smith

29

FSIS RegulationsComments

From:	Gregory R. McClarren [attable@uci.net]	
Sent:	Wednesday, March 08, 2006 12:16 AM	04-006P-29
To:	FSIS RegulationsComments	04-006P
Subject:	Meat Recall Origin Regs	Gregory R. McClarren

Good day:

We are commenting on the FSIS proposed regulations on "meat recall and store secrecy." Pardon us if the title is slightly incorrect.

As consumers we are very concerned with food origin and consumer knowledge and information. It makes us better consumers.

We believe that we have a right to know. We believe that extends to food recalls, to food alerts and to which stores are involved with particular alerts or recalls. To a certain degree we do NOT TRUST our government nor a corporation to act in our best interest.

Therefore we wish to have full knowledge in a timely manner e.g. as soon as possible of any such alerts or recalls. This includes store chains and even states or locales within states that may be effected.

On a positive note we wish to express our pleasure with new sourceing rules that went into effect for fish & seafood last year. This allows us to know which country, whether fresh or frozen and whether farmed or wild caught. Kroger's "Fred Meyer" chain is excellent in fulfilling this rule while we find Safeway and Ray's [a PNW independent] is not as good. We would like this approach to be used with meats as well down to the notion of states or subregions of the USA e.g. Pacific NW or Southern California.

Thank you and good day. You may contact us if questions.

Elizabeth & Gregory McClarren

04-006P-30
04-006P
John Munsell

30

Comment Info: ==========

General Comment:I am writing in support of the FSIS proposal to publish lists of Retail Consignees
during Meat or Poultry Product Recalls.

Traditional agency responsibiliites to protect the public from food-borne outbreaks
as well as ensuring that meat and poultry products are wholesome would be
enhanced by the timely release of retailer names which may have received
contaminated products. Informed consumers would then be enabled to identify
potentially harmful foods in their possession, and return the food to the retailer for
disposition and/or subsequent microbiological testing. Denying consumer access
to such vitally important retailer information adversely impacts consumers' ability
to protect themselves.

Another advantage of releasing retailer names is the resultant retailer trace back
pressure placed against the source plant of the contamination. Retailers will now
be forced to deal with irate (but grateful) consumers, and will respond with a
proactive commitment to pressure the source plant to implement corrective
actions to prevent recurring shipments of contaminated meat to the retail
establishment.

Releasing retailer information is a win-win situation, in which not only do
consumers benefit from public release of vital information, but the true source
plants are forced by their retail consuemrs to prevent recurrences, or lose future
sales.

Comments submitted by:
John W. Munsell
President, Montana Quality Foods & Processing
Manager, Foundation for Accountability in Regulatory Enforcement (FARE)

04-006P-31
04-006P
Larisa Sparrowhawk

31

FSIS RegulationsComments

From: Larisa Sparrowhawk [petaltothemetal@aol.com]
Sent: Saturday, April 08, 2006 6:56 PM
To: FSIS RegulationsComments
Subject: Re: [Docket No. 04-006P]

Thank you for proposing to publicize the list of retail stores where voluntarily recalled meat and poultry products have been sold. The retail information for recalled meat is very important to consumers so they can better protect themselves from adulterated products.

Now if we could only make recalls mandatory, not voluntary, when the USDA or FSIS finds contaminated product, I'd be quite happy.

Sincerely,

Larisa Sparrowhawk
4415 Courtneys Corner Rd
Bealeton, VA 22712

04-006P-32
04-006P
Comment Info: ========== Mark Hellermann

32

General Comment:The proposed regulation to make lists of retailers available to the public, during a
meat or poultry, recall is a big step in the right direction for the FSIS. It is a basic
right of consumers to know where recalled meat has been sold and it is a
responsibility of the US government, through the FSIS, to provide that infromation.
It would be useful to consumers if the information on sources of recalled
meat/poultry were broadcast on the radio and TV and listed in the newspaper as a

public service announcement. There is no down side to this requiremant--it can only
help to protect the safety and health of the public.
Thankyou, M. Hellermann CHE CCE, Chef/Instructor, NYRestaurant School

Mark Hellermann

04-006P-33
04-006P
Comment Info: ==========Muriel Berry

33

General Comment:I believe this list of retailers receiving distribution of these recalled products would
be very good for consumers to be able to refer to. It should help us all out a considerably.

04-006P-34
04-006P
34

Comment Info: ========== Antoinette Floyd

General Comment:After reviewing the proposed rule, it only makes sense that the recall would include the
retail consignee. I never realized that it didn't contain this information. As a consumer,
if I knew of a store I shopped at regularly, had meat on recall, I would definetly be
checking my freezer and refrigerator for that product.

I also believe that by providing this information, there will be more recalled meat
recovered instead of only a small amount.

I took the time to view the current meat recalls and noticed that there hasn't been much
recovered. Just providing the public with the state seems to me to be insufficient
information and the public isn't so willing to go through their items to double check that
they don't have a recalled item. I think that by providing them with the specific retail
store, the consumer would be digging for recalled products and thus the recovery rate
will increase.

35

04-006P-35
04-006P
Barbara J. Maupin

From: FSIS RegulationsComments
Sent: Thursday, March 09, 2006 7:18 AM
To: Levine, Victoria; Levine, Victoria
Subject: FW: Document #04-006P

-----Original Message-----
From: Barbara Maupin [mailto:barb@itresources-ss.com]
Sent: Wednesday, March 08, 2006 2:57 PM
To: FSIS RegulationsComments
Subject: Document #04-006P

Per the article in the 3/7/06 issue of The Oregonian, I am writing to express my support that the USDA publish/reveal the names of the specific stores where meat product is being recalled on the USDA website. I understand that when it comes to the meatpacking industry that mistakes and oversights can be made that can cause health issues for the public and that the stores where recalled meat is sold is not necessarily at fault. Personally, a single incident will not deter me from patronizing that store. I believe it is critical that the public be armed with as much information as possible in order to act as another safety net against consumption of meat that's been recalled.

Thank you,
Barbara J. Maupin
Aloha OR 97007

Barbara J. Maupin
IT Resources
500 N. Walker, Suite E100
Oklahoma City, OK 73102
Ph: 405-232-3850
barb@itresources-ss.com
www.itresources-ss.com

04-006P-36
04-006P
B. Sachau

36

From: bk1492@aol.com
Sent: Thursday, April 06, 2006 10:57 AM
To: diane.jones@fsis.gov; dianejones@fsis.usda.gov; rodney.frelinghuysen@mail.house.gov
Subject: public comment on federal register of 4/6/06 vol 71 #66 pg 17384

fed reg doc e6-5013
9 cfra part 390
dkt 2006 0009
mtg on availability of retail consigneesduring meat recalls
on 4/14/06 from 9:30 to 12 noon in washington dc.
please send me an 800 number so i can join this meeting. i think that the public of course has a right to know the names of any meat consignee. it is clear the public has a right to protect itself from harm.

b sachau
15 elm st
florham park nj07932

04-006P-37
04-006P
B. Sachau

37

From: Bk1492@aol.com
Sent: Thursday, April 06, 2006 5:41 PM
Cc: rodney.frelinghuysen@mail.house.gov
Subject: Re: public comment on federal register of 4/6/06 vol 71 #66 pg 17384

its really strange how these agencies have enough federal tax dollars to jet all over the united states for meetings (or are they luxury jaunts on the taxpayers backs) and you cant put a net meeting on so that the public can truly join, or even let them listen on a teleconference. please make those comments part of the meeting too. i guess the corrupt washington bureaucracy thinks it is entitled and the public is just there to be bled to death.with no input.

i thought this was government by the people. this attitude in your letter certainly shows it is government by the power elite.
b. sachau
15 elm st
florham park nj 07932

04-006P-38
04-006P
Carrie Bubenzer

38

OES-Director

From: alanam_28@yahoo.com%inter2 [alanam_28@yahoo.com]
Sent: Wednesday, May 03, 2006 4:13 PM
To: Johanns, Mike
Subject: To the USDA. Support end to meat recall secrecy!

May 3, 2006

Secretary Michael Johanns
Office of the Secretary, U.S. Department 1400 Independence Avenue SW Washington, DC 20250

Dear Secretary Johanns,

I'm writing to urge you to go forward with the proposed rule requiring the U.S. Department of Agriculture to make public the names of retail and commercial establishments where potentially tainted meat and poultry is being sold. I don't think it is right for government to hold onto information that can imperil my health and safety and not disclose it to me and other consumers like me.

Specifically, I refer to the rule "Sharing of Firms' Distribution Lists of Retail Consignees During Meat or Poultry Product Recalls" (RIN: 0583-AD10). It calls on the Food Safety and Inspection Service (FSIS) to "make available to the general public lists of the retail consignees of meat and poultry products that have been voluntarily recalled by a federally inspected meat or poultry products establishment."

Ultimately, Congress needs to give USDA mandatory recall authority so the USDA does not have to promise confidentiality in return for prompt
- voluntary participation by meat producers and distributors.
Fortunately, USDA can, through this rule, give consumer the power to identify and avoid tainted meat themselves before it is consumed.

The current misguided policy already has had serious consequences.
On December 2003, a cow infected with mad cow disease was found in Washington State and the infected meat entered the food supply, mixed with 37,000 pounds of meat from other cows. It was sold in six western states, including California. Since California was one of 12 states that signed a secrecy agreement with the USDA, officials there were given the names of the retailers that were selling recalled meat.
But local health officials in California were not allowed to let the public know the names of the retailers, so consumers were left in the dark, unable to protect themselves from buying and ingesting contaminated meat.

I commend FSIS for proposing this rule in the first place. The American public has too much at stake for this rule not to be considered and adopted at the earliest possible date.

Sincerely,

Ms. Carrie Bubenzer
7639 Knue Rd Apt C
Indianapolis, IN 46250-2124

Ms. KAPTUR. All right. I thank you very much. Thank you, Madam Chair.

E. COLI TESTING

Ms. DELAURO. I will get this information to my colleague, Mr. Kingston. The economic cost of E. coli illnesses, and this comes from CDC, the annual cost, $405 million, which includes $370 million for premature deaths, $30 million for health care, $5 million for lost productivity, just for E. coli.

If you sometimes do not want to deal with the humanity of the issue, you deal with the economics of the issue.

Let me just ask a couple of questions with regard to the Topps recall. This was in the New York Times, Dr. Raymond, last October.

You said "We haven't shut the door on mandatory standards for E. coli testing and prevention."

Could you just speak to that issue for a moment?

Dr. RAYMOND. Yes, ma'am. As you know, right now, it is not mandatory that every company that makes ground beef must test their product at any frequency.

It is one of the issues with the survey that we are doing of the companies that do deal with beef, and in this case, particularly those that deal with ground beef.

We are going to take a look and see how many do test and at what frequency they test, and the agency, along with many other things found on the survey, will have some very serious discussions about whether we need to change policies, directives, even perhaps go through rule making to do things that will help protect the food supply.

Ms. DELAURO. I like to give people the benefit of the doubt, but what makes you believe in the accuracy of the information that you will get back about the testing or how much, when, et cetera?

You have concerns about the flaws in the system where it is not reported. How then does that become the basis for future decisions when our ability to verify—this is about trusting and verifying—how do you address that?

Dr. RAYMOND. For this particular issue, I believe we have a great deal of confidence because the survey was completed and the information was gathered by our own inspection workforce out there, and then was confirmed by the plant after the inspector gathered—the inspectors also have access to these testing results on a regular basis in these plants. They know which plants are testing and at what frequency they are testing.

Ms. DELAURO. I would be anxious to follow up on that with you to find out how that really is working. I was really pleased because you said we have not shut the door on mandatory standards for E. coli testing and prevention.

Dr. RAYMOND. Right.

TOPPS RECALL

Ms. DELAURO. You know what my views are on that.

Further with regard to Topps, Topps cut its microbial testing on fresh ground beef from once a month to three times a year. The Department considers that inadequate, and we discovered that after

an eight year old girl in Albany, New York was sickened by the ground beef.

The Agriculture Department scrutinized the Elizabeth plant and said the plant had few problems, then we find out that they were testing once a month and now it is three times a year, and that level, you find inadequate.

Federal investigators said they had recently learned that the company failed to require adequate testing on the raw beef they bought from domestic suppliers.

The Agriculture Department acknowledged that its safety inspectors who were in the Topps' plant for an hour or two each day never cited the company for these problems.

The Agriculture Department investigators found that something had changed. Dr. Raymond said a lot of policies they had in place were not followed.

They were not cited for any of these problems. This is a plant that had been subject to review. Presumably, it was or should have been on some sort of a watch list.

I was not here earlier but I understand, Dr. Raymond, that you said when there is a change of ownership of a plant, that you have a change as well in infection of the meat.

Did that happen at Topps?

Dr. RAYMOND. That policy was not in place at that time. It is partly as a result of Topps that we took a look at that.

Ms. DELAURO. That was last fall?

Dr. RAYMOND. Topps was in September; yes.

Ms. DELAURO. This is a new policy?

Dr. RAYMOND. Yes.

Ms. DELAURO. I also believe, Dr. Raymond, and correct me if I am wrong, you blamed Topps for changing their policies. It sounds like at least you have talked about a policy that I would have guessed was in place for a long time, a long standing time, so when you change ownership, you then go through the protocol again. You know, what is the testing regime. You did this just recently.

What does that say about the management of FSIS that things went so far off course in this plant, and in fact, it was not discovered until a child got sick.

Dr. RAYMOND. Topps, to me, I do not want to call it a watershed moment or anything else, but there were things with Topps that convinced me that we can and we must do a better job and we must start immediately, and that is when we looked at our whole E. coli initiative programs that we have announced, partly because of Topps.

We looked at if the plant changes ownership or management, should that invoke increased inspections. It was not being done as routine before, but we have worked on policy for that so it will be. We can learn.

It also showed me, and I will just say it very publicly, it showed me that some of the critics of what we were trying to do with risk based inspections were more right than I gave them credit for.

Ms. DELAURO. I appreciated that comment, Dr. Raymond. I believe the genuineness of your comments on that issue.

Dr. RAYMOND. On that issue, again, I know we can and we must and we will do better. Topps should not have happened but it did.

Because of Topps, I hope we have measures in place now that there will never be another Topps.

Topps and Hallmark are totally different situations and scenarios about how they happened. We have to address them both so that neither one of them ever happens again. We can learn.

INSPECTION ACTIVITIES

Ms. DELAURO. I would just say to you, and please do not misunderstand, I believe that this points out—I value the sincerity of your comments. That is very, very important.

What I also believe is true, and I have not come to this conclusion lightly, the same way I did not come to the conclusion on the risk based, that FSIS, and I am not individually pointing at individuals, I really believe that FSIS does not have a handle on what is actually happening.

That is what is of serious concern to me, and I believe it is a serious concern to you, in terms of putting in place a structure that allows it to have a handle on what is happening.

Again, like risk-based, unless we know what is happening, we cannot move forward. Everything that we do cannot be the fundamental change that is necessary for us to be able to move forward.

I do not know if you concur.

Dr. RAYMOND. I do concur. When we get to where we are ready to talk to you about rolling out risk-based inspections, I think you will be very pleased with what you are going to see with what we have done because of your direction and the amendments and the OIG's audit.

I think we will have something that instead of driving a beat up old Ford, perhaps we will have a Cadillac. I think you will be very proud of it. I think it will make the food supply safer.

As far as your comments about not having a handle on what is happening in these plants, I do not know that I would go quite that far, but I do know that we have difficulties in each and every one of these 6,200 plants that we do inspect.

We do not have consistency across the board. That is very problematic and troublesome to me, and the new public health information system will help us tremendously with that. Topps showed me that lack of consistency. It should not have happened. We need consistency.

The last thing I will say is because of my concern with what is happening out in the field, it is one of the reasons I asked Mr. Almanza to come and join us on our management team, with the rest of our very fine management team that we have in place, that have been working in the field office for a long time.

Al grew up in the plants, spent his life. I needed that ability for someone who grew up in a plant and was on the line, and over the 30 years of his working with the agency, showing he could do more than just work on the line.

Al brings that leadership to us to help us get a better handle on what is going on in the plants along with Dr. Peterson, and Mr. Smith, and Judy Riggins and all the other ones working in these areas.

Ms. DELAURO. Again, I thank you. I must tell you honestly I still am not deterred from my view that I think in order to focus our

attention truly day in and day out on food safety, that ultimately we need to make sure the singular focus is on food safety, and whether those activities lie within the USDA, FDA, or one of the other 13 or so agencies that are out there.

I believe part of this difficulty is the missions and the blurring of the missions. Sometimes it may not be avoided. I was borne out again with the Wall Street Journal on February 26.

This is trade and public health. I believe in trade. Public health in my view ought to trump the trade issue. I think some things have gotten out of hand because of the industry and their product.

RISK-BASED INSPECTION

Let me just ask a question on the risk-based. Can you tell us as of today, when you expect the public health information system to be fully operating?

Dr. RAYMOND. The third quarter of calendar year 2009.

Ms. DELAURO. Does the budget request accommodate the costs?

Dr. RAYMOND. Yes, it does.

Ms. DELAURO. I have a concern, which I expressed when FDA was here the other day, and this was on drug safety, so we were not talking about food responsibilities.

It is about agreeing to the recommendation and the implementation. To be very honest with you, what I discovered with the FDA, and this was drug safety, that they have agreed to a lot of recommendations. Ten years or 15 years since anything was done. That is unacceptable.

My concern is that when are we implementing these recommendations in fact, so that we can move forward to a risk-based system. I do not believe we can move forward before we put these recommendations in place and implement them.

Dr. RAYMOND. I agree with you. Of the 35 recommendations, there are two things that are probably key to our time line, and one is we have to have the public health information system running.

That answers many of the recommendations that the OIG made, many of the recommendations are answered by saying we will do the public health information system, and they are in agreement with those answers.

The other one that is time limited, we cannot do this, because we must meet the OIG's recommendation, is to do food safety assessments in those plants that produce 85 percent of the meat and poultry products in this country. We must have completed a food safety assessment using the new objective criteria as opposed to the old criteria.

We always wanted to use food safety assessments and our risk-based algorithms, but it was not objective, it was subjective, and I did not know how to incorporate that in.

We have changed the way we do the food safety assessments, and that is time-consuming also.

I do not know. Do we have any kind of projection? May of 2009 is when we anticipate we will have those food safety assessments done.

Those are two key factors that are very measurable and we cannot do risk-based inspections until we have those done.

Ms. DELAURO. We are not moving towards risk-based inspections until we have these recommendations implemented?

Dr. RAYMOND. You are correct.

Ms. DELAURO. We are talking about 35 recommendations, in place, with actions?

Dr. RAYMOND. Of the 35 recommendations, there are about eight or so that are definitely linked to risk-based inspections. The others are definitely linked to having a better food safety inspection system. They all kind of interconnect and inter-correlate; yes.

Ms. DELAURO. I truly do want to know what is being regarded as imperative before we try to move to a risk-based system versus what are the items that are the key ones.

Dr. RAYMOND. The two keys are getting the food safety assessments done and having an up and running functional public health information system.

Ms. DELAURO. You said that there were about eight or so. I want to know how you have delineated what you view and whether the OIG concurs that you can or cannot move before the eight or the remainder can be implemented.

Dr. RAYMOND. May we get back to you on that one?

Ms. DELAURO. Yes, please. That is for the record.

[The information follows:]

Since FSIS began to talk publicly about risk-based inspection (RBI) in processing in November 2005, the agency has ensured an open and transparent process involving all public health and food safety stakeholders and will continue to do so.

Of the 35 recommendations, eight directly address the proposed RBI processing establishment algorithm (#3–#10). Seven recommendations, however, also directly addressed the conduct of food safety assessments (FSAs), which USDA's Office of Inspector General feels must be expanded and improved before RBI can be implemented.

FSIS had always planned to include FSA results in the RBI algorithm, but initially planned to test RBI prior to quantifying FSA results for inclusion in the algorithm.

Dr. RAYMOND. Thank you.

POULTRY SLAUGHTER FACILITIES

Ms. DELAURO. Talk to me about what you are doing with the poultry slaughter facilities and what your intentions are.

Dr. RAYMOND. Our intentions with poultry slaughter, young poultry slaughter, is to go forward with rule making to allow us to change the way we do inspection in those facilities based partly on what we have learned from the HIMP projects and make it a better system throughout.

We will go through formal rule making. We have taken it to the National Advisory Committee for Meat and Poultry Inspection and have given them our proposal, and it is on our Web page.

Ms. DELAURO. You said earlier this was potentially—you are looking for this information service piece to be in place before you can do anything.

Dr. RAYMOND. Correct.

Ms. DELAURO. That is May of 2009?

Dr. RAYMOND. The information piece is the third quarter actually of calendar year 2009, so July to September.

Ms. DELAURO. Nothing is going to happen on this issue of the poultry slaughter facilities until you have this other piece in place; is that right?

Dr. RAYMOND. I think it is right because I do not think we can do rule making in less than two years, the way the rule making process is. I certainly do not see any way to have it——

Ms. DELAURO. Have you started the rule making process?

Dr. RAYMOND. We are in the process of writing a proposed rule. It has not gone through any kind of clearance or anything like that yet. We are just in the early, early stages.

Ms. DELAURO. What consideration was given to eliminating the maximum line speeds at poultry slaughter facilities and how could this in any way contribute to public health?

Dr. RAYMOND. The line speeds will be part of the consideration, and line speeds are part of the consideration based on the Salmonella Initiative also. Those plants that consistently come in at very low positive rates on the Salmonella sets will be allowed the opportunity to propose to us different ways they can bring about increasing efficiencies within their slaughter systems.

That is half the question. I am sorry, I forgot the other half.

Ms. DELAURO. It had to do with public health.

Dr. RAYMOND. The HIMP plants that we currently have, and I think I had a slide or a poster last year at this hearing, and I would be glad to make it available to you, the Salmonella rates on carcasses in the plants that are in the HIMP Program are dramatically lower than the rates in the traditional ultra slaughter plants, having more off line inspection services, we do believe, helps drive down Salmonella contamination rates on those carcasses.

WORKER SAFETY

Ms. DELAURO. Has FSIS given any consideration to worker safety?

Dr. RAYMOND. We always consider worker safety when it relates to our workforce. I do not believe any of this impacts our workforce. As far as the workers on the lines, that is a CDC or OSHA issue.

Ms. DELAURO. Are you aware of any studies on this issue?

Dr. RAYMOND. I am not aware of any studies that have ever been done; no.

Ms. DELAURO. Has FSIS directed inspectors to report worker safety concerns relating to line speed to OSHA?

Dr. RAYMOND. Do you know, Al?

Mr. ALMANZA. Actually, we have a mechanism in place where we have a reporting mechanism for fatigue, for illnesses, for injuries.

Ms. DELAURO. Is there a Memorandum of Understanding between OSHA and USDA on line safety? Is there anything that exists out there?

Mr. ALMANZA. Not that I am aware of. I would be glad to look into it.

Ms. DELAURO. Yes, would you?

Mr. ALMANZA. Yes, ma'am.

[The information follows:]

FSIS and the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) signed a Memorandum of Understanding (MOU) in 1994 to guide the working relationship of the two agencies. Although the MOU does not specifically address line safety, it established a process and framework to: 1) train FSIS meat and poultry inspection personnel to improve their ability to recognize serious workplace hazards within the meat and poultry industry; 2) reinforce procedures for meat and poultry inspection personnel to report unsafe and unhealthy working conditions to which they are exposed to the appropriate authorities; 3) institute new procedures for meat and poultry inspection personnel to refer to OSHA serious workplace hazards affecting plant employees; and 4) coordinate possible inconsistencies between OSHA job safety and health standards and FSIS sanitation and health standards.

A copy of the MOU is submitted for the record.

[The information follows:]

Memorandums of Understanding

Delineate policies, procedures and responsibilities which will guide the working relationship of the U.S. Department of Labor (OSHA) and the (USDA - FSIS).

Memorandums of Understanding - Table of Contents

- **Information Date:** 02/04/1994
- **Agreement Agency:** OSHA and USDA

MEMORANDUM OF UNDERSTANDING
between
The U.S. Department of Labor
Occupational Safety and Health Administration
and
The U.S. Department of Agriculture
Food Safety and Inspection Service

I. PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to delineate policies, procedures and responsibilities which will guide the working relationship of the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) and the U.S. Department of Agriculture (USDA Food Safety and Inspection Service (FSIS).

Specifically, this MOU establishes a process and framework to: 1)train FSIS meat and poultry inspection personnel to improve their ability to recognize serious workplace hazards within the meat and poultry industry; 2) reinforce procedures for meat and poultry inspection personnel to report unsafe and unhealthy working conditions to which they are exposed th the appropriate authorities: 3)institute new procedures for meat and poultry inspection personnel to refer to OSHA serous workplace hazards affecting plant employees: and 4) coordinate possible inconsistencies between OSHA job safety and health standards and FSIS sanitation and health standards.

This agreement establishes a foundation for the training of FSIS inspectors in the recognition of serious workplace hazards and for a referral system.

It is not OSHA's expectation or desire that through this training FSIS inspectors would be able to supplant OSHA expertise in identifying serious workplace hazards/ FSIS inspectors will be trained in a manner and to a degree established under Section VI. of this agreement. FSIS inspectors will be trained to recognize and refer serious workplace hazards (see expected to, identify, evaluate, or refer serious workplace hazards affecting plant employees that tend to arise only after protracted, cumulative exposure, such as those related to repetitive motion and noise.

II. DEFINITION OF HAZARDS TO BE REFERRED

For purposes of this agreement, a serious workplace hazard is a condition such that there is a substantial probability that death or serious physical harm could result. Examples of these types of hazards appear in the attached appendix.

III. AUTHORIZATION

This MOU is authorized under general and specific OSHA and FSIS statutory authorities. General OSHA and FSIS statutory authorities permit each agency to enter into agreements with other Federal agencies in order to further the legislative objectives listed below. Specific statutory authorities for each agency are as follows:

A. OSHA

1. The Occupational Safety and Health Administration (OSHA) was established under the authority of the Occupational Safety and Health Act (OSHA Act) of 1970 (P.L. 91-596) which authorizes the Secretary of Labor to assure safe and healthful working conditions for men and women by "authorizing enforcement of standards developed under the Act; assisting and encouraging the States in their efforts to assure safe and healthful working conditions; and providing for research, information, education, and training in the field of occupational safety and health."

2. Section 7(c)(1) of the OSH Act authorizes the Secretary "to use, with the consent of any Federal agency, the services, facilities, and personnel of such agency" in carrying out his or her responsibilities.

3. Section 18 of the OSH Act provides for States which desire to assume responsibility for the development and enforcement of occupational safety and health standards within their borders, to submit a State plan for OSHA for approval. Upon approval, these States, referred to as Plan States, may operate their own Federally-monitored safety and health programs which must be "at least as effective as" the Federal program.

4. Section 19 of the OSH Act requires the head of each Federal agency to establish and maintain an effective and comprehensive occupational safety and health program and to provide safe and healthful places and conditions of employment for Federal employees, consistent with the standards promulgated under the OSH Act. Executive Order No. 12196, issued in accordance with Section 19, gives Federal employees the right to report unsafe and unhealthful working conditions to the appropriate Federal authorities.

B. FSIS

1. FSIS is responsible for administering and enforcing the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) which authorize the Secretary of Agriculture to promulgate such rules and regulations as are necessary for the efficient execution of the provisions of these acts. These rules and regulations prescribe requirements designed to assure that meat, meat food products, and poultry products, capable of use as human food, will not be adulterated or misbranded when delivered to the consumer.

2. Section 301(c) of the Federal Meat Inspection Act (FMIA) and section 5(c) of the Poultry Products Inspection Act (PPIA) provide that States must develop and effectively enforce, with respect to establishments operating wholly in intrastate commerce in the State, requirements "at least equal to" those under the FMIA and PPIA.

IV. CLARIFICATION OF AUTHORITIES AND RESPONSIBILITIES

The content of this agreement is not intended to diminish or otherwise affect the authority or responsibilities of OSHA or FSIS to administer their respective statutory functions. FSIS meat and poultry personnel are not agents of OSHA and their presence in no way relieves meat and poultry industry employers or employees of their responsibilities under the OSH Act.

Specifically:

A. OSHA

OSHA remains the government agency charged with safety and health oversight responsibilities in the meat and poultry industries. e.g., encouraging and assisting employers and employees to reduce workplace hazards; researching occupational safety and health problems; and developing and enforcing standards to assure, as far as possible, a safe and healthful workplace for all employees.

B. FSIS

FSIS's primary responsibilities continue to be to administer a comprehensive system of inspection laws to ensure that meat and poultry products moving in interstate and foreign commerce for use as human food are safe, wholesome, and accurately labeled.

FSIS inspection personnel, pursuant to executive Order No. 12196, have a right to report unsafe and unhealthful working conditions within their own workplaces and to which they are exposed. Such reports are to be handled as complaints in accordance with Federal Agency Program procedures currently in effect. This MOU in no way alters the normal procedure used by FSIS inspectors to report a workplace safety and health hazard that affects them to their supervisor or to the FSIS Deputy Administrator, Administrative Management.

C. Employers

Employers in the meat and poultry industries continue to have responsibilities as specified in the OSH Act, e.g., the responsibility to provide a workplace free from recognized hazards; the responsibility to examine workplace conditions to ensure they conform to applicable standards; and the responsibility to inform all employees about OSHA.

D. EMPLOYEES

Employees in the meat and poultry industries continue to have responsibilities and rights as outlined in the OSH Act.

V. BACKGROUND

A. GENERAL

The OSH Act requires employers to furnish a place of employment that is free from recognized hazards that cause or are likely to cause death or serious physical harm and to comply with occupational safety and health standards. In order to determine employer compliance with safety and health standards and regulations, Federal and Plan State (reference Section VI) compliance safety and health officers (CSHOs) conduct investigations and inspections of work-sites.

FSIS meat and poultry inspectors also conduct inspections of employer work-sites, but the purpose of these inspections is to protect consumers by ensuring that meat and poultry products for use as human food are safe, wholesome and accurately labeled. In the course of these inspections, however, FSIS meat and poultry inspectors are also in a position to observe safety concerns or be presented with information concerning conditions about the safety or health of plant employees.

FSIS currently trains its meat and poultry inspectors in occupational safety and health matters, but this training is limited. Under the terms of this MOU, OSHA will support and coordinate with FSIS to train FSIS inspections personnel i recognizing and reporting serious workplace hazards, thereby reinforcing and supplementing their previous training.

B. Standards Development

Coordinated Standards Development outlined in Section VI.B of this MOU covers the substance of the OSHA/FSIS May 1982 MOU. The may 1982 MOU will be superseded by the signing of this agreement.

VI. SUBSTANCE OF THE AGREEMENT

A. TRAINING

1. Objective

The primary objective of the training conducted under the terms of the MOU is to heighten the awareness of meat and poultry inspectors in the recognition of serious workplace hazards. After receiving instruction, FSIS will be better able to:

(a) recognize and report unsafe or unhealthful working conditions within their own workplace and to which they are exposed, in furtherance of Executive Order No. 12196; and

(b) recognize and refer to FSIS headquarters those instances where plant employees are exposed to serious workplace hazards.

2. Development

OSHA and FSIS will cooperate in developing and conducting the training program designed in support of the MOU. OSHA representatives will participate with an FSIS joint team comprised of representatives from the FSIS Human Resource Development Division (HRDD), the International Programs import inspection staff, the Inspection Operations (IO) Safety and Health Steering Committee, and the National Joint Council of Food Inspection

Locals. The team, with OSHA participation, will address such issues as necessary including:

-- evaluating current safety modules in FSIS courses and recommending changes;

-- determining the target population for field training;

-- developing training topics pertinent to FSIS workplace conditions. The training will focus on (1) OSHA's or Plan State's statutory authority and enforcement program as it applies to the meat and poultry industry: (2) serious workplace hazards frequently cited by OSHA in meat and poultry facilities, e.g. machine guarding and personal protective equipment (PPE); (3) OSHA workplace fire safety standards which require employers to provide proper exits, fire fighting equipment, emergency plans and employee training to prevent fire deaths and injuries in the workplace; (4) procedures for notifying FSIS management officials of serious workplace hazards to which plant employees are exposed.

-- developing instructional objectives for each topic:

-- determining approximate training time for each topic:

-- obtaining slides, photographs and other visuals illustrating occupational safety hazards present in meat and poultry plants;

-- designing evaluation instruments for the core training sessions and for the training to be delivered by those receiving the core training.

OSHA will then develop training which meets the instructional objectives of all training topics and which is fully compatible with the training delivery implementation plans devised by the FSIS joint team and OSHA participants.

3. Training Delivery and Evaluation

OSHA will provide an initial training session to all members of the FSIS joint team, as designated in paragraph VI.A.2, and additional FSIS personnel as deemed necessary. The training material used at the initial training session will be evaluated by attendees, and will be adjusted, as appropriate, based on these evaluations. These FSIS personnel will conduct subsequent training with involvement of OSHA to the general target group of FSIS inspectors.

OSHA will provide all training materials for the initial session and one additional master copy to HRDD for subsequent field training. OSHA will provide two additional master copies to HRDD when all agreed upon revisions are completed. OSHA training personnel will be on-site for the first training session with FSIS field personnel. Evaluations provided by group of FSIS personnel and OSHA participants will be used to determine if additional revisions are necessary before nationwide delivery.

When field training has been completed, OSHA and FSIS will analyze field personnel supplied evaluations to assure that the primary objective of the MOU is achieved.

B. Coordinated Standards Development

In administering their respective responsibilities, OSHA and FSIS will, to the extent possible, consult and exchange information with each other through the coordinating offices named in section VIII of the MOU. Specifically, the offices will:

1. Coordinate standards development programs in order to minimize possible inconsistencies between standards, establish standard setting priorities, and identify other issues where coordination is desirable.

2. Exchange information and reports on general enforcement matters and on particular situations of common concern to each agency.

3. Make every effort to achieve uniformity of approach in long-range standard development planning.

4. Obtain legal and policy positions on statutory authority regarding the extent to which the other agency can remedy a particular condition or item that may be within the regulatory authority of that agency.

C. Referrals

In the course of an FSIS inspection. FSIS meat and poultry inspectors might either recognize a serious workplace hazard or may receive complaints about unsafe or unhealthful working conditions of plant employees.

Though FSIS inspectors are not to perform the role of OSHA inspectors, they will be trained to recognize serious workplace hazards. FSIS inspectors will report those serious workplace hazards affecting plant employees to their agency headquarters. Agency headquarters officials will simultaneously refer these hazards to OSHA and notify plant management to the referral. The report of a hazard shall be in writing, using OSHA designated forms and consistent with guidance set forth in this MOU and implementing agency directives. OSHA will handle such reports as formal complaints and schedule an inspection according to existing procedures for such complaints. OSHA will receive all referrals and notify Plan States when appropriate. FSIS will afford the same confidentiality to the plant employees making a complaint as that afforded by OSHA.

VII. PLAN STATES

A. OSHA

OSHA will encourage States which operate their own occupational safety and health programs under a plan approved by OSHA as provided for in Section 18 of the OSH Act (Plan States) to participate in activities outlined in this MOU as appropriate.

B. FSIS

FSIS will propose to States administering State meat and poultry inspection programs that they implement policies and procedures consistent with those outlines in the MOU.

VIII. EVALUATION

OSHA and FSIS will work together to evaluate the effectiveness and impact of the agreements reached and actions taken under the terms of the MOU. Specifically, OSHA and Plan States will record information regarding referrals made to OSHA by FSIS and State inspection programs. Information will include, but will not be limited to: 1) the number of referrals; 2) the number of inspections made in response to FSIS referrals; and 3) the number and types of hazards cited on the inspections.

Evaluation data will be reviewed by both OSHA and FSIS annually. Based on the evaluation of related data and feedback from OSHA, FSIS inspectors and meat and poultry employers and employees, adjustments to the MOU will be made, as appropriate.

IX. COORDINATION

A. training Issues

Training issues regarding this agreement will be coordinated between OSHA's Director, Office of Training and Education and FSIS's Director, HRDD.

B. Operational Issues

Issues regarding safety-related and health-related referrals by USDA inspectors will be coordinated between OSHA's Office of Field Programs and FSIS's Deputy Administrator, Administrative Management.

C. Interagency Policy and Standards Development Issues

Resolution of interagency policy issues concerning this agreement, including efforts to coordinate standards development, will be coordinated between OSHA's Director of Policy and FSIS's Director of Policy Evaluation and Planning Staff.

X. CONDITIONS OF AGREEMENT

The OSHA/FSIS MOU signed on May 24, 1982, is superseded by this MOU.

This MOU will become effective on the date of the last signature and shall continue in effect unless: 1) the agreement is modified in writing by mutual consent of both parties; 2) the annual evaluation required in Section VIII is not performed; or 3) the agreement is terminated by either party upon thirty (30) days advance written notice to the other

Each inspector's responsibility to make referrals will not take effect until that inspector has completed the training provided for in this MOU.

FSIS and OSHA agree to initiate training as soon as practicable.

This MOU in no way restricts FSIS from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.

Specific work projects or activities involving the transfer of money, services, or property between the agencies to this MOU shall require execution of separate agreements or contracts. Each subsequent agreement between the parties to this MOU shall comply with all

applicable statutes and regulations, including those statutes and regulations applicable to procurement activities, and must be independently authorized by appropriate statutory authority.

Nothing in this MOU shall obligate FSIS or OSHA to expend appropriations or to enter into contract or other obligation.

APPENDIX

SERIOUS WORKPLACE HAZARDS

As stated under Section I of the MOU, FSIS inspectors will not be trained to and therefore, will not be expected to identify or evaluate or refer serious workplace hazards that tend to arise only after protracted, cumulative exposure, such as those related to repetitive motion and noise. A serious workplace hazard is a condition such that there is a substantial probability that death or serious physical harm could result. Examples of these hazards include, but are no limited to:

No emergency evacuation plans.

Blocked means of egress or exits.

Unmarked exits.

Lack of machine guards.

No control of hazardous energy during plant maintenance of equipment.

Electrical hazards.

Broken or missing guardrails.

Falling object hazards.

Walking/working surfaces. e.g. drain covers.

Lack of personal protective equipment.

Release or spill of a toxic chemical.

Plant workers reporting or exhibiting irritation of the eyes, nose and throat due to exposure to an unknown substance.

Plant workers exposed to hazardous chemicals not included in the plant's hazard communication program.

Plant workers reporting exposure to asbestos.

Plant workers entering confined space without the protection of a confined space entry program.

Plant workers exposed to carbon monoxide during warehousing operations.

Plant workers exposed to operations involving a dust hazard.

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Occupational Safety & Health Administration
200 Constitution Avenue, NW
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UNITED FOOD GROUP RECALL

Ms. DELAURO. Thank you very much.

Let me just ask another question about the United Food Group recall. I think that was last July of last year.

Dr. RAYMOND. Close; yes.

Ms. DELAURO. 5.7 million pounds of beef.

The Inspector General said "FSIS inspection personnel do not always follow instructions in linking NRs identifying recurring sanitary deficiencies.

However, even when the NRs were linked, FSIS inspection personnel did not have the guidance on when to take further enforcement action when addressing repetitive non-compliance violations.

This occurred because FSIS did not issue the necessary criteria for evaluating a repetitive non-compliance violation and to establish when further enforcement action must be taken as recommended in a prior OIG audit report."

The IG indicated that these prior audit reports were issued previously. Can you explain why FSIS did not get around to doing this?

Dr. RAYMOND. Do you want to try? I cannot.

Mr. ALMANZA. In fact, we did issue guidance to do that, and we incorporated that into our training. We are still in the process of doing that. The changes were articulated in our Directive 5000.1.

Ms. DELAURO. This goes back to previous years' IG reports. I told you on drug safety, they told us it had not been done for the last 10 to 15 years. I am worried about 35 recommendations and where they are going.

This is 5.7 million pounds. You are committed to doing this. You said you were going to do it. You did not do it.

Mr. ALMANZA. Yes, ma'am. This Directive 5000.1 was issued in 2004.

Ms. DELAURO. I am going to take a look at a document I have here. This was the IG report on RBI, the recent report.

"The official stated that in his view the average inspector did not have the technical expertise to develop that type of NR because they lack sufficient training and expertise."

This is the most recent report from the IG. You do not know what to say. I do not know what to say. You did not do it.

Mr. ALMANZA. I would say we are still in the process of making changes. In the survey and the checklist that we developed, and I know you have been provided copies of that, it helps us to look at the level of comprehension as far as the guidance that we are giving, and I certainly understand what you are reading there.

We are doing a better job at changing those, and we are going to make some regulations and policies based on the survey and checklist that we did.

Ms. DELAURO. Again, this is the IG. "In the months preceeding large recalls by two establishments on ground beef potentially contaminated with E. coli, the FSIS inspection personnel listed multiple NRs and sanitary deficiencies."

We have United Food Group. Then we have Topps. Then we see Hallmark/Westland.

Nothing gets done in the interim here with the OIG recommendations to then prevent. The operative word is "prevent" and not react.

All we are in the business of doing is reacting. Even with data, and even with information, and even with the IG, I am beginning to wonder maybe why we fund the IG or the GAO because they make all these recommendations and they do all this work and apparently nobody is paying attention to any of it.

You did not pay attention to what they said to do. Therefore, we keep having these things occur.

Dr. Raymond.

Dr. RAYMOND. Yes. I share your frustration. With the OIG recommendations——

Ms. DELAURO. President Clinton used to say that all the time, I share your pain.

Dr. RAYMOND. I will not touch that one. [Laughter.]

Not on the record.

The December audit report that came out, we knew what it was going to say, because we were working closely with the OIG, so we could begin to move.

We have timelines and milestones set to address this particular issue, and the PHIS will address this issue to a good degree. It will help us link, instead of relying on individual inspectors or their supervisors to do these linkages.

You are right. We keep hearing about if you would have done the linkage, perhaps you would not have had the recall. I could not agree with you more.

I did not come here to supervise recalls. I came here to drive down the number. Unfortunately, it has gone in the wrong direction. I will do everything I can before I leave to help drive down that number again or get the things moving right, and I do believe strongly in this public health information system, and that it will help us do that linkage, and we will rely less on individuals, but we will have flags that will go up, and then we can say let's go take a look at why that flag popped up.

I do believe you will be very pleased with what we are going to produce. If we need to come up some time and give you a very detailed summary of what we are doing, I would be glad to do that.

Ms. DELAURO. If you can get to us like in five days or so, before the due date of one of these actions, if you will, if you can let us know what is happening, if we are going forward, what it is, et cetera, so we have some idea of how this is progressing.

Dr. RAYMOND. You want that by the end of the next week for the record?

Ms. DELAURO. What I want to do, it is a dynamic process here. When these due dates occur, you have four or five of them, I think, coming up on March 15. We really want to know what is happening with these efforts before the date comes or may go, what has been put in place.

Dr. RAYMOND. We will go back and start working on that this afternoon.

CHINESE CHICKEN

Ms. DELAURO. That is great. I think I have just one more comment and that is about one of the issues that I spent a lot of time on, and that is Chinese chicken.

We have had so many scandals involving China over the last several months. You can put the list together as well as I can. Heparin is on the front page of today's Washington Post and the New York Times. It looks like it has caused more than 20 deaths.

You have had several meetings, as I understand it, with the Chinese Government representatives. You were quoted as saying that the U.S. wants to "get back to business as usual with China." I am not sure there are a lot of people in the nation who share that view.

We now read that China is the largest growing export market for U.S. chicken and that getting its poultry products from the U.S. is China's top agricultural export goal.

There again, you are a public health official, Dr. Raymond, and not a trade promoter.

Dr. RAYMOND. Correct.

Ms. DELAURO. You know the kinds of issues we have. With China, we do not know. We have no idea what we would consider an acceptable level of government regulations.

How can we possibly think we can?

Dr. RAYMOND. We have a very robust system, and we deal with countries who do want to import to the United States, of which there are currently 34, and we have determined them to have equivalent systems.

Before we give them that status, we will do paper audits to make sure they have rules and regulations and laws and statutes in place that are similar to ours or at least equivalent to ours, and then once that has been satisfied, we will do in-country audits.

In the case of China, we did three in-country audits before we finally determined their inspection system to be equivalent, including daily inspections by Federal inspectors.

At that point in time and in addition, for whatever product they do want to export, of course, we will work with APHIS to make sure there are no animal health issues, and in this case with China, APHIS tells us that as long as the chicken is cooked, there will be no animal health issues.

We began that rule making process to allow China to export domestic poultry products that have been slaughtered and further processed and cooked in China.

We do annual audits in every country that does export to the United States, and we do inspection at the border, re-inspection. Every product that comes from China would be re-inspected at the import houses, and ten percent, once it was down to a normal routine fashion, ten percent of that product would be more closely inspected, including pathogen and residue testing.

Obviously, when a new country comes on board, we are going to increase that level of testing until we have developed a level of comfort with them.

Ms. DELAURO. I have two or three questions and then we are going to wrap this up and let you go do your business.

If the Chinese violate the rules, do you honestly think you will catch them?

Dr. RAYMOND. The annual audits, we may not catch it that day, but the annual audits should very definitely be able to track where the poultry product came from.

Ms. DELAURO. I just want to refresh your memory that FDA and DOT have failed to stop some of these problems. Have any plants in China expressed an interest in being approved to export to the United States?

Dr. RAYMOND. I am sorry. I could not hear your question.

Ms. DELAURO. Have any plants in China expressed interest in being approved to export to the United States?

Dr. RAYMOND. First of all, the other agencies that you mentioned do not do annual audits in these countries. They do not do equivalency evaluations, and they do not re-inspect all products that come into this country and do the robust microbiological and residue pathogen testing that we do.

As far as any specific plants, I do not know for sure. I have been in one plant that I know has an interest in exporting to the United States, but I do not know that any plant has raised their hand.

Bill, can you help me out, when we do the audits, are those plants that specifically want to export?

Dr. James says we have four plants that expressed interest in exporting to the United States.

Ms. DELAURO. Has FSIS or anyone else in USDA sent any staff to China to help them prepare for possibly exporting poultry to the United States?

Dr. RAYMOND. Not recently, but when we were doing our in-country audits, yes, we worked with them to help make certain their system would be at least equivalent to ours.

Ms. DELAURO. We are preparing for this export of poultry to the United States? If so, when would staff go and to what cost to the taxpayers?

Dr. RAYMOND. I will get that for you, but I will assure you that no one has gone since the amendment was put on our bill last year that did not allow us to expend any of the funds for implementation or further movement of the rule. We have sent no one over there for this purpose since then.

[The information follows:]

FSIS employees performed three in-country equivalence audits of China's food safety system before Congress barred the use of funds to establish or implement a rule to allow poultry products to be imported to the United States from China. In May 2004, five FSIS employees visited China, at a cost of approximately $25,000. In December 2004, five FSIS employees visited China, at a cost of approximately $25,000. In July 2005, two FSIS employees visited China, at a cost of approximately $18,000. A few of the employees who went to China in May 2004 and December 2004 were FSIS lab technicians who stayed in China for only a few days. The two employees who went to China in July 2005 stayed for the full duration of the audit. Therefore, the cost per person of the third trip was higher.

Ms. DELAURO. I want to just say thank you for being here today. I want to say a particular thank you to my colleagues. We do work across the aisle. It is wonderful.

I do very, very much appreciate your time and your efforts.

We will have additional questions for the record, and what information we have requested, it will be helpful if you will provide it.

Dr. RAYMOND. We will.
Ms. DELAURO. Thank you. This hearing is adjourned.

QUESTIONS SUBMITTED FOR THE RECORD
FOOD SAFETY AND INSPECTION SERVICE

QUESTIONS SUBMITTED BY CHAIRWOMAN DELAURO

Ms. DeLauro: Please update the Committee on research being conducted by the Agricultural Research Service.

Response: The Agricultural Research Service conducts food safety research designed to yield science-based knowledge on the safe production, storage, processing and handling of plant and animal products, and on the detection and control of toxin-producing and/or pathogenic bacteria and fungi, parasites, chemical contaminants and plant toxins, to assist regulatory agencies and the food industry in reducing the incidence of foodborne illnesses.

The Cooperative State Research, Extension, and Education Service seeks to reduce the incidence of foodborne illness and provide a safer food supply by supporting research, education, and extension activities addressing current priority issues and multiple disciplines in food safety. Some examples include food safety basic and applied research, antimicrobial resistance, consumer and professional food safety education, food processing technology, and food biosecurity. Food safety research is supported through the National Research Initiative, the National Integrated Food Safety program, both of which are awarded competitively. Hatch Act and other formula funds support food safety projects, including multi-State projects.

The Economic Research Service conducts economic research on food safety programs and policies, including consumer benefits from risk reduction, production tradeoffs in reducing hazards, impact of proposed regulations and international harmonization, and the implications of changing demographics on food safety economics.

The Food and Nutrition Service's (FNS) food safety education funds are used to reinforce and expand its efforts to provide Child Nutrition Programs operators with continuous, effective training and technical assistance in food safety and food defense. FNS develops materials, ensures their delivery at all appropriate levels, makes training available at all possible levels, and facilitates the implementation of food safety requirements into the operators' food service operations.

The Food Safety and Inspection Service (FSIS) is the public health agency responsible for ensuring that the Nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and accurately labeled and packaged. FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, the Humane Methods of Slaughter Act, and the regulations that implement these laws. FSIS inspection program personnel perform antemortem and postmortem inspection procedures to ensure public health requirements are met at federally-inspected establishments; and ensures that State meat and poultry inspection programs have standards that are "at least equal to" Federal standards. FSIS also ensures that meat, poultry, and processed egg products imported to the United States are produced under standards

"equivalent" to U.S. inspection standards, and facilitates the certification of exported goods.

The Office of the Chief Economist houses the Office of Risk Assessment and Cost Benefit Analysis (ORACBA), which employs scientists who serve on the Executive Board of the 18-agency Risk Assessment Consortium (RAC). ORACBA provides financial support for RAC programs to advance development and understanding of risk assessment; ensures major USDA food safety regulations are supported by sound risk assessments and economic analyses; and provides technical advice to agencies and international organizations on modeling dose-response relationships.

Risk assessment methods are used to assess risk reduction potential of alternative livestock production practices and antimicrobial interventions in slaughter and processing environments. Figures related to the food safety research being conducted by the Agricultural Research Service and other USDA agencies are submitted for the record.

[The information follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Food Safety Research Programs
(Dollars in Thousands)

	2007 Actual	2007 FTE	2008 Estimate	2008 FTE	2009 Budget	2009 FTE
Agency						
Agricultural Research Service (ARS)	$105,176	819	$104,495	819	$105,762	822
Cooperative State Research, Education, and Extension Service (CSREES)	24,824	8	24,721	8	39,420	8
Economic Research Service (ERS)	693	5	693	5	693	5
Food and Nutrition Service (FNS)	775	0	1,991	0	2,000	0
Food Safety and Inspection Service (FSIS)	892,136	9,276	929,742	9,515	951,946	9,515
Office of the Chief Economist (OCE)	370	3	368	3	387	3
Total, Food Safety Programs	**1,023,974**	**10,111**	**1,062,010**	**10,350**	**1,100,208**	**10,353**

Ms. DeLauro: Please provide an updated organization chart for the record and discuss any changes to the table printed last year.

Response: An updated organization chart for FSIS is under review by the Department and will be provided once approved.

Ms. DeLauro: Please update the Committee on the 2007 test of the A-123 and on work on other financial and accounting procedures.

Response: FSIS complied with the requirements of A-123, Appendix A by performing the following:

- Documenting internal controls over financial reporting;
- Assessing design of key controls;
- Testing effectiveness of properly designed controls;
- Documenting and evaluating the test results; and
- Developing plans to remediate non-existent/ineffective control deficiencies

Based on the results of the 2007 assessment, FSIS can provide reasonable assurance that internal controls over financial reporting are operating effectively. FSIS did identify and document three control deficiencies that were corrected and retested. In addition, recent initiatives by the Office of the Chief Financial Officer (OFCO) have been implemented to improve financial management. These initiatives include:

- Tracking corrective action plans; and
- Establishing a financial oversight and continuous improvement staff within OCFO.

In 2008, FSIS identified several areas for improvement, involving the lack of effective review of unliquidated obligations (the amount of financial obligations not yet expended or paid out in the financial system), a lack of review and approval of system overrides, and lack of evidence for suspense file and variance analysis reports.

To address these issues, FSIS has implemented a monthly scorecard to monitor open obligations. In addition, FSIS has implemented a system to ensure review and approval of system override records and suspense file and variance analysis reports to ensure compliance.

Ms. DeLauro: Please update the Committee to the extent necessary on the MOU signed between FSIS and APHIS that addresses emergency reimbursement issues in the future. Has the agreement worked as intended?

Response: FSIS has developed and signed a Memorandum of Understanding with the Animal and Plant Health Inspection Service (APHIS) to address reimbursement issues specific to the control and eradication of Highly Pathogenic Avian Influenza (HPAI). As prescribed in the agreement, FSIS has established a cadre of volunteers to assist APHIS in the control and eradication of HPAI. The volunteers are in the process of being medically cleared by APHIS for use of personal protective equipment in preparation for deployment in case of an outbreak. A reimbursable agreement has been prepared for approximately $1.2 million to be paid by APHIS for FSIS deployment. The agreement will be signed and executed if an outbreak occurs. For other large-scale emergencies requiring the activation of Emergency Support Function (ESF) # 11 (Agriculture and Natural Resources Annex), FSIS will use Mission Assignments that will obligate funds to FSIS directly from the Department of Homeland Security, Federal Emergency Management Agency (FEMA). ESF-11 is comprised of USDA (APHIS, FSIS, the Food and Nutrition Service (FNS)) and the Department of Interior as primary agencies. USDA (APHIS as lead) is the ESF-11 Coordinator.

During FY 2008, FSIS prepared six Pre-scripted Statements of Work that have been approved by FEMA as Pre-scripted Mission Assignment. These

have become part of the official library of funding obligation tools FSIS will use for getting reimbursement for its emergency response activities.

Ms. DeLauro: What is the current funding level for the New Technology Office? Briefly describe the roles and functions of this office if it is still in operation.

Response: The New Technology Office did not receive cooperative agreement funding, and is no longer in operation.

Ms. DeLauro: Is there still a staff person assigned to the activities formerly carried out by the Food Safety Institute of the Americas?

Response: No, there is no longer a staff person assigned to the activities formerly carried out by the Food Safety Institute of the Americas.

Ms. DeLauro: Please update the Committee on spending in 2008 on laboratory capability, by lab, including both the 2007 base and any 2008 increases.

Response: In FY 2008, $3.48 million was spent for all FSIS laboratories. This amount represents a $2.5 million increase over the FY 2007 base for this laboratory equipment.

This funding enhanced the capability of the three FSIS laboratories: Eastern ($486 thousand), Midwestern ($1.48 million), Western ($494 thousand), as well as the Food Emergency Response Network (FERN), a joint laboratory partnership project between the Food and Drug Administration (FDA) and selected State public health laboratories ($1.02 million). These laboratories must have the ability to respond to emergencies from all hazards. Food emergencies can be caused by a vast array of novel chemical, biological and radiological contaminants. Our laboratories continue to strive for equipment with the broadest capability, which will allow the identification of an expansive range of potential contaminants. For example, FSIS has enhanced our mass spectrometry equipment, which confirms the identities of unknown contaminants.

Ms. DeLauro: Please update the table in last year's hearing volume on budget initiatives. Please include additional rows if necessary.

Response: The information is submitted for the record.

[The information follows:]

(Dollars in Millions)

Initiative	FY 2007 Base	FY 2007 +/-	FY 2008 Base	FY 2008 +/-	FY 2009 Budget Request
Risk Assessment/ Microbiological Testing	2.00		2.00		2.00
Food Safety Regulatory Essentials (FSRE) Training/Skills	5.90		5.90		5.90
Training/Entry	5.80		5.80		5.80
Training/Ongoing	8.70		8.70		8.70
Media Campaign	0.75		0.75		0.75
Pathogen Capacity Testing	4.40		4.40		4.40
Equivalency Review	7.90		7.90		7.90
Industry Growth	4.20	11.00	15.20		15.20
BSE Surveillance	3.10		3.10		3.10
Humane Slaughter Staffing	5.50		5.55	0.02	5.57
Fully Support Frontline	519.20	18.17	537.37	15.58	552.96
Food & Agriculture Defense	6.86	2.55	9.41	0.07	9.48
Food Emergency Response Network (FERN)	2.92	8.43	11.35		11.35
FERN Data Systems	1.48	0.74	2.22		2.22
Bio-surveillance	3.22		3.22		3.22
Lab Capacity	3.07	0.03	3.10		3.10
Biosecurity Training	2.49		2.49		2.49
Public Health Data Communications Infrastructure System (formerly FAIM and Humane Activities Tracking (HAT))*	14.90		14.95		14.95
Enhance Public Health Assessments	2.21		2.21		2.21

Initiative	FY 2007 Base	FY 2007 +/-	FY 2008 Base	FY 2008 +/-	FY 2009 Budget Request
CODEX	3.67	0.07	3.74	0.09	3.83

* In FY 2008, FSIS realigned its information technology portfolio. PHDCIS (formerly FAIM) now includes FAIM, HATS, and a portion of the FACTS initiative. FY 2007 has been adjusted for comparability.

Ms. DeLauro: Did FSIS reprogram any funds to cover inspector salaries or expenses in fiscal year 2007 or 2008?

Response: No funds were reprogrammed in FY 2007 or FY 2008 to cover inspector salaries or expenses.

Ms. DeLauro: Did FSIS reprogram any funds for any other purpose in 2007 or 2008?

Response: FSIS did not shift appropriated funds from one purpose to another within 2007 or 2008.

Ms. DeLauro: Are any hiring freezes currently in place for FSIS for any positions? Which offices or positions are affected?

Response: Yes, the fiscal year (FY) 2006 operating guidelines issued by the Agency on December 1, 2005 are still in effect with very few exceptions. The guidelines restricted hiring on all positions except those at the front-line level. FSIS issued new guidelines in October 2006, under which front-line inspection continues to be exempt from the Agency's hiring restrictions. Front-line positions are defined as:

- Office of Field Operations - Food Inspectors, Consumer Safety Inspectors, Consumer Safety Officers (Enforcement, Investigations, and Analysis Officers), Public Health Veterinarians, Front-Line Supervisors, District and Deputy District Managers, and District Veterinary Medical Specialists.
- Office of International Affairs - Import Inspectors, Import Surveillance/Liaison Officers, Lead Import Surveillance/Liaison Officers, and Supervisory Food Inspectors (Regional Import Supervisors).
- Office of Program Evaluation, Enforcement and Review - Compliance Officers (Program Investigator), Supervisor Compliance Officers (Program Investigators), Supervisory Compliance Officers (Regional Manager), Veterinary Medical Officers (Program Auditor-International), Consumer Safety Officers (Program Auditor).
- Office of Public Health Science - Bench Scientist and Supervisory Scientist (Chemists, Microbiologist).

The hiring restriction guidelines required that an exception to the restrictions had to be submitted with justifications to the Office of the Administrator.

After operating under a strict hiring freeze for all non-frontline positions during most of FY 2006, the Agency continued with hiring restrictions in FY 2007 and FY 2008 by capping all non-frontline staffing levels at or below the non-frontline staffing level as of August 31, 2006. The Administrator approved eleven exceptions to this policy in FY 2008: five positions were approved in the Human Resources Operations group to support hiring additional inspectors; two positions were approved to support import/export activities; two positions were approved to support additional risk analysis efforts; and two positions were approved to support the Agency's public affairs and consumer outreach efforts.

Ms. DeLauro: Please update the information requested in the Office of the Secretary questions for the record to include travel by Dr. Raymond from February 11, 2008, through his last day in office.

Response: The information is currently being compiled and will be sent to Congress as soon as possible.

Ms. DeLauro: In response to questions for the record for the Office of the Secretary on Agency travel to conferences, FSIS reported that in FY 2006 it had sent numerous personnel and expended substantial sums to attend conferences listed as "PHV." What does PHV stand for and why did FSIS spend so much money for these conferences?

Response: These travel expenditures were not for conferences. They were expenditures for Public Health Veterinarian (PHV) training sessions. FSIS began offering the PHV training course in May 2004. This course is required as a condition of employment for all newly hired FSIS in-plant veterinarians. It has also been provided to veterinarians who were already assigned to establishments when the training became available.

The course includes training on many subjects, including post-mortem inspection, microbiological and residue testing, labeling, food defense, and sanitation. The course also includes five hours of training conducted by a District Veterinary Medical Specialist. Two of those hours cover ante-mortem inspection and three hours cover verification of the requirements for the humane handling of livestock. The training includes a review of the Humane Methods of Slaughter Act and the FSIS regulations regarding the requirements for the humane handling of livestock. It also covers humane slaughter methods, humane methods of moving livestock in holding pens, conditions that might cause injury to animals, how to verify that establishments are complying with the requirements for humane handling through the Humane Activities Tracking System, and the actions to take if inhumane handling is observed.

Ms. DeLauro: In response to questions for the record for the Office of the Secretary on cash awards and bonuses, FSIS reported that the amount spent in 2007 was far higher than in 2003 through 2006. Please explain the reason for this.

Response: Throughout FY 2006 and the beginning of FY 2007 was a very difficult time for FSIS. Budget, in-plant staffing shortages, and information technology problems presented the Agency with many challenges, and particularly presented challenges for the in-plant

workforce. Despite these challenges, our in-plant inspection program personnel carried out our public health mission successfully.

As a result of this success, the Agency and the Office of Field Operations (OFO) gave an extra effort award to employees to recognize them for a job well done. The extra effort award recipients included Food Inspectors, Consumer Safety Inspectors, Import Inspectors, Supervisory Consumer Safety Inspectors, and Public Health Veterinarians. This extra effort award was the reason for the increase in cash awards and bonuses in FY 2007, compared to those awards prescribed from FY 2003 through FY 2006.

DOMESTIC INSPECTIONS

Ms. DeLauro: Please update last year's table showing the number of U.S. plants inspected in fiscal years 2007 and 2008 and the number estimated for 2009.

Response: The information is provided for the record.

[The information follows:]

Federally-Inspected Establishments (including U.S. territories)

	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimated
Slaughter Plants	116	121	125	124	122
Processing Plants	3,993	4,029	3,989	3,948	3,899
Combination Slaughter and Processing Plants	905	927	878	882	871
Talmadge-Aiken Plants 1/	362	368	375	382	377
Import Establishments	137	151	155	132	145
Egg Processing Plants	71	64	76	78	77
Other Plants 2/	674	622	684	711	705
Total	6,258	6,282	6,282	6,257	6,196

1/ Federal slaughter, processing and combination plants that are inspected by State employees under Federal supervision.
2/ "Other" plants would be warehouses and identification service locations.

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the volume of meat and poultry inspected at slaughter to reflect the separate cost associated with each from fiscal year 1995 through 2008.

Response: The information is submitted for the record.

[The information follows:]

Volume and Cost of Meat and Poultry Inspected At Slaughter

Fiscal Year	Millions of pounds			Slaughter inspection cost, in millions of dollars		
	Red Meat*	Poultry		Meat	Poultry	Total
1995	43,663	41,303		134	180	314
1996	44,689	43,572		133	185	318
1997	40,522	44,233		139	193	332
1998	42,300	43,200		148	196	344
1999	42,249	46,882		162	211	373
2000	44,788	48,137		156	230	386
2001	47,397	46,728		162	244	406
2002	42,237	50,444		164	248	412
2003	43,563	49,243		174	270	444
2004	43,611	52,790		193	261	454
2005	45,633	55,324		202	330	532
2006	46,855	56,683		233	313	546
2007	47,605	57,138		153	260	413
2008	50,266	59,531		163	272	435

* This data does not include Bison, Deer/Reindeer, Elk, Cattalo and Water Buffalo.

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the number of poultry carcasses inspected from fiscal year 1994 through 2008. What is the estimate for 2009? Please also briefly describe the inspection process for poultry.

Response: The information is submitted for the record.

[The information follows:]

Poultry Carcasses Inspected Per Fiscal Year (In millions)					
Fiscal Year	Young Chickens	Mature Chickens	Turkeys	Ducks	Others
1994	7,014	174	278	21	5.2
1995	7,303	163	279	19	5.5
1996	7,517	154	290	20	5.3
1997	7,646	164	289	22	9.5
1998	7,416	159	266	22	8.9
1999	7,896	176	262	24	7.8
2000	8,082	170	262	24	9.7
2001	7,780	152	252	26	10.4
2002	8,322	173	263	24	10
2003	7,967	151	259	23	8.8
2004	8,501	140	286	25	2
2005	8,979	150	251	27	2
2006	8,898	134	252	28	1.7

Poultry Carcasses Inspected Per Fiscal Year (In millions)					
Fiscal Year	Young Chickens	Mature Chickens	Turkeys	Ducks	Others
2007	8,861	131	263	27	2.1
2008 Estimated	9,062	153	273	25	2.7
2009 Estimated	9,234	156	282	23	3.5

As required by the Poultry Products Inspection Act, each poultry carcass presented for slaughter is inspected by FSIS. Antemortem inspection consists of observing the live birds in crates on transport vehicles prior to unloading. Inspection program personnel observe the general health of the birds and look for indications of infectious diseases, such as laryngotracheitis and chlamydiosis.

Traditional postmortem inspection consists of observing the outside, inside, and viscera of each bird. The on-line inspection program personnel evaluate the pathological and physiological status of the carcass and internal organs looking for any signs of septicemic disease or general systemic disturbance that might indicate the presence of a condition that would render the carcass, or any part, unsafe or unwholesome. Off-line inspection program personnel are simultaneously verifying the plant's execution of its HACCP food safety system.

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the number of livestock inspected at slaughter, by species, for fiscal years 1994 through 2008. What is the estimate for 2009? What does the inspection consist of?

Response: Credible projections for FY 2009 are not possible. The information is submitted for the record.

[The information follows:]

Livestock Inspected Per Fiscal Year (In thousands)						
Year	Cattle	Calves	Sheep	Goats	Swine	Equines
1994	33,179	1,191	4,645	365	90,206	109
1995	35,681	1,395	4,512	333	94,490	113
1996	37,690	1,723	4,268	421	93,397	113
1997	35,809	1,579	3,743	375	78,489	88
1998	33,273	1,447	3,386	396	93,259	71
1999*	33,680	1,268	3,390	463	88,902	62
2000	35,136	1,103	3,315	530	93,385	50
2001	37,641	1,333	3,463	592	96,600	62
2002	31,404	1,034	2,922	553	89,855	43
2003	33,334	1,003	2,668	610	91,143	44
2004	31,515	876	2,679	582	98,416	59
2005	31,847	757	2,582	536	103,849	88
2006	32,860	682	2,540	561	103,600	102
2007	33,472	769	2,497	613	105,610	58
2008 Estimated	34,180	866	2,473	654	115,431	0

* During FY 1999, problems in data processing/software in the Animal Disposition Reporting System, an FSIS database containing information on birds and animal slaughtered commercially, caused duplicate records to be processed. This inflated FY 1999 inspection totals for livestock used in prior years' versions of this table. The FY 1999 figures used here are corrected amounts developed from a reconstruction of the FY 1999 database.

As required by the Federal Meat Inspection Act, 100 percent of livestock carcasses presented for slaughter are inspected by FSIS. Antemortem inspection consists of observing the livestock at rest and in motion. Inspection program personnel observe the general health of the livestock and look for abnormalities indicative of significant infectious or degenerative diseases. Should an animal exhibit central nervous symptoms or be non-ambulatory (downer), the animal is condemned on antemortem and prohibited from inclusion into human food. Animals with symptoms suggestive of a foreign animal disease (such as Foot and Mouth Disease, etc.) are held and referred to APHIS.

Postmortem inspection consists of observation, incision, and palpation of internal organs at three strategic steps in the slaughter process. These steps include head inspection, viscera inspection and rail/carcass inspection. At each step inspection program personnel evaluate the physiological status of the carcass and internal organs looking for any suggestion of a septicemic disease, general systemic disturbance, infestation, or residue that might indicate the presence of a condition needing to be retained for final disposition by a Public Health Veterinarian. This assures the elimination of carcasses that may present a risk to public health.

Ms. DeLauro: How many firms currently hold grants of inspection to irradiate meat and poultry?

Response: In 2007, three establishments held grants of inspection to commercially irradiate meat and poultry. As of the end of FY 2008, four establishments have grants to commercially irradiate meat and poultry.

Ms. DeLauro: How many plants in the United States are operating under the HAACP system? Does this include all FSIS regulated plants? What plants do not operate under HAACP?

Response: All meat and poultry plants under Federal inspection operate under HACCP. As of September 2008, there were 5,269 plants operating with the HACCP system in the United States. This group of plants consists of slaughter, processing, combination slaughter and processing, and Talmadge-Aiken plants; it does not include import establishments, egg processing plants, or other plants.

Ms. DeLauro: Please provide for the record a description of FSIS activities relating to humane slaughter enforcement. How have these activities changed since the revelation of problems with humane slaughter enforcement in a plant in California earlier this year?

Response: FSIS ensures that the approximately 800 Federally-inspected establishments that slaughter livestock comply with the

Humane Methods of Slaughter Act (HMSA), which requires that all livestock be slaughtered by humane methods. As part of their routine, ongoing and continuous inspection and enforcement duties, all FSIS inspection program personnel are obligated and expected to take appropriate actions, including suspending operations, if appropriate, of a livestock slaughter establishment if they observe violations of HMSA. FSIS strictly enforces the provisions of the Act. In FY 2006, there were 18 suspensions for humane handling and slaughter violations, 12 suspensions in FY 2007, and 88 suspensions in FY 2008.

FSIS has 15 highly-trained District Veterinary Medical Specialists (DVMSs), one per District, who are subject matter specialists dedicated to providing technical expertise and oversight related to humane handling and slaughter. The Agency continues to increase Agency training and education efforts to ensure that all field personnel understand their authorities and rigorously enforce HMSA. All FSIS livestock inspection program personnel are trained in humane handling and understand that they are required and obligated to take immediate enforcement action when a humane slaughter violation is observed. Since the Hallmark/Westland Meat Packing Company humane handling enforcement action, FSIS's Office of Field Operations (OFO) has held monthly conference calls between the DVMSs nationwide and Regulatory Operations from headquarters. OFO also conducts off-site correlations with the DVMSs every 12 to 18 months. This year's correlation was in a location that allowed the attending DVMSs to visit slaughter plants, in order to enhance their correlation experience. Humane handling reviews by DVMSs are documented on a newly-standardized review form and stored in an Agency database that will be incorporated into the Public Health Information System (PHIS) once the system is fully developed.

The Humane Activities Tracking System (HATS) provides FSIS with an accurate and complete accounting of the time spent by FSIS inspection program personnel performing specific tasks and the results of that inspection related to humane handling and slaughter under the requirements of the HMSA.

In FY 2006, $4 million was provided to continue to incorporate HATS into the FAIM architecture. The funding allowed the Agency to increase connectivity for inspection program personnel. By incorporating HATS into FAIM, FSIS is utilizing real time inspection data on humane handling and slaughter to strengthen enforcement of HMSA. The funding was available for FY 2006 and FY 2007. Field connectivity efforts have continued in FY 2008 and are continuing to improve.

The FY 2006 Agriculture Appropriations Act included a provision to require the Agency to employ no fewer than 63 full time equivalent (FTE) positions above the FY 2002 level during FY 2006 for purposes dedicated solely to inspection and enforcement related to HMSA. During FY 2007, FSIS more than met this requirement and noted more than 121 FTEs in the Electronic Animal Disposition System (e-ADRS) data. FSIS continued this extremely important effort during FY 2008, devoting over 157 FTEs to HMSA enforcement during that time period (an increase of approximately 29 percent over FY 2007). Much of this increase was directly in response to the Hallmark/Westland Meat Packing Company humane handling enforcement action.

On December 7, 2007, FSIS issued Directive 6100.3, which covers verification of good commercial practices (GCPs) in poultry slaughter plants by in-plant FSIS personnel and subsequent action expected by those personnel. In addition to continuing the above efforts, FSIS developed and implemented a new GCP review form developed through a DVMS working group for use when a DVMS is reviewing commercial practices in poultry slaughter establishments. The form is currently saved in an electronic format and will be incorporated into the PHIS when the new information system is fully developed.

On March 3, 2008, as a result of the Hallmark/Westland Meat Packing Company humane handling enforcement action, FSIS issued Notice 17-08 to all FSIS inspection program personnel directing them to increase significantly the time that they spent conducting humane handling verification activities at all levels and to document those verification activities in HATS program. This began on March 10, 2008, and continued until May 6, 2008, a total of 60 days.

During this 60-day period, surveillance and inspection activities were prioritized and focused based on existing data, such as the category of livestock handled at the facility, humane handling data, observations made at the facility during regular inspection, and a plant's operating schedule.

In particular, FSIS focused humane handling activities at establishments where older or potentially distressed animals were slaughtered, such as facilities that handle dairy/beef cows or veal calves. At these facilities, the time spent performing HATS activities was increased by at least 50 percent and up to 100 percent above the time spent on those activities during a six month period in CY 2007. At facilities with contracts from the Agriculture Marketing Service (AMS) for school lunch programs, HATS verification time was doubled, regardless of the type or class of the animal slaughtered. At facilities where non-ambulatory livestock were infrequently presented, such as in slaughter facilities that handled young market classes including steers, heifers, market hogs, and lambs, an additional 50 percent of HATS verification was required.

Later in FY 2008, increased surveillance was extended indefinitely for plants producing school lunch product (constituting a permanent 25 percent increase in the level of humane handling activities by FSIS inspection personnel at these establishments).

Ms. DeLauro: Please provide the Committee a table of the total number of inspection hours worked beyond the regularly scheduled shifts, broken out by voluntary, holiday, or any other specific category for the past three years. Also include the fees collected for each category. What voluntary inspections did FSIS perform in FY 2007 and 2008?

Response: FSIS charges inspected establishments an hourly fee for inspection performed at the request of the plant on overtime or during holidays. FSIS also provides a range of voluntary inspection under the Agricultural Marketing Act (AMA). These voluntary inspections are for species not covered as amenable species, such as rabbits, bison, and game animals; or for inspection procedures beyond

those required for Federal inspection, chiefly for certification required for products exported from the United States. The information is submitted for the record.

[The information follows:]

Overtime/Holiday and Voluntary Inspection
Summary of Pay Hours, Billings, and Collections
For FY 2006, FY 2007, and FY 2008

Fiscal year/Service Type	Pay Hours Worked and Billed*	Fees Billed*	Fees Collected*
FY 2006			
Over Time(OT) /Holiday	2,312,792	123,387,737	124,999,823
Voluntary	127,560	6,252,820	5,876,155
FY 2007			
OT/Holiday	2,314,492	124,057,504	132,131,880
Voluntary	171,682	7,963,556	8,456,556
FY 2008			
OT/Holiday	2,434,469	143,279,205	145,645,483
Voluntary	189,719	10,077,725	10,242,448

* The billed amount represents the actual bills that were sent out to the establishments in the fiscal year, but the Agency often receives collections during the current year for bills sent during the prior year. Increased collection efforts over the last two years have been extremely successful.

For both types of inspection, the Agency is required to be fully reimbursed for the inspection services from the establishments receiving inspection, and the fees are calculated to recover the full costs.

Ms. DeLauro: Please update the Committee on your plans for "virtual" inspections. Explain how and when this would be implemented and the impact on resources. Has FSIS obtained an opinion from the Office of General Counsel on the legality of this? If so, what was the opinion?

Response: The idea behind "virtual" inspection is to conduct certain administrative tasks associated with inspection through a more effective use of technology. Under such a system, an inspector would occasionally review an establishment's records from a remote location separate from regular onsite inspection. While the Agency continues to view this as a concept that the Agency may revisit, FSIS is not actively pursuing this approach at this time. Therefore, the Agency has not yet obtained a formal opinion from the Office of the General Counsel.

FOREIGN INSPECTION AND IMPORTS

Ms. DeLauro: Please provide a table showing the timetable for, and status of, FSIS's implementation of each of the 19 recommendations included in the OIG report on controls over imported meat and poultry products, 24601-08 Hy (August 2008).

Response: The information is submitted for the record.

[The information follows:]

Recommendation	Completion Date	Status (as of 9/30/08)
1. Determine whether the current 20 percent error rate provides a sound basis for evaluating the equivalence of a country's food safety system and document the basis for the error rate accepted as reasonable.	10/31/2008	Open
2. Develop and implement protocols for documenting deviations from the guidelines on visiting the minimum number of establishments as part of the onsite audit. The documentation should provide sufficient, competent evidence that the establishments visited provide a reasonable basis for concluding that the country's food safety system remains equivalent to the U.S. system.	10/31/2008	Open
3. Develop and implement protocols for documenting which establishments are selected for review as part of the: (a) random sample and (b) judgmental sample. The protocols should also specify where this information will be documented (e.g., in the onsite audit report).	10/31/2008	Open
4. Develop and implement criteria for judgmentally selecting foreign establishments for onsite review. The selection criteria should consider such information as (a) reinspection results from FSIS' information system, or any subsequent system, (b) deficiencies noted in prior onsite audits, (c) establishments with a pattern of being decertified and subsequently recertified, and (d) any other appropriate evaluation factors.	10/31/2008	Open
5. Revise OIA's Management Control Manual to include the protocols for (1) determining which equivalence deficiencies would question a country's overall equivalence determination and (2) postponing and cancelling a scheduled enforcement audit. The protocol for questioning country equivalence should also describe how FSIS officials will document and justify the decisions made.	10/31/2008	Open
6. Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from new countries in OIA's Management Control Manual.	10/31/2008	Open
7. Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from countries that had been suspended in OIA's Management Control Manual. These procedures should define the period of time that would cause an onsite audit to be performed before the country resumes exporting product to the United States.	10/31/2008	Open

Recommendation	Completion Date	Status (as of 9/30/08)
8. Determine the appropriate number of intensified inspections for physical and laboratory failures that ensure the safety and wholesomeness of imported products and document the necessary revisions to procedures for intensified inspections.	10/31/2008	Open
9. Clearly document the level of reinspection being performed on imported product in FSIS' information system and ensure that scheduled inspections are suspended when the level of inspection is intensified.	1/31/2010	Open
10. Develop and implement procedures that require inspectors to perform physical reinspections first and for FSIS import inspection personnel to perform unscheduled inspection on skipped lots associated with lots that failed reinspection.	10/31/2008	Open
11. Take the appropriate action on the approximately 325,000 pounds of product from the 12 skipped lots associated with lots that failed physical reinspection.	10/31/2008	Open
12. Document the procedures to guide inspectors' decisions on what data sources to use for a shipment's production date.	2/28/2008	Open
13. Implement an edit check in the information system, or any subsequent revision, to validate that inspectors used adequate data source to verify a shipment's production date.	1/31/2010	Open
14. Perform an assessment, including any other appropriate FSIS units, to determine whether foreign establishments should be required to provide the lot's production date.	10/31/2008	Open
15. Develop and implement procedures for performing standard analyses of data in the new information system to determine that data were reasonable, complete, and accurate. The procedures should identify the FSIS officials responsible for performing the analyses and following up on discrepancies noted.	10/24/2008	Closed
16. In the new information system, implement an edit check to alert users when inspection results have not been recorded. As part of this analytical tool, FSIS should also establish the expected timeframes for recording inspection results.	6/31/2010	Open
17. In the new information system, implement an edit check to ensure that only appropriate amounts are entered into the information system (e.g., negative amounts are not entered, rejected weights do not exceed the presented weight, and valid production dates are entered).	6/31/2010	Open
18. In the new information system, require that the reason for not performing an inspection task be recorded in a standard way (e.g., pick the reason from a drop down menu). FSIS should also develop and implement a standard analysis to evaluate the reasons inspection tasks are not performed in order to revise the types of inspections assigned.	6/31/2010	Open

Recommendation	Completion Date	Status (as of 9/30/08)
19. Include the training of import inspection personnel in FSIS' reassessment of the effectiveness of the Agency's training programs that is currently scheduled to be completed by September 2008.	9/30/2008	Action completed. Pending submission of materials with the Department for closure.

Ms. DeLauro: Please update last year's table showing the number of foreign plants inspected in fiscal years 2006 through 2008 and the number estimated for 2009.

Response: The information is provided for the record.

[The information follows:]

	Foreign Country	Establishments Audited FY 2006 (Actual)	Establishments Audited FY 2007 (Actual)	Establishments Audited FY 2008 (Actual)	Establishment Audited FY 2009 (Projected)
1	Argentina	12	6	11	6
2	Australia	10	8	13	8
3	Austria*	Suspended	2	3	2
4	Belgium	1	1	1	1
5	Brazil	16	8	13	8
6	Canada	21	24	35	24
7	Chile	3	3	7	3
8	China**	Not Eligible/NCE*	NCE	Not Audited	Not Scheduled
9	Costa Rica	3	2	3	2
10	Croatia	3	1	3	1
11	Czech Republic	Not Audited	1	2	1
12	Denmark	Not Audited	8	13	8
13	England	2	1	2	1
14	Finland	4	2	4	2
15	France	4	2	3	2
16	Germany	6	3	5	3
17	Honduras	3	2	2	2
18	Hungary	Not Audited	2	5	2
19	Iceland	Not Audited	5	Not Audited	5
20	Ireland	Not Audited	1	3	1
21	Israel	10	7	8	7
22	Italy	13	8	8	8
23	Japan	Not Audited	2	4	2
24	Mexico	13	8	11	15
25	The Netherlands	Not Audited	5	9	5
26	New Zealand	13	10	6	10
27	Nicaragua	5	2	5	2
28	Northern Ireland	2	1	2	1
29	Poland	Not Audited	6	8	6
30	Romania	Not Audited	Not Exporting	4	2
31	San Marino***	1	1	1	1

	Foreign Country	Establishments Audited FY 2006 (Actual)	Establishments Audited FY 2007 (Actual)	Establishments Audited FY 2008 (Actual)	Establishment Audited FY 2009 (Projected)
32	Slovakia****	NCE; Audited govt. inspection offices and labs	NCE/Suspended	NCE/Suspended	NCE/Suspended
33	Spain	7	4	5	4
34	Sweden	2	1	2	1
35	Uruguay	13	8	11	8
TOTALS		167	145	212	154

* Austria was suspended throughout FY 2007, but audited in September 2007 and in November 2007 relisted as eligible to export based on the audit results, thereby bringing the total number of eligible countries to 34 in FY 2008.
**: The final rule to add China to the list of countries eligible to export processed poultry products to the United States was published on April 24, 2006, but China was not eligible to certify establishments until May 25, 2006. Since becoming eligible to certify establishments for export, China has yet to certify any establishments that would subsequently be subject to FSIS audit. In addition, current law prohibits FSIS from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.
***: San Marino became eligible to certify establishments for export as of October 4, 2005.
****: Slovakia became eligible to certify establishments for export as of April 11, 2005. Slovakia has agreed not to certify any establishments as a result of the FY 2006 FSIS audit findings, which has the same effect as a voluntary suspension. They will remain unable to export product to the United States until corrective actions acceptable to the FSIS can be provided and verified.
NCE (No Certified Establishments): No establishments were certified for export to the United States.
Cancelled: Country audit cancelled; therefore, no foreign establishments were audited.
Postponed: Country audit postponed; therefore, no foreign establishments were audited during that fiscal year. Still eligible to export to U.S.
Not Audited: No audit was conducted during the fiscal year.

Ms. DeLauro: Please update the lists on pages 319-322 of last year's hearing volume on the countries and the type and volume of product imported in fiscal years 2007 and 2008.

Response: The information is provided for the record.

[The information follows:]

Imported Meat and Poultry Presented into the United States
FY 2007

Country	Species	Process Category	Pounds Presented
Argentina	Beef	Thermally Processed Shelf Stable	7,719,967
Argentina	Beef	Heat Treated-Shelf Stable	6,343,495
Argentina	Beef	Fully Cooked-Not Shelf Stable	28,084,236

Country	Species	Process Category	Pounds Presented
Australia	Beef	Raw Product Ground	112,391
Australia	Beef	Raw Product Not Ground	671,550,795
Australia	Beef	Thermally Processed Shelf Stable	2,322,371
Australia	Beef	Heat Treated-Shelf Stable	6,047
Australia	Beef	Fully Cooked-Not Shelf Stable	24,780
Australia	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	119,871
Australia	Combination	Thermally Processed Shelf Stable	53,325
Australia	Goat	Raw Product Not Ground	24,238,288
Australia	Lamb	Raw Product Not Ground	91,381,571
Australia	Lamb	Thermally Processed Shelf Stable	52,576
Australia	Lamb	Fully Cooked-Not Shelf Stable	1,764
Australia	Mutton	Raw Product Not Ground	38,351,247
Australia	Mutton	Thermally Processed Shelf Stable	186,321
Australia	Pork	Raw Product Not Ground	219,943
Australia	Ratite	Raw Product Not Ground	281,074
Australia	Veal	Raw Product Not Ground	12,252,985
Brazil	Beef	Thermally Processed Shelf Stable	89,545,160
Brazil	Beef	Not Heat Treated-Shelf Stable	186,090
Brazil	Beef	Heat Treated-Shelf Stable	32,321,989
Brazil	Beef	Fully Cooked-Not Shelf Stable	27,856,367
Canada	Beef	Raw Product Ground	754,964
Canada	Beef	Raw Product Not Ground	668,581,986
Canada	Beef	Thermally Processed Shelf Stable	4,436,446
Canada	Beef	Not Heat Treated-Shelf Stable	7,963
Canada	Beef	Heat Treated-Shelf Stable	7,732,178
Canada	Beef	Fully Cooked-Not Shelf Stable	2,149,193
Canada	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	9,999,280
Canada	Chicken	Raw Product Ground	66,875
Canada	Chicken	Raw Product Not Ground	85,949,644
Canada	Chicken	Thermally Processed Shelf Stable	9,469,477
Canada	Chicken	Not Heat Treated-Shelf Stable	610,790
Canada	Chicken	Heat Treated-Shelf Stable	367,839
Canada	Chicken	Fully Cooked-Not Shelf Stable	21,866,038
Canada	Chicken	Heat Treated-Not Fully cooked-Not Shelf Stable	46,623,195
Canada	Combination	Raw Product Ground	36,740
Canada	Combination	Raw Product Not Ground	3,248
Canada	Combination	Thermally Processed Shelf Stable	349,838
Canada	Combination	Not Heat Treated-Shelf Stable	13,200
Canada	Combination	Heat Treated-Shelf Stable	86,990
Canada	Combination	Fully Cooked-Not Shelf Stable	365,124
Canada	Combination	Heat Treated-Not Fully cooked-Not Shelf Stable	6,877,602
Canada	Duck/Geese	Raw Product Not Ground	4,518,573
Canada	Duck/Geese	Thermally Processed Shelf Stable	1,539
Canada	Duck/Geese	Not Heat Treated-Shelf Stable	2

Country	Species	Process Category	Pounds Presented
Canada	Duck/Geese	Fully Cooked-Not Shelf Stable	65,883
Canada	Duck/Geese	Products with Secondary Inhibitors-Not Shelf Stable	999
Canada	Equine	Raw Product Not Ground	205,873
Canada	Guinea/squab	Raw Product Not Ground	4,709
Canada	Lamb	Raw Product Ground	177
Canada	Lamb	Raw Product Not Ground	493,163
Canada	Mutton	Thermally Processed Shelf Stable	89,344
Canada	Mutton	Heat Treated-Not Fully cooked-Not Shelf Stable	8,374
Canada	Pork	Raw Product Ground	217,434
Canada	Pork	Raw Product Not Ground	741,070,067
Canada	Pork	Thermally Processed Shelf Stable	2,906,857
Canada	Pork	Not Heat Treated-Shelf Stable	6,219,124
Canada	Pork	Heat Treated-Shelf Stable	12,920,844
Canada	Pork	Fully Cooked-Not Shelf Stable	48,334,374
Canada	Pork	Heat Treated-Not Fully cooked-Not Shelf Stable	52,015,055
Canada	Pork	Products with Secondary Inhibitors-Not Shelf Stable	110,901
Canada	Turkey	Raw Product Ground	2,212,322
Canada	Turkey	Raw Product Not Ground	14,869,580
Canada	Turkey	Thermally Processed Shelf Stable	116,639
Canada	Turkey	Not Heat Treated-Shelf Stable	17,639
Canada	Turkey	Heat Treated-Shelf Stable	2,196
Canada	Turkey	Fully Cooked-Not Shelf Stable	906,780
Canada	Turkey	Heat Treated-Not Fully cooked-Not Shelf Stable	3,247,473
Canada	Veal	Raw Product Ground	4,613
Canada	Veal	Raw Product Not Ground	25,226,552
Canada	Veal	Fully Cooked-Not Shelf Stable	88
Canada	Veal	Heat Treated-Not Fully cooked-Not Shelf Stable	19,345
Chile	Beef	Raw Product Not Ground	1,982,833
Chile	Lamb	Raw Product Not Ground	8
Chile	Pork	Raw Product Not Ground	2,398,994
Costa Rica	Beef	Raw Product Not Ground	14,436,438
Costa Rica	Beef	Not Heat Treated-Shelf Stable	29
Croatia	Pork	Thermally Processed Shelf Stable	386,495
Denmark	Pork	Raw Product Not Ground	80,004,907
Denmark	Pork	Thermally Processed Shelf Stable	5,264,468
Denmark	Pork	Not Heat Treated-Shelf Stable	880,326
Denmark	Pork	Heat Treated-Shelf Stable	98,151
Denmark	Pork	Fully Cooked-Not Shelf Stable	8,228,316
Finland	Pork	Raw Product Not Ground	2,652,983
France	Combination	Thermally Processed Shelf Stable	1,461
France	Duck/Geese	Raw Product Not Ground	224,636
France	Duck/Geese	Thermally Processed Shelf Stable	26,951

Country	Species	Process Category	Pounds Presented
France	Duck/Geese	Fully Cooked-Not Shelf Stable	19,720
France	Pork	Thermally Processed Shelf Stable	659
Germany	Pork	Thermally Processed Shelf Stable	87,362
Germany	Pork	Not Heat Treated-Shelf Stable	736,359
Honduras	Beef	Raw Product Not Ground	168,000
Hungary	Pork	Fully Cooked-Not Shelf Stable	835,051
Iceland	Lamb	Raw Product Not Ground	112,024
Ireland	Pork	Raw Product Not Ground	4,204,263
Israel	Chicken	Fully Cooked-Not Shelf Stable	682,518
Israel	Turkey	Fully Cooked-Not Shelf Stable	1,749,763
Italy	Pork	Thermally Processed Shelf Stable	7,525
Italy	Pork	Not Heat Treated-Shelf Stable	7,410,523
Italy	Pork	Fully Cooked-Not Shelf Stable	1,278,902
Japan	Beef	Raw Product Not Ground	228,952
Mexico	Beef	Raw Product Ground	6,239,815
Mexico	Beef	Raw Product Not Ground	30,376,373
Mexico	Beef	Thermally Processed Shelf Stable	215,679
Mexico	Beef	Fully Cooked-Not Shelf Stable	1,103,711
Mexico	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	2,968,254
Mexico	Chicken	Raw Product Not Ground	190,464
Mexico	Chicken	Fully Cooked-Not Shelf Stable	11,036,607
Mexico	Chicken	Heat Treated-Not Fully cooked-Not Shelf Stable	4,687,806
Mexico	Combination	Fully Cooked-Not Shelf Stable	6,365,471
Mexico	Goat	Raw Product Not Ground	8,215
Mexico	Lamb	Raw Product Not Ground	47,615
Mexico	Pork	Raw Product Ground	11,321
Mexico	Pork	Raw Product Not Ground	3,906,913
Mexico	Pork	Thermally Processed Shelf Stable	272,853
Mexico	Pork	Heat Treated-Shelf Stable	22
Mexico	Pork	Fully Cooked-Not Shelf Stable	13,400,504
Mexico	Pork	Heat Treated-Not Fully cooked-Not Shelf Stable	138,472
Mexico	Turkey	Raw Product Not Ground	1,102
Mexico	Turkey	Fully Cooked-Not Shelf Stable	8,714,385
Netherlands	Pork	Raw Product Not Ground	822,245
Netherlands	Pork	Thermally Processed Shelf Stable	395,331
New Zealand	Beef	Raw Product Not Ground	373,771,652
New Zealand	Beef	Thermally Processed Shelf Stable	2,417,517
New Zealand	Beef	Heat Treated-Shelf Stable	176,441
New Zealand	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	320
New Zealand	Combination	Thermally Processed Shelf Stable	3,450
New Zealand	Goat	Raw Product Not Ground	416,680
New Zealand	Lamb	Raw Product Not Ground	45,839,891
New Zealand	Lamb	Thermally Processed Shelf Stable	99,753
New Zealand	Lamb	Fully Cooked-Not Shelf Stable	11

Country	Species	Process Category	Pounds Presented
New Zealand	Lamb	Heat Treated-Not Fully cooked-Not Shelf Stable	79
New Zealand	Mutton	Raw Product Not Ground	2,363,806
New Zealand	Mutton	Thermally Processed Shelf Stable	36,750
New Zealand	Pork	Raw Product Not Ground	65,085
New Zealand	Ratite	Raw Product Not Ground	52,180
New Zealand	Veal	Raw Product Not Ground	22,327,959
Nicaragua	Beef	Raw Product Ground	38,616
Nicaragua	Beef	Raw Product Not Ground	67,974,888
Northern Ireland	Pork	Raw Product Not Ground	1,786,200
Poland	Pork	Thermally Processed Shelf Stable	2,284,783
Poland	Pork	Fully Cooked-Not Shelf Stable	15,988,367
San Marino	Pork	Fully Cooked-Not Shelf Stable	967
Spain	Pork	Not Heat Treated-Shelf Stable	1,614,851
Spain	Pork	Heat Treated-Shelf Stable	1,274
Spain	Pork	Fully Cooked-Not Shelf Stable	60,757
Sweden	Pork	Raw Product Not Ground	670,557
United Kingdom	Pork	Raw Product Not Ground	1,326,636
Uruguay	Beef	Raw Product Not Ground	304,917,162
Uruguay	Beef	Thermally Processed Shelf Stable	7,034,347
Uruguay	Beef	Not Heat Treated-Shelf Stable	714,381
Uruguay	Beef	Heat Treated-Shelf Stable	816,426
Uruguay	Beef	Fully Cooked-Not Shelf Stable	2,830,852
TOTAL			3,896,012,195

Imported Meat and Poultry Presented into the United States
FY 2008

Country	Species	Process Category	Pounds Presented
Argentina	Beef	Thermally Processed Shelf Stable	3,879,401
Argentina	Beef	Heat Treated-Shelf Stable	5,416,626
Argentina	Beef	Fully Cooked-Not Shelf Stable	21,258,952
Australia	Beef	Raw Product Ground	150,130
Australia	Beef	Raw Product Not Ground	501,635,887
Australia	Beef	Thermally Processed Shelf Stable	3,058,828
Australia	Beef	Heat Treated-Shelf Stable	5,276
Australia	Beef	Fully Cooked-Not Shelf Stable	25
Australia	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	35,112
Australia	Combination	Thermally Processed Shelf Stable	12,003
Australia	Goat	Raw Product Not Ground	21,162,921
Australia	Lamb	Raw Product Not Ground	88,420,850
Australia	Lamb	Thermally Processed Shelf Stable	60,875
Australia	Lamb	Fully Cooked-Not Shelf Stable	21,795
Australia	Mutton	Raw Product Ground	30,566

Country	Species	Process Category	Pounds Presented
Australia	Mutton	Raw Product Not Ground	35,180,660
Australia	Mutton	Thermally Processed Shelf Stable	180,461
Australia	Pork	Raw Product Not Ground	128,958
Australia	Ratite	Raw Product Not Ground	145,272
Australia	Veal	Raw Product Not Ground	12,021,252
Brazil	Beef	Thermally Processed Shelf Stable	78,121,028
Brazil	Beef	Not Heat Treated-Shelf Stable	451,777
Brazil	Beef	Heat Treated-Shelf Stable	26,667,787
Brazil	Beef	Fully Cooked-Not Shelf Stable	16,788,607
Canada	Beef	Raw Product Ground	6,094,731
Canada	Beef	Raw Product Not Ground	627,276,831
Canada	Beef	Thermally Processed Shelf Stable	3,988,564
Canada	Beef	Not Heat Treated-Shelf Stable	35,817
Canada	Beef	Heat Treated-Shelf Stable	28,210,047
Canada	Beef	Fully Cooked-Not Shelf Stable	1,162,076
Canada	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	11,091,405
Canada	Chicken	Raw Product Ground	129,925
Canada	Chicken	Raw Product Not Ground	98,616,953
Canada	Chicken	Thermally Processed Shelf Stable	6,380,820
Canada	Chicken	Not Heat Treated-Shelf Stable	843,791
Canada	Chicken	Heat Treated-Shelf Stable	1,375,868
Canada	Chicken	Fully Cooked-Not Shelf Stable	23,850,908
Canada	Chicken	Heat Treated-Not Fully cooked-Not Shelf Stable	43,677,778
Canada	Combination	Raw Product Ground	3,322
Canada	Combination	Raw Product Not Ground	4,032
Canada	Combination	Thermally Processed Shelf Stable	193,188
Canada	Combination	Not Heat Treated-Shelf Stable	97,069
Canada	Combination	Heat Treated-Shelf Stable	3,633,190
Canada	Combination	Fully Cooked-Not Shelf Stable	261,195
Canada	Combination	Heat Treated-Not Fully cooked-Not Shelf Stable	7,525,847
Canada	Duck/Geese	Raw Product Ground	44
Canada	Duck/Geese	Raw Product Not Ground	4,487,497
Canada	Duck/Geese	Thermally Processed Shelf Stable	573
Canada	Duck/Geese	Fully Cooked-Not Shelf Stable	95,939
Canada	Duck/Geese	Heat Treated-Not Fully cooked-Not Shelf Stable	2,729
Canada	Duck/Geese	Products with Secondary Inhibitors-Not Shelf Stable	170
Canada	Equine	Raw Product Not Ground	1,457,453
Canada	Guinea/squab	Raw Product Not Ground	1,149
Canada	Lamb	Raw Product Ground	369
Canada	Lamb	Raw Product Not Ground	335,122
Canada	Lamb	Thermally Processed Shelf Stable	39,376
Canada	Lamb	Fully Cooked-Not Shelf Stable	2,171
Canada	Mutton	Thermally Processed Shelf Stable	96,249

Country	Species	Process Category	Pounds Presented
Canada	Pork	Raw Product Ground	159,984
Canada	Pork	Raw Product Not Ground	588,847,911
Canada	Pork	Thermally Processed Shelf Stable	2,860,990
Canada	Pork	Not Heat Treated-Shelf Stable	6,434,633
Canada	Pork	Heat Treated-Shelf Stable	9,780,427
Canada	Pork	Fully Cooked-Not Shelf Stable	41,505,311
Canada	Pork	Heat Treated-Not Fully cooked-Not Shelf Stable	50,716,021
Canada	Pork	Products with Secondary Inhibitors-Not Shelf Stable	172,991
Canada	Turkey	Raw Product Ground	2,568,514
Canada	Turkey	Raw Product Not Ground	11,850,964
Canada	Turkey	Thermally Processed Shelf Stable	118,203
Canada	Turkey	Not Heat Treated-Shelf Stable	19,767
Canada	Turkey	Fully Cooked-Not Shelf Stable	488,085
Canada	Turkey	Heat Treated-Not Fully cooked-Not Shelf Stable	2,364,669
Canada	Veal	Raw Product Ground	3,306
Canada	Veal	Raw Product Not Ground	26,760,378
Canada	Veal	Fully Cooked-Not Shelf Stable	272
Canada	Veal	Heat Treated-Not Fully cooked-Not Shelf Stable	41,396
Chile	Beef	Raw Product Not Ground	2,233,773
Chile	Chicken	Raw Product Not Ground	1,135,312
Chile	Pork	Raw Product Not Ground	5,237,990
Chile	Turkey	Raw Product Not Ground	406,813
Costa Rica	Beef	Raw Product Not Ground	13,357,276
Croatia	Pork	Thermally Processed Shelf Stable	379,744
Denmark	Pork	Raw Product Not Ground	90,226,865
Denmark	Pork	Thermally Processed Shelf Stable	789,471
Denmark	Pork	Not Heat Treated-Shelf Stable	900,520
Denmark	Pork	Heat Treated-Shelf Stable	424,541
Denmark	Pork	Fully Cooked-Not Shelf Stable	1,802,214
Finland	Pork	Raw Product Not Ground	2,219,034
France	Combination	Thermally Processed Shelf Stable	1,948
France	Duck/Geese	Raw Product Not Ground	224,734
France	Duck/Geese	Thermally Processed Shelf Stable	28,970
France	Duck/Geese	Fully Cooked-Not Shelf Stable	23,993
Germany	Pork	Thermally Processed Shelf Stable	65,232
Germany	Pork	Not Heat Treated-Shelf Stable	657,648
Honduras	Beef	Raw Product Not Ground	3,722,990
Hungary	Pork	Fully Cooked-Not Shelf Stable	460,108
Iceland	Lamb	Raw Product Not Ground	109,688
Ireland	Pork	Raw Product Not Ground	4,682,461
Israel	Chicken	Fully Cooked-Not Shelf Stable	743,568
Israel	Turkey	Fully Cooked-Not Shelf Stable	901,435
Italy	Pork	Thermally Processed Shelf Stable	6,063
Italy	Pork	Not Heat Treated-Shelf Stable	7,882,119

Country	Species	Process Category	Pounds Presented
Italy	Pork	Fully Cooked-Not Shelf Stable	1,363,521
Japan	Beef	Raw Product Not Ground	297,456
Mexico	Beef	Raw Product Ground	2,175,498
Mexico	Beef	Raw Product Not Ground	32,050,615
Mexico	Beef	Thermally Processed Shelf Stable	5,214
Mexico	Beef	Not Heat Treated-Shelf Stable	333
Mexico	Beef	Fully Cooked-Not Shelf Stable	1,059,186
Mexico	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	2,008,649
Mexico	Chicken	Raw Product Not Ground	65,991
Mexico	Chicken	Fully Cooked-Not Shelf Stable	11,241,469
Mexico	Chicken	Heat Treated-Not Fully cooked-Not Shelf Stable	5,670,030
Mexico	Combination	Fully Cooked-Not Shelf Stable	6,019,289
Mexico	Combination	Heat Treated-Not Fully cooked-Not Shelf Stable	337,497
Mexico	Goat	Raw Product Not Ground	30,957
Mexico	Lamb	Raw Product Not Ground	43,313
Mexico	Pork	Raw Product Ground	11,263
Mexico	Pork	Raw Product Not Ground	4,510,345
Mexico	Pork	Thermally Processed Shelf Stable	187,698
Mexico	Pork	Fully Cooked-Not Shelf Stable	14,381,557
Mexico	Pork	Heat Treated-Not Fully cooked-Not Shelf Stable	97,652
Mexico	Turkey	Fully Cooked-Not Shelf Stable	10,871,207
Netherlands	Pork	Raw Product Not Ground	4,466,601
Netherlands	Pork	Thermally Processed Shelf Stable	3,001,557
Netherlands	Pork	Heat Treated-Shelf Stable	18,360
New Zealand	Beef	Raw Product Not Ground	355,394,883
New Zealand	Beef	Thermally Processed Shelf Stable	2,167,623
New Zealand	Beef	Heat Treated-Shelf Stable	1,530,797
New Zealand	Beef	Heat Treated-Not Fully cooked-Not Shelf Stable	58,202
New Zealand	Goat	Raw Product Not Ground	422,600
New Zealand	Lamb	Raw Product Not Ground	43,459,979
New Zealand	Lamb	Thermally Processed Shelf Stable	99,683
New Zealand	Mutton	Raw Product Not Ground	13,118,639
New Zealand	Mutton	Thermally Processed Shelf Stable	80,235
New Zealand	Pork	Raw Product Not Ground	52,605
New Zealand	Ratite	Raw Product Not Ground	45,257
New Zealand	Veal	Raw Product Not Ground	22,382,177
Nicaragua	Beef	Raw Product Ground	2,288
Nicaragua	Beef	Raw Product Not Ground	78,643,746
Northern Ireland	Pork	Raw Product Not Ground	2,908,612
Poland	Pork	Raw Product Not Ground	244,709
Poland	Pork	Thermally Processed Shelf Stable	1,821,625
Poland	Pork	Fully Cooked-Not Shelf Stable	20,859,854

Country	Species	Process Category	Pounds Presented
San Marino	Pork	Fully Cooked-Not Shelf Stable	951
Spain	Pork	Raw Product Not Ground	69,239
Spain	Pork	Not Heat Treated-Shelf Stable	1,424,234
Spain	Pork	Fully Cooked-Not Shelf Stable	36,163
Sweden	Pork	Raw Product Not Ground	1,916,402
United Kingdom	Pork	Raw Product Not Ground	612,480
Uruguay	Beef	Raw Product Not Ground	58,631,438
Uruguay	Beef	Thermally Processed Shelf Stable	2,066,660
Uruguay	Beef	Not Heat Treated-Shelf Stable	460,278
Uruguay	Beef	Heat Treated-Shelf Stable	874,204
Uruguay	Beef	Fully Cooked-Not Shelf Stable	678,435
TOTAL			3,279,104,835

NOTE: "United Kingdom" is used to refer to England, Wales and Scotland. However, only England is currently eligible to export products to the United States.

Imported Egg Products into the United States
FY 2007

Country	Products	Pounds
CANADA	Dried Products	1,391,853
	Pasteurized Liquid/Frozen	3,905,390
	Unpasteurized Liquid/Frozen	15,199,905
	TOTAL	20,497,148

Imported Egg Products into the United States
FY 2008

Country	Products	Pounds
CANADA	Dried Products	1,262,350
	Pasteurized Liquid/Frozen	2,760,369
	Unpasteurized Liquid/Frozen	17,731,986
	TOTAL	21,754,705

Ms. DeLauro: Please update the tables in last year's hearing record showing the number of countries eligible to export to the U.S., and the number that actually exported products to the U.S. in fiscal years 2007 and 2008. Please explain the reason behind any increase or decrease over 2006 or between 2007 and 2008.

Response: In FY 2006, there were 33 countries eligible to export to the United States, and 29 countries that actually exported. Austria had been removed from the eligibility list in FY 2006 after being suspended for a lack of certified establishments, but the country became eligible to export again in FY 2007.

The countries that actually export to the United States have not changed since FY 2006. In FY 2006, China became eligible to export to the United States processed poultry from birds born and raised in the United States or another country eligible to export raw poultry to the

United States, and was added to the eligibility list. However, current law prohibits FSIS from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.

[The information follows:]

Countries Eligible to Export to the United States and Countries that Exported to the United States during FY 2007 and FY 2008

Eligible Countries (34) [as of September 30, 2008]	FY 2007 Actual Exporters (29)	FY 2008 Actual Exporters (29)
Argentina	Argentina	Argentina
Australia	Australia	Australia
Austria	No exports to US	No exports to US
Belgium	No exports to US	No exports to US
Brazil	Brazil	Brazil
Canada	Canada	Canada
Chile	Chile	Chile
China*	No exports to US	No exports to US
Costa Rica	Costa Rica	Costa Rica
Croatia	Croatia	Croatia
Czech Rep	No exports to US	No exports to US
Denmark	Denmark	Denmark
Finland	Finland	Finland
France	France	France
Germany	Germany	Germany
Honduras	Honduras	Honduras
Hungary	Hungary	Hungary
Iceland	Iceland	Iceland
Ireland	Ireland	Ireland
Israel	Israel	Israel
Italy	Italy	Italy
Japan	Japan	Japan
Mexico	Mexico	Mexico
Netherlands	Netherlands	Netherland
N. Zealand	N. Zealand	N. Zealand
Nicaragua	Nicaragua	Nicaragua
No. Ireland	No. Ireland	No. Ireland
Poland	Poland	Poland
Romania	No exports to US	No export to US
San Marino	San Marino	San Marino
Spain	Spain	Spain
Sweden	Sweden	Sweden
United Kingdom	United Kingdom	United Kingdom
Uruguay	Uruguay	Uruguay

* Current law prohibits FSIS from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.

Ms. DeLauro: What countries have applications pending to export meat, poultry or egg products to the U.S.? Please update the table on page 324 of last year's hearing volume.

Response: The information is provided for the record.

[The information follows:]

Countries with Applications Pending To Export Meat, Poultry, or Egg Products to the United States

COUNTRY	PRODUCT(S)	STATUS
Argentina	Poultry	Document Assessment
Australia	Eggs	Document Assessment
Barbados	Meat	Document Assessment
Belgium	Poultry	Document Assessment
Bosnia/Herzegovina	Meat	Document Assessment
Brazil	Poultry	Document Assessment
British Virgin Islands	Meat	Document Assessment
Bulgaria	Meat	Document Assessment
China	Poultry/slaughtered	On-Site Audit
Colombia	Meat	Document Assessment
Costa Rica	Poultry	On-Site Audit
Denmark	Poultry	Document Assessment
Ecuador	Poultry	Document Assessment
Egypt	Meat	Document Assessment
Greece	Meat and Poultry	Document Assessment
Guatemala	Poultry	Document Assessment
Honduras	Poultry	On-Site Audit
India	Meat and Poultry	Document Assessment
Jamaica	Meat and Poultry	Document Assessment
Jordan	Meat and Poultry	Document Assessment
Korea	Meat and Poultry	On-site Audit
Latvia	Meat, Poultry and Processed Egg Products	Document Assessment
Lithuania	Meat, Poultry and Processed Egg Products	Document Assessment
Lebanon	Poultry	Document Assessment
Malaysia	Poultry	Document Assessment
Mexico	Processed Egg Products and Poultry	On-Site Audit
Montenegro	Meat	Document Assessment
Namibia	Meat	Document Assessment
Pakistan	Meat and Poultry	Document Assessment
Panama	Meat and Poultry	Document Assessment
Peru	Poultry	Document Assessment
Philippines	Meat	Document Assessment
Poland	Poultry	Document Assessment
Portugal	Meat	Document Assessment
Russia	Meat	Document Assessment
Serbia	Meat	Document Assessment

COUNTRY	PRODUCT(S)	STATUS
Singapore	Poultry	Document Assessment
Slovenia	Poultry	Document Assessment
South Africa	Meat and Poultry	Document Assessment
Spain	Poultry	Document Assessment
Sweden	Poultry	Document Assessment
Taiwan	Poultry	Document Assessment
Thailand	Poultry	Document Assessment
Turkey	Meat	Document Assessment
Ukraine	Meat	Document Assessment

Note: A number of the countries listed already export meat and/or poultry products to the United States; however, they have applied to export additional products that they are not currently permitted to export to the United States.

Document Assessment: Refers to the FSIS equivalence review process of the foreign country's documents. These documents are the foreign country's responses to the five FSIS public health, risk-based questionnaires and copies of their relevant inspection laws and regulations. Countries in this category include those that plan to submit the documents and those that have submitted documents, which are being reviewed by FSIS officials.

On-Site Audit: Refers to an in-country review by a multi-disciplinary team of FSIS officials conducted once the document review portion is completed or near completion. All aspects of a foreign country's inspection system are evaluated to ensure equivalence with the United States inspection system and consistency with the documentation submitted to FSIS for review.

Ms. DeLauro: Please update the Committee on the use of an initial on-site assessment of foreign inspection systems. Is this still a pilot?

Response: FSIS has begun piloting a new approach for the initial equivalence determination process, which includes an "initial on-site assessment." This process has already been used in a few countries as a means of gathering information about a foreign inspection system on-site and securing the responses to the questionnaires and relevant regulations, laws, and directives in the foreign country.

FSIS did not conduct any initial assessment audits for foreign meat, poultry, and/or processed egg products inspection systems in FY 2007, but in FY 2008, FSIS conducted two initial assessments of the meat inspection systems of Serbia and Montenegro.

This new approach, which is still considered a pilot, is intended to facilitate a more efficient, thorough, and expeditious review and decision for the final certification of a foreign country seeking eligibility to export meat, poultry, and/or processed egg products to the United States.

Ms. DeLauro: How are exporting countries certified? Has this certification process changed over the last few years?

Response: Any country can apply for eligibility to export meat, poultry, or processed egg products to the United States. Normally, the application process begins with a letter to FSIS from a foreign government asking for clearance to export its products for sale in U.S. commerce. FSIS responds to these letters with a standard package consisting of questionnaires designed to collect detailed information about the foreign food regulatory system and copies of pertinent U.S. laws, regulations, and other documents. The initial package provides an applicant country with information about the U.S. meat and poultry food regulatory system and conveys expectations about sanitary measures that FSIS anticipates in an equivalent foreign system. In summary, the initial eligibility package explains the level of sanitary protection that FSIS requires.

Foreign countries often take months to assess the initial eligibility package and complete all necessary questionnaires. Upon request, FSIS provides advice and guidance to foreign governments concerning any portion of the application process. When the completed application is received, FSIS conducts an initial document analysis. In many cases, further information or clarification is needed. FSIS advises the foreign government of data or other information needed to finish the evaluation and works collaboratively with its food regulatory officials to facilitate this process. Upon completion of the document analysis step, FSIS makes a decision as to whether the foreign food regulatory system documentation (1) meets all U.S. import requirements in an equivalent manner and (2) cumulatively provides the same level of public health protection as the domestic food safety regulatory system. If this step is satisfactorily completed, FSIS then carries out an on-site, initial equivalency audit of the entire foreign meat, poultry, and/or processed egg products food regulatory system.

Initial equivalence audits are conducted by a multidisciplinary team of experts. Composition of the audit team may include a veterinarian, food technologist, microbiologist, chemist, residue technician, compliance officer, document analysis case officer, and others as needed. In some instances, auditors may possess multiple skills and will perform more than one function. The audit planning process begins with each auditor becoming completely familiar with all documentation submitted by the foreign government. The audit scope includes system records such as country laws, regulations, notices, and other program implementation documents; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, and testing methodologies; and special U.S. import requirements such as pathogen reduction and HACCP programs. Data collection instruments are devised to evaluate each foreign food regulatory system component.

During the on-site audit, FSIS auditors correlate foreign program documentation with observations about program delivery. Thus, the goal of an initial equivalence audit is to verify that the foreign food regulatory system has satisfactorily implemented all the exporting country's laws, regulations, and other inspection or certification

requirements that FSIS found to be equivalent during the document analysis step.

Follow-up audits are conducted when necessary to complete the initial equivalence on-site process. When both the document analysis and on-site audit steps have been satisfactorily completed, FSIS publishes a proposed rule in the *Federal Register* that announces the results of the first two steps and proposes to add the country to its list of eligible exporters. Upon receipt of public comments, FSIS makes a decision about system equivalence based upon all available information and publishes a final rule in the *Federal Register* announcing country eligibility.

Although the equivalence determination process has not changed significantly in recent years, FSIS has begun piloting a new approach for this process, which includes an "initial on-site assessment." This process has been used in a few countries already as a means of gathering information about a foreign inspection system on-site and securing the responses to the questionnaires and relevant regulations, laws, and directives in the foreign country. A multidisciplinary team of experts is sent to the foreign country to assess the status of the foreign food regulatory system. This initial on-site assessment does not eliminate or replace the document review or on-site audit steps, but is intended to facilitate a more efficient, thorough, and expeditious review and decision for the final certification of a foreign country seeking eligibility to export meat, poultry, and/or processed egg products to the United States.

Ms. DeLauro: How many slaughter and processing plants were inspected in all certified countries in each of fiscal years 2007 and 2008?

Response: In FY 2007, FSIS conducted inspection system audits in all of the 33 countries that were eligible to export and were exporting. As part of these system audits, various levels of the foreign inspection system oversight, such as headquarters, district, and local level offices were audited. In addition, residue and microbiological laboratories were audited, and 142 establishments were reviewed in the 34 foreign countries that were audited during FY 2007. An audit in Hong Kong was not conducted because the country did not have any establishments certified for export to the United States. An audit of Switzerland was not conducted because the country was suspended. The final rule to add China to the list of countries eligible to export processed poultry products to the United States was published on April 24, 2006, but China was not eligible to certify establishments until May 25, 2006. Since becoming eligible, China has yet to certify any establishments that would subsequently be subject to FSIS audit and the FY 2009 Continuing Resolution bars FSIS from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China Austria was suspended throughout FY 2007, but was audited in September 2007 and relisted in November 2007 as eligible to export based on the audit results, thereby bringing the total number of eligible countries to 34 in FY 2008. In Slovakia there were no certified establishments, but an audit of laboratories and inspection offices was still conducted. Audits that were conducted in FY 2007 included on-site reviews of a sample of

slaughter and processing establishments in each country, as well as various levels of inspection oversight and laboratories.

FSIS conducted audits of all eligible countries in FY 2008, including approximately 213 establishments in the 34 countries that are currently eligible to export to the United States.

Ms. DeLauro: If an imported product is found to be unfit after the product passes inspection at the port of entry, to what extent can this product be traced back to its country of origin? Has FSIS made any changes to the way it handles the recalls or trace backs of imported product over the past year? What improvements has FSIS made to the Automated Import Inspection System to facilitate product trace-backs?

Response: The Federal meat and poultry inspection laws provide that imported product that has passed port-of-entry reinspection and entered the United States be treated as domestic product. All products entering the United States carry labeling on the shipping container indicating the country and plant of origin. Consumer-ready products are fully labeled with the country and plant of origin, which is retained throughout the distribution chain.

FSIS traceback procedures apply to domestically produced product, as well as imported product that has passed port-of-entry reinspection. A shipment of contaminated meat can be traced back to the country-of-origin by use of box labels, production codes, and paperwork, including the application for import inspection and the foreign country health certificate. FSIS traceback of imported products is effective unless the products are further processed under U.S. inspection and no longer carry the original labeling. At this point, FSIS is reliant on industry record keeping, providing the details from the product used in production. If the products are further processed, they can be traced back to the establishment where the further processing occurred. Information collected is provided to the foreign inspection system to take corrective actions and to provide a report to FSIS.

The Automated Import Inspection System (AIIS), a computer database system, captures information such as shipping markings on the cartons and health certification numbers. All shipments received at U.S. ports of entry are reviewed for documentation and labeling. This information allows FSIS to better track shipments of meat, poultry, and processed egg products once they enter the country. The system links inspectors at all ports of entry, allowing information on shipments and violations to be shared immediately. FSIS employees can access the AIIS to verify whether imported products have received import reinspection upon entry into the United States. During the past year, the Agency has not made any changes to the system for tracing back imported product to the country-of-origin. However, FSIS continues to evaluate the system and will incorporate improvements into the Public Health Information System (PHIS), which will replace the AIIS.

As part of this new system, FSIS has identified business and functional requirements that will enable the interface with Custom and Border Protection's Automated Commercial Environment / International Trade Data System. Ineligible shipments (e.g. originating from an unapproved country) will be rejected at the port of entry. FSIS will receive

advance notice of eligible imported product when the importer files entry with U.S. Customs and Border Protection, which will include the application for FSIS inspection. This will enable FSIS to track movement of the shipment to the designated import establishment. In addition, the PHIS will enable receipt of electronic certification directly from the foreign governments that have the ability, which will provide more secure government-to-government transmission of data. Inspection results will be more quickly communicated to the foreign governments, enabling follow-up and appropriate corrective actions when their products are rejected.

Ms. DeLauro: Please list the countries for which you did equivalence determinations in fiscal years 2006 through 2008. Please include a synopsis of the findings or conclusions.

Response: The equivalency determination charts, below, are submitted for the record.

[The information follows:]

FY 2006 FSIS Equivalence Determinations

Country	Date*	Equivalence Determination	Equivalent?
Australia	January 10, 2006	Residue control program.	YES
Australia	February 21, 2006	Postmortem inspection procedure - no examination of heads and tongues (when not used for human consumption) of sheep and swine carcasses.	YES
Australia	March 3, 2006	Analytical testing methods for *Salmonella* and *Listeria monocytogenes.*	YES
Australia	March 9, 2006	Analytical testing methods for generic *E. coli.*	YES
Australia	June 22, 2006	Analytical testing methods for *Listeria monocytogenes.*	YES
Australia	August 24, 2006	Analytical testing methods for *E. coli* O157:H7.	YES
Belgium	June 7, 2006	Analytical testing methods for *Listeria monocytogenes.*	YES
Belgium	June 27, 2006	Analytical testing methods for *Salmonella.*	YES
Belgium	June 28, 2006	Analytical testing methods for *Listeria monocytogenes.*	YES
Canada	February 23, 2006	Generic *E. coli* testing for minor species.	YES

Country	Date*	Equivalence Determination	Equivalent?
Canada	March 2, 2006	High line speed inspection system for beef.	YES
Canada	June 29, 2006	Testing program for *Listeria monocytogenes*: plant employees take samples, private laboratories analyze samples.	YES
Chile	April 20, 2006	*Salmonella* enforcement strategy: in the case of a positive result, establishments require immediate corrective actions and additional sampling.	YES
Chile	April 20, 2006	*Salmonella* samples: location samples are taken from and size of samples taken. *Salmonella* testing strategy: requires year round, ongoing sampling.	YES
China	May 3, 2006	Analytical testing methods for *Listeria monocytogenes*.	YES
China	May 4, 2006	Analytical testing methods for *Salmonella*.	YES
China	May 23, 2006	Residue methods for detection of: chloramphenicol, streptomycin, flouroquinolones, phenicols, clenbuterol, organochlorines, PCBs, penicillins, tetracyclines, benzylpenicillin, nitroimidazoles, nitrofurans, neomycin.	YES
England	March 20, 2006	Analytical testing methods for *Salmonella*.	YES
European Union	November 28, 2006	Use of alternative sampling tools for sampling of generic *E. coli*.	YES
Ireland	June 18, 2006	Analytical testing methods for *Salmonella*.	YES
Netherlands	November 17, 2006	Visual inspection of mesenteric lymph nodes in hogs.	YES
New Zealand	January 25, 2006	Generic *E. coli* testing program for sheep and goats.	YES

Country	Date*	Equivalence Determination	Equivalent?
New Zealand	March 6, 2006	Government oversight - use of third party, non-government inspectors.	YES
New Zealand	August 30, 2006	Visual only inspection of the carcass except for palpation of the inner surface of the ventro-lateral abdomen.	YES
Northern Ireland	April 24, 2006	Analytical testing methods for *Salmonella*.	YES

* In FY 2006, the date denoted the date on which the decision memorandum was signed for a particular equivalence determination. As of FY 2007, the tracking system noted the date of the official letter notifying the inquiring foreign country of the equivalence decision.

FY 2007 FSIS Equivalence Determinations

Country	Date Country Notified	Equivalence Determination	Equivalent?
Australia	March 30, 2007	Generic *E. coli* Testing Program.	YES
Australia	April 3, 2007	*E. coli* O157:H& Analytical Lab Method (AOAC 996.09).	YES
Australia	April 4, 2007	*Salmonella* Analytical Lab Method (AOAC Biocontrol 1-2).	YES
Australia	August 29, 2007	Modified labeling program for retained water.	YES
Australia	August 29, 2007	Eliminates the incision of the atlantal lymph nodes in cattle.	YES
Brazil	January 8, 2007	Suspends an establishment from the list of certified establishments after the establishment has failed the third Salmonella set. This decision changes the 12/14/99 decision.	YES
Canada	May 10, 2007	Bax System (MFLP 28) for all ready-to-eat (RTE) products.	YES
Chile	August 10, 2007	Private laboratories analyze samples for Salmonella.	YES
Denmark	January 30, 2007	*Salmonella* Analytical Lab Method (iQ-Check Method).	YES
New Zealand	April 18, 2007	Modification to procedures affecting carcass separation during the slaughter and dressing process in establishments exporting meat to the United States.	YES
New Zealand	August 30, 2007	Conducts post-mortem inspection of sheep and goat carcasses after removal of the head.	YES

Country	Date Country Notified	Equivalence Determination	Equivalent?
Northern Ireland	July 20, 2007	*Salmonella* Analytical Lab Method (NF 11).	NO
Slovakia	April 18, 2007	*Salmonella* Analytical Lab Method (ISO 6579).	YES
Slovakia	April 20, 2007	*Salmonella* Analytical Lab Method (ISO 11290-1).	YES
Slovakia	May 25, 2007	*Salmonella* Analytical Lab Method (ISO 11290-2).	NO
Spain	February 23, 2007	Species verification program is equivalent.	YES

FY 2008 FSIS Equivalence Determinations

Country	Date Country Notified	Equivalence Determination	Equivalent?
Argentina	February 8, 2008	*E. coli* O157:H7 Analytic Lab Method (VIDAS ECO).	NO
Argentina	February 8, 2008	VIDAS *Listeria monocytogenes* 11 (LMO2).	YES
Argentina	February 8, 2008	VIDAS *Listeria monocytogenes* (LIS).	YES
Argentina	February 8, 2008	VIDAS Listeria Species Xpress (LSX).	YES
Argentina	February 8, 2008	VIDAS ICS and Selective Plate (HE BS, XLD) Method (Raw).	YES
Argentina	February 8, 2008	VIDAS ICS and *Salmonella* (SLM) Method Enzyme-linked Immunosorbent Assay (ELFA) Method (Raw).	YES
Argentina	February 8, 2008	VIDAS *Salmonella* (SLM) Method (Raw).	YES
Argentina	February 12, 2008	VIDAS ICS and *Salmonella* (SLM) Method Enzyme-linked Immunosorbent Assay (ELFA) in RTE foods.	NO
Argentina	February 12, 2008	VIDAS *Salmonella* (SLM) in RTE foods.	NO
Argentina	February 12, 2008	VIDAS ICS and Selective Plate (HE BS, SMID) in RTE foods.	NO
Argentina	February 12, 2008	VIDAS ICS and Selective Plate (HE BS, XLD) in RTE foods.	NO

Country	Date Country Notified	Equivalence Determination	Equivalent?
Australia	December 5, 2007	AQIS has defined a lot as comprising all those cartons, packages or containers of beef components either: (1) packed on a given packing line and based on SSOP; (2) determined by the establishment based on the implementation of a statistically based sample.	YES
Australia	December 5, 2007	Private laboratories analyze samples for *E. coli* O157:H7.	YES
Australia	April 3, 2008	Private laboratories analyze samples for *Listeria monocytogenes*.	YES
Australia	April 3, 2008	Establishment employees collect the samples for *Listeria monocytogenes*.	YES
Australia	August 5, 2008	Australia requests exemption from SRM removal regulation.	YES
Australia	August 5, 2008	Australia requests exemption from prohibition on slaughter of non-ambulatory, disabled cattle.	NO
Austria	January 1, 2008	*Listeria monocytogenes* Analytical Lab Testing Method (Adopted FSIS Method).	YES
Austria	February 7, 2008	BIOKITS (Cooked) Species Identification Kit (Tepnel).	YES
Belgium	July 9, 2008	Use of private laboratories.	YES
Brazil	January 8, 2008	Modified enforcement strategy.	YES
Canada	November 16, 2007	Biocontrol Assurance GDS (MFLP-16).	YES
Canada	January 2, 2008	*Listeria monocytogenes* Analytical Lab Method (MFLP-28).	YES
Canada	January 2, 2008	*Salmonella* Analytical Lab Method (MFLP-29).	YES
Canada	January 2, 2008	*Salmonella* Analytical Lab Method (MFHPB-20).	YES
Canada	January 2, 2008	*E. coli* O 157:H7 Analytical Lab Method (MFLP-94).	NO
Canada	January 3, 2008	*Listeria monocytogenes* Analytical Lab Method (MFHPB-30).	YES
Canada	February 20, 2008	*Salmonella* Analytical Lab Method (MFLP-70).	NO
Canada	February 28, 2008	*E. coli* O157:H7 Analytical Lab Method (MFLP-80).	YES

Country	Date Country Notified	Equivalence Determination	Equivalent?
Canada	April 21, 2008	*Salmonella* Analytical Lab Method (MFLP-20 [meat, eggs]).	YES
Canada	April 21, 2008	*Salmonella* Analytical Lab Method (MFHPB-24 VIDAS SLM [eggs]).	YES
Canada	June 9, 2008	*E. coli* O157:H7 Analytical Lab Method (MFLP-16).	YES
Canada	June 9, 2008	*E. coli* O157:H7 Analytical Lab Method (MFLP-19).	YES
Canada	June 9, 2008	*E. coli* O157:H7 Analytical Lab Method (MFLP-30).	YES
Canada	June 23, 2008	*E. coli* O157:H7 Analytical Lab Method (MFLP 12).	YES
Canada	July 22, 2008	*Salmonella* Analytical Method (MFLP-32).	YES
Canada	August 25, 2008	National Program for *E. coli O157:H7*.	YES
Chile	May 8, 2008	*E. coli* O157:H7 Analytical Lab Method [VIDAS ECO (Screening)].	NO
Chile	May 8, 2008	*E. coli* O157:H7 Analytical Lab Method [VIDAS ICE (Confirmatory)].	NO
Chile	August 25, 2008	National program for *E. coli* O157:H7.	YES
Costa Rica	March 18, 2008	National program for *E. coli* O157:H7.	YES
Costa Rica	March 28, 2008	*E. coli* O157:H7 Analytical Lab Method (MBA-PT-010).	YES
Costa Rica	June 26, 2008	Use of private laboratories to analyze samples.	YES
Costa Rica	July 9, 2008	*E. coli* O157:H7 Analytical Lab Method (MBA-PT-010 Version 2).	NO
Denmark	July 9, 2008	*Salmonella* Analytical Lab Method for Ready-to-Eat (RTE) Products (VIDAS SLM).	NO
Denmark	July 9, 2008	*Salmonella* Analytical Lab Method for Raw Product (VIDAS SLM).	YES
Denmark	July 9, 2008	*Salmonella* Analytical Lab Method for RTE Products (VIDAS Easy SLM).	NO
Denmark	July 9, 2008	*Salmonella* Analytical Lab Method for Raw Products (VIDAS Easy SLM).	YES
European Union	August 4, 2008	*Salmonella* testing program for raw product.	NO
European Union	August 4, 2008	Condemned and inedible products.	YES
European Union	August 4, 2008	Post-mortem inspection procedures.	NO

Country	Date Country Notified	Equivalence Determination	Equivalent?
European Union	August 4, 2008	Ante-mortem inspection procedures.	NO
European Union	August 4, 2008	EC 882 Official Controls on Feed and Food, Animal Health and Animal Welfare.	YES
European Union	August 4, 2008	Government oversight controls.	NO
European Union	August 4, 2008	Sanitation performance standards.	YES
European Union	August 4, 2008	Sanitation standard operating procedures.	NO
European Union	August 4, 2008	Hazard analysis and critical control point system.	NO
Mexico	September 11, 2008	National program for E. *coli* O157:H7.	YES
Netherlands	July 16, 2008	Visual post-mortem inspection of market hogs.	YES
New Zealand	December 21, 2007	National program for *E. coli* O157:H7.	YES
New Zealand	February 21, 2008	TECRA Visual Immunoassay.	YES
New Zealand	February 21, 2008	*E. coli* O157:H7 Analytical Lab Method Neogen Reveal (24h enrichment).	YES
New Zealand	February 21, 2008	Bax *E. coli* O157:H7 PCR.	YES
New Zealand	February 21, 2008	*E. coli* O157:H7 Analytical Lab Method [Visual Immuno-Precipitate (VIP)].	YES
New Zealand	August 5, 2008	Exemption from SRM removal regulation.	YES
New Zealand	August 5, 2008	Exemption from slaughter of non-ambulatory, disabled cattle.	NO
Nicaragua	March 28, 2008	*E. coli* O157:H7 Analytical Lab Method.	NO
Nicaragua	March 28, 2008	National program for *E. coli* O157:H7.	NO
Nicaragua	August 15, 2008	National program for *E. coli* O157:H7.	YES
Spain	February 21, 2008	*Listeria monocytogenes* Analytical Lab Method (PEE/LSPV/068).	YES
Spain	February 21, 2008	*Salmonella* Analytical Lab Method (PEE/LSPV/012).	YES
Spain	February 21, 2008	Board of Castilla and Leon Protocol.	YES
Uruguay	April 1, 2008	National program for *E. coli* O157:H7.	YES

Ms. DeLauro: Once FSIS determines equivalence in a country exporting meat and poultry products to the United States, is there any follow up inspection at ports of entry or the retail level? Please

describe how recent changes to the AIIS system have contributed to this process.

Response: After clearing U.S. Customs and Border Protection and the Animal and Plant Health Inspection Service (APHIS) protocols, every imported meat and poultry shipment must be presented for reinspection to FSIS. All shipments received at U.S. ports of entry are reviewed for documentation and labeling. When a meat or poultry shipment is presented for reinspection, the AIIS scans its records to verify eligibility. Shipments are denied reinspection and refused entry if the foreign country is not eligible to export to the United States, if the establishment that produced the product has not been certified for export to this country; if the product presented for reinspection is not eligible; if the shipping marks are not unique; or if APHIS has animal health restrictions on the country. AIIS, which is a centralized database, generates reinspection assignments for FSIS port-of-entry inspection personnel and stores results of these inspections.

In addition, when a presented lot is selected by the AIIS for more intense reinspection, various types of inspection, including product examination or laboratory testing, such as microbiological, chemical residues or food chemistry, will be generated and completed. Products that fail reinspection are rejected and must be re-exported, converted to non-human food, or destroyed.

The AIIS data and inspection results are used during audit planning, including information such as the types of products shipped, as well as products that are refused entry. Adjustments may be made to the frequency or type of inspection performed at port of entry, based on the results from the audits of the foreign country's inspection system.

Ms. DeLauro: Please update the Committee on the status of FSIS equivalency determinations of Canada.

Response: In 2004, FSIS completed a side-by-side review of the Canadian inspection system and found several differences in the system. Since that time, FSIS has provided equivalence determinations for Canada in several areas, such as pre-shipment review of HACCP records (completed on December 22, 2004), *E. coli* O157:H7 test methods (completed on December 29, 2005), and a national sampling and testing program for ready-to-eat meat and poultry products (completed on June 29, 2006). In each of these cases, FSIS found the Canadian system to be equivalent to that in the United States. The equivalence determination on Canadian less-than-daily inspection is still under review by FSIS. FSIS was recently informed by Canada that they have completed the year-long peer-reviewed study on less-than-daily inspection. They are in the process of analyzing their data, and will provide a draft when it is ready. The study results will be part of the information used to make the less-than-daily inspection equivalence determination.

Ms. DeLauro: In FY 2006 through 2008, what percentage of imports did FSIS inspect and what percentage of products was analyzed in the lab? How does FSIS determine the percentage of imports that will go through additional reinspection activities? Please provide a table

showing percentages inspected and analyzed in fiscal years 1998 through 2008.

Response: The Agency performs port-of-entry inspection on all FSIS-regulated meat, poultry, and processed egg products coming into the United States, with a few exceptions. Every shipment is presented to an FSIS inspector, who verifies proper certification, accurate count, general condition, and labeling compliance.

In addition, more than 10 percent of these shipments are randomly selected for more in-depth reinspection using a statistical sampling plan that allocates samples by species and HACCP process categories. The level of sampling is based on the volume of each species imported from the country within each process category. The target sample size provides a 95 percent level of confidence of detecting an unacceptable outcome in at least one lot if that outcome is present in one percent of the imported lots from the country's system. AIIS randomly assigns product examinations to shipments that are presented at ports of entry, which undergo a physical examination for visible defects. Shipments selected for reinspection are subject to additional laboratory testing, such as microbiological, food, or residue chemistry, depending on the type of product presented for importation.

The results of the examinations are entered into the AIIS. In the event of an inspection failure, the AIIS will direct follow-up samples of the same product from the plant of origin. In addition, an increased level of sampling can be instituted for plants and for a country as a result of FSIS audits of the country's inspection system.

The percentage of meat and poultry receiving these more in-depth inspections, as well as the number of inspection tasks performed, are submitted for the record.

[The information follows:]

Imported Meat and Poultry
Percent Reinspected
Number of Inspections Performed
Percent Physical Examination and Laboratory Analysis

Fiscal Year	Percentage of Shipments Reinspected (Combined physical and laboratory types of inspection)	Number of Inspections Performed		
		Total number of inspections performed	Number of Physical Inspections Performed (percentage of total inspections performed)	Number of Laboratory Inspections Performed (percentage of total inspections performed)
1998	20.9%			
1999	21.8%			
2000	18.8%			
2001	18.5%			
2002	20.2%			

Fiscal Year	Percentage of Shipments Reinspected (Combined physical and laboratory types of inspection)	Number of Inspections Performed		
		Total number of inspections performed	Number of Physical Inspections Performed (percentage of total inspections performed)	Number of Laboratory Inspections Performed (percentage of total inspections performed)
2003*	6.7%	21,531	18,061 (83.9%)	3,470 (16.1%)
2004	7.7%	26,426	20,264 (76.7%)	6,162 (23.3%)
2005	9.7%	45,854	34,180 (74.5%)	11,674 (25.5%)
2006	15.4%	63,763	49,087 (77.0%)	14,676 (23.0%)
2007	11.1%	49,558	38,513 (77.7%)	11,045 (22.3%)
2008	10.5%	44,620	33,996 (76.2%)	10,620 (23.8%)

*The AIIS was redesigned in 2002 and FSIS is unable to report the specific types of inspection assignments from the previous system.

Ms. DeLauro: Please list, by country, the number of plants inspected in fiscal years 2004 through 2008 and indicate the number of plants in each country that were found to be not consistent with USDA policies and standards. What is FSIS' course of action for dealing with these plants that have substandard practices?

Response: Establishments with substandard practices can be delisted if found to have any serious deficiency that shows they are not meeting standards equal to those required in U.S. domestic plants. Examples include instances of direct product contamination; poor environmental sanitation that could lead to direct product contamination; lack of a Sanitation SOP or failure to implement an existing procedure; no HACCP plan or an inadequate plan or not following an existing plan; no testing for generic *E. coli*; less than continuous inspection coverage in slaughter plants; humane slaughter violations; and any other fundamental requirement of equivalence.

Foreign inspection services are expected to recertify a delisted plant upon correction of all deficiencies that resulted in its delistment. During the next annual audit, FSIS visits any plant that was delisted the year before to verify that its deficiencies have been corrected.

[The information follows:]

Foreign Inspection System Audits of Eligible Countries for FY 2004

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
1	Argentina	Oct/Nov 03 May/June 04	24 10	0 0
2	Australia	June/July 04	14	1
3	Austria*			
4	Belgium	Jan 04	1	0

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
5	Brazil	Nov 03 Aug/Sept 04	6 12	0 1
6	Canada**			
7	Costa Rica	June 04	3	1
8	Croatia	March 04	4	0
9	Czech Republic	May 04	2	0
10	Denmark	Sept 04	13	0
11	Dom. Republic***			
12	England	Mar/April 04	2	0
13	Finland	Jan 04	5	0
14	France	Jan/Feb 04 Sept/Oct 04	11 4	3 0
15	Germany	May 04	5	0
16	Honduras	Dec 03	2	0
17	Hong Kong****			
18	Hungary	Oct/Nov 03 April 04	7 2	1 0
19	Iceland	Sept 04	3	0
20	Ireland	June 03	4	0
21	Israel*[5]			
22	Italy *[6]			
23	Japan	Aug/Sept 04	4	0
24	Mexico	April/May 04	21	4
25	The Netherlands	April/May 04	9	0
26	New Zealand	Sept/Oct 04	13	0
27	Nicaragua	Nov 03	3	0
28	Northern Ireland	April 04	2	0
29	Poland	Nov/Dec 03 July/Aug 04	10 9	4 0
30	Romania	May/June 04	3	0
31	Spain	March 04	6	0
32	Sweden	Sept/Oct 04	2	0
33	Switzerland*[7]	July 04	1	0
34	Uruguay	Feb/March 04	14	0

* Audit canceled and Austria suspended.

** Canada audit was postponed; two audits of Canada conducted in FY05.

*** Not eligible to ship product to the United States because voluntarily suspended.

**** Hong Kong decertified its only establishment in May 2001. No country audit was conducted.

*[5] An audit of Israel was not conducted due to auditor safety issues and State Department security concerns.

*[6] The audit of Italy was postponed until October 2004 (FY 2005).

*[7] Switzerland declined the request for an annual audit in FY 2003 and was suspended. An audit was conducted in 2004.

Foreign Inspection System Audits of Eligible Countries for FY 2005

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
1	Argentina	Sept/Oct 05	12	0
2	Australia	May/June 05	19	1
3	Austria*			
4	Belgium	Mar/Apr 05	1	0
5	Brazil	Mar/Apr 05	15	3
		June 05	6	0
		July 05	8	0
6	Canada	Dec 04	15	0
		Feb 05	5	0
		May/June 05	35	0
7	Chile	Dec 04	2	0
		Aug 05	2	0
8	China	Dec 04	7	0
		July/Aug 05	4	0
9	Costa Rica	Nov 04	3	0
10	Croatia	March 05	3	0
11	Czech Republic	July 05	1	0
12	Denmark	June/Aug 05	13	0
13	Dom. Republic**			
14	England	May/June 05	2	0
15	Finland	Feb/Mar 05	5	0
16	France	Sept/Oct 04	4	0
17	Germany	Apr/May 05	5***	0
18	Honduras	Feb/Mar 05	2	0
19	Hong Kong****			
20	Hungary	Sept 05	1	0
21	Iceland	Sept 04	3	0
22	Ireland	Sept 05	3	0
23	Israel*[5]			
24	Italy	Oct/Nov 04	13	0
		Mar/May 05	13	0
25	Japan	Jan 05	4	0
26	Jordan	Feb 05	6	0
27	Mexico	Nov 04	12	0
		Mar 05	6	0
		June/July 05	14	0
28	The Netherlands	May/June 05	10	0
29	New Zealand*[6]			
30	Nicaragua	Oct 04	3	0
		Jan/Feb 05	3	0
31	Northern Ireland	May 05	2	0
32	Poland	May/June 05	9	0
33	Portugal	Apr/May 05	2	0
34	Romania	July/Aug 05	4	1
35	Spain	Dec 04	6	0
		Mar/Apr 05	6	0
36	Sweden	Aug 05	2	0
37	Switzerland*[7]			
38	Taiwan	Apr 05	6	0

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
39	Thailand	Sept 05	5	0
40	Uruguay	Feb/Mar 05	11	0

* Austria suspended.
** Not eligible to ship product to the United States because voluntarily suspended.
*** One pork slaughter establishment was proposed for future certification. It would have been delisted if it had been certified.
**** Hong Kong decertified its only establishment in May 2001. No country audit was conducted.
*[5] An audit of Israel was not conducted in FY 2005 due to auditor safety issues and State Department security concerns. Instead, the audit occurred in December 2005, just after FY 2005 ended.
*[6] The FY 2005 audit in New Zealand was delayed two weeks until the first week of FY 2006.
*[7] Switzerland declined the request for an annual audit in FY 2005 and remained suspended.

Foreign Inspection System Audits of Eligible Countries for FY 2006

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
1	Argentina	Aug/Sept 06	12	0
2	Australia	Aug 06	10	0
3	Austria*			
4	Belgium	Dec 05	1	0
5	Brazil	Oct/Nov 05	8	0
		Aug/Sept 06	8	0
6	Canada	Oct 05	0	0
		Apr/May 06	21	0
7	Chile	Mar/Apr 06	3	0
8	China**			
9	Costa Rica	Oct 05	3	0
10	Croatia	Mar/Apr 06	3	0
11	Czech Republic	Not Audited	0	0
12	Denmark	Not Audited	0	0
13	Dom. Republic***			
14	England	Nov 05	2	0
15	Finland	Nov 05	4	0
16	France	Nov/Dec 05	4	1
17	Germany	Nov/Dec 05	6	0
18	Honduras	Oct 05	3	0
	Honduras-poultry	Nov 05	1	0
19	Hong Kong****			
20	Hungary	Not Audited	0	0
21	Iceland	Not Audited	0	0
22	Ireland	Not Audited	0	0
23	Israel*[5]	Nov/Dec 05	10	2
24	Italy	Nov/Dec 05	13	0
25	Japan	Not Audited	0	0

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
26	Mexico	Nov/Dec 05 Sept 06	5 8	0 0
27	The Netherlands	Not Audited	0	0
28	New Zealand*[6]	Oct/Nov 05	13	0
29	Nicaragua	Feb/Mar 06	5	0
30	Northern Ireland	Mar/Apr 06	2	0
31	Poland	Not Audited	0	0
32	Romania	Not Audited	0	0
33	San Marino	Dec 05	1	0
34	Slovakia	Oct 05	0	0
35	Slovenia	Oct/Nov 05	1	0
36	Spain	Mar/Apr 06	7	0
37	Sweden	Jan 06	2	0
38	Switzerland*[7]			
39	Uruguay	Nov/Dec 05	13	0

* Austria suspended.

** The final rule to add China to the list of countries eligible to export processed poultry products to the United States was published on April 24, 2006, but China was not eligible to certify establishments until May 25, 2006. Since becoming eligible to certify establishments for export, China had not certified any establishments that would subsequently be subject to FSIS audit, and the FY 2009 Continuing Resolution bars from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.

*** Not eligible to ship product to the United States because voluntarily suspended.

**** Hong Kong decertified its only establishment in May 2001. No country audit has been conducted since and the country has been removed from the list of eligible countries.

*5 An audit of Israel was not conducted in FY 2005 due to auditor safety issues and State Department security concerns. Instead, the audit occurred in December 2005, just after FY 2005 ended.

*6 The FY 2005 audit in New Zealand was delayed two weeks until the first week of FY 2006.

*7 Switzerland declined the request for an annual audit in FY 2005 and remained suspended.

Foreign Inspection System Audits of Eligible Countries for FY 2007

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
1	Argentina	July/Aug 07	6	0
2	Australia	Aug/Sept 07	8	0
3	Austria*	Sept 07	2	0
4	Belgium	Feb/March 07	1	0
5	Brazil	Aug/Sept 07	8	0
6	Canada	May/June 07	24	1
7	Chile	Mar/Apr 07	3	1
8	China**			
9	Costa Rica	Feb 07	2	0

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
10	Croatia	Sept 07	1	0
11	Czech Republic	May 07	1	0
12	Denmark	April/May 07	8	0
13	Dom. Republic***			
14	England	May 07	1	0
15	Finland	May 07	2	0
16	France	March/April 07	2	0
17	Germany	April/May 07	3	0
18	Honduras	Jan/Feb 07	2	0
19	Hong Kong****			
20	Hungary	May 07	2	0
21	Iceland Iceland*[5]	Oct 06 Sept 07	2 3	0 0
22	Ireland	June 07	1	0
23	Israel	Nov 06	7	0
24	Italy	Feb/March 07	8	1
25	Japan	Jan/Feb 07	2	0
26	Mexico	Aug/Sept 07	8	1
27	The Netherlands	March 07	5	0
28	New Zealand	April/May 07	10	0
29	Nicaragua	Feb/March 07	2	0
30	Northern Ireland	May 07	1	0
31	Poland	March/April 07	6	0
32	Romania	Not Audited	Not Exporting	0
33	San Marino	March 07	1	0
34	Slovakia	Not Audited	NCE/Suspended	0
35	Slovenia	Not Audited	Not Audited	0
36	Spain	Mar 07	4	0
37	Sweden	April 07	1	0
38	Switzerland*[6]			
39	Uruguay	March 07	8	0

* Austria was suspended throughout FY 2007, but was audited in September 2007 and in November 2007 relisted as eligible to export as a result of the September audit findings.

** The final rule to add China to the list of countries eligible to export processed poultry products to the United States was published on April 24, 2006, but China was not eligible to certify establishments until May 25, 2006. Since becoming eligible to certify establishments for export, China had not certified any establishments that would subsequently be subject to FSIS audit, and the FY 2009 Continuing Resolution bars China from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.

*** Not eligible to ship product to the United States because voluntarily suspended.

**** Hong Kong decertified its only establishment in May 2001. No country audit has been conducted since and the country has been removed from the list of eligible countries.

*[5] The second audit conducted in Iceland in FY 2007 was actually part of the FY 2008 audit cycle. However, the audit was conducted in September 2007 (FY 2007) in order to facilitate a more thorough audit of lamb slaughter and processing operations which peak in that country during September rather than October.

*[6] Switzerland declined the request for an annual audit in FY 2005 and remained suspended.

Foreign Inspection System Audits of Eligible Countries for FY 2008

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
1	Argentina		11	0
2	Australia		13	0
3	Austria*		3	0
4	Belgium		1	0
5	Brazil		13	2
6	Canada		35	1
7	Chile		7	0
8	China**			
9	Costa Rica		3	0
10	Croatia		3	0
11	Czech Republic		2	0
12	Denmark		13	0
13	Dom. Republic***			
14	England		2	0
15	Finland		4	0
16	France		3	0
17	Germany		5	0
18	Honduras		2	0
19	Hong Kong****			
20	Hungary		5	0
21	Iceland*[5]		0	0
22	Ireland		3	0
23	Israel		8	0
24	Italy		8	1
25	Japan		4	0
26	Mexico		11	3
27	The Netherlands		9	0
28	New Zealand		6	0
29	Nicaragua		5	0
30	Northern Ireland		2	0
31	Poland		8	0
32	Romania		4	0
33	San Marino		1	0
34	Slovakia		NCE/Suspended	0
35	Slovenia		Not Audited	0
36	Spain		5	0
37	Sweden		2	1
38	Switzerland*[6]			

	Eligible Country	Date of Audit	Number of Plants Audited	Number of Plants Delisted
39	Uruguay		11	0

* Austria was suspended throughout FY 2007, but was audited in September 2007 and in November 2007 relisted as eligible to export as a result of the audit findings.

** The final rule to add China to the list of countries eligible to export processed poultry products to the United States was published on April 24, 2006, but China was not eligible to certify establishments until May 25, 2006. Since becoming eligible to certify establishments for export, China has yet to certify any establishments that would subsequently be subject to FSIS audit and the FY 2009 Continuing Resolution bars China from using funds to establish or implement a rule allowing poultry products to be imported into the United States from China.

*** Not currently eligible to ship product to the United States because voluntarily suspended.

**** Hong Kong decertified its only establishment in May 2001. No country audit has been conducted since and the country has been removed from the list of eligible countries.

*[5] Two audits of Iceland were conducted in FY 2007. The second audit was actually part of the FY 2008 audit cycle. However, the audit was conducted in September 2007 (FY 2007) in order to facilitate a more thorough audit of lamb slaughter and processing operations which peak in that country during September rather than October.

*[6] Switzerland declined the request for an annual audit in FY 2005 and remains suspended.

Ms. DeLauro: In 2007 or 2008, did any foreign countries or companies refuse FSIS access to plants? If so, which countries and what was the response by FSIS?

Response: During FY 2007 and 2008, there were no plants that were scheduled for audit that refused access to FSIS.

Ms. DeLauro: What percentage of meat and poultry in the U.S. marketplace is imported? How does the percentage of imported meat and poultry products in 2007 and 2008 compare with the past three years? Why has the quantity of imports, as reflected in the numbers reported in last year's hearing record, declined in recent years?

Response: In FY 2008, FSIS inspected 3.28 billion pounds of meat and poultry products imported into the United States from 29 eligible foreign countries, which is approximately 5 percent of domestic production. In FY 2007, FSIS inspected 3.89 billion pounds from 29 eligible foreign countries. In FY 2006, 3.84 billion pounds were imported from 29 eligible countries; in FY 2005, 4.24 billion pounds were imported from 28 countries; and in FY 2004, 4.21 billion pounds were imported from 27 countries. The quantity of imports fluctuates each year due to varying market conditions and changes in the number of eligible export countries and establishments as a result of factors such as the addition of new countries, delistment of individual establishments and/or the suspension of countries.

Ms. DeLauro: Please give the Committee some specific information on the elements of the equivalency audits done by USDA scientists to determine the ability of a foreign country to meet U.S. standards for meat.

Response: The audit goal is to verify that foreign governments are regulating certified plants in a manner that ensures they maintain the same level of public protection achieved by U.S. establishments. It is important to note that the purpose of annual FSIS equivalence verification audits is to evaluate foreign inspection systems; not individual foreign establishments. All foreign food regulatory system equivalence audits are scheduled annually and are conducted in four phases: planning, execution, evaluation, and feedback. For example, an annual system equivalence verification audit would consist of the following activities:

1. PLANNING. FSIS prepares a consolidated annual plan to audit each country that exports meat, poultry, or processed egg products to the United States. Individual country audit plans are based, in large part, upon prior experience with the exporting country. For example, all previous FSIS audit reports are reviewed to identify issues for inclusion in the current audit. Port-of-entry reinspection data are also reviewed at this time to determine trends and identify areas of special interest for audit. These documents and data are used by FSIS to develop an audit plan that is customized for each country. The plan includes a list of foreign establishments selected for centralized records review. A subset of these establishments is further selected for on-site audit. FSIS uses a statistical method for establishment selection. Additional establishments may be added for cause. The audit plan is transmitted to the exporting country for comment before implementation. The audit protocol is sufficiently detailed to inform the exporting country of the audit objectives, scope and criteria, who will be visiting, what they wish to see, where they wish to go, and when they wish to do so. Special emphasis is given to adoption of new sanitary measures or food regulatory system changes that have occurred since the last audit either through initiative of the exporting country or in response to new U.S. import requirements.

2. EXECUTION. An auditor or audit team is dispatched to the exporting country's inspection headquarters and/or to sub-offices as agreed to in the audit protocol. Opening discussions are held with exporting country officials to determine if the national system of inspection, verification, and enforcement is being implemented as documented, and to identify significant trends or changes in operations. The FSIS auditor examines a sample of program records that document regulatory activities by the exporting country and accompanies country officials on field visits to a representative sample of establishments that are eligible for export to the United States. Exporting country officials conduct a review to verify that each selected establishment continues to achieve the U.S. level of sanitary protection. Particular attention is paid to how eligible establishments address food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe establishment activities and correlate review findings made by exporting country officials. Selected microbiological and chemical laboratories are also reviewed, and a farm or feedlot is visited to

verify animal drug controls. In a closing meeting, the FSIS auditor provides exporting country officials with an overview of conditions observed and ensures that audit observations are clearly understood.

3. EVALUATION. FSIS conducts a post-audit evaluation of all data collected on-site. When evaluating audit data, FSIS considers how sanitary measures of the foreign food regulatory system compare or contrast to those used in the United States and determines whether the foreign system cumulatively provides the same level of protection.

4. FEEDBACK. FSIS sends the exporting country a draft audit report and provides them an opportunity to comment on its findings. After consideration of the country's comments, a final report is prepared. An action plan is mutually developed to address any issues raised by the audit. These issues are tracked by FSIS until resolution and are automatically included as items of special interest in the next audit.

Equivalence verification audit reports are posted on the FSIS Web site (www.fsis.usda.gov) after the final version is delivered to the audited country. In some instances, when a more in-depth audit of a country is deemed necessary, FSIS will dispatch an interdisciplinary team of experts to conduct an equivalence verification. Occasionally, a country may be identified for more than one audit per year. These decisions are made on a case-by-case basis.

Ms. DeLauro: In an initial system audit for equivalence determination, how are representative establishments selected for observation by FSIS personnel? Does the foreign government select the establishments or does FSIS? What are the criteria used for such selection?

Response: During an initial equivalence audit, a foreign country offers FSIS a list of establishments that are interested in exporting FSIS-inspected product to the United States and have implemented FSIS or FSIS-equivalent requirements. FSIS audits all of the establishments on this proposed list. While the list of proposed establishments is submitted by the foreign country, it is based on the country's responses to FSIS questions that are submitted prior to the start of the audit. In advance of an initial equivalence audit, FSIS requests information from the foreign countries in three areas to clarify the scope of the audit: (1) a list of slaughter and processing establishments certified as fully meeting the FSIS inspection requirements and, therefore, eligible to export poultry products to the United States (2) a list of the microbiological and residue laboratories approved by the foreign government to test meat, poultry and/or processed egg products destined for the United States; and (3) a list of government offices (central, regional, local, etc.) that would provide direct oversight of the certified establishments.

Ms. DeLauro: How much did FSIS spend on Equivalency Review audits in FY 2007 and 2008? How does this level of spending compare with the amount planned for FY 2009? What is done on the audits?

Response: In 2007, FSIS spent approximately $3 million, and in FY 2008, FSIS spent approximately $4 million on equivalence audits of foreign countries' food safety regulatory systems to ensure equivalence

with FSIS requirements. In FY 2009, FSIS expects to spend approximately $3.5 million.

An auditor or audit team is dispatched to the exporting country's inspection headquarters and to sub-offices as agreed to in the audit protocol. Opening discussions are held with exporting country officials to determine if the national system of inspection, verification, and enforcement is being implemented as documented and to identify trends or changes in operations. The FSIS auditor examines a sample of program records that evidence exporting country regulatory activities and accompanies country officials on field visits to a representative sample of establishments that are eligible for export to the United States. Particular attention is paid to how eligible establishments address food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe establishment activities. Selected microbiological and chemical laboratories are also reviewed. In a closing meeting, the FSIS auditor provides exporting country officials with an overview of conditions observed and ensures that audit observations are clearly understood.

Ms. DeLauro: How many plants will be audited in FY 2009?

Response: FSIS has scheduled audits of all eligible countries in FY 2009 and plans to audit approximately 154 establishments in the 34 countries currently eligible to export to the United States as part of its annual foreign inspection system audit process.

FSIS conducts system audits of the inspection systems of eligible foreign countries rather than establishment-by-establishment audits. As part of these system audits, various levels of the foreign inspection system of oversight, such as headquarters, district, and local level offices are audited. A sampling of slaughter and processing establishments in each country, as well as laboratories performing chemical and microbiological sampling on products destined for the U.S. are reviewed in order to facilitate a comprehensive view of the state of equivalence and inspection oversight being conducted by the foreign government.

Ms. DeLauro: Who does the audits? What are their qualifications?

Response: An individual FSIS auditor or a team of FSIS auditors may be dispatched to a foreign country to conduct an audit depending on the circumstances. Routine, annual audits are typically conducted by a single auditor, generally a veterinarian who is cross trained to also look at microbiological and chemical analysis activities in laboratories, as well as government oversight and enforcement functions.

In the case of an initial equivalence or an enforcement audit, a multidisciplinary team of experts conducts the audit. These audit teams may be comprised of individuals with the following specialties: veterinarian, food technologist, microbiologist, chemist, residue technician, compliance officer, document analysis case officer, and others as needed. All individuals on the audit team are FSIS employees. Audit team members frequently have advanced degrees within their respective scientific specialty areas and are selected for

inclusion on an audit team based on their respective area of expertise, as well as their extensive knowledge and experience dealing with U.S. inspection requirements. Scientific knowledge and expertise in U.S. inspection requirements are essential to the initial equivalence and enforcement audit process and are required for audit team participation in order to ensure that the standards of a given foreign inspection program are consistent with what is required in the United States.

Ms. DeLauro: How frequently does FSIS actually inspect foreign plants?

Response: All foreign certified establishments must maintain the same standards applied to domestic establishments. Primary surveillance of foreign plants is conducted by the foreign inspection service during continuous inspection in each certified slaughter and processing establishment. FSIS schedules equivalence verification audits annually in every exporting country and visits a sample of certified establishments. It is important to note that the purpose of annual FSIS equivalence verification audits is to evaluate foreign inspection systems; not individual foreign establishments. The audit goal is to verify that foreign governments are regulating certified plants in a manner that ensures they maintain the same level of public protection achieved by U.S. establishments.

Ms. DeLauro: For what reasons are foreign plants delisted? Did FSIS find products from delisted firms at U.S. ports of entry in 2006, 2007 or 2008?

Response: A foreign plant can be delisted if it were found to have any serious deficiency that shows it is not meeting standards equal to those achieved in domestic plants. Examples include instances of direct product contamination; poor environmental sanitation that could lead to direct product contamination; lack of a sanitation standard operating procedure or failure to implement an existing procedure; no HACCP plan, an inadequate plan, or not following an existing plan; no testing for generic *E. coli*; less than continuous inspection coverage; humane slaughter violations; and any other fundamental requirement of equivalence.

All eligible countries and foreign establishments are listed in AIIS, which will block entry of any shipment that originates from an establishment that is not listed. The amount of products from delisted firms found at the border varies from year to year. In FY 2006, for instance, 69,425 pounds from four foreign establishments were blocked from entry into the United States at port of entry because the establishments had been delisted while product was in route to the United States. In FY 2007, 131,921 pounds from seven establishments were blocked from entry, and in FY 2008, 93,731 pounds from four establishments were prevented from entering the United States.

Ms. DeLauro: Please provide a table listing resources (dollars and FTEs) directed to equivalency audits, foreign inspection, and border inspection in 2007 and 2008 and estimated for 2009.

Response: The information is submitted for the record.

[The information follows:]

	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimated
Equivalency audits and foreign inspection	$3,000,000	$4,000,000	$3,500,000
Border (port-of-entry) reinspection	9,000,000	8,000,000	10,000,000
Total	12,000,000	12,000,000	13,500,000
Full-time equivalents	140	140	140

Ms. DeLauro: Please update as necessary the information provided last year on the dual export certification process and on electronic export certificates.

Response: FSIS is integrating inspection, surveillance, enforcement, and work scheduling activities within PHIS. U.S. export certification capabilities are being developed in partnership with industry and other USDA agencies, including APHIS, the Agricultural Marketing Service (AMS), and the Foreign Agricultural Service (FAS). Industry will apply for export certification services (provided by both AMS and FSIS) and will be able to check the status of shipments for which export certificates have been requested. Additionally, it will ensure that all USDA inspection and verification actions are completed for each shipment in accordance with U.S. and importing country requirements.

Effective on April 28, 2008, FSIS initiated electronic certification of products imported from New Zealand, enabling receipt of limited data fields directly into the existing AIIS. These data include the health certificate number, number of units, net weight, foreign establishment number where the product was produced, and product name/description. This electronic transfer of data occurs when the shipment is certified for export to the United States and provides advanced notification that the shipment is in transit. FSIS also has the option to view an image of the health certificate online (through secure Web access to the NZFSA).

The ability to exchange export certificates electronically with foreign governments will minimize opportunities to fraudulently manipulate or reproduce export certificates - a significant vulnerability in the current paper-based system. Business and design requirements for PHIS will build upon the system developed with four Mexico-approved U.S. exporting establishments in July 2003, and will leverage more up-to-date technologies and functionality borrowed from other USDA systems; particularly the E-Permits system recently implemented by APHIS and existing foreign systems, such as the paperless certification system operated by the governments of New Zealand and Australia. Future interface with other foreign governments' certification systems, whether for imported or U.S. exported products, is contingent on the design and development of PHIS. Once PHIS is implemented, FSIS will interface with Australia, Canada, and New Zealand for receiving electronic certification for imported products. FSIS will have the ability to transfer electronic export certificates, working with Canada, Japan and Mexico during this initial release of the system.

Ms. DeLauro: How much did FSIS collect for its work related to imports and exports?

Response: In FY 2007, FSIS collected $742,362.78 for import inspection activities carried out beyond the minimal requirement by the Federal inspection acts. An additional $39,455.24 in reimbursements was collected for import inspection done at the request of import establishments. In FY 2008, FSIS collected $625,962.41 for overtime and $41,804.32 in reimbursements for voluntary import inspection activities.

Exported products begin as federally-inspected and passed domestic products whose cost of inspection is borne by FSIS. In FY 2007, FSIS collected $6,773,139.79 for voluntary inspection activities related to exports, while an additional $238,531.83 was collected for reimbursable inspection activities. In FY 2008, $8,768,751.05 was collected for voluntary inspection activities on product destined for export, while $284,642.43 was collected for reimbursable activities done at the request of the establishment during overtime and holiday periods.

Ms. DeLauro: The Action Plan for Import Safety says that "USDA will fund food-safety related workshops for APEC." Are the funds for this coming from FSIS? If not, where in USDA are they coming from? If so, how much will be spent on these workshops? Please indicate what workshops are or were funded, where they were held, the participants (from USDA and abroad) and the topics.

Response: In FY 2008, FSIS and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) provided technical assistance to USDA's FAS and the U.S. Department of State to develop and deliver three food defense workshops in Peru in collaboration with FDA. It was funded by FAS. We also conducted similar outreach in Egypt in January 2008, funded by FAS as part of the Middle East Partnership Initiative. Participants from the United States included FAS, FSIS, FDA, and the U.S. Department of State.

TRADE ISSUES

Ms. DeLauro: How much did FSIS spend in dollars and FTEs on trade matters in each of fiscal years 2003 through 2008? How much is budgeted in 2009?

Response: FSIS does not initiate trade-related activities, but rather provides technical expertise on public health and food safety issues to FAS and the United States Trade Representative (USTR) related to the trade initiatives they are pursuing.

Over the last seven years, there have been several organizational changes within the Agency that make the tracking of funding and FTEs associated with any one program area and function (such as trade-related matters) difficult. Nonetheless, Agency expenditures have been relatively consistent in recent years. Similar to other Agency programs, most of the Office of International Affairs (OIA) budget - 90 percent (about $14.7 million in FY 2008) - is allocated to salaries and benefits, and nearly all of the budget and personnel (135 of 166

employees) are devoted to the mission-critical activities of auditing and evaluating the meat and poultry inspection systems of foreign countries exporting to the United States and import reinspection and surveillance on the perimeter of the country. Among the activities covered by the remaining approximately 10 percent (approximately $1.9 million in FY 2008) is leadership for FSIS participation in Codex Alimentarius and technical support to FAS and USTR in bilateral and multilateral activities related to meat and poultry export.

INFORMATION TECHNOLOGY

Ms. DeLauro: In last year's hearing record, you indicated that FSIS was working to consolidate a number of its IT data systems into the Public Health Data Infrastructure Communications Information Systems (PHDICIS). Where does this effort stand? What advantages does PHDICIS offer FSIS? Will the consolidation lead to any cost savings and if so, what are the estimates?

Response: FSIS has continued to move forward with the consolidation of systems and processes through the Public Health Information Consolidations Projects (PHICP) investment. The Public Health Data Communications Infrastructure System (PHDCIS) investment is the effort to support, maintain, and enhance the FSIS technical infrastructure (i.e. data center, network, computers, etc.). As part of the PHICP investment, the Agency has started the Public Health Information Systems project, which will replace several legacy applications (such as PBIS and AIIS) and will automate selected manual processes (such as providing for electronic export certification). PHIS will leverage applicable services from USDA's Enterprise Shared Services (such as enterprise hosting and eAuthentication). Currently, PHIS has completed business and functional requirements gathering and is moving into the design phase. The consolidation will allow system customers to use a single, web-based system instead of multiple client-server systems to enter data more efficiently and effectively for analysis and reporting. The estimated cost savings are submitted below.

[The information follows:]

Federal Quantitative Benefits				
Outlying Years(after implementation)	Budgeted Cost Savings	Cost Avoidance	Justification for Budgeted Cost Savings	Justification for Budgeted Cost Avoidance
Budget Year +1	$8,068,363	$3,418,363	1/	2/
Budget Year +2	8,310,414	3,520,914	1/	2/
Budget Year +3	8,559,726	3,626,541	1/	2/
Budget Year +4 & Beyond	67,556,237	28,621,883	1/	2/
Total LCC Benefit	92,494,740	39,187,701	LCC = Life-cycle cost $27,603,712	

1/ Difference between the cost to operate and maintain current legacy system and to operate and maintain this alternative.

2/ Amount of cost avoided from operating and maintaining current legacy systems.

Ms. DeLauro: Please provide the Committee with a list of all current IT systems at FSIS. To the extent that older systems have been folded into or replaced by newer systems, please provide a clear flow-chart that links the original systems to the new systems.

Response: The following is a list of the current FSIS systems:

- AssuranceNet
- Automated Import Information System (AIIS)
- Comprehensive Zoonotic Disease Surveillance System (CZDSS)
- Electronic Animal Disposition Reporting System (eADRS)
- Electronic Sampling System
- Enterprise Reporting System (ERS)
- Label Information System (LIS)
- Laboratory Information Management System (LIMS)
- Laboratory Sample Flow System (LSFS)
    - Pathogen Reduction Enforcement Program (PREP) (child under LSFS)
    - Residue (child under LSFS)
    - Laboratory Electronic Application for Results Notification (LEARN) (child under LSFS)
    - Laboratory Electronic Application for Results Notification II (LEARN II) (under development)
    - Biological Information Transfer and E-mail System (BITES) (child under LSFS)
    - Microbiological and Residue Computer Information System (MARCIS) (child under LSFS)
    - Fast Antimicrobial Screen Test (FAST) (child under LSFS)
    - Swab Test On Premises (STOP) (child under LSFS)
- Non-Routine Incident Management System (NRIMS)
- PBIS - Performance-Based Inspection System
    - System Tracking *E. coli*-Positive Suppliers (STEPS)(child under PBIS)
    - DIS (child under PBIS)
    - Electronic Animal Disposition Report System (eADRS) (child under PBIS)
    - Resource Information System (RIS) (child under PBIS)
- USDA Meat and Poultry Hotline
- Consumer Complaint Monitoring System II (CCMSII)

The following is a list of general support systems:

- DataWarehouse
- Desktop
- Enterprise
- Network

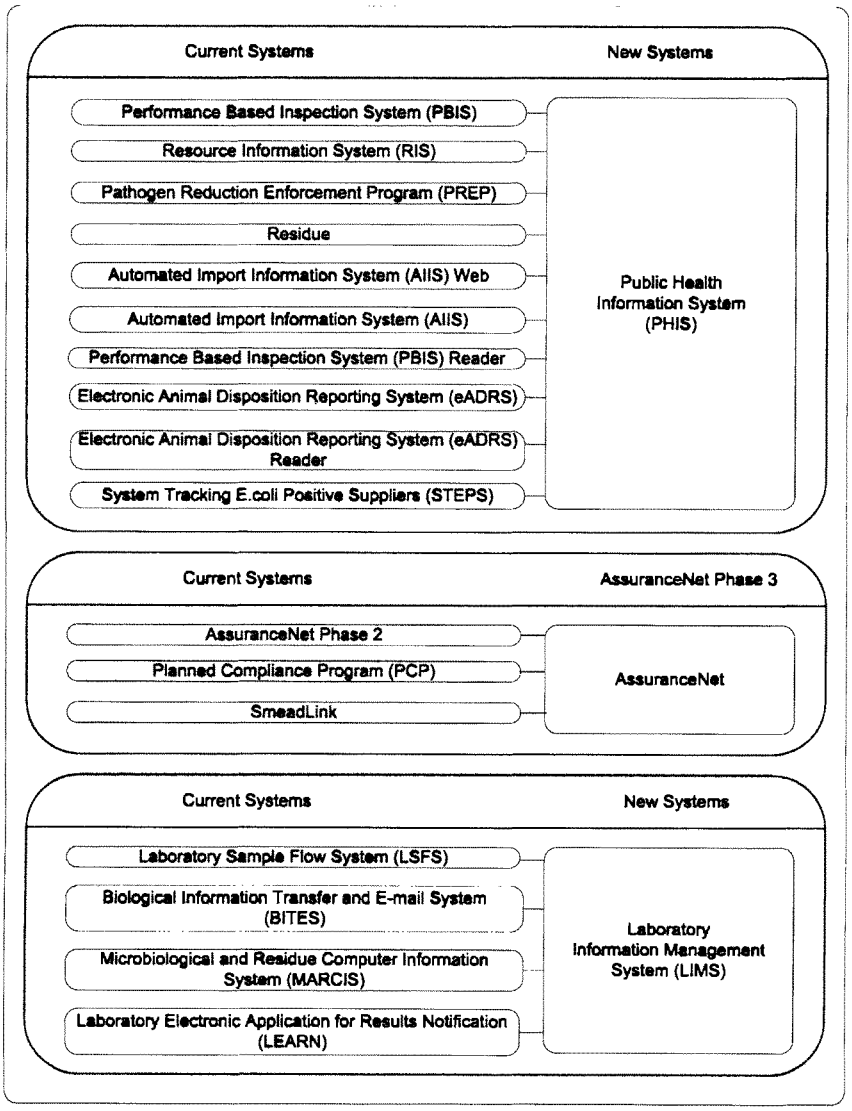
The Public Health Information System (PHIS) and the Laboratory Consolidation Initiative will provide new functionality and incorporate existing systems. PHIS will incorporate PBIS, AIIS, and eADRS. The Laboratory Consolidation Initiative will integrate LEARN and Electronic

Sampling Program applications into the Laboratory Information Management System (LIMS).

AssuranceNet, the Agency's management control system, also includes the "In-Commerce System." The In-Commerce System is the compliance and enforcement system for the Agency and is currently in extended user acceptance testing. The In-Commerce System incorporates data from the Planned Compliance Program (PCP). This data includes firm name, address, telephone number, list of officials, and follow up dates for specific compliance activities, but does not include any details about the compliance activities.

A flow chart of current systems and new systems is provided for the record.

[The information follows:]


Current Systems
New Systems
Performance Based Inspection System (PBIS)
Resource Information System (RIS)
Pathogen Reduction Enforcement Program (PREP)
Residue
Automated Import Information System (AIIS) Web
Automated Import Information System (AIIS)
Performance Based Inspection System (PBIS) Reader
Electronic Animal Disposition Reporting System (eADRS)
Electronic Animal Disposition Reporting System (eADRS) Reader
System Tracking E.coli Positive Suppliers (STEPS)
Public Health Information System (PHIS)
Current Systems
AssuranceNet Phase 3
AssuranceNet Phase 2
Planned Compliance Program (PCP)
SmeadLink
AssuranceNet
Current Systems
New Systems
Laboratory Sample Flow System (LSFS)
Biological Information Transfer and E-mail System (BITES)
Microbiological and Residue Computer Information System (MARCIS)
Laboratory Electronic Application for Results Notification (LEARN)
Laboratory Information Management System (LIMS)

Ms. DeLauro: Please provide a table showing funding for all systems for 2006-2008 and planned for 2009.

Response: The table below provides the current and planned spending for the PHICP investment, which encompasses the Agency systems. This is based on the OMB300 business cases in section I.B.1.a.

Summary of Spending for Project Phases (funding in millions)

	PY-1 and earlier	PY 2008	CY 2009
Planning	$0.20	$2.10	0.00
Acquisition	19.09	4.38	$2.73
Subtotal Planning and Acquisition	19.29	6.48	2.73
Operations and Maintenance	4.21	3.68	3.16
TOTAL	23.50	10.16	5.89
Government FTE Costs	5.18	3.76	1.48

Ms. DeLauro: Please update the Committee on the status of Phase I of FAIM for state inspectors. Which states have not fully implemented it? What is the status of Phase II of the program? What will it cost to complete Phase I and II? What is the timeframe for completing this entire project? What is requested in the FY 2009 budget for these phases?

Response: Phase I of the PHDCIS, which now incorporates the Field Automation and Information Management (FAIM) program, for State inspectors has only slightly progressed further than last year due to State funding issues that limit State matching funds which are required to participate in the PHDCIS program. Approximately 140 more computers need to be requested by the States and then delivered to complete Phase I. Minnesota dropped out of the PHDICIS program; but Kansas and Indiana are implemented. States not participating or not yet fully implemented in PHDICIS include Georgia, Louisiana, Missouri, Minnesota, and Wyoming.

Phase II, the replacement phase for State inspectors, is progressing and will continue indefinitely because computers will continue to be replaced and annual operating expenses for software, maintenance, technical support, and other services will continue and need to be funded. The Federal share to complete Phase II has gone up significantly due to increase of Service Desk costs and factoring in the cost of high-speed access which translates to higher annual telecom costs.

In order to complete Phase I, it will require approximately $308,757.00 total (computer costs for the 140 computers), which will be split evenly between the Federal Government and State Governments at $154,378.50 each. FSIS anticipates that the annual Federal Government share of the costs for Phase II will be approximately $1,643,156.00

(consists of 50 percent costs for 746 State inspectors and 100 percent costs for 343 Talmadge-Aiken/Cross-Utilization inspectors).

The timeframe for completing this entire project cannot be determined because Phase I is dependent on the States obtaining program funding. Phase II will continue indefinitely.

Ms. DeLauro: What is the status of expanding access by FSIS to foreign governments' electronic systems? To which countries' systems does FSIS currently have access? To which countries does it expect to have access in 2009?

Response: Effective on April 28, 2008, FSIS initiated electronic certification with the New Zealand Food Safety Authority (NZFSA), enabling receipt of limited data fields directly into AIIS. These data include the health certificate number, number of units, net weight, foreign establishment number where the product was produced, and product name/description. This electronic transfer of data occurs when the shipment is certified for export to the United States and provides advanced notification that the shipment is in transit. FSIS also has the option to view an image of the health certificate online (through secure Web access to the NZFSA).

Future interface with other foreign governments' certification systems, whether for imported or US exported products, is contingent on the design and development of the PHIS. Once PHIS is fully deployed, FSIS will interface with Australia, Canada, and New Zealand for receiving electronic certification for imported products. FSIS will have the ability to transfer electronic export certificates, working with Canada, Japan, and Mexico during this initial phase.

Ms. DeLauro: What is the status of FSIS getting a direct connection to the Automated Commercial Environment/International Trade Data System (ACE/ITDS)? Please provide a full timeline for achieving this and the budgetary resources necessary to do so. Does FSIS pay CBP for the training of its employees or does that come out of CBP's budget? If the former, how much funding is included in the 2009 request for this and what would be the cost of getting all employees trained? Where does FSIS stand in terms of getting all clearances for its staff?

Response: Currently, the ACE Secure Data Portal, essentially a secure Web-based access to U.S. Customs and Border Protection (CBP) entry summary data, provides over 40 FSIS users access to shipment information. Approved users have appropriate security clearances as defined by CBP in the draft FSIS-CBP data exchange Memorandum of Understanding (MOU). ACE Portal access is an interim solution for FSIS to use Customs entry data in its import control program. When FSIS completes the design and development of the PHIS, direct system-to-system interface with ACE will become functional.

There are no training costs associated with using the ACE Portal. These approved users have access to CBP's on-line training, which is sufficient to enable the new user to navigate the Web page and to develop and/or generate reports. There will be no cost to FSIS in FY 2009 for ACE Portal Access. CPB is not charging FSIS. However, when

this component of PHIS is developed (anticipated for FY 2010), we will need to train an estimated 300 persons, including all Import Inspectors, their supervisors, Import Surveillance Liaison Officers (ISLOS), OIA headquarters staff, and staff in OPEER, OPPD, and OFDER.

Currently, FSIS has security clearances completed or in process for all import inspectors, ISLOs, and OIA headquarter management. Security clearance requirements for system users under PHIS-ACE/ITDS operations, and subsequent scope of the number of employees that will be required to have a secret level clearance has not been defined yet.

The projected PHIS timeline milestones are provided below. The development and deployment of PHIS includes its integration with ACE\ITDS. The milestone schedule is based on this development effort, the current scope, and the risk mitigation strategy. The PHIS will be installed in February 2010, after which it will go through accreditation for six months with expected deployment at the end of June 2010. A chart of PHIS milestones and their projected completion dates is provided for the record.

[The information follows:]

PHIS Milestone	Projected Completion Date
System Architecture	Nov 2008
Development	Feb 2010
Deployment	Jun 2010

Ms. DeLauro: Did USDA comply with OMB Memorandum M-07-23, dated September 10, 2007, regarding the ITDS?

Response: USDA's Office of the Chief Information Officer submitted the Department's action plan prior to November 12, 2008, in full compliance with OMB Memorandum M-07-23. Included in this Action Plan are the milestones identified by CBP (as managing partner), and appropriate completion dates for each agency, based on the ITDS completion schedule identified at that time.

STATE MEAT AND POULTRY INSPECTIONS

Ms. DeLauro: Please discuss the implementation by FSIS of section 11015 of the Food, Conservation and Energy Act of 2008. How many plants do you estimate will seek approval under the section? What additional costs for FSIS do you estimate for 2009 and 2010 in carrying out this section, both direct costs to FSIS and reimbursements to states?

Response: Section 11015 of the Food, Conservation and Energy Act of 2008, which was enacted on June 18, 2008, supplements the existing Federal-State cooperative inspection program with a new provision whereby State-inspected plants with 25 or fewer employees can apply and could be selected by the Secretary to join a new program under which State employees would administer Federal regulations, and thus ship interstate. This new program will not be implemented until the Secretary promulgates final regulations to carry out this new

inspection program. The 2008 Farm Bill requires that these regulations be finalized not later than 18 months from the date that this provision became law.

Estimates for FY 2009 and FY 2010 are currently in development and will be provided to the Committee when complete.

Ms. DeLauro: What is the status of FSIS' implementation of the recommendations in the 2006 OIG report on state meat and poultry inspection programs? Has a management decision been reached on the remaining two recommendations?

Response: FSIS has implemented and closed all of the recommendations in the 2006 OIG report on State meat and poultry inspection programs. Hence, the audit is closed.

Ms. DeLauro: What are Talmadge-Aiken plants? How many plants fall under this definition?

Response: Talmadge-Aiken plants are meat and poultry slaughter, processing, and combination (slaughter and processing) establishments that operate under Federal inspection regulations administered by State inspection personnel. For the plants operating in this manner, FSIS has signed State-Federal cooperative agreements under the authority of the Talmadge-Aiken Act (7 U.S.C. 450). Enacted in 1962, the Act provides the Secretary of Agriculture with authority to enter into agreements with the States for the administration and enforcement of Federal laws and regulations by State agencies. Under these agreements, State employees administer Federal meat and poultry inspection in specified establishments and the Federal marks of inspection are applied to the products. USDA supervises Talmadge-Aiken plant inspection and reimburses the States at the rate of 50 percent of the estimated cost of administering inspection under Talmadge-Aiken arrangements. As of September 30, 2008, there are 382 Talmadge-Aiken plants.

Ms. DeLauro: Please update the table that appears in last year's hearing record showing a cost breakout, by state, of the existing Grants to States program to include fiscal year 2007 and 2008 actuals and estimates for fiscal year 2009, taking into account section 11015 of the 2008 farm bill. Please provide a general description of the Grants to States program and how it benefits FSIS.

Response: The State Cooperative Inspection program must operate under State laws and regulations and grant legal authority "at least equal to" that provided under the Federal Meat Inspection Act and the Poultry Products Inspection Act, which impose mandatory antemortem and postmortem inspection, reinspection, sanitation requirements, recordkeeping requirements, and enforcement provisions. The State inspection system must be "at least equal to" that of the Federal system that ensures safe, wholesome, unadulterated meat and poultry products. The State inspection program protects consumers from meat and poultry products that are unwholesome, economically adulterated, or not truthfully labeled. It provides assurance to the public by enforcing all applicable regulations and taking appropriate enforcement action in the event of non-compliance or potentially unsafe product.

Benefits of engaging a State agency in cooperative inspection efforts versus the FSIS accomplishing these mandatory requirements alone include cost savings and other cooperative benefits to FSIS. All activities of the program are performed by State employees and the applicable costs are paid through the State's accounting system. The expenses are reported to FSIS and the States obtain up to 50 percent of the program costs. Therefore, since total State program expenditures were approximately $49 million in FY 2008, we can assume the operations would cost FSIS at least $98 million without the States' cooperation. With the State cooperative programs, FSIS is relieved from conducting a substantial amount of human resource activities and administrative activities.

Section 11015 of the Food, Conservation and Energy Act of 2008, which was enacted on June 18, 2008, supplements the existing Federal-State cooperative inspection program with a new provision whereby State-inspected plants with 25 or fewer employees can apply and could be selected by the Secretary to join a new program under which State employees would administer Federal regulations, and thus ship interstate. This new program will not be implemented until the Secretary promulgates final regulations to carry out this new inspection program. The 2008 Farm Bill requires that these regulations be finalized not later than 18 months from the date that this provision became law, including a public comment period.

Given that the rulemaking process will not be completed until FY 2010, we estimate that there will be no increase in Federal reimbursements to the States in FY 2009, and that States will only be able to receive additional Grants-to-States funding for Section 11015 plants as early as FY 2010.

The information is provided for the record.

[The information follows:]

Grants to State Programs
[In thousands of dollars]

State	2007 Actual*	2008 Actual	2009 Est.**
Alabama	$1,605	$1,741	$1,741
Arizona	623	593	593
Delaware	268	259	259
Georgia	2,752	2,885	2,885
Illinois	5,140	5,369	5,369
Indiana	1,786	1,842	1,842
Iowa	1,589	1,718	1,718
Kansas	1,792	1,819	1,819
Louisiana	2,056	2,200	2,200
Maine	166	192	192
Minnesota	959	1,010	1,010
Mississippi	1,359	1,595	1,595

Grants to State Programs [In thousands of dollars]			
State	2007 Actual*	2008 Actual	2009 Est.**
Missouri	609	661	661
Montana	545	558	558
New Mexico	705	0	0
North Carolina	3,672	4,009	4,009
North Dakota	295	346	346
Ohio	5,007	4,997	4,997
Oklahoma	1,848	1,807	1,807
South Carolina	1,445	1,563	1,563
South Dakota	805	817	817
Texas	4,417	4,556	4,556
Utah	1,212	1,341	1,341
Vermont	351	375	375
Virginia	1,507	1,690	1,690
West Virginia	749	695	695
Wisconsin	3,736	3,950	3,950
Wyoming	386	463	463
Reserves, Unallocated	970	5	5
TOTAL	47,354	49,056	49,056

* The State allocations for FY 2007 were amended near the end of the fiscal year due to changing program requirements. Therefore, they are different than the numbers provided in the FY 2008 Questions for the Record.
** The FY 2009 allocations to the States will be based on analysis of the budget requests received from each State. The FY 2009 estimates do not include any impact from the implementation of Section 11015 of the 2008 farm bill. Given that the rulemaking process will not be completed until FY 2010, we estimate that there will be no increase in Federal reimbursements to the States in FY 2009.

CONDEMNED PRODUCT

Ms. DeLauro: Please update the table on domestic condemned product in last year's hearing volume to include fiscal years 1995 through 2008, and provide a similar table for imported condemned product.

Response: The information is provided for the record.

[The information follows:]

Condemned Domestic Product

Fiscal Year	Poultry (Thousands of head)	Livestock (Thousands of head)	Liquid Egg Products (1,000-pound increments)
1995	79,998	469	139,000
1996	82,665	546	145,000
1997	87,573	543	153,000
1998	80,668	591	181,000
1999	87,862	707	274,000
2000	94,758	680	209,000
2001	59,565	680	274,000
2002	49,907	571	232,000
2003	46,088	562	306,000
2004	51,458	572	265,000
2005	52,387	580	268,000
2006	47,627	578	275,232
2007	45,827	565	271,232
2008 Estimated	45,171	542	279,121

Imported Meat and Poultry
Pounds Refused or Rejected
Percent presented for entry that is refused or rejected

Fiscal Year	Meat and Poultry, combined (pounds) (percent)
1995	11,254,278 (0.5%)
1996	10,459,044 (0.4%)
1997	9,548,458 (0.4%)
1998	9,922,999 (0.4%)
1999	14,038,438 (0.4%)
2000	8,948,950 (0.2%)
2001	8,034,201 (0.2%)
2002	9,643,750 (0.3%)
2003*	6,279,509 (0.2%)

Fiscal Year	Poultry (pounds) (percent)	Meat (pounds) (percent)
2004	212,004 (0.2%)	7,524,641 (0.2%)
2005	499,954 (0.3%)	13,886,042 (0.3%)
2006	401,574 (0.2%)	11,370,654 (0.3%)
2007	133,825 (0.1%)	9,054,344 (0.2%)
2008 Estimated	363,998 (0.1%)	11,102,934 (0.4%)

* Calendar year data used

Imported Egg Products
Refused or Rejected
Percent presented for entry that is refused or rejected

Fiscal Year	Egg Products (pounds)
1995	Not available*
1996	Not available*
1997	Not available*
1998	Not available*
1999	Not available*
2000	47,554 (0.6%)
2001	30 (0.0%)
2002	142,134 (1.2%)
2003	340 (0.0%)
2004	20,064 (0.2%)
2005	0 (0.0%)
2006	6,352 (0.1%)
2007	0 (0.0%)
2008 Estimated	48,000 (0.2%)

* Responsibilities for imported egg products were transferred to FSIS from AMS in 1995, but the database the Agency currently uses did not exist until 2000.

Ms. DeLauro: Please explain the wide degree of year-to-year variation in the data in the table on page 348 of last year's hearing record, entitled "Imported Egg Products Refused or Rejected."

Response: The quantity of imported processed egg product that is refused or rejected fluctuates each fiscal year due to varying amounts of product and varying types of violations of FSIS regulatory requirements.

In FY 2000, a tanker was refused because the product was identified as unwholesome. This refusal accounted for almost 47,000 pounds of product. Additional product was refused because of labeling issues.

In FY 2002, most of the product identified as refused was dried egg product and the reason for refusal was transportation damage. Most of the processed egg product that is exported to the United States is in tankers or plastic pails and transportation damage is rare for these types of containers. The data shows that after 2002, exportation of dried egg product decreased considerably. In 2002, there were instances in which the product was refused because CBP officials did not sign the FSIS Form 5200-8. Presently, if CBP officials neglect to sign the form, FSIS contacts them and asks for verification that the product was presented. If they can provide proof, we move forward with the reinspection. Some additional product was refused because of labeling issues.

In FY 2004, there appeared to be a problem with product not being completely frozen, which resulted in some refused entries.

In FY 2005, no product was identified as having been refused entry. It is likely that, as a result of communication with the Canadian Food Inspection Agency (CFIA), Canadian exporters are better informed of other options, such a re-labeling.

In FY 2006, product was refused because the physical amount of identified product was more than what was reported on the inspection certificate. A new certificate could have been issued to cover the product, but CFIA elected not to use this option.

RECALLS

Ms. DeLauro: Please provide a list of recalls for fiscal years 2007 and 2008, the reason for the recall, and the amount recalled.

Response: The information is provided for the record.

[The information follows:]

Recalls for Fiscal Year 2007 (47)

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
029-06	10/06/06	JIMS'S MARKET AND LOCKER, INC.	BACTERIA: *E. COLI* O157:H7	5,226
030-06	10/12/06	HERMAN FALTER PACKING CO.	BACTERIA: *LISTERIA MONOCYTOGENES*	1,178
031-06	10/23/06	OMAHA BEEF COMPANY INC.	BACTERIA: *E. COLI* O157:H7	1,680
032-06	11/17/06	MIRAB USA, INC.	ANIMAL DRUG RESIDUE	23,200
033-06	11/24/06	HONEYBAKED FOODS INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	46,941
034-06	12/07/06	THE MEAT PALACE, INC.	MISLABELING	2,100
001-07	01/03/07	PAP'S LOUISIANA CUISINE	BACTERIA: *LISTERIA MONOCYTOGENES*	290
002-07	01/05/07	GOLD STAR SAUSAGE CO., INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	15,514
003-07	01/09/07	SIGMA FOODS, INC.	MISLABELING	19,488
004-07	01/23/07	AGRIPROCESSORS, INC.	UNDERPROCESSING	2,700
005-07	01/24/07	WATER LILIES FOOD, INC.	UNDECLARED ALLERGEN	77,730
006-07	01/25/07	GARDEN LEAF FOODS	BACTERIA: *LISTERIA MONOCYTOGENES*	1,591
007-07	01/26/07	HILL MEAT CO.	UNDERPROCESSING	1,080
008-07	01/29/07	THE NATURAL STATE MEAT CO.	BACTERIA: *E. COLI* O157:H7	4,240
009-07	02/03/07	MORGAN FOODS	UNDECLARED ALLERGENS	6,317
010-07	02/05/07	THE WORNICK COMPANY	UNDECLARED ALLERGEN	7,848
011-07	02/12/07	CONAGRA FOODS, INC.	UNDERPROCESSING	402,623

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
012-07	02/28/07	CAROLINA CULINARY FOODS	BACTERIA: *LISTERIA MONOCYTOGENES*	2,800,000
013-07	02/27/07	FIRST QUALITY SAUSAGE	BACTERIA: *LISTERIA MONOCYTOGENES*	930
014-07	03/02/07	TYSON FRESH MEATS	BACTERIA: *E. COLI* O157:H7	16,743
015-07	03/09/07	HEMPLER FOODS GROUP	UNDECLARED ALLERGEN	5,084
016-07	03/27/07	KRAFT FOODS GLOBAL, INC.	INSUFFICIENT COOLING DURING PROCESSING	1,800
017-07	04/13/07	EARLE OF SAUSAGE	BACTERIA: *STAPHYLOCOCCUS AUREUS*	330
018-07	04/18/07	PATRICK CUDAHY, INC.	UNDECLARED ALLERGEN	5,625
019-07	04/20/07	HFX, INC.	BACTERIA: *E. COLI* O157:H7	259,230
020-07	04/20/07	RICHWOOD MEAT CO, INC.	BACTERIA: *E. COLI* O157:H7	107,943
021-07	05/01/07	DIESTEL TURKEY RANCH	BACTERIA: *LISTERIA MONOCYTOGENES*	6,907
022-07	05/10/07	PM BEEF HOLDINGS, LLC	BACTERIA: *E. COLI* O157:H7	117,500
023-07	05/11/07	DAVIS CREEK MEATS AND SEAFOOD	BACTERIA: *E. COLI* O157:H7	129,000
024-07	05/18/07	KAYEM FOODS, INC.	UNDECLARED ALLERGEN	35,580
025-07	06/03/07 06/06/07 06/09/07	UNITED FOOD GROUP, LLC	BACTERIA: *E. COLI* O157:H7	5,700,000
026-07	06/05/07	THE REALLY COOL FOOD COMPANY	BACTERIA: *LISTERIA MONOCYTOGENES*	140
027-07	06/08/07	TYSON FRESH MEATS, INC.	BACTERIA: *E. COLI* O157:H7	40,440
028-07	06/15/07	WASHINGTON BEEF	INSANITARY CONDITIONS	82,286
029-07	06/19/07	PAMPANGA FOODS	MISLABELING	2,762
030-07	06/21/07	SAMS FOOD GROUP, INC.	MISLABELING	13,300
031-07	06/29/07	STATE OF TENNESSEE COOK CHILL	BACTERIA: *LISTERIA MONOCYTOGENES*	2,768
032-07	07/06/07	AGRIPROCESSORS, INC.	MISLABELING	35,860
033-07	07/19/07 07/21/07	CASTLEBERRY'S FOOD COMPANY	BACTERIA: *CLOSTRIDIUM BOTULINUM*	21,700,000
034-07	07/21/07	ABBOTT'S MEAT INC.	BACTERIA: *E. COLI* O157:H7	26,669
035-07	07/25/07	CUSTOM PACK, INC.	BACTERIA: *E. COLI* O157:H7	5,920
036-07	08/14/07	IAN'S NATURAL FOODS	UNDECLARED ALLERGEN	12,894
037-07	08/16/07	FRANK WARDYNSKI & SONS, INC.	UNDECLARED SULFITES	17,000

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
038-07	09/05/07	FAIRBANK RECONSTRUCTION CORP.	BACTERIA: *E. COLI* O157:H7	884
039-07	09/14/07	STONE MEATS, INC.	PIECES OF METAL	11,250
040-07	09/25/07 09/29/07	TOPPS MEAT COMPANY, LLC	BACTERIA: *E. COLI* O157:H7	21,700,000
041-07	09/29/07	IMPERO FOODS AND MEATS, INC.	BACTERIA: *E. COLI* O157:H7	65

Recalls for Fiscal Year 2008 (52)

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
042-07	10/06/07	CARGILL MEAT SOLUTIONS CORPORATION	BACTERIA: *E. COLI* O157:H7	845,000
043-07	10/09/07	ALIKI FOODS, INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	70,400
044-07	10/11/07	CONAGRA FOODS	BACTERIA: *SALMONELLA*	83,900,000
045-07	10/13/07	J & B MEATS CORPORATION INC.	BACTERIA: *E. COLI* O157:H7	173,554
046-07	10/13/07	ARKO VEAL CO.	BACTERIA: *E. COLI* O157:H7	1,900
047-07	10/24/07	BLUE RIBBON MEATS	BACTERIA: *E. COLI* O157:H7	8,200
048-07	10/27/07	DEL-MAR PROVISION CO., INC.	BACTERIA: *E. COLI* O157:H7	50
049-07	11/01/07	GENERAL MILLS OPERATIONS	BACTERIA: *E. COLI* O157:H7	3,300,000
050-07	11/01/07	ANNEX FOODS	POSSIBLE ADULTERATION	4,374
051-07	11/03/07	CARGILL MEAT SOLUTIONS CORP.	BACTERIA: *E. COLI* O157:H7	1,084,384
052-07	11/08/07	CIRCLE FOODS, LLC	PIECES OF METAL	3,750
053-07	11/15/07	DOUBLE B FOODS, INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	98,000
054-07	11/24/07	AMERICAN FOODS GROUP, LLC	BACTERIA: *E. COLI* O157:H7	95,927
055-07	12/06/07	CUSTOM CULINARY, INC.	UNDECLARED ALLERGENS	990
056-07	12/10/07	SPECIALTY FOODS GROUP, INC.	UNDECLARED ALLERGEN	98,772
057-07	12/17/07	SNAPPS FERRY PACKING	BACTERIA: *E. COLI* O157:H7	102
058-07	12/25/07	THE MARAMONT CORPORATION	BACTERIA: *LISTERIA MONOCYTOGENES*	88
001-08	01/05/08	MARK'S QUALITY MEATS, INC.	BACTERIA: *E. COLI* O157:H7	13,150
002-08	01/12/08	ROCHESTER MEAT COMPANY	BACTERIA: *E. COLI* O157:H7	188,000
003-08	01/26/08	PERDUE FARMS, INC.	UNDECLARED ALLERGEN	24,710

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
004-08	02/01/08	CHEF'S REQUESTED FOODS, INC.	UNDECLARED ALLERGENS	8,910
005-08	02/17/08	HALLMARK/WESTLAND MEAT PACKING CO.	ADULTERATED PRODUCT	143,383,823
006-08	03/02/08	MEIJER DISTRIBUTION CENTER	BACTERIA: *LISTERIA MONOCYTOGENES*	2,184
007-08	03/03/08	COSTCO WHOLESALE	BACTERIA: *LISTERIA MONOCYTOGENES*	10,368
008-08	03/04/08	INOVATA FOODS	BACTERIA: *LISTERIA MONOCYTOGENES*	3,780
009-08	03/04/08	GOURMET BOUTIQUE	BACTERIA: *LISTERIA MONOCYTOGENES*	6,970
010-08	03/14/08	CAGLE'S INC.	ADULTERATED PRODUCT	943,000
011-08	03/29/08	KOCH FOODS	MISLABELING	1,420
012-08	04/04/08	ELKHORN VALLEY PACKING LLC	PROHIBITED MATERIALS	406,000
013-08	05/03/08	GOURMET BOUTIQUE, LLC	BACTERIA: *LISTERIA MONOCYTOGENES*	286,320
014-08	05/08/08	PALAMA HOLDINGS, LLC	BACTERIA: *E. COLI* O157:H7	68,670
015-08	05/12/08	FAIRBANK RECONSTRUCTION CORP.	PIECES OF PLASTIC	22,481
016-08	05/16/08	JSM MEAT HOLDINGS COMPANY, INC.	BACTERIA: *E. COLI* O157:H7	UNDETERMINED
017-08	05/21/08	CECINA LOS AMIGOS	BACTERIA: *LISTERIA MONOCYTOGENES*	290
018-08	06/08/08	DUTCH'S MEAT, INC.	BACTERIA: *E. COLI* O157:H7	13,275
019-08	06/09/08	GOURMET FOODS, INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	130
020-08	06/26/08	BELTEX CORPORATION	PROHIBITED MATERIALS	2,850
021-08	06/26/08	PARADISE LOCKER MEATS	PROHIBITED MATERIALS	120
022-08	06/30/08 07/03/08	NEBRASKA BEEF, LTD.	BACTERIA: *E. COLI* O157:H7	5,300,000
R01-08	06/25/08 07/03/08	THE KROGER CO.	BACTERIA: *E. COLI* O157:H7	UNDETERMINED
023-08	07/14/08	NESTLE PREPARED FOODS COMPANY	PIECES OF PLASTIC	199,417
024-08	07/23/08	BEEF PACKERS, INC.	BACTERIA: *E. COLI* O157:H7	1,560
025-08	08/05/08	DBC, INC.	BACTERIA: *LISTERIA MONOCYTOGENES*	285
026-08	08/06/08	TYSON FOODS, INC.	UNDECLARED ALLERGEN	51,360
027-08	08/06/08	S&S FOODS LLC	BACTERIA: *E. COLI* O157:H7	153,630
028-08	08/07/08	DALLAS CITY PACKING, INC.	PROHIBITED MATERIALS	941,271
029-08	08/08/08 08/14/08	NEBRASKA BEEF, LTD.	BACTERIA: *E. COLI* O157:H7	1,360,000
030-08	08/10/08	PALAMA HOLDINGS, LLC	BACTERIA: *LISTERIA MONOCYTOGENES*	4,535

CASE#	DATE	ESTABLISHMENT	PROBLEM TYPE	POUNDS RECALLED
031-08	08/11/08	RENNA'S MEAT MARKET	BACTERIA: *E. COLI* O157:H7	780
032-08	08/19/08	SIMMERING SOUP, INC.	UNDECLARED ALLERGEN	987
033-08	08/21/08	NESTLE PREPARED FOODS COMPANY	FOREIGN MATERIALS	215,660
034-08	09/30/08	FOOD EVOLUTION	BACTERIA: *LISTERIA MONOCYTOGENES*	16

Ms. DeLauro: For each year, provide a summary of number of recalls due to pathogen, undeclared substances, mislabeling, or other problem type.

Response: The information is provided for the record.

[The information follows:]

Number of Recalls

PROBLEM TYPE	FY 2007	FY 2008
BACTERIA, *LISTERIA MONOCYTOGENES*	10	13
BACTERIA, *E.COLI* O157:H7	15	20
BACTERIA, *SALMONELLA*	-	1
BACTERIA, *STAPHYLOCOCCUS AUREUS*	1	-
BACTERIA, *CLOSTRIDIUM BOTULINUM*	1	-
UNDECLARED SUBSTANCE/ALLERGEN	8	6
MISLABELING	5	1
UNDERPROCESSING/PROCESSING DEFECT	4	-
EXTRANEOUS MATERIAL/FOREIGN MATERIAL	1	4
PROHIBITED MATERIALS	-	4
OTHER	2	3
TOTAL	47	52

Ms. DeLauro: Does FSIS have an oversight process in place to continually evaluate the efficacy of its recall practices?

Response: In 2004, FSIS implemented a new system for verifying the effectiveness of recalls for meat and poultry products to strengthen public health protection. FSIS field personnel conduct effectiveness checks of meat and poultry recalls ensuring that proper and adequate customer notification is made by the recalling firm and that the firm makes all reasonable efforts to retrieve and appropriately dispose of the recalled products. Effectiveness checks allow the Agency to verify that the actions of the recalling firm are made swiftly and accurately in the best interest of public health.

The recall effectiveness check verification process is based on risk, dependent on the public health concern of the recall and the number of customers. This risk-based system allows the Agency to better target its resources to protect public health. Statistically-based guidance directs the number of effectiveness checks conducted.

Effectiveness checks are most intensive for Class I recalls when they are illnesses, outbreaks, or school lunch implications. The system also addresses the recommended timeframes for initiating and reporting the verification process which is based on the class of the recall. An objective procedure is used to verify appropriate recall product disposition or destruction by consignees.

Ms. DeLauro: In FY 2007 and 2008, did any firm reject the FSIS Recall Committee's recommendation to conduct a recall? If so, please provide a synopsis of each case. What is FSIS' course of action in such a case?

Response: FSIS has never had a company ultimately refuse to cooperate with a recall. However, if a firm did refuse, FSIS could use its statutory authority to detain and seize product and warn the public.

Ms. DeLauro: What is the timeframe for determining a recall from the initial findings to the formal announcement of a recall?

Response: A recall can be triggered initially by findings from FSIS, product testing, inspection activities, consumer complaints, establishment findings, or epidemiological data. A confirmed positive lab result from the FSIS microbiological monitoring programs for *E. coli* O157:H7 in raw ground beef; and *Listeria monocytogenes* and *Salmonella* in ready-to-eat meat and poultry products is acted upon immediately if the product has entered commerce. Other triggers require investigation to establish that product adulteration or mislabeling occurred and to determine the type and amount of product involved. Once this is established, a recall is triggered immediately. When the recall is actually announced depends upon several factors. A Recall Committee deliberation usually takes place within the hour. However, a critical factor which impacts the time between this deliberation and the recall announcement is acquisition of complete and accurate product descriptions and distribution information. The Agency urges the company to provide this information as soon as possible so the formal announcement of the recall can be issued as soon as possible. Based on this process, the timeframe fluctuates on a case-by-case basis. Because of the importance to public health, it should be noted that decisions are made on a 24 hours a day, seven days a week basis, and typical working hours are not a consideration in the decision-making process.

Ms. DeLauro: When do you consider a recall closed?

Response: FSIS recommends that a recall case be terminated or closed when the affected product that was available in commerce at the time of the recall is either disposed of, is under FSIS control, or the firm has documented control of the product.

In recalls associated with illnesses, FSIS reviews any available epidemiological data before initiating recall closure. If data indicate that illnesses continue to occur because product remains in commerce, the recall case remains open. The Agency continues to investigate the cause of the illness and identify suspect product to remove from commerce. The Recall Management Staff (RMS) may request that the firm expand the recall if evidence indicates that additional

products are implicated in cause of the illness. However, if data indicate that no additional illness associated with the recalled product are being reported, and there are no signs that recalled product remains in commerce, RMS initiates closing of the recall.

After all recall effectiveness and product disposition checks are completed, the FSIS field manager overseeing these activities prepares a Final Recall Effectiveness Report to the Director, RMS, by compiling all the information that was obtained.

FSIS considers the status of a recall closed upon satisfactory completion of the recall effectiveness checks along with the recalling firm's written notification to the FSIS that they have made all reasonable efforts to recall and dispose of the products.

Ms. DeLauro: What is the average amount of time a recall remains open? Why do some recalls take longer than others? Please provide examples.

Response: On May 24, 2004, FSIS implemented a new system for verifying the effectiveness of recalls for meat and poultry products to strengthen public health protection. FSIS field personnel conduct effectiveness checks of meat and poultry recalls ensuring that proper and adequate and timely customer notification is made by the recalling firm.

The recall effectiveness check addresses the recommended timeframes for initiating and reporting the verification activities within FSIS as follows:

Recall classification	Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:	Following their initiation, FSIS verification activities should be substantially completed within a period of:
Class I	3 days*	10 days
Class II	5 days	12 days
Class III	10 days	17 days

* *Working* days: Working days may include Saturday and Sunday, depending upon the risk associated with a recalled product.

Most recall effectiveness checks are completed within the timeframes outlined above. Recalls are typically closed upon satisfactory completion of the recall effectiveness checks along with the recalling firm's written notification to the FSIS that they have made all reasonable efforts to recall and dispose of the products. However, the following are different scenarios that may cause a recall to take longer to close:

- FSIS has completed the recall effectiveness checks but the firm is still not satisfied that all affected products are no longer in commerce. This depends largely on the following factors:
    1. Amount being recalled.
    2. The number of consignees.

3. The geographical area of distribution. Some recalls with foreign countries distribution requires longer periods of time to verify product control.

- If data indicate that illnesses continue to occur because product remains in commerce, the recall case remains open.

Historically, the length of time that a recall remained open varied from one day to 12 months. For FY 2008, there have been 52 recalls, 43 of which have been closed. The average length of open time for those that are now closed was 9.5 weeks, with a range between one and 46 weeks.

Ms. DeLauro: Please provide for the record the total number of pounds involved in recalls during the last ten years, and the amount and percentages of products recovered.

Response: The information is provided for the record.

[The information follows:]

Calendar Year	Number of Pounds Recalled	Number of Pounds Recovered	Percentage of Pounds Recovered
1997	28,194,395	10,874,144	38.6%
1998	44,167,058	10,522,186	23.8%
1999	39,687,649	9,537,741	24.0%
2000	22,743,092	3,624,154	15.9%
2001	33,410,564	6,617,181	19.8%
2002	58,911,071	9,655,289	16.1%
2003	3,593,574	824,413	22.9%
2004	2,882,018	1,836,970	63.7%
2005	6,446,149	2,720,903	42.2%
2006	5,947,933	892,762	15.0%
2007	143,063,822	49,854,285	34.8%
2008 (as of 9/30/08)	153,615,952	53,779,088	37.0%

These numbers can be found on FSIS' Web site at: http://www.fsis.usda.gov/FSIS_Recalls/Quantity_Recovered_by_Case_2007/index.asp and http://www.fsis.usda.gov/FSIS_Recalls/Quantity_Recovered_by_Case_2008/index.asp.

The amount of product(s) recovered during a firm's recall efforts is reported to FSIS by the recalling firm. The total amount of product recovered may be affected by numerous circumstances. While 100 percent recovery has occurred, this is not always possible. The products subject to recall may have already been consumed or were discarded at the time the recall was issued. There have been cases where no product was recovered due to a very short shelf life of the product.

Ms. DeLauro: What is the status of FSIS's completion of the agreed-upon actions in the OIG report on recall procedures, 24601-09 Hy (August 2008)?

Response: The Office of the Inspector General's report on recall procedures was issued in August 2008 and contained two recommendations, both of which achieved management decision on August 7, 2008. In response to the first recommendation, FSIS developed and implemented a protocol for determining the number of samples to collect at establishments during outbreak investigations. FSIS requested final action from the Office of the Chief Financial Officer for this recommendation on October 15, 2008, and this request is pending approval. In response to the second recommendation, FSIS has drafted a new Directive for investigating foodborne illnesses and revised its Directive for handling recalls. Once those Directives are finalized and issued, FSIS will request final action for that recommendation.

LAB ACCREDITATION

Ms. DeLauro: What is the significance of being an FSIS-accredited lab? What kind of work do these labs do?

Response: The Accredited Laboratory Program (ALP) provides a Proficiency Testing (PT) Program which is a type of external quality control to measure laboratory accuracy. Proficiency testing is a valuable quality tool for laboratories carrying out analytical measurements. The PT Program helps the laboratory focus on its output by providing the laboratory with a snapshot of the measurements and quality system. When accredited, labs in ALP may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Accreditation is limited to chemical testing of meat and poultry food products.

The significance of being an FSIS-accredited laboratory and participating in the PT Program is:

- Laboratories have the ability to test Federal meat and poultry products;
- Successful performance in an external PT Program is a key indicator of high laboratory quality;
- Verifies that the performance of each laboratory is in line with other laboratories performing the same tests;
- Regular participation in the program over time (the accreditation standard requires a minimum of 2-4 proficiency test samples mailed to participating labs per year) gives the laboratory manager an objective means of assessing and proving the reliability of the data they produce.
- Enables the laboratory to demonstrate to their customers that their products are defensible, their personnel are competent and their results are accurate;
- Laboratories are participating in an established proficiency testing program in which to compare and monitor analytical proficiency;
- Laboratories can identify areas where improvements in their testing and measurements are needed;
- Laboratories can identify further training for their staff; and

- Provides standards to meet requirements for competence of testing and calibration laboratories, which are covered in the International Organization for Standardization 17025 Guide.

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the total number of labs that were accredited, the total number of accreditations, and the cost to include fiscal years 2007 and 2008 and estimates for 2009.

Response: The information is submitted for the record.

[The information follows:]

Accredited Laboratories (Dollars in thousands)			
Fiscal Year	Accredited Laboratories	Number of Accreditations	Fees
1995	148	184	$440
1996	150	186	$360
1997	140	177	$363
1998	137	173	$365
1999	126	159	$406
2000	120	149	$246
2001	112	141	$204
2002	114	141	$216
2003	100	125	$194
2004	94	116	$183
2005	91	113	$176
2006	69	83	$211
2007	69	81	$365
2008	71	83	$383
2009 Estimate	75	89	$400

The decreases in number of accreditations and accredited laboratories are due to a combination of factors. Changes in FSIS programs with the implementation of HACCP systems have resulted in fewer official samples being sent to non-Federal laboratories. For this reason, some laboratories have determined that it is no longer in their business interest to be accredited by FSIS. Some other reasons for the decreases include laboratories going out of business, consolidations of laboratories, and laboratory accreditations being revoked for failure to meet FSIS quality control criteria. In 2008, there was a slight increase, and we expect this trend to continue.

Ms. DeLauro: The table in last year's hearing record showed the number of accreditations were decreasing. What is the reason for this?

Response: The decrease in the number of accreditations was a result of the increase in fees. In 2008, there was a slight increase, and we expect this trend to continue.

Ms. DeLauro: Does FSIS fully recover the cost of accrediting labs?

Response: Yes, FSIS fully recovers the cost of accrediting labs.

Ms. DeLauro: What happens to the accreditation fees after they are collected? What is the balance of funds? If there is a balance, does FSIS have any current plans for its use?

Response: Accreditation fee collections are placed in a no-year account, which is available for future laboratory accreditation costs. At the end of FY 2007, the account balance was $224,000. At the end of FY 2008, the balance was $195,500.

FSIS has current plans for the use of the balance. FSIS' ALP uses a software program developed in-house to statistically check data from accredited laboratories. The versions of the software are now more than twenty years behind modernized software. FSIS has already awarded a contract in the amount of $137,140 to develop replacement software, which will reduce the risk of lost data, improve operations of ALP check sample activities, and protect the public health by providing assurance that quality of data generated by the accredited chemistry laboratories is reliable and accurate.

Ms. DeLauro: Did FSIS implement its incremental fee increase in fiscal year 2006? If not, why? If so, did the initial decline in the number of accredited labs that you indicated you expected materialize?

Response: Yes, FSIS implemented its incremental fee increase in FY 2006 and FY 2007. The program saw an initial 24 percent decline in the number of accredited labs during the first year after the fee increase was implemented. This percentage was higher than anticipated, but there has been no additional decrease in the number of accredited laboratories since that time. In fact, in FY 2008, the number has increased.

EXEMPT ESTABLISHMENTS

Ms. DeLauro: How many plants are exempt from the inspection provisions of the Federal Meat Inspection Act? How does FSIS monitor exempt facilities and what action does FSIS take if such a facility exhibits practices that lack the necessary standards for non-exempt firms?

Response: Approximately 1,600 State-inspected plants and about 700 federally-inspected plants are conducting custom exempt operations. In addition, approximately 1,600 known firms that are not inspected are engaged in custom exempt operations. While the 1,600 exclusively custom exempt plants do not require inspection (e.g., they are not required to develop and maintain HACCP plans and Sanitation SOPs, and they are not subject to mandatory antemortem and postmortem inspection), these facilities are required to be maintained and operated in a sanitary manner and product is to be marked "Not for Sale" (under the FMIA) or "Exempt P.L." with the number of the public law (P.L. 90-492 or a State law) under which the products are exempt (under the PPIA).

The adulteration provisions of the Federal Meat Inspection Act are applicable to custom exempt product. Custom exempt operations are only exempt from the inspection provisions of the Federal Meat Inspection Act. Custom exempt plants are reviewed by FSIS annually, or more often if warranted based on previous reviews. Should adulterated products be found, the products are detained until made wholesome or destroyed. Should an unsanitary condition be found, the area of the unsanitary condition is prohibited from use until the owner of the facility corrects the condition. FSIS inspection program personnel conducting the review document their findings and the FSIS District Manager issues an appropriate "Letter of Warning" to the owner. Based on the risk noted from the previous review findings, the facility is scheduled for review the next quarter. Repeated findings of adulterated product or unsanitary conditions may lead the Agency to seek removal of the facility's custom exempt privilege through legal channels.

Ms. DeLauro: How many custom exempt plants received a "letter of warning" in fiscal year 2007 or 2008? Did any have their exemption revoked? How does the number of warning letters for those years compare to 2005 and 2006? What does it mean for a custom exempt plant to have its exemption revoked?

Response: The meat and poultry laws exempt certain custom or other operations from inspection, such as facilities that custom slaughter animals or poultry, or custom process meat or poultry, for owners of the animals. FSIS conducts periodic reviews of custom slaughtering and processing operations and facilities to determine compliance with sanitation, adulteration, mislabeling, and other statutory and regulatory requirements for exempt facilities. FSIS documents review findings, which are provided to custom exempt operators. FSIS issues written warning notices when operators fail to maintain compliance or fail to implement corrective actions to comply with statutory and regulatory requirements. When insanitary conditions create health hazards, FSIS may withdraw custom exempt privileges through issuance of a Notice of Ineligibility, and require the business to cease custom exempt operations. When this happens, custom operators have the opportunity to correct violations, enter settlement agreements to resolve actions and resume operations, or contest the basis for the action at a hearing.

A table on written notices issued to custom operators and actions taken by FSIS to withdrawal custom exempt privileges from custom operators is submitted for the record.

[The information follows:]

FSIS Enforcement Activities for Custom Exempt Plants				
	FY 2005	FY 2006	FY 2007	FY 2008
Written Notices	3	0	2	5
Withdrawal of Custom Exemption	5*	3*	3	2

* FSIS recently revised the Enforcement Activity for the Withdrawal of Custom Exempt Privilege to appropriately report the actual number of withdrawals of custom exempt privilege. Therefore, the FY 2005 and FY 2006 numbers reported in the FY 2008 Questions for the Record (one (1) and zero (0), respectively) have been updated to reflect this revision.

Ms. DeLauro: Can a plant be exempt for a part of its production on a daily or weekly basis?

Response: Under the Curtis Amendment of 1970 to the Federal Meat Inspection Act (21 USC 623), an establishment can be exempt for a part of its production on a daily or weekly basis if it is producing product for the sole use of the owner of the product, his or her household, guests, or employees. However, such establishments must perform a thorough clean-up following exempt activities before operating under Federal inspection and must keep inspected and exempted product separated and identified. The Curtis Amendment does not apply to the Poultry Products Inspection Act. A custom exempt poultry plant is prohibited from operating under a grant of inspection and cannot engage in the business of buying and/or selling poultry.

TESTS

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the number of SOS, STOP, CAST, and FAST tests performed to include fiscal years 2007 and 2008. Does FSIS plan to alter or replace any of these tests in fiscal year 2007 or 2008? Please indicate the purpose of each test from a public health perspective.

Response: The information is provided for the record.

[The information follows:]

Residue Test by Fiscal Year					
Fiscal Year	SOS	STOP	CAST	FAST	TOTAL
1992	106,133	117,858	79,666	--	303,657
1993	101,118	116,600	85,033	--	302,751
1994	127,742	93,428	54,783	17,831	293,784
1995	26,273	74,632	79,542	68,410	248,857
1996	17,682	41,428	19,448	96,805	175,363
1997	11,415	37,140	12,529	52,393	113,477
1998	9,484	36,630	7,751	122,273	176,138
1999	9,410	35,993	5,582	125,534	176,519
2000	8,891	32,980	5,554	154,949	202,374
2001	7,813	24,250	737	211,985	244,785
2002	9,050	20,631	--	217,485	247,166
2003	8,026	14,346	--	229,680	252,052
2004	1,454	6,915	--	142,998	151,367
2005	--	4,517	--	106,730	111,247
2006	--	3,626	--	108,374	112,000
2007	--	2,979	--	160,184	163,163
2008	--	225	--	176,558	176,783
SOS = Sulfa on Site					

STOP = Swab Tests on Premises
CAST = Calf Antibiotic and Sulfa Tests
FAST = Fast Antimicrobial Screen Test

In 2006, FSIS replaced STOP for swine with FAST, which will test for both sulfonamides and antibiotics in swine. The FAST test detects more antibiotics and can be implemented in more swine plants. The purpose of each test is as follows:

- Fast Antimicrobial Screen Test (FAST) - FAST is used to screen samples for certain antibiotic and sulfonamide residues in bovines and swine as a first step in preventing potentially violative product from entering the food supply, thereby protecting the public health and supporting the Agency's mission to ensure that the commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome and correctly labeled and packaged.

- Swab Test on Premises (STOP) - STOP is used to screen samples for certain antibiotic and sulfonamide residues in all production classes as a first step in preventing potentially violative product from entering the food supply, thereby protecting the public health and supporting the Agency's mission to ensure that the commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome and correctly labeled and packaged.

- Kidney Inhibition Swab (KIS) Test - The Kidney Inhibition Swab is a-simple-to-use inhibition test for screening broad spectrum antimicrobial drugs in fresh or thawed kidney tissue. KIS reagents are self contained, solvent free, and pre-measured in a single use, disposable swab format. Results take less than three hours. Speed, sensitivity, and simplicity are clear advantages with the KIS Test. The KIS test is designed to absorb kidney serum at slaughter facilities. If antimicrobial drugs are present, microbial growth in the KIS vial is inhibited which prevents a color change to yellow. Thus, positives remain blue.

FSIS is in the process of replacing the field screening test for FAST and STOP with KIS. Only one vendor has been interested in producing the FAST and STOP kits, and they are no longer willing to make them. A Solicitation for Offers was opened in FY 2008 for a field screening test to replace both FAST and STOP. The vendor with the KIS test was selected through this competitive process, after a successful field test of KIS was conducted, and initial kits are expected to be available and distributed to all field locations by the end of the first quarter of FY 2009. There are enough FAST supplies to continue performing all required FAST tests until the new KIS supplies are distributed to the field. There are no STOP test materials remaining, so for now, the FAST test has replaced the STOP test in all field establishments. In the future, the KIS test will replace both.

Ms. DeLauro: What were the results of these procedures? How do these results compare with those results over the past three years? Are these changes linked to an increase and/or decrease in violations?

Response: In FY 2007, there were 4,059 total positive test results out of a total of 163,163 tests taken, including 30 by STOP and 4,029 by FAST. While the amount of positive test results in FY 2007 was much higher than in FY 2006 (when there were 2,900 total positive test results out of 112,000 tests taken), the overall percentage of positive test results decreased between FY 2006 and FY 2007, from 2.6 percent, to 2.5 percent of the tests performed. In FY 2008, there were 3,333 total positive test results (all taken by FAST) out of a total of 176,783 tests taken. The percentage of positive test results decreased significantly between FY 2007 and FY 2008, from 2.5 percent, to 1.9 percent of the tests performed.

[The information follows:]

Positive Field Test Results				
Fiscal Year	FAST	STOP	SOS	TOTAL
2001	5,948	360	9	6,317
2002	1,703	124	10	1,837
2003	5,082	149	11	5,242
2004	3,448	53	5	3,506
2005	2,487	21	--	2,508
2006	2,883	17	--	2,900
2007	4,029	30	--	4,059
2008	3,333	0	--	3,333

Ms. DeLauro: What actions has FSIS taken in response to the OIG memorandum dated January 29, 2008, on *E. coli* testing?

Response: The January 29, 2008, memorandum on *E. coli* O157:H7 testing contained no recommendations for FSIS.

Between October 2007 and January 2008, FSIS conducted a checklist to be completed by FSIS personnel, which profiled various practices in raw beef establishments. The results of this effort were summarized in a report that was posted on FSIS' Web site in August 2008. This report detailed the responses to each question and discussed the major findings as identified by FSIS. The public was also provided the opportunity to comment on the data in the report. FSIS received one public comment about the report in the 45 days after its posting. Briefings have been provided to industry and consumers. The checklist results have also been integrated with other Agency data to provide information on establishments that had 2007 *E. coli* O157:H7 positives and recalls, testing and intervention practices by HACCP size, testing and intervention practices by production volume category, raw beef component usage by beef grinding operations, shift practices by production category and changes in establishment practices via comparison to earlier food safety assessments.

Based in part on the results of the Checklist, FSIS issued a Guidance Document on Sampling in August 2008. Analysis of checklist data has also informed the Agency about shift operations at establishments. This has led to an assessment of how samples are collected for the risk-based raw ground beef sampling program. The checklist questions are also being incorporated into a revised food safety assessment program, which will result in the collection of more quantitative data that will be easier to analyze and report. FSIS

intends to utilize information from the checklist to enhance the risk-based sampling programs and to identify any gaps in the Agency's sampling programs.

FOOD EMERGENCY RESPONSE NETWORK (FERN)

Ms. DeLauro: What is the manner in which funding for FERN is allocated to individual labs? How much has each received per year from the start of the project?

Response: FERN was created to provide an integrated means of protecting the food supply at the national, State, and local levels. FERN is a coordinated initiative between FSIS and the Department of Health and Human Services' Food and Drug Administration (FDA) to develop an integrated laboratory network capable of providing ongoing surveillance and monitoring of food, as well as conducting the extensive sampling necessary in the event of a terrorist attack, act of nature, or hoax that affects the food supply. Consumer safety will be enhanced through FERN's ability to conduct extensive sampling necessary in the event of a food safety emergency, and it would also serve to restore consumer confidence in the safety of the Nation's food supply.

FSIS provides funding for cooperative agreements with competitively selected labs. FSIS spent $1.16 million of FY 2005 funds for FERN cooperative agreements (18 laboratories), and $1.16 million of FY 2006 funds for FERN cooperative agreements (17 laboratories), $2.9 million of FY 2007 funds for FERN cooperative agreements (21 labs), and $11.35 million of FY 2008 funds for FERN cooperative agreements (25 labs).

[The information follows:]

Total FERN CAP Awards by Laboratory and Fiscal Year

FERN Cooperative Agreement Laboratories	Total FY 2005 Award	Total FY 2006 Award	Total FY 2007 Award	Total FY 2008 Award
Arkansas Department of Health	$97,900	$25,000	$95,600	$164,000
Delaware Department of Health and Social Services	80,112	50,000	138,382	215,000
Florida Department of Agriculture and Consumer Affairs	40,200	48,100	85,699	502,000
Hawaii Department of Health, State Laboratories Division	93,225	65,000	150,000	475,000
Indiana Department of Health	33,375	59,445	116,858	226,200
Massachusetts Department of Public Health, State Laboratory Institute	92,000	74,200	149,745	900,000
Michigan Department of Agriculture and Department of Health	95,000	90,000	150,000	444,000

FERN Cooperative Agreement Laboratories	Total FY 2005 Award	Total FY 2006 Award	Total FY 2007 Award	Total FY 2008 Award
Minnesota Department of Agriculture	47,525	89,056	244,086	1,010,400
Montana Department of Public Health and Human Services	49,700	49,600	159,083	210,000
Nebraska Department of Agriculture	75,900	48,000	91,400	147,000
New Hampshire Public Health Laboratories	35,401	75,000	165,552	235,000
New Jersey Department of Health and Senior Services	85,171	89,028	164,983	646,000
New York State Department of Agriculture	85,295	65,000	150,000	433,800
Ohio Department of Agriculture, Consumer Analytical Laboratories	79,700	90,000	150,000	210,000
Rhode Island Department of Health	30,250	N/A	N/A	N/A
South Carolina Department of Health and Environmental Control	12,400	96,571	225,724	177,000
South Dakota State University Veterinary Diagnostics Laboratory	77,000	90,000	165,000	210,000
Virginia Division of Consolidated Laboratory Services	52,000	60,000	150,000	859,600
Alaska Environmental Health Laboratory	N/A	N/A	165,000	250,000
Arizona State Public Health Laboratory	N/A	N/A	174,450	890,000
California Department of Public Health	N/A	N/A	145,550	200,000
Texas Office of Texas State Chemist	N/A	N/A	198,300	205,000
Colorado Department of Agriculture	N/A	N/A	N/A	245,000
Iowa University of Iowa Hygenic Laboratory	N/A	N/A	N/A	300,000
North Carolina Department of Agriculture	N/A	N/A	N/A	219,000
Washington Department of Health	N/A	N/A	N/A	226,000
Illinois Institute of Technology	N/A	N/A	N/A	1,000,000
University of Georgia	N/A	N/A	N/A	700,000

Ms. DeLauro: Please provide a detailed progress report on the FERN labs and communication system. Which labs are part of the system?

Response: FSIS continues work in method development and demonstration of analytical proficiency) and with the University of Minnesota (for Web site development and specific establishment of the FERN laboratory directory). FERN has continued to improve the eLEXNET data reporting system. In addition, FERN is collaborating with the National Center for Food Protection and Defense, located at the University of Minnesota, for Web site development and specific establishment of the FERN laboratory directory. This project will assure integration into the routine operations of all member State and local laboratories such that gap analyses, training opportunities, and coordination with Federal agencies will be improved. The primary intent of the current funding is to enable appropriate security interfaces to allow individual Federal and State agency participants to control access to potentially sensitive data of specific importance to FERN. FERN established five Regional Coordination Centers that serve as the primary points of contact for laboratories across the country. The Regional Coordination Centers are located in Athens, Georgia; Rockville, Maryland (which will eventually be located in Jamaica, New York); Alameda, California; Denver, Colorado; and St. Paul, Minnesota.

FSIS continues direct funding to 25 labs (to manage, maintain, and expand their capacity and capabilities including triage/risk assessment development and the development of four training centers); proficiency test contracts (to provide proficiency samples and validation samples for CAP studies); and readiness-response exercises with National Guard Civil Support Teams in conjunction with local emergency management agencies and FERN.

FSIS has cooperative agreements with the following 25 State laboratories to build capacity to test for biological threat agents in food:

State	Division
1. Alaska	Alaska Environmental Health Lab
2. Arizona	Arizona State Public Health Lab
3. Arkansas	Arkansas Department of Health
4. California	California Department of Public Health
5. Colorado	Colorado Department of Agriculture
6. Delaware	Delaware Health and Social Services
7. Florida	Florida Department of Agriculture and Consumer Affairs
8. Hawaii	Hawaii State Laboratories Division, Department of Health
9. Indiana	Indiana State Department of Health
10. Iowa	University of Iowa Hygienic Lab
11. Massachusetts	Massachusetts Department of Public Health, State Lab Institute
12. Michigan	Michigan Department of Agriculture & Michigan Department of Health
13. Minnesota	Minnesota Department of Agriculture
14. Montana	Montana Department of Public Health & Human Services
15. Nebraska	Nebraska Department of Agriculture
16. New Hampshire	New Hampshire Public Health Laboratories

17.	New Jersey	New Jersey Department of Health and Senior Services
18.	New York	New York State Department of Agriculture
19.	North Carolina	North Carolina Department of Agriculture
20.	Ohio	Ohio Department of Agriculture, Consumer Analytical Lab
21.	South Carolina	South Carolina Department of Health & Environmental Control
22.	South Dakota	South Dakota Animal Disease Residue & Diagnostic Lab, South Dakota State University
23.	Texas	Texas Office of the Texas State Chemist
24.	Virginia	Virginia Division of Consolidated Laboratory Services
25.	Washington	Washington Department of Health

The FDA has agreements with the following 16 State laboratories to develop capacity to respond to chemical and radiological attacks on the food supply:

Eleven Chemical Cooperative Agreements:

State	Division
1. Arizona	Arizona Department of Health Service
2. California	California Department of Public Health
3. California	Regents of the University of California
4. Connecticut	Connecticut Agriculture Experimental Station
5. Colorado	Colorado Department of Public Health
6. Florida	Florida Department of Agriculture
7. Iowa	University of Iowa
8. Minnesota	Minnesota Department of Agriculture
9. New Hampshire	New Hampshire Department of Public Health
10. Ohio	Ohio Department of Public Health
11. Virginia	Virginia Division of Consolidated Labs

Five Radiological Cooperative Agreements:

State	Division
1. Maryland	Maryland Dept. of Health & Mental Hygiene
2. New York	Health Research/New York Department of Health
3. Texas	Texas Dept. of State Health Services Laboratory
4. Washington	Washington State Public Health Laboratory
5. Wisconsin	Wisconsin State Laboratory of Hygiene

Ms. DeLauro: What is the performance of the lab communications network? How is it tested?

Response: FSIS and FDA, together, currently have cooperative agreements with 41 of the 150 laboratories in FERN. Of these 41 laboratories, FSIS has cooperative agreements with 25, and FDA has cooperative agreements with 16. However, these 41 laboratories are not fully capable of performing the activities that will be eventually expected in a robust FERN. Additional equipment, training, and testing are necessary. Additional laboratories will be added over the next several years, as appropriated funding permits. The FERN labs have access to the electronic laboratory exchange network (eLEXNET) communications network, which is used for many purposes. All of the

labs funded by cooperative agreements use the eLEXNET to report real-time lab test results, as do the labs participating in the various proficiency testing exercises. In addition, it serves as a repository for contact and capability information for each of the member labs. FERN methods are posted on the eLEXNET. FERN uses the eLEXNET to collaborate and share real-time lab test results, resulting in quicker recognition and therefore more rapid response to an outbreak. To respond to any food-related event, surveillance and swift detection is essential. eLEXNET replaces a slower system with an electronic disease and data reporting system.

The eLEXNET is tested through repetitive use and is monitored by personnel assigned the responsibility for eLEXNET oversight. As mentioned above, the system is used on a continual and recurring basis for maintaining and updating contact information, as well as for data input from work relating to cooperative agreements, proficiency testing exercises, and surveillance assignments.

Ms. DeLauro: What is the initial cost per lab, and what are the recurring costs?

Response: The costs per laboratory can vary widely depending on the equipment required, the reagents required, the training necessary, and other factors. FSIS estimates that the average cost to build the capacity to make a laboratory operational in FERN is between $500,000 and $600,000.

Recurring costs are estimated to be small when compared to the cost of building the initial capability, but will of course, depend on the level of ongoing surveillance testing that is deemed necessary at different threat levels, as well as the costs of the various projects carried out by the laboratories for FERN, such as method validations, kit evaluations, and the development and implementation of triage/risk assessment protocols. Recurring costs would include items such as the costs of laboratory reagents, supplies consumed as part of ongoing surveillance testing, and costs associated with continuing to assess proficiency.

Future capacity building costs could be either for (1) adding additional laboratories to the operational network, or (2) adding additional threat agent capability in the initial laboratories.

Ms. DeLauro: Please break down in detail how you spent funding for FERN in 2008 and what you plan for 2009.

Response: For FY 2008, FSIS spent $9.6 million in direct funding to 25 labs (to manage, maintain, and expand their capacity and capabilities including triage/risk assessment development and the development of four training centers); $1 million for proficiency test contracts (to provide proficiency samples and validation samples for (CAP) studies); and $700,000 for readiness-response exercises with National Guard Civil Support Teams in conjunction with local emergency management agencies and FERN.

We will continue to fund FERN at the $11.35 million level in FY 2009. This money will go to support the four training centers, provide for a national training workshop for the Network, provide for

proficiency test contracts (to provide proficiency samples and validation samples for (CAP) studies), continue readiness-response exercises with National Guard Civil Support Teams in conjunction with local emergency management agencies and FERN, support FERN's interactivity with the Foodshield Web site, support the critical reagent program's supply stream of reagents, kits, etc. for the FERN labs, and strengthen the cooperative agreement program with the States through continued support of the existing CAP labs (and the possible addition of other State laboratories to the program).

CODEX

Ms. DeLauro: Please provide a very brief summary of the major Codex Alimentarius actions related to food safety activities that occurred in 2008 and that you expect in 2009.

Response: The Codex Alimentarius Commission last met (in its 31th session) in Geneva in July 2008 and approved 41 new or revised standards or related texts, which had been developed by the 22 executive, commodity, general subject, and regional Codex committees and task forces that met prior to the Commission session. Among the main accomplishments at the 31th session are:

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals.
- Annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food.
- Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.
- Guideline for Validation of Food Safety Control Measures.
- Implementing Appendix to the Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.
- Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios for "further processing" and for "ready-to-eat."
- Model Export Certificate for Milk and Milk Products.
- Definition for "advertising" applicable to the Guidelines for Use of Nutrition and Health Claims.
- Food additive provisions of the General Standard for Food Additives.
- Code of Practice for the Reduction of 3-MCPD During the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products containing Acid-HVPs.
- Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods.

The Commission also approved recommendations for 24 items of new work to be undertaken by Codex committees. These items include:

- Three new work proposals on antimicrobial resistance dealing with risk profiling, risk assessment and risk management to be carried out by the recently established Task Force on Antimicrobial Resistance.

- Development of commodity-specific annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables.
- Development of Principles and Guidelines for Foreign Audits. Development of a Generic Model Health Export Certificate
- Revision to the Guidelines on Nutrition Labeling as part of the World Health Organization Global Strategy on Diet, Physical Activity and Health.
- Guidelines and Principles for Substances used as Processing Aids.

Finally, the Commission revoked six existing standards and related texts; it dissolved the Task Force on "Foods Derived from Biotechnology and the Task Force on the Processing and Handling of Quick Frozen Foods; and it adjourned *sine die* the Committee on Natural Mineral Waters.

In 2009, the United States expects that the Commission will:

- Address the question of the relationship between Codex (inter-governmental) international standards and food standards established by private entities.
- Decide on whether to initiate new work on animal feeding.
- Resolve the issue of whether to incorporate the Lactoperoxidase system into the Code of Hygienic Practice for Milk and Milk Products.

Ms. DeLauro: What is the total budget for Codex Alimentarius activities, by agency, for USDA in FY 2007 and 2008, and estimated for FY 2009?

Response: Within USDA, FSIS, the Foreign Agricultural Service, the Agricultural Marketing Service, and the Grain Inspection, Packers, and Stockyards Administration participate in Codex Alimentarius activities. The following table identifies actual and budgeted funding by FSIS and approximate funding by other agencies:

[The information follows:]

USDA Funding for Codex Alimentarius
(Dollars in Thousands)

	2006 Actual	2007 Actual	2008 Actual	2009 Estimate
FSIS	3,599	3,668	3,735	3,827
FAS	550	833	950	1,000
AMS	249	243	322	284
GIPSA	52	53	55	50
Total, USDA	4,450	4,797	5,062	5,161

Ms. DeLauro: Are any USDA funds used to support the Codex activities of US government agencies other than those in USDA? If so, how much and does USDA seek reimbursement from those agencies for those costs? If not, why not?

Response: The U.S. Codex Office and the U.S. Manager for Codex are located in USDA. The Under Secretary for Food Safety, as the highest ranking food safety official in the United States, chairs the U.S. Codex Policy Committee. With FSIS being the lead Federal agency responsible for Codex activities, FSIS funds cover many indirect or overhead costs associated with the training of all delegates to Codex Committees, including non-USDA employees. These delegates are employees of USDA, the Department of Health and Human Services, the Environmental Protection Agency and the National Marine Fisheries Service. The Foreign Agricultural Service has also supported Working Group and/or Drafting Group meetings of Codex Committees.

USDA does not seek reimbursement for these costs. Either many of the costs are marginal, and would require a greater expense to recoup the indirect costs, or the costs are not specifically related to the mission of a single agency or Department, and reimbursement for services could therefore be difficult to attain. Delegate training is a core function of the Codex mission and something that we consider a valid investment in the success of Codex policy-making around the globe.

INSPECTORS

Ms. DeLauro: What has been the average attrition for FSIS inspectors each year over the past 5 years? What is USDA doing to ensure that there is a qualified inspection workforce for the future?

Response: The retention rate of in-plant inspection program personnel as of September 30, 2008, was 93.4 percent. FSIS has maintained strong retention rates of over 90 percent per year during the past decade. Attrition rates are monitored so that trends can be incorporated into recruitment plans.

FSIS is using a number of creative mechanisms to ensure that the Agency is able to hire and retain a quality inspection workforce for the future. Some of these tools include:

- Targeting more colleges for potential qualified employees.
- Offering relocation incentives to new hires in hard-to-fill or shortage locations.
- Offering college loan repayment incentives to employees in specified locations.
- Offering recruitment bonuses to qualified personnel.
- Using Superior Qualifications to set the rate of basic pay above the minimum level.
- Offering performance awards for front-line inspectors.
- Offering a retention incentive for select employees who would be likely to leave Federal service in lieu of the incentive.
- Offering dual waiver compensation for reemployed annuitants.

Ms. DeLauro: How many inspector positions were vacant, by district, on September 30, 2007 and September 30, 2008?

Response: The information is attached for the record.

[The information follows:]

IN-PLANT VACANCY DATA	
September 30, 2007	
DISTRICT	VACANCIES
Alameda	53
Denver	88
Minneapolis	31
Des Moines	75
Lawrence	45
Springdale	80
Dallas	82
Madison	18
Chicago	38
Philadelphia	41
Albany	58
Beltsville	44
Raleigh	74
Atlanta	76
Jackson	58
TOTAL	861

IN-PLANT VACANCY DATA	
September 30, 2008	
DISTRICT	VACANCIES
Alameda	34
Denver	41
Minneapolis	20
Des Moines	81
Lawrence	33
Springdale	46
Dallas	68
Madison	14
Chicago	47
Philadelphia	17
Albany	50
Beltsville	30
Raleigh	48
Atlanta	70
Jackson	24
TOTAL	623

Ms. DeLauro: Does FSIS have a system for keeping track of when inspectors do not make required daily inspections at processing plants? If not, why not? If so, please indicate how many inspections have not been made on average each year.

Response: Yes, the PBIS database enables inspection personnel to enter one of three reason codes for scheduled PBIS procedures that were not performed on a given day. The PBIS reason code change will indicate when personnel did not perform inspections and the reason, such as 1) the plant was not operating, 2) there were no animals to slaughter or product produced, or 3) other. To provide for more effective analysis, FSIS is currently programming a new PBIS reporting feature that will capture, using the three procedure-not-performed codes, plant specific results that will enable us to more accurately respond to this question. This re-programming is targeted for completion by January 31, 2009. Using current data capabilities, FSIS does not have any information that indicates required daily inspections are not occurring. Upwards of 10 percent of the approximately 4,000 processing plants nationwide conduct seasonal or infrequent (e.g., 1-2 days per week) operations. FSIS also tracks work accomplishments through the Agency's management control system, called AssuranceNet. Currently, FSIS has more full-time in-plant personnel (food inspectors, consumer safety inspectors, and public health veterinarians) than at any time since 2001. The number of regulated establishments has decreased approximately six percent since 2001, although the volume of federally-inspected and passed meat and poultry product slaughtered increased by 16.65 percent between FY 2001 (94,125,000,000 pounds) and FY 2008 (109,797,000,000 pounds).

Ms. DeLauro: Please provide the Committee with a status report on the implementation of the AssuranceNet management control system and results of the analysis of its data that you indicated in last year's question you would provide to the Committee, for publication in this year's hearing volume.

Response: Last summer, adjustments were made to the AssuranceNet tool that factored in the "not performed" codes, making the AssuranceNet reporting on percent scheduled procedures performed by inspection personnel even more accurate. The system provides indicators where there may be an excessive number of scheduled procedures not performed. As the supervisor or District Analyst identifies outliers using the AssuranceNet system, they are then expected to use PBIS to drill down into detailed inspection data to pinpoint specifically where one or more inspection assignments may be underperforming scheduled work.

FSIS is further improving its ability to make these determinations by reprogramming reporting in PBIS to enable reporting on "not performed" codes in more detail and in a manner that will match the way this data is factored into AssuranceNet results. This re-programming is targeted for completion by January 31, 2009.

FSIS put in place specific instructions for monitoring and reacting to AssuranceNet data on a monthly basis. The instructions were published in March 2008 in FSIS Notice 19-08, "AssuranceNet Data Monitoring Responsibilities and Instructions for Office of Field Operations Managers." This Notice clarifies that AssuranceNet reports

and analyses are appropriate for monitoring organizational performance at the district and circuit level. The Notice states that the establishment level data in AssuranceNet can be utilized to determine if there are outliers that would warrant additional investigation, such as by drilling down into the details using PBIS and other tools.

As the table below illustrates, overall, there has been a steady decrease in the percentage of scheduled inspection procedures not performed. This trend is evident even when counting procedures that were not performed because the plant was not operating and/or the process to be verified was not available to be verified. Defining and using Reason Codes 01 ("Not Operating") and 02 ("No Processing/Slaughter") allowed for more accurate depiction of how often procedures are not being performed for these reasons, versus other reasons and enabled supervisors using AssuranceNet and PBIS to better pinpoint the assignments on which underperformance was an issue.

Percent Scheduled Not Performed by Calendar Years 2005-2008*

Activity/Procedure	2005	2006	2007	2008*
Activity 01 Sanitation Standard Operating Procedures				
Including 1 and 2**	28%	25%	25%	23%
Excluding 1 and 2**	N/A***	24%	15%	12%
Activity 03 Hazard Analysis and Critical Control Point				
Including 1 and 2**	36%	32%	32%	30%
Excluding 1 and 2**	N/A***	31%	15%	13%
Procedure 06D01/06D02 Sanitation Performance Standards				
Including 1 and 2**	24%	20%	20%	18%
Excluding 1 and 2**	N/A***	19%	9%	7%

*Through September 30, 2008.
**Reason Code 1 is "Not Operating". Reason Code 2 is "No Processing/Slaughter".
***Not/Applicable because codes 1 and 2 introduced in 2006.

Ms. DeLauro: How many meat and poultry inspectors are funded in the fiscal year 2009 request? How many were employed in FY 2007 and 2008? Is this a sufficient number of inspectors to meet food safety goals and the needs of the industry?

Response: The FY 2009 President's budget seeks to fund approximately 7,700 in-plant full-time meat, poultry, and processed egg product inspection program personnel, and approximately 310 staff year equivalents for other than permanent inspection personnel within FSIS' Office of Field Operations (OFO). The Agency believes this would be sufficient to meet the needs of the industry. As of September 30, 2007, FSIS had approximately 7,500 full-time employees assigned to in-plant meat, poultry and processed egg products inspection within OFO. Additionally, OFO used nearly 300 staff year equivalents of other than

permanent personnel in performing in-plant inspection. As of September 30, 2008, FSIS had approximately 7,600 full-time employees assigned to in-plant meat, poultry and processed egg products inspection within OFO. Additionally, OFO used nearly 300 staff year equivalents of other than permanent personnel in performing in-plant inspection.

FSIS inspection program personnel continue to provide inspection services for all establishments under its jurisdiction by employing alternative staffing strategies and fully utilizing available field inspection employees to address the demands of each particular area.

Ms. DeLauro: In which regions are there vacancies that are difficult to fill, or in which firms have had to cut back on operating hours due to lack of in-plant inspections? How is FSIS addressing this problem?

Response: There are numerous locations throughout our Districts where it has been historically difficult to fill Public Health Veterinarian (PHVs) and food inspectors, such as positions in remote rural areas or high cost-of-living locations. More recently, the Agency has experienced difficulty filling Consumer Safety Inspector positions in the Albany District. In order to attract the necessary talent, FSIS offers recruitment incentives, such as recruitment bonuses, pay for travel to first post of duty, and agreements with veterinary schools to recruit more employees and better prepare veterinarians for a career with FSIS.

FSIS inspection program personnel continue to provide inspection services for all establishments under its jurisdiction by employing alternative staffing strategies and fully utilizing available field inspection employees to address the demands of each particular area. Some Districts have had to make extensive use of relief inspectors and intermittent inspectors. The Agency is not aware of any establishments having to reduce operating hours due to shortage of inspection resources.

Ms. DeLauro: What percentage of your workforce is eligible to retire? Please describe your succession planning efforts.

Response: There are a total of 4,386 employees eligible to retire within one year, which constitutes 43.3 percent of the FSIS workforce.

FSIS has provided detailed input to USDA in preparation for USDA's five-year succession plan.

The overarching Agency goal is continued reduction of foodborne hazards and diseases from meat, poultry, and processed egg products. Effective Agency leadership is one of several prerequisites for achievement of this goal.

The Agency leadership strategic vision requires that leaders in critical occupations and in the chief managerial/executive occupation continue to increase their mastery of leadership competencies. FSIS leaders need to demonstrate a science-based mastery of the work directed, including an understanding of risk-based inspection and

public health strategies. They also need to increase their mastery of soft skills for motivating and managing employee performance. Finally, they need to increase mastery of technology and financial management competencies to keep up with government trends (electronic government, pay-for-performance systems, and results-oriented mission management).

The Agency's strategic vision requires leaders in mission support occupations to increase their mastery of leadership competencies. They must lead the way in developing and fielding tools for effective management of human capital technology, financial resources, employee and organizational performance, and organizational change.

FSIS has established a competency-based management and leadership training program to provide high quality training for the Agency's current supervisors, managers, and leaders, and to help fill critical vacancies at all levels in the future. Research shows that one of the top reasons why high performing employees leave an organization is that they are unhappy with their supervisor. Therefore, developing supervisory and management skills helps to ensure organizational effectiveness and to retain talented employees. The program is designed to provide supervision, management, and leadership training to employees from the pre-supervisory level through the senior executive level to prepare a cadre of employees to fill critical leadership positions. In FY 2008, FSIS conducted the following training and development activities to ensure FSIS has well-trained and competent individuals prepared to advance in the supervisory ranks. These steps were also taken to align Agency Succession Planning with the requirements of the President's Management Agenda:

- The Basic Supervisor Training course is for Supervisory Public Health Veterinarians, Supervisory Consumer Safety Inspectors and/or Frontline Supervisors with little or no supervisory experience or training. During FY 2008, 106 employees were trained.
- The Advanced Frontline Supervisor training is for GS-13 field supervisors and their State counterparts. During FY 2008, 42 participants completed the training.
- The Leadership Assessment and Development Program targets managers at the GS13-15 level who have at least two years of experience with supervision or oversight responsibility. During FY 2008, 20 participants completed the course.
- The New Supervisor Program is targeted to develop all new supervisors in the Agency who do not work in at the field level. During FY 2008, 102 new supervisors were trained.
- The Leadership Potential Program (LPP) is for GS 9-13 employees who show leadership potential. The LPP serves as the foundation to the Agency management and leadership training program. This competitive program requires supervisory endorsement. During FY 2008, 27 participants completed the program.
- During FY 08, FSIS initiated a pilot program to explore methods to capture knowledge by working with experienced employees and developing methods to transfer that knowledge to other employees or groups. Some of the methods included developing standard operating procedures, identifying key contacts, and outlining case studies.

Ms. DeLauro: Please describe in detail any challenges you have in recruiting front-line employees and initiatives you are using to overcome those challenges. What incentives do you use? If incentives are used, what were the amounts spent in the last three years? What is the success rate of these incentives?

Response: There are numerous locations throughout our Districts where it has been historically difficult to fill Public Health Veterinarians' (PHVs) and food inspectors' positions, such as positions in remote rural areas or high cost-of-living locations. More recently, the Agency has experienced difficulty filling Consumer Safety Inspector positions in the Albany District.

Hiring Flexibilities and Authorities

FSIS has aggressively used recruitment and retention flexibilities to attract qualified personnel into hard-to-fill positions. Much of our success has been built upon our effective use of:

- Payment of up to 25 percent Basic Pay, used as a one time payment. However, an annual payment for up to 4 years (shortage locations) has recently been approved and is being implemented.
- Payment of Travel and Transportation to First Duty Station (PHVs) and Food Inspectors in shortage locations).
- Superior Qualifications Appointments (setting salary at a rate higher than step 1).
- Student Loan Repayment (shortage locations).
- Direct-Hire Authority has been requested to hire PHVs and Food Inspectors, which would permit more immediate appointment of applicants to shortage locations.
- The Career Intern Program has been used extensively, especially for mission critical occupations, and boasts a 95 percent conversion rate for career interns into the competitive service.
- Crediting non-Federal and uniformed service towards the calculation of new hires' annual leave accrual rate (also known as Creditable Service for Annual Leave Accrual).
- Waivers of retirement annuity reductions for retirees returning to Federal service in PHV and Food Inspector positions has been recently approved and is available for use.

As the incentives that the Agency is utilizing have increased over the course of the last several years, it is difficult to quantify and compare the success rate of these incentives from year to year. Given the ongoing utilization, we nonetheless believe that the incentives are successful, particularly in hard-to-fill locations.

[The information follows:]

Recruitment Bonus/Cash Incentive Data by District
(does not include student loan repayment)

DISTRICT	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Headquarters	588	0	0	0	0
Alameda	117,034	107,301	57,863	118,171	134,610
Denver	101,394	11,310	12,993	24,127	260,263

Recruitment Bonus/Cash Incentive Data by District (does not include student loan repayment)					
DISTRICT	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Minneapolis	0	0	0	115,709	64,496
Springdale	114,089	67,860	106,325	168,193	189,293
Lawrence	221,642	210,027	119,211	208,156	250,215
Dallas	12,982	5,000	204,408	259,451	127,420
Chicago	5,000	0	10,174	148,339	53,554
Des Moines	190,118	28,701	77,998	130,549	170,813
Madison	191,633	116,849	94,399	14,432	107,243
Atlanta	147,203	68,217	103,529	183,233	24,656
Jackson	93,907	150,942	123,158	270,735	180,773
Raleigh	103,527	106,637	124,360	167,458	148,496
Albany	36,615	55,999	0	34,785	53,773
Philadelphia	55,157	68,917	72,101	204,398	100,988
Beltsville	0	27,124	23,732	57,911	34,751
TOTAL	1,390,888	1,024,882	1,130,249	2,105,647	1,901,344

Ms. DeLauro: What is the average FSIS tenure, in number of years, of inspection personnel?

Response: As of September 2008, FSIS calculates the average length of service for in-plant inspection program personnel to be 13.9 years. The calculation includes all permanent full-time Food Inspector, Consumer Safety Inspector, and PHV employees below grade 13 in field locations and averages their length of service to the Federal Government.

Ms. DeLauro: Please define the term "front-line" employees. Does that include "in-plant" employees?

Response: The term "front-line" employees refers to employees that are essential to the day-to-day operation of food safety inspection, compliance and laboratory work, as well as associated suspension. This group consists of "in-plant" inspection personnel and front-line supervisors, as well as other employees who do not work at specific plants but work in the field and not in Federal offices. Thus, the term "front-line" employee includes, but is not limited to, "in-plant" employees. Front-line employees include: Food Inspectors, Consumer Safety Inspectors, Public Health Veterinarians, Enforcement Investigations and Analysis Officers, Import Inspectors, Import Surveillance Liaison Officers, and Compliance and Investigations Division employees.

Ms. DeLauro: How many in-plant food inspectors are there? Please provide a description and breakout of inspectors by on-line and off-line.

Response: In FY 2008 there are approximately 7,365 in-plant food inspectors, of which 4,034 are on-line and 3,331 are off-line (as of September 2008). In-plant employees make up the overwhelming majority of the field inspection force and are the only ones designated as "on-line" or "off line." Other "front-line" inspection employees are not identified by these terms.

Ms. DeLauro: How much time does an inspector spend at processing plants, including travel time? Has the average amount of time spent at a plant increased or decreased over time? Explain the increase or decrease.

Response: On average, inspection program personnel spend approximately 2 hours and 35 minutes verifying food safety requirements and traveling between plants on a typical processing assignment within a standard eight hour shift. However, the time can vary according to the specific conditions at an establishment. For example, inspection program personnel may spend additional time at establishments depending on the complexity of the operations; if an establishment has ongoing public health concerns; or when additional activities are required.

This marks a decrease since last year, when inspection program personnel spent 3 hours and 20 minutes verifying food safety requirements and traveling between plans on a typical processing assignment within a standard eight hour shift. This decrease is a result of a review of inspection assignment efficiencies conducted by FSIS in April 2008, which evaluated the distances traveled by FSIS inspection program personnel and shifted assignments to minimize those distances. The average amount of time spent in each plant did not decrease.

Ms. DeLauro: How many computers have been delivered to field staff to date? What is the plan to deliver the remainder or to replace older models?

Response: The information is submitted for the record.

[The information follows:]

Phase I - original deployment 1996-2001	4,241
Phase II - replacement cycles	
FY 2001	1,149
FY 2002	0*
FY 2003	1,607
FY 2004	917
FY 2005	1,031
FY 2006	495
FY 2007	665
FY 2008	2,500

*Deferred to 2003 for new software load

For FY 2009, 5,000 computers are expected to be delivered to FSIS headquarters, field, and State employees.

Ms. DeLauro: What is the current status of inspector communication?

Response: For FY 2008, this effort was no longer separately funded. Instead, this effort was consolidated into the PHDCIS business case.

On December 31, 2007, under the Agency's HATS/Broadband project, FSIS completed installation of over 2,300 broadband connections (including component hardware and software) to all fixed plant and patrol inspection assignments. Now, most FSIS inspection program personnel are linked to a near real-time data communications infrastructure. This improved access is vital for the Agency personnel who are collecting the data out in the field, and allows them to spend more of their time on inspection activities.

The HATS/Broadband project is currently in the operations and maintenance phase, which involves disconnecting any plants that no longer operate, and providing broadband connections to newly-operating establishments and new inspection assignments.

Ms. DeLauro: Do any inspectors currently use PDAs? If so, how many and what percentage of the total workforce?

Response: The FSIS Office of Field Operations has approximately 450 Blackberry PDAs in operation. These are typically assigned to supervisory or technical personnel. No PDAs are assigned to consumer safety inspectors or food inspectors.

INSPECTOR TRAINING

Ms. DeLauro: Please update the table in last year's hearing record that details the Agency's training budget and programs to include 2008 actual and 2009 proposed.

Response: The information is provided for the record.

[The information follows.]

Training program and intended audience	FY 2004 $13.5 Million (includes $5.7 million increase)	FY 2005 $20.6 Million (includes $7.2 million increase)	FY 2006 $20.6 Million	FY 2007 $20.6 Million	FY 2008 $20.6 Million	Projected FY 2009 $20.6 Million
Training - Food Safety Regulatory Essentials - customized 2-4 week class Intended audience - Consumer Safety Inspectors (CSIs), Public Health Veterinarians (PHVs), Import Inspectors	1,300 trained (actual)	1,400 trained (FSIS continued training CSIs; and began training supervisors (PHVs) and Import Inspectors)	1,500 trained	1,402 trained (FSIS began training GS-7s for online-offline duties)	1,197 trained	1,300 projected
Entering Food Inspector (FI) training - 1 week class Intended audience - Food Inspectors (poultry and livestock slaughter inspectors)	90 trained	997 trained (includes 100% of all entering FIs, plus reaching backlog from 3 previous years)	540 trained	520 trained	690 trained	550 projected
Entering Public Health Veterinarians - 9 week class Intended audience - PHVs	60 trained	171 trained (includes 100 percent of all entering PHVs trained, plus reaching backlog from 4 previous years)	179 trained	127 trained	80 trained	100 projected

Training program and intended audience	FY 2004 $13.5 Million (includes $5.7 million increase)	FY 2005 $20.6 Million (includes $7.2 million increase)	FY 2006 $20.6 Million	FY 2007 $20.6 Million	FY 2008 $20.6 Million	Projected FY 2009 $20.6 Million
Entering Enforcement Investigations and Analysis Officers (EIAOs) - 3 week class Intended audience - EIAOs and PHVs	200 trained	158 trained	120 trained	79 trained	450 trained (includes 91 trained at entry level; 62 supervisors trained on EIAO methods; and 297 received advanced methods training)	300 projected
Program Investigator - 2 week class Intended audience - Program Investigators	150 trained	358 trained	48 trained	218 trained	37 trained	50 projected
Front-Line Supervisor - 2 week class Intended audience - Front-Line Supervisors and Inspectors In Charge (in plant supervisors)	150 trained	77 trained (includes 100% of all Front- Line Supervisors, and began providing training to supervisors at the in plant level)	123 trained (includes 37 Front Line Supervisors and 86 in plant supervisors)	172 trained (includes 40 Front Line Supervisors and 132 in plant supervisors)	148 trained (includes 42 Front Line Supervisors and 106 in plant supervisors)	150 projected

Training program and intended audience	FY 2004 $13.5 Million (includes $5.7 million increase)	FY 2005 $20.6 Million (includes $7.2 million increase)	FY 2006 $20.6 Million	FY 2007 $20.6 Million	FY 2008 $20.6 Million	Projected FY 2009 $20.6 Million
Emerging policies - various Intended audience - to be determined based on the policies	3,500 trained CSIs, Public Health Veterinarians, EIAOs, Program Investigators, industry, academia	6,000 trained in homeland security policies and procedures includes CSIs, PHVs, EIAOs, Program Investigators, industry, academia	3,000 trained	6,900 trained in food safety, sampling, and processing	4,787 trained in sampling, food safety, and food defense	5,000 projected

Ms. DeLauro: How many entry-level inspection and enforcement personnel are hired each year? What percentage receives essential training within one year? Within six months? Please provide the numbers for each answer. Is training provided before they are given assignments?

Response: Each year, FSIS hires, on average, approximately 300 entry-level food inspectors and approximately 75 Public Health Veterinarians. In addition, approximately 250 employees transition into the Consumer Safety Inspector occupation, either through promotion or reassignment. FSIS employs 108 compliance investigators and 10 misconduct investigators, as well as about 40 enforcement specialists and supervisors. Further, FSIS hires approximately 12 entry-level investigators each year; the other positions are filled through promotion or reassignment. Due to the changes and improvements that have resulted from the increased funding that FSIS has received for Consumer Safety Inspector training, 100 percent of the employees hired as entry-level employees, as well as those who are promoted into inspection and enforcement occupations, now receive mission-critical training within one year of entering on duty. A substantial majority of employees receive the training within the first six months of being hired. In fact, an FSIS study matching Agency training data with human resource data showed that the average amount of time from the effective date of a personnel action (i.e., a hiring or a promotion) until the start date of an employee's training is 62 days.

Both inspection and enforcement employees receive some of their required training before they are sent to their assignments, and they complete their required training after they report to their duty stations. The required training employees receive before they report to their duty stations includes New Employee Orientation, where they learn about the public health regulatory mission of the Agency, and the important role they play to ensure food safety. They also learn about the Acts (Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act), Regulations, and Directives that guide their work. If they use a computer in their work, they are given computer skills training, which includes training on the software they use (i.e., Microsoft Word), as well as Agency-specific computer applications. Employees also receive an in-plant orientation and informal on-the-job mentoring. Once this training is completed, employees are sent to the appropriate classroom training to learn specific job duty skills. Further, the rigorous FSIS program trains its investigators in surveillance, investigation, and enforcement methods, as well as the FSIS statutes and authority, case evidence procedures, report writing, criminal, civil, and administrative enforcement, outbreak investigations, interview techniques, and investigator safety.

Ms. DeLauro: How are you measuring the effectiveness of the training? What conclusions have you reached about its effectiveness to date?

Response: FSIS uses the methods for measuring the effectiveness of training recommended in the GAO report, "*A Guide for Assessing Strategic Training and Development Efforts in the Federal Government*" (GAO-04-546G). These methods are also the industry standard recommended by Goldstein in "*Training in Organizations: Needs*

Assessment, Development, and Evaluation." These methods are used to assess the effectiveness of all FSIS training programs. Training participants complete a post-course evaluation, which indicates how satisfied they are with the learning atmosphere and the confidence they have in performing their duties based on what they have learned in the class. Participants also complete a pre-test and a post-test covering job knowledge. A comparison between the scores on the pre-test and the post-test showed that the knowledge improvement that was gained as a result of attending Food Safety Regulatory Essentials training averaged 15 percent. This improvement was statistically significant.

Also, periodically, a third party conducts post-course evaluations once employees have returned to the job. For example, with regard to the Food Safety Regulatory Essentials training, a formal survey was conducted to find out whether the training was making a difference on the job. The survey took place four months after participants completed the training. The results indicated that over 90 percent of the participants felt that the training was extremely helpful in teaching them how to perform their food safety verification activities consistently and accurately. Over 90 percent reported that their supervisors had noted an improvement in the quality of their work. The supervisors of these employees were also surveyed after they returned to the job. Nearly all (91 percent) supervisors stated they observed improvement in the trainees' work. This type of information is gathered for all FSIS training programs on a regular basis. FSIS also subjects all of its courses to the rigorous standards required by the International Association of Continuing Education and Training (http://www.iacet.org/standards/intro_CG.htm) and is an authorized provider of continuing education. FSIS is planning to conduct evaluations of how well employees apply the training when they return to their job by gathering information from the employee and their supervisor.

Ms. DeLauro: What role will distance learning play in the training? How effective is it for initial scientific training versus update courses? Please describe your progress in implementing web-based training. Do all of the regional training center programs provide the same content?

Response: FSIS relies on distance learning training for intermediate and advanced training. It is also used to provide New Employee training and computer skills training for entering employees. It is not used for initial scientific training. The initial scientific training is done in a classroom setting due to the complex and comprehensive nature of its content.

Distance learning training enables FSIS to rapidly train existing personnel in updated policies and procedures issued to address emerging issues. For example, in FY 2008, FSIS provided updated training through distance learning to its field workforce on new policies and procedures related to food safety microbiological sampling, slaughter inspection, import inspection, and food defense. The training was provided to over 5,287 employees performing the inspection duties related to these policies. FSIS also used net meetings to provide educational seminars to employees on specified risk material removal, *E. coli* O157:H7, and statistical process control.

FSIS continues to expand its utilization of AgLearn, the USDA's Web-based learning management system. FSIS participated as an early adopter of AgLearn. FSIS is working with two training contractors to assist in developing Agency-specific e-learning courses. These courses enable employees to receive training on FSIS computer applications such as the Performance Based Inspection System (PBIS), the In Plant Performance System (IPPS), and FSIS policies using the computer, saving the costs of travel to training.

All regional trainers are providing the same content when they conduct Agency training classes. The content is consistent with Agency policies. This consistency is needed to ensure that inspection program personnel perform job duties accurately. Regional trainers receive training to ensure that they are teaching content that is consistent with Agency policies. Regular meetings are conducted to update regional trainers when program changes are implemented. The content of the regional courses is posted on the FSIS Web site for public review at:
http://www.fsis.usda.gov/FSIS_Employees/Regional_Training/index.asp.

Ms. DeLauro: How many AgLearn training courses did FSIS employees complete in fiscal years 2007 and 2008? How does that compare to 2006?

Response: FSIS is increasingly using AgLearn to provide intermediate and advanced training to on-board employees. It also uses AgLearn to provide computer skills training for entering employees.

In FY 2007, employees completed 6,900 FSIS-developed AgLearn courses covering food safety, the IPPS, microbiological sampling, and other consumer protection. In FY 2008, employees completed nearly 5,000 FSIS-developed AgLearn courses covering microbiological sampling, slaughter inspection, food defense, and import inspection. This compares with FY 2006, when employees completed 3,000 FSIS-developed AgLearn courses covering IPPS, microbiological sampling, and export certification.

Training through AgLearn has been extremely successful at ensuring that when FSIS issues new policies, employees receive training on the policies so that they can keep pace with Agency advances. FSIS expects to increase the number of courses and the amount of training done through AgLearn. FSIS also relies on the use of AgLearn to provide federally-mandated training, such as civil rights training, IT security training, and No Fear Act training.

However, AgLearn cannot substitute for the entry-level training that is done through the classroom. Due to the complexity and scope of the content that must be covered with entry-level employees, it is essential to provide them with classroom training to ensure that they will be able to perform their food safety and food defense duties effectively.

Ms. DeLauro: What is the fiscal year 2008 base for training and the proposed funding for 2009? Will the proposed FY 2009 funding level enable FSIS to train all newly hired inspection personnel and keep

field inspection personnel up to date in HACCP, pathogen reduction and food safety sampling?

Response: The FY 2008 base for training is $20.6 million, and FSIS expects to maintain that level of funding for FY 2009. This base funding enables FSIS to train all newly-hired inspection program personnel and to keep the existing field inspection program personnel up to date through the Food Safety Regulatory Essentials training in HACCP, pathogen reduction, and food safety sampling. The funding provides training containing updated scientific and public health principles to the inspection workforce through regional training. The occupational groups receiving this training include Food Inspectors, Consumer Safety Inspectors, PHVs, Program Investigators, Import Inspectors, and Enforcement Investigations and Analysis Officers. The base funding also enables FSIS to train inspection program personnel through regional training when they are hired or promoted and provide existing inspection program personnel with training on emerging issues so that their skills are current with program changes.

Through this base funding, FSIS also provides training to its field supervisors so that they have the regulatory, scientific, and technical knowledge to ensure that public health and food defense programs and policies are implemented appropriately by inspection program personnel. The base funding further enables FSIS to provide training to support a management and leadership training program for the Agency's public health leaders and managers that is consistent with the principles of the President's Management Agenda, which includes succession planning.

Ms. DeLauro: Please update the information provided last year on the percentage of all on-board front-line employees to be trained by the end of FY 2008.

Response: The information is submitted for the record.

[The information follows:]

On-board Front-line Employees Trained

Position - Number of employees	Number Trained in FY 2004	Number Trained in FY 2005	Number Trained in FY 2006	Number Trained in FY 2007	Number Trained in FY 2008
Food Inspector - 2,700	90	997	540	520	553
Consumer Safety Inspector (CSI)* - 6,697	1,300	1,400	1,500	1,300	1,197
Public Health Veterinarian (PHV) -- 640	60	171	179	150	80
Enforcement Investigations and Analysis Officer (EIAO)** - 669 (includes 237 EIAOs and all PHVs)	200	158	120	100	91

* All incoming CSIs receive FSRE training for raw products. However, as CSIs are promoted, they receive additional FSRE training appropriate to the type of product covered in their assignments. In FY 2007, FSIS began offering FSRE training to GS-7s who perform offline HACCP duties. This increased the number of employees to be trained.
** Course offered prior to 2004

SMALL AND VERY SMALL PLANTS

Ms. DeLauro: Please provide the budget for the Small and Very Small Plant Outreach program for five years, including FY 2008, as well as FY 2009 estimated. Within these totals, please break out the amount spent on HACCP outreach.

Response: In FY 2005, FY 2006, and FY 2007, FSIS spent approximately $650,000 each year on HACCP outreach to small and very small plants. In FY 2008, FSIS spent approximately $1 million on HACCP outreach for the small and very small plants. In FY 2009, FSIS plans to spend $2 million on HACCP outreach for small and very small plants. This will include providing "how to" workshops, printing and distributing guidance for small and very small operators, developing and distributing instructional workbooks and videos, conducting educational net meetings, and developing training materials that can be used by small and very small plants.

Ms. DeLauro: Please update the Committee on any new initiatives relating to small and very small plants.

Response: On March 7, 2008, FSIS announced a new program office dedicated to supporting the Agency's continued efforts in outreach to small and very small plants and education of FSIS personnel. The Office of Outreach, Employee Education and Training (OOEET) will provide consolidated access, resources and technical support for small and very small plants to better assist them in providing safe and wholesome meat, poultry and processed egg products. The establishment of OOEET enhances the Agency's ongoing effort to assist small and very small plants with implementing food safety and public health regulations.

In FY 2008, FSIS conducted the following activities to educate small and very small plants to help them improve their food safety systems:

- Sent EIAO's to conduct over 100 proactive visits at small and very small plants to explain to them how they can prepare for a food safety assessment and to offer them resources to help improve their food safety system.
- Conducted 22 face-to-face Regulatory Education Sessions in 20 states with over 375 participants reviewing *E. coli* O157:H7 policies and draft Compliance Guidance.
- Conducted 12 educational net seminars for 196 small and very small plant participants. The topics of these seminars included FSIS policies related to the removal of SRMs in beef slaughter and processing operations, Statistical Process Control (SPC),

control of *E. coli* O157:H7 in beef products, new food safety technologies, and generic labeling. These meetings were recorded and placed on the FSIS Web site at: http://www.fsis.usda.gov/news_&_events/Reg_Education_Videos/index.asp.

- Launched a monthly publication mailed to small and very small plant operators, "*Small Plant News*."
- Provided resource materials including printed materials as well as videos.
- Maintained an extensive web page with resources designed to meet the needs of small and very small plants.
- Issued flood guidance to small and very small plants to help them prepare for and react to floods. The guidance was posted on the FSIS Web site and mailed to operators.
- Collaborated with primary investigators from the University of Connecticut and Pennsylvania State University on a study of small and very small plant training needs funded by the Cooperative State Research, Education and Extension Service.
- Developed a workbook and updated a video in collaboration with humane handling expert, Dr. Temple Grandin, to educate small and very small livestock slaughter operators on the need for a systematic approach to humane handling.

Ms. DeLauro: What did FSIS do in fiscal years 2007 and 2008,and what does it plan for 2009, to assist small and very small plants in complying with the HACCP regulations, especially those regulations relating to Listeria monocytogenes requirements for RTE meat and poultry?

Response: During FY 2007 and FY 2008, FSIS distributed resource materials to small and very small plants, including copies of the compliance guidelines, and copies of a video and booklet prepared by Pennsylvania State University, "Control of *Listeria monocytogenes (Lm)* in Small Meat and Poultry Establishments," to all establishments that produce ready-to-eat (RTE) products. The compliance guidelines were specifically developed to provide small and very small plants with validation documentation that can serve as the basis for meeting the control measures specified in the regulation, when followed. In FY 2007, FSIS posted a summary of the compliance guidelines on its Web site, which includes updated recommendations for controlling *Lm*. In FY 2008, FSIS posted guidance on antimicrobial agents to control for *Lm* in post lethality exposed RTE products.

FSIS conducted an outreach Web seminar in FY 2007, reviewing the compliance guidelines for controlling *Lm* in small and very small establishments that produce RTE product. In FY 2008, FSIS conducted a net meeting for small and very small operators on new technologies for RTE products. Also in FY 2008, FSIS conducted its first regulatory education session for small and very small plants based on the *Lm* compliance guidelines. For FY 2009, FSIS will distribute printed resources, conduct additional Regulatory Education Sessions, net meetings, and will hold "how to" workshops to help small and very small plants producing RTE products improve their food safety systems that control for *Lm*.

Ms. DeLauro: What are the compliance rates for large, small, and very small firms?

Response: FSIS inspection program personnel performed and recorded in the automated Performance Based Inspection System (PBIS) over 8.5 million inspection procedures during FY 2008 to determine whether inspected plants met regulatory requirements. For FY 2008, plants operating under the Hazard Analysis and Critical Control Point (HACCP) System have a 98.64 percent compliance rate. The information is provided for the record.

[The information follows:]

FY 2008 (All Quarters)		
Plant Size	% Non Compliant	% Compliant
Large	2.12	97.88
Small	1.18	98.82
Very Small	0.98	99.02

Ms. DeLauro: Has USDA witnessed or quantified a decline in the number of small or very small firms over the past five years?

Response: FSIS has witnessed an increase in the number of small firms and a decrease in the number of very small firms over the past five years.

EGG PRODUCTS

Ms. DeLauro: Please describe FSIS responsibilities for egg products inspection and Salmonella enteritidis.

Response: Under the authority of the Egg Products Inspection Act (EPIA), the mission of FSIS as a public health regulatory agency is to ensure that certain shell eggs and all processed egg products are wholesome, not adulterated and properly marked, labeled, and packaged. The Food and Drug Administration (FDA) addresses on-farm and retail practices associated with the safety of table-ready shell eggs. FSIS began inspecting certain shell egg packers and processed egg products plants in 1995 as a result of legislation in 1994 which consolidated all USDA food safety efforts into a single food safety agency, FSIS. Currently, FSIS carries out its food safety responsibilities through an inspection program in processed egg products plants that relies on FSIS inspection program personnel for detection and correction of plant sanitation and food safety problems.

Between 1995 and 2006 (the time period for which FSIS has calculated the incidence of positive samples in its regulatory testing program), FSIS analyzed samples of pasteurized liquid egg products and found the percent positive samples for *Salmonella* spp. to be 0.46 percent, and the percent positive samples for *Salmonella* Enteritidis (SE) to be 0.083 percent. In an October 2001 through March 2003 nationwide baseline survey designed to identify the prevalence of pathogens of public health concern in pre-pasteurized liquid egg products, FSIS found the prevalence of *Salmonella* spp. to be 74.0

percent and of SE to be 30 percent. FSIS is using this survey data to develop proposed lethality performance standards for egg products.

To support FSIS' development of proposed lethality performance standards, FSIS held a public meeting in October 2004 to discuss two draft quantitative risk assessments, one on SE in shell eggs and one on *Salmonella* spp. in liquid egg products. FSIS updated the 1998 joint FSIS-FDA risk assessment on SE because the 1998 risk assessment did not fully address risk strategies associated with egg products, and FSIS gathered new baseline survey data on the prevalence of *Salmonella* spp., including SE, in pre-pasteurized liquid egg products. The updated risk assessment will assist FSIS as it moves towards a more science- and risk-based food safety strategy for shell eggs and processed egg products.

In raw meat and poultry, the percent positive of SE in regulatory samples is very low compared to that of processed egg products. However, the percent positive of *Salmonella* spp., which includes SE, is the target set of organisms that FSIS tracks in its regulatory programs.

FSIS is enhancing its risk-based approach to inspection and is focusing on the HACCP system of process control in inspected meat and poultry facilities to reduce the percent positive of *Salmonella* spp. in certain classes of raw meat and poultry.

On February 27, 2006, FSIS published a *Federal Register* Notice (04 - 026N) that described how FSIS will use the results from its *Salmonella* verification sampling program for meat and poultry establishments to enhance public health protection. Under the initiative, FSIS will provide the results of its *Salmonella* performance standard testing to establishments on a sample-by-sample basis as soon as they become available. FSIS inspection program personnel collect product samples from individual establishments over the course of a defined number of 51 sequential days for broilers to complete a sample set. The product samples are then sent to FSIS laboratories for analysis. Establishments had been receiving the results after the entire sample set was tested, analyzed, and compared with the performance standard. The more rapid disclosure of testing results under the initiative will allow establishments to identify promptly any need for improved process controls in slaughter or dressing operations and respond effectively.

In addition, FSIS is posting quarterly nationwide data for *Salmonella* on its Web site, as compared to the past practice of posting annually; conducting follow-up sampling sets as needed; and providing new compliance guidelines for the poultry industry. Following two completed sample sets, FSIS will categorize each establishment according to the percentage of positive *Salmonella* samples. Establishments in the category demonstrating the best control (meaning, 50 percent or less of the performance standard or baseline guidance) for the pathogen (Category 1) will be tested no more than once a year, but at least once every two years. The other two categories (Categories 2 and 3, from 51 percent of, and greater than, the performance standard or baseline guidance, respectively) will be subject to retesting at any time. If a facility does not meet the performance standards on two consecutive sets, a food safety assessment

will be conducted. Categorization of establishments based on *Salmonella* positive samples will allow the Agency to pursue a comprehensive strategy for combating the pathogen and provide the industry incentives to control the prevalence of *Salmonella*.

Comprehensive food safety assessments address the overall design of the food safety system and also allow FSIS the ability to successfully reduce the prevalence of pathogens with proper focusing of resources. The food safety assessments that have been performed to date in poultry slaughter and processing establishments have found that, when properly addressed in the establishment's food safety systems, *Salmonella* levels in performance standard samples can be controlled and maintained.

From October 1, 2005 through February 1, 2006, FSIS performed 60 food safety assessments in poultry slaughter and processing establishments. FSIS analyzed these reports and found that establishments that failed to meet the performance standard had flaws in the design and execution of their control procedures. However, once corrective actions were implemented to properly address the *Salmonella* hazard in the establishments' food safety system, establishments demonstrated an ability to maintain good control of *Salmonella*. As an example, in one broiler plant, the percentage of positive *Salmonella* rate decreased from 30 percent to two percent following FSIS' Food Safety Assessment.

In January 2008, FSIS issued a *Federal Register* Notice (73 - 18) announcing that any establishment operating with a waiver to certain inspection regulations would need to operate according to criteria identified in the *Salmonella* Initiative Program (SIP). SIP would require establishments to conduct testing for *Salmonella*, as well as generic *Escherichia coli* and *Campylobacter*. To maintain the waiver, the establishment would need to take steps to ensure that the percent positive rate for *Salmonella* remained at or below half the current performance standard for *Salmonella*. This action, ultimately, would affect most all broiler operations since most all operations have a current waiver to allow on-line reprocessing (OLR) of contaminated birds. OLR decreases the physical handling of the birds. Physical handling has been shown to cause an increase in the counts of microorganisms. Thus, SIP should have a positive impact on public health because establishments would specifically be demonstrating that *Salmonella* and other enteric pathogens are properly controlled. FSIS asked for public comment on the SIP criteria. FSIS expects to issue a follow-up Federal Register Notice on SIP before the end of calendar year 2008.

Ms. DeLauro: Last year in response to a question for the record, FSIS said that it would publish a proposal to bring egg production under HAACP. Did you do so? If not, why not and when will this occur? When will a final rule be in place?

Response: Because of competing priorities, FSIS has not yet published a proposal to bring processed egg production under HACCP. FSIS intends to publish this proposal in 2009. Because there will be a comment period associated with the proposed rule and the need to analyze the comments before determining a course of action for finalizing the rule, implementation of a final rule likely would not be

initiated until late in calendar year 2010, at the earliest. The Agency will determine what training is appropriate and ensure the best use of its resources when the rulemaking is complete.

ATHENS FACILITY

Ms. DeLauro: In the final 2008 bill, Congress provided FSIS with the authority to spend up to $650,000 for a laboratory sample facility. What has happened to date with respect to this?

Response: The design of the Athens laboratory sampling facility is near completion. A contractor has been selected and the contract has been awarded. Construction is scheduled to start before the end of calendar year 2008 and should be completed within six to eight months.

CONSUMER INFORMATION

Ms. DeLauro: How many calls did the Meat and Poultry Hotline receive in fiscal years 2007 and 2008? How does this compare with the two previous fiscal years? What is the annual cost of the Hotline service?

Response: During FY 2008, the USDA Meat and Poultry Hotline received 77,576 phone calls. In FY 2007, the Hotline received 80,822 phone calls. In FY 2006, the Hotline received 84,530 phone calls; and in FY 2005, the Hotline received 87,747 phone calls.

The decrease in consumer calls to the USDA Meat and Poultry Hotline has been offset by an expansion of alternate FSIS food safety tools available to consumers. The Agency's Web-based food safety virtual representative, "Ask Karen" allows consumers to access food safety questions directly from their computer 24 hours a day, seven days a week. In 2008, FSIS launched a series of educational podcasts tailored to address food safety education issues for consumers. This series is complemented by the launch of SignFSIS, a series of videocasts that have been translated into American Sign Language for consumers who are deaf or hard of hearing. In addition, FSIS has a comprehensive list of topical consumer-oriented food safety educational materials (available in Spanish and other languages), numerous food safety education studies, and publications available on the FSIS Web site. Consumers can also e-mail questions to a Meat and Poultry e-mail inbox. Through the Meat and Poultry e-mail inbox, FSIS received 124 e-mails in FY 2005, 184 e-mails in FY 2006; 216 e-mails in FY 2007; and 294 e-mails in FY 2008.

The annual cost for salaries and benefits for the Hotline currently is approximately $800,000.

Ms. DeLauro: What is FSIS' budget for consumer outreach and education activities in FY 2009? How does this compare to how much FSIS spent in FY 2007 and 2008? How are you leveraging Federal dollars in this effort?

Response: FSIS spent $1.4 million for FY 2007 and $2.4 million for FY 2008 for food safety education. This increase in FY 2008 is due

to two new consumer outreach and education initiatives. Funds were committed toward a major Food Safety Conference scheduled for late 2009. This conference follows a very successful program in 2006. In addition, the Agency began working with the General Services Administration for the design and development of a new Food Safety Mobile. The Mobile will allow the Agency to more directly engage consumers in food safety at events nationwide. Further, it will allow the Agency to assist communities with critical public health and food safety matters during emergencies. Under the continuing resolution for FY 2009, consumer outreach and education activities will continue at the FY 2008 funding level.

To leverage our funding, FSIS continues to work closely with the Department of Health and Human Services' Food and Drug Administration and the Centers for Disease Control and Prevention, other USDA agencies, and State and local public health departments, in developing consistent, science-based consumer food safety messages. FSIS also continues to work closely with the Partnership for Food Safety Education, a not-for-profit organization that unites industry associations; professional societies in the fields of food science, nutrition, and health; consumer groups; and the U.S. government; to educate the public about safe food handling. Other non-profit organizations with which we continue to partner include the American Dietetic Association, the American Egg Board, the Association of Food and Drug Officials, the Canadian Partnership for Consumer Food Safety Education, the Consumer Federation of America, and NSF International.

Ms. DeLauro: How are you measuring the effect of your consumer education efforts and what have those measurements shown?

Response: Evaluation measures continue to be coordinated and conducted in cooperation with partners to more effectively leverage resources. Ongoing nationwide surveys and consumer focus group studies will continue to be one mechanism employed to evaluate and measure the effectiveness of the campaign and the impact on consumer behaviors.

Formal evaluation plans to measure the success of the Be Food Safe campaign include two types of evaluation: 1) Process Evaluation, which documents and assesses the implementation of the campaign and quantifies what was done, when, where, how, and who was reached; and 2) Outcome Evaluation, which assesses the degree to which the campaign achieved its objectives on the basis of the movement of the target audience through the stages of behavior change toward maintenance of safe food handling behaviors.

The first phase of the evaluation process was begun with educators in FY 2007. At that time, food safety partners were interviewed about their use of the Be Food Safe campaign materials to gather qualitative data. These interviews provided richer support for how the materials would be used and shared with consumers. The food safety partners for this project included Food and Drug Administration Public Affairs Specialists; the Cooperative State Research, Education, and Extension Service; and attendees at the 2006 Food Safety Education Conference. Based on comments provided by educators, revisions to the Be Food Safe toolkit were completed and the educators were contacted later in FY 2007 for additional feedback on the revised Be Food Safe toolkit.

FSIS has measured the effectiveness of the campaign and the food safety messages by evaluating the effectiveness of the campaign at raising the level of awareness of safe food handling practices, the ability of the campaign to change attitudes about safe food handling, and the expected changes in food preparation behavior. FSIS will continue to solicit feedback and measure the effectiveness of its consumer education efforts in cooperation with its food safety partners.

Ms. DeLauro: Last year, you stated that formal evaluation plans for the Be Food Safe campaign were being finalized. Were those plans finalized? If so, please discuss.

Response: During FY 2008, funds provided for a formal evaluation of the *Be Food Safe* campaign were used to develop a media evaluation plan, a consumer survey tool, and for the work necessary to obtain OMB approval for the use of the consumer survey to evaluate the effectiveness of the planned media campaign. Upon approval by OMB of the consumer survey tool, and during FY 2009, FSIS plans to conduct a test market evaluation of consumer awareness of and response to *Be Food Safe* campaign messages. The results of this test market analysis, which is targeted in four U.S. cities that were selected for mixed demographics, will form the basis for a broader national assessment in 2010.

ENFORCEMENT

Ms. DeLauro: Please update the table that appears in last year's hearing record showing the number of FSIS enforcement activities, to include fiscal years 2007 and 2008. Please provide an explanation for all significant decreases and/or increases over the past three years.

Response: The information is submitted for the record.

[The information follows:]

FSIS Enforcement Activities 1995-1999					
	1995	1996	1997	1998	1999
Suspensions of inspection	n/a	n/a	64	77	118
Cases received	1,039	776	797	1,409	2,370
Cases filed with hearing clerk	6	17	6	6	9
Prosecutions	27	41	22	24	23
Civil injunctions	7	7	1	3	0
Seizures	1	1	1	0	2
Warning letters	1,361	1,063	1,097	1,626	2,778
Withdrawal of custom exempt privilege				2	1
Administrative Orders	5	8	12	7	8

FSIS Enforcement Activities 1995-1999					
	1995	1996	1997	1998	1999
Detentions	586	466	327	631	941
Pounds detained (millions)	10.1	31.3	44	16	20.6
Recalls monitored	48	23	25	40	55
Planned reviews	10,170	8,716	7,648	10,746	10,198
Random reviews	27,732	22,383	18,494	5,430	33,778
Total Reviews	37,902	31,099	26,142	16,176	43,976

FSIS Enforcement Activities 2000-2005						
	2000	2001	2002	2003	2004	2005
Suspensions of inspection	184	119	126	119	106	96
Cases received	2,386	1,540	977	506	618	742
Cases filed with hearing clerk	6	6	8	5	13	19
Prosecutions	12	9	11	15	21	18
Civil injunctions	2	4	4	7	2	3
Seizures	1	0	1	0	2	0
Warning letters	2,283	1,837	1,331	655	893	1,000
Withdrawal of custom exempt privilege	0	1	0	0	4	5**
Administrative Orders	4	6	8	4	10	12
Detentions	769	627	536	329	367	492
Pounds detained (millions)	34.0	13.4	36.8	13.0	3.1	78.1
Recalls monitored	76	66	119	77	55	51
Planned reviews	8,030	11,921	13,749	6,364	6,617	6,733
Random reviews	31,362	20,303	15,450	5,552	8,977	10,422
Total Reviews	49,392	32,224	29,199	11,886	15,594	17,155

FSIS Enforcement Activities 2006-2008			
	2006	2007	2008
Suspensions of inspection	105	67	164
Cases received	763	524	566
Cases filed with hearing clerk	8	4	6
Prosecutions	12	25	9
Civil injunctions	4	3	5
Seizures	0	0	0
Warning letters	1,084	719	549

FSIS Enforcement Activities 2006-2008			
	2006	2007	2008
Withdrawal of custom exempt privilege	3**	3	2
Administrative Orders	12	6	6
Detentions	519	459	367
Pounds detained (millions)	6.7	19	7.4
Recalls monitored	40	47	52
Planned reviews	7,102	5,933	*
Random reviews	12,035	5,988	*
Total Reviews	19,140	11,921	11,317

* Starting in fiscal year 2008, Planned and Random Reviews were combined into total surveillance reviews.

** FSIS recently revised the Enforcement Activity for the Withdrawal of Custom Exempt Privilege to appropriately report the actual number of withdrawals of custom exempt privilege. Therefore, the FY 2005 and FY 2006 numbers reported in the FY 2008 Questions for the Record (one (1) and zero (0), respectively) have been updated to reflect this revision.

Overall, the number of enforcement actions has remained steady for the past few years. FSIS has seen an increase in some areas of enforcement for FY 2008, such as the number of suspensions of inspection and recalls monitored. This is attributed to FSIS' increased focus on humane handling of livestock and other compliance activities. Staffing allocations, effective recruitment, enforcement training, and enhanced management controls also contributed to increased enforcement actions. These factors have dramatically increased the effectiveness of FSIS' enforcement program. The increase in number of recalls monitored in FY 2008 can be attributed to increased incidence of *E. coli* O157:H7.

Ms. DeLauro: In what ways can USDA initiate a withholding, suspension, or withdrawal action? Does a hearing need to take place, or is notification and withdrawal of inspectors also an option? How many times - and for how many plants - did FSIS withhold inspections in FY 2006 through 2008?

Response: USDA has the authority to initiate a withholding, suspension, or withdrawal action based on sanitation or HACCP violations, including: failure to collect and analyze samples for the presence of generic *E. coli*; failure to develop or implement sanitation standard operating procedures (Sanitation SOPs); or failure to develop or implement a required HACCP plan. USDA may also initiate a withholding, suspension, or withdrawal action for other violations, such as inhumane slaughter or insanitary conditions.

In situations where a plant produces or ships adulterated product without taking corrective actions, FSIS takes immediate action to

withhold the USDA mark of inspection. A withholding action may affect all product in the establishment or only product from a particular process.

If the Agency decides that it is necessary to withdraw inspection from a plant, FSIS must file a complaint with the USDA Hearing Clerk. The plant may request a hearing before an Administrative Law Judge. If the action is based on insanitary conditions, the plant will remain closed while proceedings go forward. In other cases that do not involve a threat to public health, operations may continue. These actions may be resolved by FSIS and the plant entering into a consent decision, which allows the plant to operate under certain specified conditions. Once inspection is withdrawn, a closed plant must reapply to receive Federal inspection.

For any type of enforcement action taken, an establishment has the right to appeal the action through supervisory channels, including the right to appeal determinations made by field supervisors to senior management officials at Agency headquarters.

In FY 2008, there were 164 instances where FSIS took action to suspend inspection at Federally-inspected establishments. In FY 2007, there were 67 instances where FSIS took action to suspend inspection at Federally-inspected establishments. In FY 2006, there were 105 such instances.

The increased instances in FY 2008 are attributed to FSIS' increased focus on the humane handling of animals, enforcement training, and enhanced management controls.

OTHER FOOD SAFETY ISSUES

Ms. DeLauro: How is the Department using microbiological performance standards? If an establishment fails to meet the microbiological standard, how long is the establishment allowed to produce products before FSIS takes regulatory action?

Response: FSIS has microbiological performance standards for both raw and RTE products. For raw products, the *Salmonella* performance standards are designed to provide an assessment of how well each establishment maintains process control in the production of carcasses and ground product. Regulatory samples are selected by FSIS and the results are reported back to the establishment in order to inform the establishment about their progress for controlling their process. In 2006, FSIS began posting aggregate quarterly *Salmonella* results on its Web site to give both industry and consumers more complete and timely information about *Salmonella* trends. The postings also provide consumers with meaningful information about overall industry performance in protecting public health.

FSIS collects samples of raw product on a daily basis until a full set of samples is received (e.g., 53 samples for ground beef). An establishment's failure of a single set within the performance standard triggers an immediate review of the establishment's food safety system by inspection program personnel, and failure of two consecutive sets

triggers an immediate food safety assessment. Establishments found not to be in compliance with food safety requirements are immediately subject to enforcement actions.

For RTE products, a positive sample result requires the establishment to implement corrective actions that are consistent with the HACCP regulatory requirements. If the establishment does not implement corrective actions that meet these requirements, enforcement actions are taken immediately.

Ms. DeLauro: Please update to the extent necessary last year's response on the Salmonella testing initiative.

Response: In 2006, FSIS changed how it targeted testing of raw classes of products midway through FY 2006. This change was outlined in the *Federal Register* (see: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-026N.htm). Importantly, FSIS targeted the sampling of broiler carcasses for testing because of evidence that the incidence of *Salmonella* appeared to be increasing for the third year in a row. As reported by FSIS (see: http://www.fsis.usda.gov/PDF/Progress_Report_Salmonella_Testing_1998-2006.pdf), positive *Salmonella* tests for broilers likely have reversed the trend and returned to just over 11 percent (as in 2003).

Since modifying the *Salmonella* verification testing program, FSIS has documented consistent improvement in the *Salmonella* percent positive testing results for broiler establishments. By the end of September 2008, of all broiler establishments that were eligible for *Salmonella* sampling, 79 percent were in Category 1 (performing at less than or equal to 50 percent of performance standard). During the same reporting period in calendar year 2006, 35 percent were in Category 1.

Ms. DeLauro: Please update to the extent necessary the response to last year's question on page 401 regarding sentinel sites.

Response: The Foodborne Disease Active Surveillance Network (FoodNet) project, a laboratory-based surveillance collaboration among 10 States, the Centers for Disease Control and Prevention (CDC), FSIS, and the U.S. Food and Drug Administration, determines the burden of foodborne disease, monitors disease trends over time, and attributes foodborne disease to specific foods.

California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee, and New Mexico comprise the ten sentinel sites. At the present time, there is no plan to add or subtract sites.

Ms. DeLauro: How much did FSIS, FDA, and CDC respectively budget for the FoodNet program in FY 2007, and what is the estimated level for FY 2008 and the request for 2009?

Response: In FY 2007, FSIS budgeted $1.5 million for FoodNet; CDC budgeted $6.6 million; and FDA budgeted $600,000. The agencies have budgeted the same amounts for FY 2008 and for FY 2009.

Ms. DeLauro: Please update the Committee on how FSIS is implementing the Listeria interim final rule. Has FSIS issued the final rule? If not, why not, and what is the timeframe for issuance?

Response: On June 6, 2003, FSIS published in the *Federal Register* an interim final rule requiring Federal establishments producing post-lethality exposed RTE meat and poultry products to take steps to further reduce the likelihood of *Listeria monocytogenes (Lm)* being present on food contact surfaces and product. The rule became effective on October 6, 2003.

FSIS provided an 18-month period for public comment on the interim final rule in order to gather information on the rule's effectiveness and to determine whether any adjustments would be needed before finalizing the rule. During the comment period, FSIS surveyed its inspection program personnel in RTE product operations on the effects of the new regulation. The Agency also established internal teams to assess the rule in the seven key areas of public health, economic impact, labeling and consumer education, sampling verification, training, small plant guidance, and retail. The findings and recommendations of the teams were summarized in a report that was made public December 2, 2004. In order to accommodate public review and comment on this report, FSIS extended the comment period for the interim final rule from December 8, 2004, to January 31, 2005.

Since then, FSIS has analyzed the comments received to determine what changes, if any, should be made to the interim final rule. The Agency also has been conducting an economic analysis of the effects of the interim rule. We anticipate publishing a final rule in 2009.

Ms. DeLauro: How much did the Agency spend on pathogen testing in FY 2007 and 2008 and what is planned for FY 2009?

Response: The Agency spent $13.12 million in FY 2007 and an estimated $15.8 million in FY 2008 for pathogen testing. FSIS plans to spend approximately $16.5 million in FY 2009.

Ms. DeLauro: What effect have microbiological performance standards had on enforcement actions? What percentage of actions are taken based on standards versus on other noncompliance?

Response: Since the Supreme Beef court decision, FSIS has been effectively using failure to meet performance standards as one indicator of ineffective food safety program design. The Agency has found that the majority of plants failing the *Salmonella* performance standard do not have a well-controlled system. The *Salmonella* performance standard failure will trigger follow-up action, including a more comprehensive, in-depth review of the establishment's entire food safety system, which may lead to an enforcement action based on that review.

Ms. DeLauro: How many Advanced Meat Recovery tests for spinal cord remnants or other SRM testing did FSIS conduct in fiscal years 2007 and 2008 and how many does it plan for 2009? What is the total cost of these tests?

Response: In FY 2007, FSIS conducted 170 tests on Advanced Meat Recovery (AMR) product. These analyses consisted of 89 initial tests and 80 follow-up tests to verify corrective action (one other test was an inspector-generated market hog). As of the end of FY 2008, 106

initial tests have been completed, and 18 follow-up tests. The numbers of follow-up tests were fewer than expected due to the fact that two establishments with unacceptable initial tests have elected not to resume production of AMR product at this time. A third establishment had yet to start the follow-up series at the end of FY 2008. Approximately 150 tests are planned for FY 2009 - 100 initial tests and 50 follow-up tests. The Agency plans to maintain its sampling frequency for beef AMR verification for FY 2009. The current sampling plan consists of testing every three weeks in plants producing beef AMR using vertebral columns as the source of product.

The total cost for beef AMR testing in FY 2007 was $14,394. The cost in FY 2008 is approximately $11,618 to date (we have not confirmed the final numbers of follow-up tests). The estimated cost of beef AMR testing in FY 2009 is $14,700 (for 150 tests). These estimates include laboratory salary costs, operating costs, salary costs for field personnel to collect samples, and laboratory and Agency overhead. Testing will continue to be funded out of our base resources.

Ms. DeLauro: Please update the Committee on work with CDC to improve foodborne illness data so that illness and product type can be determined. Is there any plan to expand the data collection beyond the current 10 states participating in FoodNet?

Response: Progress has been made in efforts to improve human illness data so that illness and product type can be determined. The Foodborne Diseases Active Surveillance Network (FoodNet) project, a laboratory-based surveillance collaboration among 10 States, CDC, FSIS, and FDA, determines the burden of foodborne disease, monitors disease trends over time, and attributes foodborne disease to specific foods. This network, with its standardized reporting methods, has improved illness data and product type determinations. At this time there is no plan to expand the network beyond 10 States.

On April 5, 2007, FSIS, CDC, and FDA held a summit on attributing illness to food at George Mason University in Arlington, Va. The food safety summit brought together scientific experts, consumer and industry representatives, and other public health stakeholders to determine what attribution data exists, how to improve attribution data, how to use attribution data more effectively and how to best share attribution data.

To further develop techniques to attribute human illness to food product types, FSIS launched a mathematical modeling project performed in collaboration with CDC and the FoodNet State partners in late 2005. The initial phase of this study was completed in July 2008. FSIS is awaiting results of a CDC study initiated to attribute illness to specific food product types through the use of "point-of-consumption" or foodborne outbreak data. FSIS is collaborating with CDC to assure that the FSIS-regulated product types are more clearly delineated in the foodborne outbreak data. These attribution studies will help to further inform FSIS regulatory actions along the farm-to-table continuum to further reduce foodborne illnesses attributed to FSIS-regulated products.

In addition to FSIS' work with the CDC on attribution, the Agency has developed a methodology for calculating FSIS-inspected product

foodborne disease attribution by combining expert elicitation and the CDC outbreak data. Such an approach is necessary because no single source of information is currently able to provide a comprehensive picture of the food attribution issue for all FSIS regulated product types. FSIS intends to use its proposed attribution methodology to establish performance objectives tied to the Healthy People 2010 goals. In addition, the Agency intends to use its attribution methodology to rank establishments in terms of public health risk in its proposed public health risk ranking algorithm. FSIS' attribution methodology has undergone peer review. In addition, the Agency has had its methodology reviewed by CDC, the National Advisory Committee on Meat and Poultry Inspection (NACMPI), and the public. The Agency has also established a contract with the National Academies of Science to have its attribution methodology reviewed.

Ms. DeLauro: In last year's record, you said that a CDC attribution study would be completed in December 2007. Was it completed and if so, what were the major conclusions? If not, when will it be completed?

Response: FSIS launched an attribution mathematical modeling project in collaboration with CDC and the FoodNet State partners in late 2005 with an expected completion date of June 2006. The expected completion date was extended due to work undertaken to address the complexities in developing and applying the mathematical model, to make use of newer data available, and to assure the results would have a strong scientific basis. The initial phase of this study was completed during the summer of 2008. A manuscript describing the results of the study is in preparation.

Ms. DeLauro: Please describe all inspection programs authorized for use at meat and poultry plants (and update last year's response, if necessary). For federally-inspected plants, describe and define all inspection programs used during the last five years, including but not limited to include minimal, limited, and proportionate inspections. Provide web links to manuals, notices, regulations, etc., that authorize these programs.

Response: FSIS has only one inspection methodology for meat and poultry establishments. All meat and poultry establishments are inspected on each shift. FSIS inspection personnel conduct carcass-by-carcass and bird-by-bird inspections at all meat and poultry slaughter establishments. All processing and slaughter establishments are inspected in accordance the HACCP inspection methodology as instructed by FSIS Directive 5000.1 and other instructional Directives and Notices found at:
http://www.fsis.usda.gov/regulations_&_policies/regulations_directives_&_notices/index.asp. Inspections are conducted and findings documented through the Performance Based Inspection System.

Because of staffing shortages in the 1970s, the Agency initiated programs called "limited" and "minimal" inspection for certain operations at certain processing establishments under which inspection was provided on less than a per shift basis. However, on April 4, 2007, FSIS issued its Notice 22-07 which officially cancelled these programs.

The term "proportional" inspection was a method under which inspection personnel provided overtime inspection services at meat and poultry processing plants covered on patrol assignments after the establishment had completed its eight hour daily shift, or on weekends and holidays. The "proportional" coverage policy had been set out in Meat and Poultry Inspection (MPI) Bulletin 81-58, which was issued in 1981 and was not in a an electronic format. On July 7, 2007, the Agency issued FSIS Directive 12,600.2 which sets out clear instructions to inspection personnel about the establishment operations that are to be covered through reimbursable overtime and how to uniformly and equitably provide such service. FSIS Directive 12,600.2 officially cancelled MPI Bulletin 81-58, and the practice of providing "proportional" coverage. The Directive can be found at http://www.fsis.usda.gov/regulations_&_policies/regulations_directives_&_notices/index.asp.

The meat and poultry regulations in 9 CFR 318.4 and 381.145 set out that processing establishments that have Total Quality Control (TQC) systems for controlling operations after ante and post mortem inspection may apply to the Agency for approval of said systems. However, all meat and poultry processing establishments are inspected in the same manner in accordance with the instruction in FSIS Directive 5000.1. Presently there are 135 establishments operating under approved TQC systems. The Agency is considering issuing through rulemaking a rule which would officially eliminate TQC.

Under the authority of 9 CFR 381.3(b), FSIS also is currently conducting a pilot program titled HACCP Inspection Models Project (HIMP) in 20 young chicken slaughter establishments, 5 hog slaughter establishments, and 4 turkey slaughter establishments. HIMP is FSIS' successful effort to determine how the Agency can improve the use of its online slaughter inspectors and continue to ensure the reduction and/or elimination of defects that pass through traditional inspection. At each of these establishments, inspection personnel make a critical assessment of each carcass or bird slaughtered at the establishment. More information can be found at: http://www.fsis.usda.gov/Science/HACCP_Based_Inspection_Models_Project/index.asp.

As set out in 9 CFR 381.76, there are five inspection systems under which poultry establishments may be inspected. They include: the Streamlined Inspection System (SIS), and the New Efficient Line Speed system (NELS) for broiler chickens and Cornish game hens; the New Turkey Inspection System for turkeys, Traditional Inspection (all species), and Ratite Inspection for ratites. In each of these systems, FSIS inspection personnel conduct bird-by-bird inspections and determine which birds should be condemned and passed for food. In traditional inspection, the FSIS inspectors inspect each bird for trim and processing defects as well as for pathology. In SIS and NELS in order to promote inspection efficiencies, FSIS inspectors inspect each bird for pathology, however establishments are required to establish systems to control for processing and trim defects based on criteria set out in 9 CFR 381.76. Inspection personnel then verify through statistical reinspection that establishments are meeting the standards.

FSIS conducts inspection of eggs and processed egg products in accordance with the Egg Products Inspection Act as set out in regulations 9 CFR 590 and 592.

FSIS also conducts voluntary poultry inspections for non-amenable birds as set out in 9 CFR 362, voluntary inspections of exotic species as set out in 9 CFR 352, and voluntary rabbit inspection as set out in 9 CFR 354. Instructions to inspection personnel for conducting these and other voluntary services are found in FSIS Directive 12,600.1 at http://www.fsis.usda.gov/regulations_&_policies/regulations_directives_&_notices/index.asp.

Ms. DeLauro: What are Notifications and Protocols? What is the process of reviewing them? Is data submitted with the notification? What is involved in review? Please give examples of when FSIS has allowed companies to use new technology while collecting data to validate its safety and conformance with Agency regulations.

Response: FSIS considers four questions about the new technologies: will they interfere with FSIS inspection; will they adversely affect the safety of FSIS inspection program personnel; will they adversely affect the safety of the food; and would the use of the technology be inconsistent with any regulation. The purpose of a notification is to address these questions. If a company or establishment believes that the answers to these questions is no, it submits data in support of this position in a notification to FSIS. The New Technology Staff endeavors to review all notifications within 60 days. If FSIS cannot determine whether one or more of these questions can be answered in the negative, it requests that the establishment or company submit a protocol to study and develop data on the question. FSIS will review a protocol to ensure that it will provide the needed data. How long the protocol review takes will depend on the quality of the protocol that the Agency receives. Again, FSIS endeavors to complete its review in 60 days, but it sometimes is not possible to meet that timeframe if the company does not respond to the Agency's suggestions in a timely manner. Once the Agency advises the firm that it has no objection to the use of the protocol, the establishment or company may begin using the technology, collecting the data necessary to address the Agency's questions.

One example of new technology is the Trisodium Phosphate (TSP) On-Line Reprocessing System. Before the Agency allowed a TSP in-plant trial, the company had to supply laboratory, scientific journal or cite Federal regulations that showed that TSP On-Line Reprocessing would not adversely affect the safety of the products; would not jeopardize the safety of the Federal inspection program personnel; would not interfere with the inspection procedures; and would not be inconsistent with Agency regulations. Once the New Technology Staff concerns were addressed, the company conducted an in-plant trial for a limited time to validate the performance of the TSP On-Line Reprocessing System under commercial conditions. The data needed for the validation was collected by the company and sent to the New Technology Staff for review. After Agency review, the in-plant trial data supported the company's claims and the Agency issued a letter stating that FSIS had no objection to the use of the TSP On-Line Reprocessing System. This procedure was followed during the New Technology validation of the

peroxyacetic acid, organic acid and acidified sodium chlorite on-line reprocessing systems.

Ms. DeLauro: Please update last year's response, as necessary, on your preparedness and response plans for highly pathogenic avian influenza.

Response: FSIS preparedness and response plans include:

- Prepared and signed an MOU with APHIS, which details the responsibilities both agencies are committing to in the control and eradication of Highly Pathogenic Avian Influenza (HPAI). The MOU includes a specific provision for APHIS to reimburse FSIS for any agreed costs under a Reimbursement or Advance of Funds Agreement. The Agreement has been drafted in collaboration with APHIS and will be signed and executed when if an outbreak of HPAI occurs.
- Prepared the FSIS Interim Response plan for HPAI which outlines the Agency's preparedness, response and recovery actions when infected or potentially infected birds are received in FSIS-regulated facilities. The plan is in the process of being updated based on new information and the results of the table top exercise.
- Conducted a table top exercise to validate the Agency's preparedness, response, and recovery strategies and identify possible gaps in response-recovery continuum. Industry, consumers, Federal, State, and local agencies participated in the exercise. Posted the results of the exercise on the Agency's Web site.
- Developed a validated test to verify the presence of HPAI virus in poultry meat.
- Conducted a risk assessment in partnership with other agencies to assess the risks associated with the consumption of infected or potentially infected poultry meat or eggs.
- Prepared and delivered awareness training for public health veterinarians on symptoms and lesions of HPAI. To date, 685 FSIS personnel have completed the training.
- Developed a communication message for consumers on proper handling procedures and cooking temperature to mitigate risks from avian influenza or other foodborne pathogens in poultry.
- Developed enhanced ante mortem and post mortem inspection procedures for domestic poultry to be used when birds from infected zones or APHIS control areas are presented for slaughter at FSIS regulated facilities.
- Committed to fund the purchase of a small stockpile of antiviral medication (Tamiflu) to be used as prophylactic treatment of inspection personnel that may have been exposed to HPAI through asymptomatic infected birds.

HOMELAND SECURITY

Ms. DeLauro: What is the total amount of homeland security funding expended for fiscal years 2007 and 2008, and proposed for 2009?

Response: FSIS' mission is protecting public health through food safety and food defense. FSIS has been increasing its laboratory capabilities to focus on possible bioterrorism agents and would use base funding to continue this. Out of base funding, the Agency maintains a Consumer Complaint Monitoring System that monitors and tracks food-related consumer complaints. Each complaint is assessed for its potential risk to human health and triaged appropriately, with possible recall of those food items that pose a risk to public health. Twenty Import Surveillance Liaison Officers (ISLOs) are stationed around the Nation and are funded out of base funding. FSIS' Office of Food Defense and Emergency Response, established in 2002, coordinates the Agency's food defense efforts.

Estimated spending for FY 2008 is $31.8 million for food defense, which is an increase over FY 2007 actual obligations of $20.0 million. The increases included $8.4 million for the Food Emergency Response Network, $0.6 million for data systems at the laboratories and $2.5 million for enhanced laboratory capabilities to detect and respond to chemical and radiological threats.

We would expect to spend the same amount for food defense in FY 2009 out of base funding.

Ms. DeLauro: What is the status of the other Food and Agriculture Defense Initiative elements, including biosurveillance?

Response: FSIS conducts numerous food defense activities in addition to its work under the Food and Agriculture Defense Initiative. FSIS has initiated a comprehensive training and education effort designed to ensure that every FSIS employee fully understands their role in preventing, or responding to, an attack on the food supply. To date, more than 6,444 employees have received biosecurity training. All FSIS headquarters employees and the Avian Influenza Pandemic Coordinators were provided with Incident Command System training. Over 1,000 employees completed this training. FSIS also provided training on the National Incident Management Systems to 144 employees. Over 665 employees completed training on Avian Influenza awareness. In FY 2008, FSIS continued to provide training on food defense policies to entering employees through the classroom format. FSIS has also provided training on food defense policies to inspectors and small and very small plants through the Regulatory Education Sessions. FSIS has completed initial training on significant incident reporting using the FSIS Incident Management System, formerly known as the Non-Routine Incident Management System. A Web-based training on FIMS enhancements is under development. Security clearance training has been completed and refresher training will be completed in FY 2008.

In addition to training, FSIS is enhancing the capabilities of the Consumer Complaint Monitoring System, an existing system used for monitoring consumer complaints, to enable it to accumulate and report data for detection of unsafe and intentionally adulterated meat, poultry or processed egg products. The enhancements include establishing a portal for consumers and States to input consumer complaints and an analytical tool to actively assess consumer complaints data to identify early trends of potentially significant public health threats or concerns. The system will also collect

information to assist FSIS with outbreak investigations by identifying the source of hazards associated with purchase and use of FSIS regulated products.

Finally, FSIS developed and implemented the "5420" Homeland Security Threat Condition Response series of FSIS directives (three of which have been updated in FY 2008) for each of the Agency's program areas that prescribe how protective measures defined by Homeland Security Presidential Directive 3, Homeland Security Advisory System are to be implemented. Directive 3 established a threat advisory system to effectively communicate the level of risk of a terrorist attack to the American people. It prescribes that agencies develop appropriate "Protective Measures" in response to each of the five threat levels established. The measures developed by FSIS include active surveillance through a series of food defense verification procedures performed daily in all FSIS-regulated facilities, including import inspection facilities and in-distribution facilities. Approximately 120,000 of these verification procedures are performed monthly. Results of the verification procedures are reported to and are analyzed by the Office of Food Defense and Emergency Response. The results of the analysis direct outreach and guidance initiatives and countermeasures development.

USER FEES

Ms. DeLauro: FSIS is proposing legislation that would allow it to collect $96 million in new user fees. Please explain how these fees would be charged, who would pay them, and what the fee structure would be. When will the legislation be submitted?

Response: In FY 2008, FSIS collected approximately $156 million through existing user fee activities for providing overtime, holiday, and voluntary inspection services. Separately, FSIS will submit a legislative proposal that will permit expansion of user fee charges for certain additional activities, with total collections estimated at $96 million. The collections will be used to reduce appropriations needs for FY 2010. A total of about $92 million would be collected through a fee from establishments based on size and type, slaughter versus processing, of the operation. An additional $4 million would be collected from plants that require additional inspection activities for performance failures such as retesting, recalls, or inspection activities linked to an outbreak.

The FY 2009 user fee legislative proposal will be submitted to Congress upon final review and approval by the Administration.

Ms. DeLauro: Please provide a table showing the amount of user fees received by quarter in fiscal years 2006 through 2008.

Response: The information is submitted for the record.

[The information follows:]

Service Fees for Inspection of Meat, Poultry and Processed Egg Products

	Reimbursable Service Fees Collected	Voluntary Service Fees Collected	Accredited Labs Fees Collected
FY 2006 1st Quarter	28,367,579	962,362	118,500
FY 2006 2nd Quarter	28,971,317	1,145,435	26,185
FY 2006 3rd Quarter	36,525,408	1,917,885	40,000
FY 2006 4th Quarter	31,135,519	1,850,473	16,000
Total, 2006	124,999,823	5,876,155	200,685
FY 2007 1st Quarter	31,295,155	1,953,114	260,000
FY 2007 2nd Quarter	33,187,335	1,906,325	45,000
FY 2007 3rd Quarter	34,678,906	2,487,005	38,400
FY 2007 4th Quarter	32,970,483	2,110,112	33,600
Total, 2007	132,131,879	8,456,556	377,000
FY 2008 1st Quarter	33,343,456	2,133,687	202,500
FY 2008 2nd Quarter	42,490,778	2,535,594	74,700
FY 2008 3rd Quarter	36,313,591	2,886,802	40,400
FY 2008 4th Quarter	33,497,657	2,686,365	47,200
Total, 2008	145,645,482	10,242,448	364,800

Ms. DeLauro: For what activities is FSIS authorized to collect user fees or charge backs? What elements of the export process are included?

Response: The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act set forth inspections that FSIS performs and those for which fees are charged. FSIS collects holiday and overtime pay at plants that are required by statute to receive mandatory inspection services. FSIS also collects fees from all facilities that request inspection and certification

services that are not required by the statutes. The Agricultural Marketing Act through 7 CFR 218 and Subpart H authorizes these types of inspection services, called voluntary reimbursable services.

The execution of export certifications that are in addition to FSIS regulatory requirements, such as additional certifications that are required by the importing country and the transferring of products for export, are considered reimbursable services.

Lastly, FSIS charges a fee for the accreditation of non-Federal analytical chemistry laboratories (Title 9, Chapter III, Section 391). Pursuant to Title 9, Chapter III, Sections 318.21 and 381.153, the Agency charges those laboratories that are accredited to analyze official meat and poultry samples for specific chemical residues or classes of chemical residues, and moisture, protein, fat, and salt.

Food Safety and Inspection Service
Questions for the Record
Submitted by Rep. Jack Kingston

NATURAL CLAIMS

Question: Is it true that for food safety and preservative effects you currently allow a number of chemical treatments of meat and poultry products with substances such as lauric arginate, acidified sodium chlorite, octanoic acid, and ozone?

Response: While all of these substances are approved for use as antimicrobials, none may be used to preserve foods.

Question: Is it true that since these treatments or substances are classified as "processing aids" that manufacturers do not have to disclose their use to consumers on the ingredient label of products in which they are used?

Response: Whether a substance is a processing aid depends on the conditions of its use. Certain applications are processing aids. For example, lauric arginate applied to fresh cuts of meat would be considered a processing aid. However, when it is used on ready-to-eat products, labeling is required. Acidified sodium chlorite, octanoic acid, and ozone are considered processing aids because they only have a momentary effect and there is little or no residue remaining in the treated foods.

Question: What standards set in regulation are the basis for the determination that these chemicals shall be considered "natural"?

Response: Processing aids are defined in 21 CFR 101.100 (a)(3) as: (1) substances that are added during the processing of a food but are removed in some manner from the food before it is packaged in its finished form; (2)substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food; or (3) substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. If the use of a substance meets this definition, it does not require ingredient labeling (i.e., because it is not present in the finished food and will not provide a lasting technical effect). Processing aids (by definition) cannot suppress the growth of microorganisms so they are not considered "preservatives."

The purpose of processing aids is to provide a momentary antimicrobial effect to treat virtually all meat and poultry at one point or another as part of an establishments HACCP plan (e.g,. the use of lactic acid to treat meat carcasses pre and post-chill and the use of chlorine in poultry chiller water). The use of processing aids is not normally disclosed in the label applications. This is because they are not considered ingredients that provide a technical effect in the meat or poultry product. Thus the use of processing aids on product labeled as natural is acceptable because such product meet the policy definition of a natural claim.

The word "natural" is a voluntary claim, and not a labeling requirement. As long as conditions are met to make the claim truthful and not misleading, the word "natural" is approved on labels. Under agency policy guidance, a meat or poultry product labeled "natural" must not contain any artificial flavoring or coloring, or a preservative, and its ingredients may not be more than minimally processed. By definition in 21 CFR 101.100(a), processing aids are not ingredients of a food.

THE RECALL OF HALLMARK/WESTLAND MEAT PRODUCTS

Question: With regard to the 143 million pound recall of meat products produced by the Hallmark/Westland Meat Packing Company, given the interlocking layers of food safety protections involved in the production of beef products today, such as the ruminant-to-ruminant feed ban, the exclusion of nonambulatory livestock from the food chain, and the separation of specified risk materials (SRMs) from meat intended for human consumption (a practice that alone reduces the risk to consumers by 99 percent according to the Harvard risk Assessment), please explain why a recall of this magnitude was warranted?

Response: Evidence from the ongoing investigation demonstrates that, over the past two years, this plant did not always notify the FSIS Public Health Veterinarian (PHV) when cattle became non-ambulatory after passing antemortem (prior to slaughter) inspection, as is required by FSIS regulations. This failure by Hallmark/Westland led to the company's February 17, 2008, voluntary recall of 143 million pounds of fresh and frozen beef products produced at the establishment since February 1, 2006.

It is important to note that certain cattle, while ambulatory when they pass antemortem inspection, may later become non-ambulatory from an acute injury or another circumstance. If such a situation occurs, FSIS regulations require the PHV to inspect the animal again and determine that the animal did indeed suffer from an acute injury before the animal is permitted to go to slaughter. Otherwise, the animal is condemned, does not go to slaughter, and therefore, does not enter the food chain.

Question: Does the enormous nature of the recall itself not create unsubstantiated fears about the safety of U.S. meat products, or send a confusing message to consumers, especially in light of the minuscule level of risk?

Response: Any food recall, large recalls in particular, contribute to unsubstantiated fears about the safety of the food supply for some consumers. However, America is better served by recalls, of whatever size, when they are needed. While it is extremely unlikely that these meat products pose a risk to human health, the recall action was deemed necessary because the establishment did not comply with FSIS regulations. The recall was designated Class II because the probability is remote that the recalled beef products would cause adverse health effects if consumed.

HUMANE METHODS OF SLAUGHTER ACT

Question: In past years we have provided funding for dozens (83 in FY 2008) of additional FTE positions dedicated to enforcement of the Humane Methods of Slaughter Act. Please explain how these funding is utilized.

Response: The FY 2008 appropriations measure increased the number of full-time equivalent (FTE) positions devoted to the Humane Methods of Slaughter Act (HMSA) enforcement to 83 FTE positions. At the end of calendar year (CY) 2007, the agency had devoted 121 FTE positions to this function.

In CY 2007, FSIS issued a total of 12 suspensions to Federally inspected establishments for humane handling violations witnessed by inspection program personnel.

Of 6,200 Federally inspected establishments, approximately 800 slaughter livestock and are therefore subject to the HMSA. In CY 2007, FSIS conducted approximately 167,540 humane handling verification activities resulting in 691 noncompliance records (0.41 percent rate of noncompliance) at these facilities. Noncompliance records for humane handling may be issued when the violation is less than egregious, such as not having water available in pens.

A $3.9 million increase in funding was provided for the period of FY 2007 and FY 2008 to cover the Humane Activities Tracking System (HATS), which provides FSIS with an accurate and complete accounting of the time spent by FSIS inspection program personnel performing specific tasks and the results of that inspection related to humane handling and slaughter under the requirements of the HMSA.

To assist in allowing inspection program personnel in the District Offices and headquarters to analyze HATS data together with other food safety verification data, FSIS' goal is also to provide a broadband connection to fixed plants and at least one point location on each patrol assignment. As of February 1, 2008, the agency had achieved a total of 2,353 connections.

Question: Are these inspectors ever used to augment the provision of antemortem inspections?

Response: Yes, these inspection personnel are used to augment antemortem inspections and monitor compliance with humane handling and slaughter in the antemortem area.

FSIS veterinarians and other inspection personnel conduct carcass-by-carcass inspection at all Federally inspected slaughter facilities and verify that establishments follow all food safety and humane handling regulations.

Inspection at a slaughter establishment begins in the antemortem area or pen, where FSIS inspection program personnel randomly inspect live animals to verify humane handling before they are moved to slaughter.

During antemortem inspection, FSIS inspection program personnel observe all animals at rest and in motion.

ANTEMORTEM INSPECTIONS

Question: I am concerned that, at least in the case of the Hallmark/Westland incident, FSIS inspectors were showing up in the yards at predictable times and intervals. Given that antemortem inspection takes place for the purpose of making sure only ambulatory animals can be presented for slaughter, might FSIS consider implementing a policy that would specifically impose more random and frequent inspections on animals awaiting slaughter?

Response: FSIS veterinarians and other inspection personnel are not stationed in the antemortem area for the entire day. They do return randomly to verify humane handling, as well as the stunning and bleeding process.

As soon as the Humane Society's video taken at Hallmark/Westland Meat Packing Company was released on January 30, 2008, Secretary Schafer called for an investigation into the matter. USDA's Office of Inspector General (OIG) is leading that investigation, with support from FSIS and the Agricultural Marketing Service. The investigation is ongoing, but we are not waiting for the completion of the investigation to act.

USDA has already taken a number of steps to strengthen our inspection system. Pending the conclusion of the investigation, FSIS has implemented a series of interim actions to verify and thoroughly analyze humane handling activities in all Federally inspected establishments.

FSIS has increased the amount of time allocated per shift by inspection program personnel to verify humane handling activities and to verify that animals are handled humanely in antemortem areas. FSIS is also conducting surveillance activities to observe the handling of animals outside the approved hours of operation from vantage points within and adjacent to the official premises.

Question: How does FSIS manage the provision of antemortem inspections?

Response: Establishments are required to notify FSIS inspection program personnel when they want animals inspected prior to slaughter.

Inspection at a slaughter establishment begins in the antemortem area or pen, where FSIS inspection program personnel randomly inspect live animals to verify humane handling before they are moved to slaughter. During antemortem inspection, FSIS inspection program personnel observe all animals at rest and in motion.

It is the establishment's responsibility to follow the HMSA. Egregious violations to humane handling requirements can lead to suspension of inspection activity within an establishment. This will stop the plant from operating.

Noncompliance records for humane handling also can be issued when the violation is less than egregious, such as not having water available in pens.

Question: If an inspector is found to have failed in his or her duty to carry out proper antemortem inspections, or any inspections for that matter, what steps can you take to counsel or discipline the inspector?

Response: Supervisors have a broad range of sanctions available to them when responding to an inspector's neglect of duty and other misconduct, regardless of the nature of the behavior. Based on factors such as the severity of the offense as well as the quality, credibility, and availability of evidence these sanctions range from informal corrective actions such as oral counseling (admonishment) to written instructions, Letters of Caution, and formal disciplinary action. Formal disciplinary actions include Letters of Reprimand, unpaid suspensions, and removal.

Question: What constitutes cause for dismissal of an inspector?

Response: Removal action should be taken only after less severe measures (reprimands, suspensions, etc.) have failed to correct the offending employee's behavior, or when the employee's behavior is of such an egregious nature that removal action is clearly warranted and supported by current case law. A removal action should be initiated only after it is clear that: (a) the employee's behavior does not conform to the accepted rules of conduct; (b) the employee displays little to no potential for rehabilitation; (c) their misconduct is systemic and ongoing; (d) their behavior demonstrates an immediate threat to food safety and public health and; (e) such action will promote the efficiency of the service.

AGENCY COORDINATION DURING THE HALLMARK/WESTLAND RECALL

Question: Since this recall involved product that was subject to AMS and FNS rules, do you feel that the three agencies and USDA management were well coordinated during this recall?

Response: USDA's Food Safety and Inspection Service (FSIS), Agricultural Marketing Service (AMS), and Food and Nutrition Service (FNS) worked together throughout the Hallmark/Westland Meat Packing Company recall and have continued to work together during the ongoing investigation.

As soon as USDA learned of the Humane Society of the United States video from Hallmark/Westland Meat Packing Company on January 30, 2008, Secretary Schafer called on USDA's Office of Inspector General to work with FSIS and AMS to conduct a thorough investigation into the matter. USDA immediately and indefinitely suspended Hallmark/Westland as a supplier to Federal nutrition assistance programs administered by FNS. In addition, USDA placed an administrative hold on AMS purchases of product from Hallmark/Westland for use in the Federal nutrition assistance programs, pending further information from the investigation.

Immediately following the FSIS announcement of the Hallmark/Westland recall, FNS issued instructions to States and program cooperators for the

recall and destruction of the Hallmark/Westland beef placed on hold on January 30, 2008, as well as Hallmark/Westland beef dating back to February 1, 2006, the time period covered by the recall. Since January 30, 2008, FNS has provided ongoing technical assistance to State distributing agencies, industry partners, and schools to assist program cooperators with the initial administrative hold and the ensuing recall. In addition, FNS collaborated with the U.S. Department of Education to disseminate information to school officials in every school district across the country.

AMS worked to purchase ground beef from other eligible suppliers for schools and other domestic recipients to replace destroyed product. Purchases and deliveries of replacement ground beef products were prioritized and expedited to ensure that sufficient products were available to local nutrition program operators.

Question: Would you improve anything about its coordination should there ever be a similar recall?

Response: The three agencies have worked closely together and will continue to strengthen their working relationships in the future.

SMALL AND VERY SMALL PLANT INITIATIVES

Question: Dr. Raymond, with regard to your testimony highlighting FSIS' actions to reach out to small and very small plants via the internet and a pending organizational change, why not have the in-plant inspectors that currently inspect these facilities, and know them best, be the people who provide compliance assistance to these plants?

Response: The in-plant inspector's primary role is regulatory. To the extent that FSIS can involve them in education, it does. For example, when the agency implements a new regulation, it asks in-plant inspectors to have an awareness meeting with the plant to make sure plant owners and operators are fully aware of regulatory requirements. FSIS also asks inspectors to distribute educational resources to operators. One of the agency's most successful ways of reaching out to small and very small operators is by having the Enforcement Investigations and Analysis Officers conduct a proactive visit to share information about how a food safety assessment is conducted at the plant, and to offer resources to help the plant improve operations. However, the job of educating is a big one, and it needs to be a coordinated effort to ensure that the information and materials supplied are consistent with agency policies. That is why FSIS created an office that has the responsibility to provide education and outreach to small and very small plants. This office is ensuring that the agency has educational materials that can be shared in person, electronically, and in a printed format. This office shares information that is not only regulatory, but also scientific and technical to help small and very small plant operators improve their food safety systems.

CONSUMER EDUCATION/PROPER FOOD PREPARATION TO AVOID ILLNESS

Question: It seems that there remains food borne illness challenges when it comes to consumer preparation of food in the home, how large is this

problem and what is the agency doing to educate consumers directly about safe food handling?

Response: According to the Centers for Disease Control and Prevention, the vast majority of reported cases of foodborne illness are not part of recognized outbreaks, but occur as individual or "sporadic" cases. Additionally, based on national surveys that assess consumer safe food handling behavior in the home, FSIS recognizes that there are gaps in consumer safe food handling practices that contribute to the incidence of foodborne illness.

To address these gaps in consumer safe food handling knowledge, FSIS continues to develop communications strategies for educating general, diverse, and at-risk audiences about safe food handling principles that help promote behavioral modification to reduce consumers' risk of getting a foodborne illness. FSIS encourages consumers to practice safe food handling and continues to educate consumers on the importance of using a food thermometer to make sure meat and poultry products are cooked to a safe minimum internal temperature. Using a food thermometer is the only sure way of knowing if food has reached a high enough temperature to destroy foodborne pathogens.

In 2006, FSIS launched a *Be Food Safe* Campaign, an updated public education effort based on the Clean, Separate, Cook, and Chill messages developed as part of the national Fight BAC!® campaign. FSIS developed the *Be Food Safe* campaign in cooperation with the Partnership for Food Safety Education, the Food and Drug Administration, and the Centers for Disease Control and Prevention because research shows that Americans are aware of food safety, but they need more information to achieve and maintain safe food handling behaviors. Further, we produce *be FoodSafe: The FSIS Magazine*, which focuses on food safety behavior trends, emerging science and research, inspection issues (domestic and international), and education programs for food workers, consumers, and caregivers.

Furthermore, FSIS routinely works closely with other government agencies, the food industry, consumer representatives, and the Partnership for Food Safety Education to help better inform consumers of these safe food handling practices.

FSIS also provides a safe food handling information tool that is available 24/7. "Ask Karen" is the FSIS Web-based food safety virtual representative that is available at www.askkaren.gov. Another safe food handling information tool that FSIS manages is the USDA Meat and Poultry Hotline (Hotline) that is staffed by food safety experts, two of which are bilingual specialists. The Hotline is available Monday through Friday from 10:00 AM to 4:00 PM and on Thanksgiving from 8:00 AM to 2:00 PM, and responds to safe food handling and preparation questions.

Among its numerous publications, many of which are in both English and Spanish, FSIS recently published the *Kitchen Companion: Your Safe Food Handbook*, a 47-page comprehensive "Handbook" for consumers that contain all the basic information about food safety that consumers may already know along with new information that may be new to them.

RECALL AUTHORITY GENERALLY/MANDATORY RECALL AUTHORITY

Question: In light of the fact that FSIS doesn't have mandatory recall authority, can you explain why instigating a recall doesn't seem to be a problem?

Response: The purpose of a recall is to remove meat or poultry from commerce as quickly as possible when there is reason to believe it is adulterated or misbranded. The current FSIS recall system is effective in ensuring the prompt recall of products.

There is no need for FSIS to have mandatory recall authority because of FSIS' statutory authority to seize and detain any product in question.

Question: Have you ever had any trouble getting a company to cooperate when a recall appeared to be needed?

Response: FSIS has never had a company ultimately refuse to cooperate with a recall. However, if a firm did refuse, FSIS could use its statutory authority to detain and seize product and warn the public.

Question: Can you please explain why the process you currently use now to instigate a recall is preferable to the concept of mandatory recall authority? It is my understanding that using the procedures you have now, you are able to initiate a recall in a much more timely fashion. Can you comment on this?

Response: The voluntary recall is the quickest way to determine where the affected product has been distributed because companies are familiar with who their customers are and can notify them much more quickly than the Federal Government could after waiting to receive such information from the company. Public health would not likely be enhanced by the addition of mandatory recall authority, because the agency already has the means to remove product quickly from commerce.

When a company conducts a recall, FSIS notifies the public through a press release, which is posted on FSIS' Web site along with a photo of the product, when practicable. They are also sent to Federal, State and local officials, as well as the media and constituent groups.

In order to improve the effectiveness of a recall, FSIS has proposed a rule that would allow the agency to make available to the public lists of retail establishments that have likely received product subject to the recall. The final rule is now in Departmental review.

Food Safety and Inspection Service
Questions for the Record
Submitted by Rep. Maurice Hinchey

RETAIL LIST RULE

Question: A USDA proposed rule, which has been going nowhere for two years, would allow the public release of the names of retailers who have received recalled meat products. The administration currently considers the information proprietary and it is widely known that the Office of Management and Budget (OMB) is holding up the proposed rule. After questioning Dr. Raymond on the subject, I questioned OMB Director Nussle at a separate hearing later that day on why OMB is holding up the rule, which as a result, protects businesses at the expense of public health. Mr. Nussle responded that OMB would look into it.

This is one of many important issues deeply affecting Americans that OMB is dragging its feet on.

Do you stand by the following statement that you made on March 6, 2006?

"We believe that publishing a list of retail establishments that have received products subject to recall will help consumers more easily determine if they purchased recalled product."

Response: Yes, I stand by my March 6, 2006 statement. Although FSIS currently posts detailed information about recalled products, including pictures when possible, on its Web site to help consumers identify products subject to recall, publishing a list of retail establishments that have received recalled products will help consumers more easily determine if they have purchased a recalled product.

Question: For the record, please explain in detail your thoughts on why OMB would hold up a rule that directly and significantly impacts the health and welfare of every American family.

Response: I can not answer on behalf of the Office of Management and Budget (OMB).

INSPECTOR VACANCIES

Question: Two weeks ago today, Dr. Kenneth Peterson (Assistant Administrator, FSIS) stated that the overall vacancy of inspectors is at about nine percent and that a 100 percent employment rate would include more than 8,000 inspectors. I am told that there are currently 7,310 inspectors.

Am I correct that in order to reach full employment, FSIS would need to hire approximately 700 inspectors?

Response: As of March 6, 2008, the permanent full-time employment level for all in-plant positions was at 7,518. In addition to hiring permanent full-time employees to provide relief coverage, the agency also

employs approximately 300 full-time equivalent staff years to provide temporary relief coverage of vacant in-plant positions by hiring other-than-permanent inspection personnel that work only when needed. The use of other-than-permanent personnel ensures mandatory coverage of inspection activities in slaughter operations while facilitating the agency's strategic use of our human capital. The agency's current in-plant employment level is higher than at any time since 2003.

Question: Am I correct in asserting that a full employment level would allow FSIS to fully meet its inspection objectives?

Response: In light of the current amount of inspection work that is being accomplished, the current staffing levels are manageable and allow the agency to meet our statutory mandates and regulatory objectives and responsibilities. FSIS continues an aggressive hiring plan including offering recruitment incentives, such as payment of relocation expenses and college tuition repayment, for qualified applicants.

Question: Is it accurate to state that inspector vacancies directly result in the risk of a less safe food supply?

Response: FSIS' current vacancy levels are very low, and do not place the meat, poultry, and egg products supply at risk. Although a full-time position may be vacant, the agency is still able to efficiently provide coverage of the vacant positions using relief personnel and other coverage strategies, including other-than-permanent inspection personnel. The coverage of slaughter vacancies is the first staffing priority for the agency since slaughter facilities cannot conduct slaughter operations if FSIS inspection personnel are not present.

Question: Will FSIS achieve full inspector employment with the $22 million budget increase the administration has proposed? If so, how?

Response: For FY 2009, FSIS is requesting an increase of $22 million above the FY 2008 level to maintain our high standards for the safety and wholesomeness of meat, poultry and egg products and our continued efforts to ensure effective inspection and policy implementation. The FY 2009 appropriation request includes funding for an increase in pay and benefit costs, which make up approximately 80 percent of FSIS' budget.

When FSIS received its final appropriation from Congress for FY 2008, including a budget increase of $27.4 million that we requested to reduce vacancy rates and meet increased demand for front-line personnel, an aggressive effort was already underway to hire a significant number of new inspectors. On October 27, 2007, FSIS achieved the goal of an additional 184 in-plant personnel, including food inspectors and consumer safety inspectors, for which the President had requested the budget increase.

Question: Is it true that the majority of the $22 million will be for mandatory employment provisions, such as a COLA and other benefits, not an influx of needed inspectors?

Response: Yes, the FY 2009 appropriation request includes funding for an increase in pay and benefit costs, which make up approximately 80 percent of FSIS' budget. FSIS is requesting an increase of $22 million above the FY 2008 level to maintain our high standards for the safety and wholesomeness of meat, poultry and egg products and our continued efforts to ensure effective inspection and policy implementation.

Question: With such a small increase, how does FSIS intend to meet the food inspection needs that have recently been brought to the attention of the Subcommittee and the public?

Response: The overarching FSIS goal is continued reduction of foodborne hazards and diseases from meat, poultry, and egg products. The agency believes the current staffing levels allow the agency to meet our statutory mandates and regulatory objectives and responsibilities. FSIS continues an aggressive hiring plan including offering recruitment incentives for qualified applicants such as payment of relocation expenses and college tuition repayment.

Food Safety and Inspection Service
Questions for the Record
Submitted by Rep. Marcy Kaptur

INSPECTIONS

Question: The President's budget for FY 2009 includes a proposed $10 million in user fees paid by retailers for the enforcement of mandatory country of origin labeling requirements. What activities will your agency take with this $10 million? How was this figure determined?

Response: According to the Agricultural Marketing Service (AMS), the expansion of mandatory labeling requirements to all covered commodities will greatly increase the cost of operating the program. The proposed fees would finance surveillance audits on all covered commodities (meat; perishable fruits, vegetables, and specialty commodities; peanuts; fish and shellfish) at retail establishments, provide training for Federal and State employees on enforcement responsibilities, and develop and maintain an automated web-based data entry and tracking system for records management and violation follow-up, as well as ten additional Federal employees to carry out the expanded program and conduct trace-back audits. AMS proposes to accomplish periodic random surveillance audits through a cooperative Federal/State network.

AMS used the experience gained through implementation of the fish and shellfish program to determine the cost of expanding the program to include the other covered commodities. The user fee cost estimate of $9.6 million was based on an expansion of current retailer review activities to incorporate all covered commodities at 5,000 retailers each year at a cost of $900 per location, performed primarily by cooperating State agencies. It also includes more detailed supplier trace-back audits of 300 items each year at 100 locations that require 40 hours per location at a cost of $1.3 million, Federal personnel to administer these enforcement activities whose salaries and support costs total $2 million, and a tracking system with an annual cost of $1.8 million to handle compliance documentation on the approximately 37,000 retail locations.

Question: As we have previously discussed, the Inspector General has made significant recommendations on the implementation of the risk based inspection system, roundly criticizing the system that FSIS was ready to start implementing. At a time when the agency is facilitating the largest recall in American history, how can FSIS look this committee and the American people in the eye and ask us to trust you. In this regard, could you please elaborate and explain in detail how FSIS plans to implement 35 recommendations made by the USDA Inspector General's Office in its December 2007 audit report?

Response: FSIS welcomes the Office of Inspector General (OIG) audit, has been working closely with OIG, and working to strengthen our system and our data collection and analysis capabilities. We are using the results of the audit to better focus our efforts and are pleased that OIG agrees with our responses to all 35 of its recommendations. FSIS recognizes and acknowledges that a better integrated system and infrastructure will better

support a comprehensive, timely, and reliable data-driven risk-based inspection program. FSIS has been working on a number of actions related to data analysis and enhancements to the agency's food safety inspection program and many are near completion.

Some recommendations directly addressed the conduct of Food Safety Assessments (FSAs), which OIG feels must be expanded and improved before RBI can be implemented and FSIS agrees. FSIS had always planned to include FSA results in the RBI algorithm, but initially planned to test RBI in "Phase I" prior to FSA results being quantified and ready for including into the algorithm.

The most significant initiative related to data analysis is the further integration of the agency's data systems to provide a comprehensive, fully automated system that will allow FSIS to quickly and accurately identify trends, including vulnerabilities in food safety systems and outbreak data, and thus allow us to more efficiently, effectively and rapidly protect public health. This system which FSIS is developing will provide a fully automated system encompassing agency data including food safety assessments, enforcement actions, testing results, noncompliance records, plant production volume, and data from plants not currently included in FSIS data systems such as establishment interventions and testing results. The system will use predictive analytics, a sophisticated and automated analysis of food safety data for trends or patterns, rather than relying on agency analysts manually collecting and combining data and then looking for patterns in the data.

As part of the agency's long-term effort to improve the use of data through more rapid transmission of data for agency analysis, FSIS initiated a program to install broadband internet connections in nearly all slaughter establishments and in at least one establishment for each patrol assignment. This means less delay in updating information and an improved ability to monitor what is occurring in establishments, discovering issues more rapidly and responding to them more quickly. We look forward to the continued relationship with all of our public health partners to better protect public health through more timely and accurate information gathering and innovative changes to our food safety inspection system.

Question: The agency has been criticized for collecting its own microbial samples from only the first shift at plants operating more than one shift. The agency has told consumer groups that it would make sure sampling occurred on all shifts. Recently, inspectors have been instructed to only sample on the first shift because the sample must be sent the same day that it is collected.

a) What is the agency's current policy on sampling at multi-shift plants?

Response: As stated in FSIS Directive 10,230.5, the carcass or ground product for sampling must be selected at random from all eligible carcasses or ground products. If there are multiple shifts, rails, coolers, chillers, or grinders, inspectors randomly select one for sample collection. Each one should have an equal chance of being selected at each sampling interval.

b) What are the documents that contain those instructions for inspectors?

Response: The FSIS Directives that contain instructions for sampling at multi-shift plants include Directives 10,240.4; 10,210.1; and 10,230.5 (most other Directives refer back to Directive 10,210.1 if there is no specific language included). The FSIS Notices that contain such instructions are Notices 31-07, 55-07, and 66-07. Baseline sampling Notices (Notice 40-08 on young turkeys and the draft swine Notice) include shift-related language as well, but it is only specific to baseline testing.

Question: In a recent food & water watch survey, 70 percent of respondents say that plants are not clean at the beginning of operations. Furthermore, this study suggests that almost 80 percent of inspectors responding claim that line speeds are too fast. Given this data, how can the agency propose increasing line speed in the new salmonella testing regime?

Response: FSIS enforces several regulations to ensure that establishments are adequately clean prior to start up and processing. Under 9 CFR 416, FSIS expects establishments to operate "in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated" (§416.1). FSIS inspectors verify the adequacy and effectiveness of establishments' sanitation procedures (§416.17) and take appropriate steps as necessary if they determine that an establishment's sanitation procedures are insufficient to meet the regulations.

If inspectors believe that carcasses are not presented in a fashion sufficient for them to perform their activities in a satisfactory manner, inspectors have the authority to slow the line speed.

As to the impact on microbial levels, FSIS considers line-speed as one of many factors within a processing system. Antimicrobial use, chiller capacity, equipment design, and skill sets of establishment personnel are also elements that influence the success of a processing system to prevent, reduce, or eliminate microbial load on finished products. Live production/grow out practices, feed withdrawal, and variability in bird size can increase the potential for contamination during slaughter under any system and at any speed if equipment and conditions are not properly adjusted. This can adversely affect the level and type of pathogens on carcasses.

The agency does not believe that because a processing system is designed to operate under faster line speeds, the system is less capable of controlling microbial levels than processing systems operating at slower line speeds.

Under the *Salmonella* Initiative Program, FSIS will allow increased line speeds in a limited number of establishments that are granted additional inspectors. FSIS will require industry to test for pathogens, including *Salmonella* at specified frequencies to verify that pathogens remain at incidences less than half the current limit. In addition, FSIS will require measurement of *Campylobacter*, and is developing an advisory performance standard for *Campylobacter*.

FSIS continues to expect establishments to validate the effectiveness of their individual food safety systems. FSIS also expects establishments to determine and implement the procedures and polices necessary to ensure that

their system is operating optimally in accordance with all applicable regulations.

RECALLS

Question: Undersecretary Raymond, I have been asking this same question for years and the answer always seems inadequate. We only talk about recalls but never refer to recovery. With the largest recall in American history underway, could you please elaborate on how much the agency believes can be recovered?

Response: The amount of product(s) recovered during a firm's recall efforts is reported to FSIS by the recalling firm. The total amount of product recovered may be affected by numerous circumstances. While 100 percent recovery has occurred, this is not always possible. The products subject to recall may have already been consumed or were discarded at the time the recall was issued. There have been cases where no product was recovered due to a very short shelf life of the product. In reference to Recall 005-2008 (Hallmark/Westland recall), 51,751,580 pounds of product have been reported by the recalling firm as recovered.

Question: Between 2002 and 2007, there were approximately the same number of recalls of potentially contaminated ground beef due to the FSIS *E. coli* O157:H7 testing program (33 recalls) as there were after consumers got sick or died (27 recalls). However, consumer illness and death resulted in 750 times the amount of potentially contaminated ground beef being recalled. During this same period, FSIS did five tracebacks from a positive result in the testing program, which resulted in the recall of close to 2 million pounds of potentially contaminated products.

Why is there such a great disparity in the volume of potentially contaminated product being recalled in these different situations?

Response: Many factors influence the volume of product recalled. The volume of product recalled is dependent upon the amount of implicated product initially produced and shipped into commerce. The size of the producing establishment may also be a factor in that a greater volume of product with a potentially larger distribution area is usually produced in a larger plant.

Samples collected by FSIS for the *E. coli* O157:H7 testing program are usually collected from a defined lot of production with a known amount of poundage. If the sample tests positive for *E. coli* O157:H7 and the implicated product(s) has entered commerce, then it is subject to a recall action. Investigations into illness or traceback activities may identify the producing firm, and potentially contaminated product, but are less likely to pinpoint a single defined lot of product as the sole source of contamination.

PROTECTING SMALL PRODUCERS

Question: Between 1998 and 2003, there were over 2,200 federally inspected establishments that produced ground beef. In 2005, FSIS's website

reported that there were approximately 1700 such facilities. The current version of the website, which was updated in February 2007 reported that there were approximately 1400. Last fall, FSIS issued Notice 65-07, which is leading to increased scrutiny of the smallest plants who do not use the new, industrial technologies during production. What evidence does FSIS have that such technologies are equally necessary in the small slaughterhouses, which do not have a moving slaughter line?

Response: The number of establishments subject to Federal inspection varies from month to month as some facilities cease operations and others begin.

Notice 65-07 was issued in response to an increased number of FSIS positive *E. coli* O157:H7 test results, an increased number of *E. coli* O157:H7 recalls, and an increased number of *E. coli* O157:H7 illness related recalls in 2007. The purpose of the Notice was to make FSIS inspectors aware of the increases and to broadly reassess how beef operations and FSIS are addressing this pathogen. Notice 65-07 was intended for all establishments with raw beef operations, without consideration of establishment size. The Checklist does not ask about new technologies or imply that new technologies are considered 'best practices'.

The removal of the hide, hooves, and gastro-intestinal tract of cattle occurs in all slaughter/dressing operations. It is the removal of these items that present the greatest opportunity for contamination of the remaining carcass and parts with pathogens, including *E. coli* O157:H7. Although the scale of operation is different and the tools used may be more complex, poor sanitary dressing procedures in either operation lead to contamination of the carcass and parts. Good manufacturing practices at either type of operation would entail the use of sound sanitary dressing procedures followed by application of intervention treatments, such as water washes, to further minimize contamination.

Question: When the Secretary testified before this subcommittee I asked him about working with us in Ohio to help small producers use the federal inspection system and today, I ask your help in the same problem. The small producers in my district have a terrible time accessing market, have to travel many miles to have their animals slaughtered or pay absurd rates to the agency to cover their inspection costs. Quoting from a recent letter received from a constituent, "Small family packers must cover the cost of travel, per diem and a $68.50 / hour labor charge for grading. This works out to costs exceeding $20 per head at some of our participating locations." It has long been my claim that the structure of USDA is designed to encourage further concentration and destruction of small and family agriculture. Small producers need your help and leadership to provide them with the power to compete in this market. For the record, please outline the steps the agency plans on taking to address this problem.

Response: Grading is handled by the Agricultural Marketing Service within USDA. FSIS values small and very small plants and understands that they have unique needs and perhaps not as many resources as large plants. In the last several years FSIS has made a concerted effort to reach out to small and very small plants with information and assistance, as well as to listen to their needs and concerns, and it will continue this effort.

The agency's Small and Very Small Plant Outreach Web page is at: http://www.fsis.usda.gov/Science/Small_Very_Small_Plant_Outreach/index.asp.

In FY 2008, FSIS established a new office, the Office of Outreach, Employee Education and Training, devoted to helping small and very small plants improve their food safety systems so that they can be competitive in the market through producing safe food. This new office works directly with States such as Ohio to provide educational materials and outreach activities to small and very small meat, poultry, and egg processors.

FSIS has initiated many programs and activities to respond to the needs of small and very small plant. FSIS issued guidance on the appeals process to help small and very small plant owners and operators understand how to appeal an inspection decision. FSIS also initiated the regulatory education sessions that bring industry and inspection personnel together to hear a common message about the regulations. As of March 2008, since the first session was conducted in June 2006, FSIS had conducted 65 regulatory education sessions involving more than 1,700 participants. FSIS also started proactive Enforcement Investigations and Analysis Officer (EIAO) visits to small and very small plants to explain the purpose and process for conducting food safety assessments and to offer resources to plant owners and operators to help them be prepared for the assessments. The reactions to these visits have been very positive by plant owners and operators. As of March 2008, since they were initiated in July 2006, FSIS had completed more than 1,500 EIAO visits. FSIS also developed a small/very small plant start-up package to help owners and operators apply for a grant of Federal inspection, and established a clearinghouse to coordinate and issue commonly asked questions and answers. In addition, more than 300 small and very small plant operators participated in Web-based scientific and technical educational seminars.

Response: Yes, Arkansas, Delaware, New Jersey, Oklahoma, and Utah have USDA-approved State Plans. FNS has also received additional caseload requests from existing CSFP States seeking to serve about 99,000 more seniors.

Ms. Kaptur: Congress has twice rejected the proposed elimination of CSFP. Has the department looked for other ways to expand this successful, vital and cost-effective program that reaches the most in-need seniors through a unique government and community partnership?

Response: The Department has not looked for ways to expand CSFP. CSFP populations largely overlap the populations of the FSP and WIC. Instead of expanding CSFP, the Administration believes that limited Federal resources would best be utilized by focusing on these core, universally available nutrition assistance programs.

Ms. Kaptur: A recent report ERS requested the urban institute conduct indicates that CSFP is performing significantly better then the PART review has suggested. When do you expect the report to be final? When this report is available, please forward a copy to the committee.

Response: We expect that the Urban Institute's report for the Economic Research Service will be final in May 2008. We will provide the report to the Subcommittee at that time.

THURSDAY, APRIL 10, 2007.

FARM AND FOREIGN AGRICULTURAL SERVICES

WITNESSES

MARK E. KEENUM, UNDER SECRETARY, FARM AND FOREIGN AGRICULTURAL SERVICES
TERESA A. LASSETER, ADMINISTRATOR, FARM SERVICE AGENCY
MICHAEL W. YOST, ADMINISTRATOR, FOREIGN AGRICULTURAL SERVICE
ELDON GOULD, ADMINISTRATOR, RISK MANAGEMENT AGENCY
W. SCOTT STEELE, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

INTRODUCTION OF WITNESSES

Ms. DELAURO. The hearing will come to order. I want to welcome Mr. Keenum, Mr. Gould, Ms. Lasseter, Mr. Yost, Mr. Steele. Thank you all for being here this morning. And let me just say in terms of my own timing, I found out late yesterday that I have been made a conferee on the farm bill, and it would appear that there is going to be a conference and that is going to occur sometime this morning or about 10:15 or so forth. So I will ask one of my colleagues to take the chair so I wanted to try to move us along if we can.

CHAIRMAN'S OPENING STATEMENT

Today will be the last budget hearing this subcommittee will hold for the administration, a special request before we embark on drafting the fiscal year 2009 agriculture appropriations bill. We intend to move full steam ahead in passing all of the appropriations bills out of the House by the recess. I am not sure of the markup or floor schedule for the Ag appropriations bill yet, but I will be sure to keep my colleagues apprised as soon as possible.

I also intend to hold additional oversight hearings during the year to provide the subcommittee members with the opportunity to learn more about programs under the bill and the impact on the American people.

While this is the final budget hearing, we have indeed saved one of the most important subjects for last. The Farm Service Agency is a large agency with over 14,000 employees that administers farm credit, commodity, conservation and emergency assistance programs for farmers and ranchers. It operates an extensive network of local county offices and service centers.

The Foreign Agricultural Service is such an important agency to this committee that we decided to convene a separate hearing last year covering just the issues under its purview.

And finally we have the Risk Management Agency which administers the critical Federal Crop Insurance Corporation Fund.

When we held our hearing covering the Farm Service Agency last year, we had a very extensive discussion about the computer problems. It appears that we may be continuing that discussion today. I am concerned that the plan that FSA has developed for its computer system is flawed and will not stabilize or modernize its program delivery system. The subcommittee has tried to address this problem for many years during many hearings, and I am sure that the Agency is just as frustrated as we are. I hope that we can find a way to resolve this issue at some point once and for all.

Another important issue I would like to focus on today is the international food aid. Everyone is aware of the soaring commodity prices around the world, and since it does not appear that these prices will be coming down anytime soon, a dangerous shortfall in key food aid commodities is emerging. According to USAID, prices for key food aid commodities have increased over 40 percent in just the past 6 months. USAID also reports the shortfall will force the program to reduce its emergency food aid operations. And to make matters worse, the Food for Peace program also is facing increased transportation costs to ship commodities overseas because of the high fuel prices.

It is critical that we try to resolve this emerging global food crisis, and I look forward to discussing how we can work together to do that. There are other important topics to cover today.

Let me stop there and let me recognize Mr. Alexander who was here at the outset. Would you care to make opening comments?

Mr. ALEXANDER. Not at this time.

Ms. DELAURO. Ms. Emerson.

Mrs. EMERSON. Thank you. We have a lot of important things to discuss, and you will have to forgive me because I am going back and forth between Energy and Water and here. But we welcome you, we thank you very much.

Ms. DELAURO. With that, Dr. Keenum, as you know, your testimony and everyone's testimony is part of the record, and have you proceed with your testimony and summarize as you see fit.

UNDER SECRETARY'S OPENING STATEMENT

Mr. KEENUM. Thank you, Madam Chair, and members of the committee. I am pleased to appear before you to present the 2009 budget proposals for the Farm and Foreign Agriculture Services Mission area. With me today I have the administrators of these three agencies: Teresa Lasseter, Administrator of the Farm Service Agency; Eldon Gould, the Administrator of the Risk Management Agency; and Michael Yost, Administrator of the Foreign Agricultural Service. I also have Scott Steele who is the director of our Office of Budget and Program Analysis accompanying us as well.

I would like to begin with the Farm Service Agency, which is the Department's lead agency for delivering farm program assistance. FSA has had a total discretionary budget for salaries and expenses of $1,522,000,000, an increase of $91.6 million from fiscal year 2008. This increase is necessary for pay and other necessary personnel compensation, and covers increases in operating expenses and inflation.

FSA has been working to address the challenges of maintaining program delivery effectiveness through its field office structure,

while also sustaining its aging and increasingly costly IT systems. Concerns about office structure and accountability highlight the crucial role of IT for FSA's capacity to continue to deliver adequate service to its farm clientele. Consequently, the 2009 budget requests an increase of $8 million for operational costs for the current IT systems.

Similarly, the supplemental appropriations of nearly $38 million provided by this committee last year was critical to supporting and stabilizing the operations for FSA's Web-based computer systems that were suffering from severe performance problems last year.

Turning now to the Risk Management Agency, the Federal Crop Insurance program represents the main risk mitigation program available to our Nation's farmers and ranchers. RMA has a discretionary budget of 77.2 million, of which 95 percent, or 73.2 million, covers salaries, benefits, rent, shared services and information technology. The remaining 5 percent, or $4 million, covers other adjustable operating expenses. RMA is requesting a $1.1 million increase above fiscal year 2008 to cover increased operating costs.

In 2007 the crop insurance program provided about $67 billion in risk protection to over 271 million acres. Our current projection is that indemnity payments to producers in 2007 will be about $3.3 billion on a premium volume of over $6.6 billion.

RMA's most critical need in the coming years is the modernization of its aging IT systems. IT modernization is critical to RMA's ability to continue operating and improving the Federal Crop Insurance program. The budget includes a two-pronged approach which will allow RMA to proceed with IT modernization in a budget-neutral manner.

I will now like to return to the Department's international programs and activities. The Foreign Agricultural Service is the lead agency for the Department's international activities. It is in the forefront of our efforts to expand and preserve overseas markets. We have seen unprecedented increases in the levels of U.S. agriculture exports, which are projected to set another record during 2008 at $101 billion.

The agriculture trade balance is also improving and is expected to reach a $25 billion surplus this year, the highest level since 1996.

To accomplish these goals the budget provides increased funding for FAS. FAS has a total discretionary budget for salaries and expenses of $173 million, an increase of $10 million from fiscal year 2008. This additional funding is needed to cover increasing personnel costs, to fund higher overseas costs, and activities that are mandated such as the Department of State's shared expenses for International Cooperative Administrative Support Services or ICASS, and also for mandated funds for the Capital Security Cost Share Program. Also, the overseas value of the U.S. dollar adds to our challenge in meeting the costs that are inherent with FAS activities.

USDA continues to provide vital assistance and global efforts to address humanitarian relief and promote economic development through international food aid programs. For the McGovern-Dole International Food for Education and Child Nutrition program, the budget includes appropriated funding of $100 million. This pro-

gram is expected to provide assistance to nearly 2 million children and mothers throughout the developing world.

I would like to highlight for the subcommittee members action we have taken during the past year to improve the delivery and effectiveness of our food aid programs. Last July, USDA announced an initiative under which uncommitted CCC-owned commodities would be exchanged for food products that can be programmed under the Department's foreign and domestic food assistance programs. This new program is referred to as Stocks-for-Food. The Stocks-for-Food program was designed to make productive use of existing CCC stocks, while enhancing the level of food assistance that could be provided during a period of higher commodity prices and fuel prices.

To date, ownership of all existing uncommitted stocks have been transferred. The program is expected to provide about $120 million of food products to our domestic and foreign food assistance programs.

In the case of the McGovern-Dole program, over $20 million in additional processed commodities will be made available, and those commodities are expected to provide assistance to as many as 650,000 program recipients.

Also The Emergency Food Assistance program, TEFAP, is expected to receive nearly $100 million in additional funding to augment this vitally important domestic food assistance program. And at this time of high commodity and food prices the Stocks-for-Food program is helping to meet the nutritional needs of numerous individuals both domestically and internationally.

In conclusion, Madam Chair, I would like to express our sincere appreciation to you and to this subcommittee for the support that you all have provided to our mission area. I look forward to working with you as you review and consider our 2009 budget proposal, and I am pleased to provide whatever assistance you may require. Thank you Madam Chair.

[The information follows:]

Statement by Mark E. Keenum
Under Secretary for
Farm and Foreign Agricultural Services
United States Department of Agriculture
Before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Madam Chairwoman and Members of the Committee, I am pleased to appear before you again this year in order to present the 2009 budget and program proposals for the Farm and Foreign Agricultural Services (FFAS) mission area of the Department of Agriculture (USDA). I am accompanied by the Administrators of the three agencies that comprise our mission area: Teresa A. Lasseter, Administrator of the Farm Service Agency; Eldon Gould, Administrator of the Risk Management Agency; and Michael W. Yost, Administrator of the Foreign Agricultural Service. We are also accompanied by Scott Steele, Director of the Office of Budget and Program Analysis.

Statements by each of the Administrators providing details on the agencies' budget and program proposals for 2009 have already been submitted to the Committee. My statement will summarize those proposals, after which we will be pleased to respond to your questions.

I would like to begin, Madam Chairwoman, by thanking you and Members of the Subcommittee for the support you have provided to our mission area and its programs. That support is important because the programs we deliver to America's farmers and ranchers – price and income support, farm credit assistance, conservation and environment incentives, risk management tools, and trade expansion and export promotion programs – provide a critical safety net for our producers and help to ensure the continued prosperity of American agriculture.

The 2009 President's budget provides the funding needed to meet our mission area priorities and ensure our continued ability to deliver our services to America's agricultural producers. It does so while also meeting the Administration's objectives of reducing the deficit and balancing the budget by 2012.

Farm Service Agency

The Farm Service Agency (FSA) is the lead agency for delivering farm assistance. It is the agency that the majority of farmers and ranchers interact with most frequently. FSA provides producers with access to farm programs such as direct and countercyclical payments, commodity marketing assistance loans, farm ownership and operating loans, disaster assistance, and certain conservation programs, such as the Conservation Reserve Program (CRP).

Farm Program Delivery

The 2009 budget request provides a fiscally responsible approach to fund essential program delivery expenses, including the most critical information technology (IT) operational expenses. However, the budget does not include estimates for implementing a new Farm Bill. We will evaluate the necessary administrative resource requirements and work with the appropriate authorizing committees to implement the new and reauthorized programs and policies, once their specific provisions and operational requirements have been determined.

FSA has been attempting to improve its operational efficiency and quality of clientele service in recent years with some success, although additional improvements are needed and many challenges remain. Since enactment of the 2002 Farm Bill, FSA has achieved success in the rapid implementation of newly authorized farm programs, timely implementation of a number of significant disaster assistance programs, and the tobacco buyout program. Many of these activities were effectively carried out with very few additional resources. Throughout this same period, FSA has reduced its staffing levels,

cut other priority expenses, and made limited improvements in IT support for some of its programs.

FSA has been working to address the challenges of maintaining program delivery effectiveness through our field office structure, while also sustaining its aging and increasingly costly IT systems. FSA State Executive Directors and committees worked with local reviewers and other agencies under the auspices of the State Food and Agriculture Councils to develop plans for an effective and efficient network of local offices in each State. This process was conducted in accordance with guidance provided by Congress in the Agriculture Appropriations Act for 2006. All 50 States and Puerto Rico submitted plans which originally proposed that 230 offices be consolidated. In total, 93 office closures have resulted from this effort, although further closures have been halted in accordance with provisions of the Consolidated Appropriations Act for 2008. These realignments will improve FSA's resource utilization.

In addition, a further review of the national office structure and operations is under way to identify more opportunities to improve efficiency. This review will also examine how FSA can position itself to implement effectively IT modernization throughout the agency once funding sources have been identified and funding becomes available.

FSA has also devoted considerable effort to improving its accountability and taking corrective actions to reduce improper payments, and we are pleased with the improvements it has made to date. During the past year, FSA made significant progress by reducing improper payments in its seven high-risk programs from 11 percent in 2006 to 2.5 percent in 2007. In the longer term, however, modernized business systems must be a bigger part of this solution, because only they can provide the tools necessary to meet acceptable standards for financial accountability and security in a cost effective manner.

These concerns about office structure and accountability highlight the crucial role of IT for FSA's capacity to continue to deliver adequate services to its farm clientele. Consequently, the 2009 budget requests an increase of $8 million for operational costs for the current IT systems. Similarly, the supplemental appropriation of nearly $38 million received last May was critical support for stabilizing the operations of the FSA web-based systems that were suffering from severe performance problems a year ago. Although these short-term stabilization efforts have been successful to date, it is essential that FSA program delivery be transitioned to a modern, centralized web-based system in order to meet minimum expectations for reliable, timely, and accountable program delivery in the future. This is the principal goal behind the agency's Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) initiative.

At this stage of its development, MIDAS is a business plan that outlines how FSA intends to modernize its entire program delivery system. It proposes to improve farm program delivery by making program benefits more accessible to producers, streamlining FSA "business" processes, and moving FSA's IT system toward a more fully integrated IT architecture. The MIDAS plan builds on the Common Computer Environment (CCE). The CCE is the web-based platform where most of FSA's automated business processes will ultimately reside. Nevertheless, a significant problem remains. The business processes and transaction methods that are being moved to the CCE platform are highly fragmented after years of program implementation on other systems. The fully implemented MIDAS plan will remedy this by reducing the complexity of these processes. The Office of Management and Budget supports the MIDAS business plan, and the Department is moving forward with the plan to the degree it can without a dedicated source of funding. At this point, a project manager has been hired, and two small contracts have been awarded. Accordingly, we have suggested to Congress a proposal requesting authority to assess farm program beneficiaries in order to secure adequate resources to implement this needed technology.

Salaries and Expenses

The budget provides $1.5 billion for FSA salaries and expenses, including credit reform transfers, for a net increase of about $92 million over the 2008 enacted level. The request reflects increases in pay-related and non-pay-related costs to sustain essential program delivery. It also includes the previously mentioned increase of $8 million for IT operational expenses to support legacy systems and maintain current IT operations during the transition to web-based systems. It continues to include certain costs in the salaries and expenses account that were previously funded in the CCE account, such as items associated with consolidated enterprise architecture and common infrastructure, the Universal Telecommunications Network, and enterprise licensing.

The budget, which assumes the current level of program workload, provides support for approximately 5,200 Federal staff years and 9,400 non-Federal staff years, which are the same as the 2008 levels. Temporary non-Federal staff years are maintained at 650. Given past experience with the potential for increased temporary workload requirements for implementing new farm programs, FSA staffing needs will be reassessed once the new Farm Bill has been enacted.

Commodity Credit Corporation

The farm commodity price and income support programs are financed through the Commodity Credit Corporation (CCC), a Government corporation for which FSA provides operating personnel. CCC also provides funding for conservation programs, including the CRP and certain programs administered by the Natural Resources Conservation Service. CCC also funds some export promotion and foreign food aid activities administered by the Foreign Agricultural Service.

CCC outlays declined from $20.2 billion in 2006 to $11 billion in 2007. Under provisions of current law, those outlays would be approximately $10.2 billion in 2008 and $10.5 billion in 2009. The reductions since 2006 primarily are due to reduced

commodity program payments for most major commodities, the result of current and projected high market prices. The rising demand for corn for the rapid expansion of ethanol production and strong export demand for most major commodities have driven prices to high levels.

Conservation Programs

The 2002 Farm Bill expanded the Department's conservation programs significantly. The CRP is the largest conservation program in the Department with about 34.7 million acres currently enrolled. That level is about 88 percent of the maximum 39.2 million acres authorized under the Farm Bill. The 2009 budget assumes modest new general signups will be held in 2008 and 2009. Because of high commodity prices and tight supplies globally and competition for increased acreage, the Department will not conduct a general signup in 2008. However, continuous signup for certain high priority land will continue. Current estimates in the budget are that acreage in CRP will decline to about 32.9 million acres by 2011, before gradually rising again if current law continues.

Farm Loan Programs

FSA plays a critical role for our Nation's agricultural producers by providing a variety of direct loans and loan guarantees to farm families who would otherwise be unable to obtain the credit they need to continue their farming operations. By law, a substantial portion of the direct loan funds are reserved each year for assistance to beginning, limited resource, and socially disadvantaged farmers and ranchers. For 2009, 25 percent of direct farm ownership loans are reserved for socially disadvantaged (SDA) borrowers and, of the funds remaining after the SDA reserve, 70 percent are reserved for beginning farmers.

The 2009 budget includes funding for nearly $900 million in direct loans and almost $2.5 billion in guarantees. This level of funding is consistent with actual program

use in 2007, and we believe these proposed loan levels will be sufficient to meet demand in 2009.

The 2009 budget maintains funding of $4 million for the Indian Land Acquisition program. For the Boll Weevil Eradication loan program, the budget maintains a request of $59 million. The amount requested is expected to fund fully those eradication programs operating in 2009.

For emergency loans, no additional funding is requested. No funding has been provided for emergency loans since 2002, due to substantial carry-over funding from prior year supplemental appropriations. As of January, about $46 million in carry-over funding remains available for use in 2008, a portion of which may also carry over into 2009. The demand for emergency loans is, by its very nature, difficult to predict. Over the past decade, actual use has ranged from a high of about $330 million in 1999 (following a devastating hurricane in Puerto Rico) to just $24 million in 2005.

Risk Management Agency

The Federal crop insurance program represents the main risk-mitigation program available to our Nation's agricultural producers. It provides risk management tools that are compatible with international trade commitments, creates products and services that are market driven, harnesses the strengths of both the public and private sectors, and reflects the diversity of the agricultural sector.

In 2007, the crop insurance program provided about $67 billion in protection on over 271 million acres. Our current projection is that indemnity payments to producers on their 2007 crops will be about $3.3 billion on a premium volume of nearly $6.6 billion. Our current projection for 2009 shows a substantial increase in the value of protection to nearly $72 billion. This projection is based on the Department's latest estimates of planted acreage and expected changes in market prices for the major agricultural crops.

The 2009 budget requests an appropriation of "such sums as are necessary" as mandatory spending for all costs associated with the program, except for Federal salaries and expenses. This level of funding will provide the necessary resources to meet program expenses at whatever level of coverage producers choose to purchase. For salaries and expenses of the Risk Management Agency (RMA), $77 million in discretionary spending is proposed. The request includes additional funding for pay costs. Staffing for RMA is projected to remain at the same level as 2008.

Information Technology

RMA's most critical need in the coming years is the modernization of its aging IT system. RMA's existing IT system is more than a decade old, well past its expected useful life. New plans of insurance such as revenue insurance, livestock insurance, and innovative indexed programs to cover pasture, rangeland, and forage (PRF) have greatly increased the size and complexity of the crop insurance program. These changes place a greater burden on the aging IT system, resulting in increased maintenance costs, and limit RMA's ability to comply with Congressional mandates pertaining to data reconciliation with FSA.

We are already seeing the impact of this aging IT system on the ability of RMA to operate the crop insurance program. Recent years have seen increases in "down-time" resulting from system failures, and it has become necessary to put "on hold" many planned program improvements. For example, in 2006, RMA published a proposed rule to replace the Actual Production History (APH), Crop Revenue Coverage (CRC), Income Protection (IP), Indexed Income Protection (IIP), and the Revenue Assurance (RA) plans of insurance and offer producers a choice of yield and revenue protection within a single policy. This action was intended to make it easier for farmers to understand their options in order to determine their best risk management tool. This combined policy would have covered nearly 85 percent of the crop insurance program's total liability and

approximately 94 percent of all policies earning a premium. However, funding for IT modernization is needed to complete this project.

Further, in July 2007, the Federal Crop Insurance Corporation Board of Directors approved a private sector proposal to extend livestock coverage to dairy producers in over 35 States, including the 15 underserved States, located primarily in the Northeast. This pilot program would have provided the first meaningful protection for dairy producers. Availability of IT funding would allow this program to be implemented.

Clearly, IT modernization is crucial to RMA's ability to continue operating and improving the Federal crop insurance program. Consequently, the 2009 President's budget includes a two-pronged approach for securing necessary funding. First, the budget re-proposes legislation that would require reinsured companies to share in the cost of developing and maintaining a new and efficient IT system. Companies participating in the program would be assessed a fee based on about one-third cent per dollar of premium sold. The fee is estimated to generate an amount not to exceed $15 million annually beginning in 2010. Participating companies receive considerable compensation from the Federal government for participating in the crop insurance program. In 2009, total compensation for delivery expenses (administrative and operating) and underwriting gains is expected to exceed $2.1 billion. This legislative proposal seeks only a very minimal amount to be used to build and maintain the IT system that makes that level of compensation possible.

Second, the 2009 budget includes language to expand the authorized purposes for use of mandatory Research & Development funds provided by the Agricultural Risk Protection Act of 2000 (ARPA). During 2006 and 2007, RMA's data mining and data warehousing activities were funded from discretionary appropriations. However, Congress encouraged USDA to find a source of mandatory funding in future years. For 2008, Congress adopted language proposed by the Administration that authorized the use of existing mandatory funding provided by ARPA to fund both data mining and the Congressionally-mandated Comprehensive Information Management System – CIMS.

The proposal in the 2009 budget would further expand the authorized uses of ARPA funds to include "the development, modernization, and enhancement of the information technology systems used to manage and deliver the crop insurance program" – our most critical need.

These two approaches will allow RMA to proceed with IT modernization in a budget neutral manner. I would note that RMA has already developed a business case for IT modernization that is fully supported by the Office of Management and Budget and the USDA Office of the Chief Information Officer.

Before leaving RMA, I would like to take a moment to point to the successes being achieved in implementing the Comprehensive Information Management System. Mandated by the 2002 Farm Bill, CIMS was intended to reduce duplicative data collections between RMA and FSA, to improve detection of fraud, waste, and abuse and, it was hoped, to serve as a model for further information management consolidation throughout the Department. That vision is coming to fruition.

CIMS has been pilot tested since 2005 beginning with 19 States. In 2008, CIMS will be taken nation-wide and will include 2005 through 2008 program information. At present, RMA and FSA data is updated weekly, and 15 web applications have been developed to provide access to FSA, RMA, NASS and OIG. CIMS currently contains information on producer, crop, county, location, and acreage data. CIMS identifies crop acres reported to FSA that are either insurable or uninsurable and reports discrepancies, such as weekly differences in reported acreage and business entities between RMA and FSA. During 2008, CIMS will be enhanced to allow access by Approved Insurance Providers and to add RMA indemnity information. In addition, a web application will be developed to utilize USDA and other government agency information on catastrophic events (such as weather, floods and drought) to determine affected RMA and FSA producers and acreage. Opportunities will also be explored to expand CIMS to other agencies in the Department.

Foreign Agricultural Service

Removing barriers and expanding trade are critical for the future economic prosperity of American agriculture. For that reason, the Department of Agriculture is an important player in efforts to further the President's trade agenda that is creating new market opportunities and ensuring that the United States remains a leader in a rules-based trading system.

Those efforts, when combined with favorable economic factors, are providing results as seen in unprecedented increases in the levels of U.S. agricultural exports. Those exports reached a record level of $82 billion in 2007, the fourth record year in a row, and are now projected to increase by $19 billion over 2007 to set yet another record of $101 billion during 2008. This would be an increase of $32 billion in just the last two years. The agricultural trade balance is also improving and is expected to reach $25 billion this year, the highest level since 1996.

We are building on these achievements with continued efforts to open new markets for U.S. agricultural exports. Achieving fundamental reform of agricultural trading practices through the Doha Round of multilateral trade negotiations remains one of our highest priorities, as it will create new jobs and promote economic development. Those talks are now at a crucial stage. In February, the Chairman of the agriculture negotiations released a revised draft text that is serving as the basis for further negotiations, with the objective of having a more comprehensive text by the spring. We remain committed to these discussions and believe a successful outcome is achievable.

Regional and bilateral trade agreements that lower tariffs and reduce trade barriers are another important avenue for expanding market opportunities overseas. Our efforts to open new markets were furthered last December when the President signed legislation implementing the Trade Promotion Agreement with Peru. Also, during 2007, negotiations for trade agreements with Panama and South Korea were completed and the

agreements signed. Those agreements, plus the agreement with Colombia, now await congressional action which is essential to ensure that American agriculture will benefit from the new market opportunities that they provide.

Maintaining access to existing markets is an increasingly important component of our work. This includes monitoring foreign compliance with trade agreements and working to avoid or reverse trade-disruptive actions. Efforts to reopen overseas markets for U.S. beef and beef products are an example of work that is done to remove technical issues that restrict trade. Markets have now been reopened or maintained in more than 40 countries that closed or threatened to close their borders after the first detection of bovine spongiform encephalopathy (BSE) in 2003. Recently, Peru, Colombia, Panama, the Philippines, Indonesia, and Barbados have removed their remaining restrictions for beef and beef products in accordance with international guidelines. We continue our efforts to secure similar action by other countries, most notably South Korea and Japan.

Salaries and Expenses

The Foreign Agricultural Service (FAS) is the lead agency for the Department's international activities and is in the forefront of our efforts to expand and preserve overseas markets. Through its network of over 100 overseas offices and its headquarters staff here in Washington, FAS carries out a wide variety of activities that contribute to securing increased export opportunities for our agricultural products.

With trade of such critical importance to the long-term prosperity of American agriculture, it is important that FAS have the resources needed to continue to represent and advocate for American agriculture on a global basis and to open new markets overseas. The budget provides a program level of $173 million for FAS in 2009, an increase of $10 million over the 2008 enacted level.

Increased funding is requested for higher overseas operating costs at the agency's overseas posts, including increased payments to the Department of State for

administrative services provided at overseas posts. Additional funding is also requested for an increase in FAS' contribution to the Capital Security Cost Sharing Program. Under that program, agencies with an overseas presence in U.S. diplomatic facilities are contributing a proportionate share of the construction of new, safe U.S. diplomatic facilities over a 14-year period.

It is important to note that the increases in FAS' overseas operating costs, including payments to the State Department for administrative services, result from a number of factors over which the agency has no control, including recent declines in the value of the dollar and overseas wage and price increases. These increases are, therefore, non-discretionary and must be met if FAS is to maintain its overseas presence at current levels and have the resources necessary to achieve its mission. Reductions in its overseas presence and operations would hinder the agency's ability to gather critical production, supply, and demand data; address market access issues and barriers to trade; carry out market promotion events; and implement trade capacity building programs.

International Food Assistance

The United States continues to provide leadership in global efforts to provide humanitarian relief and promote economic development through foreign food assistance.

For the McGovern-Dole International Food for Education and Child Nutrition Program, the budget includes appropriated funding of $100 million that will be supplemented by anticipated reimbursements from the Maritime Administration to provide a total program level of $108 million for 2008. That program level is expected to provide assistance to approximately 2 million children and mothers throughout the developing world. More than 16 million children and mothers have now received educational and nutritional benefits from the McGovern-Dole program and its predecessor, the Global Food for Education Initiative.

For the P.L. 480 Title II donations program, which responds to emergency food relief needs and addresses the underlying causes of food insecurity through non-emergency programs, the budget includes a projected program level of nearly $1.4 billion for 2009. This includes $1.2 billion of appropriated funding requested in the budget, plus projected reimbursements from the Maritime Administration for prior year cargo preference related expenses.

Similar to recent years, the budget proposes that all funding for P.L. 480 be provided through Title II donations during 2009 and includes no additional funding for Title I concessional credit or grant program. This reflects our recent experience during which an increasing share of U.S. foreign food assistance has been directed to emergency situations in which food aid is critical to preventing famine and saving lives. At the same time, demand for food assistance provided through concessional credit has declined significantly.

In addition, to help improve the timeliness, efficiency, and effectiveness of the U.S. response to overseas food needs, the budget proposes that the Administrator of the Agency for International Development have the authority to use up to 25 percent of Title II funding to purchase commodities in locations closer to where they are needed. As the President stated in his State of the Union address, the flexibility provided by this authority will help to break the cycle of famine. It will expedite the response to food aid needs by allowing commodities to be purchased more quickly and closer to their final destination, while increasing the total amount of commodities that can be procured to meet those needs. It is important to understand that U.S. commodities will continue to play the primary role in U.S. foreign food aid purchases and will be the first choice for meeting global needs. Furthermore, with this authority commodities would be purchased from developing countries and not from developed countries, such as the European Union.

We have taken other steps to improve the delivery and effectiveness of our food aid programs. Last July, USDA announced an initiative under which uncommitted CCC-

owned commodities would be exchanged for food products that can be programmed under both the Department's foreign and domestic food assistance programs. This new program is referred to as Stocks-for-Food. The Stocks-for-Food Program was designed to make productive use of existing CCC stocks, while enhancing the level of food assistance that could be provided during a period of higher commodity prices. To date, ownership of all existing uncommitted stocks has been transferred and, due to significant increases in commodity prices since July, the initiative is expected to provide nearly $120 million of food products for our domestic and foreign food assistance programs. In the case of the McGovern-Dole Program, over $20 million in additional processed commodities will be made available, and those commodities are expected to assist as many as 700,000 program participants. Also, The Emergency Food Assistance Program (TEFAP) is expected to receive nearly $100 million in additional funding to augment this vitally important domestic food assistance program. In this time of high commodity prices, the Stocks-for-Food Program is helping to meet the nutritional needs of numerous individuals both domestically and internationally.

Finally, the budget also includes an estimated program level of $340 million for the CCC-funded Food for Progress program, which supports the adoption of free enterprise reforms in the agricultural economies of developing countries. The statutory authority for the Food for Progress program is expected to be extended in the new Farm Bill.

Agricultural Reconstruction Activities in Afghanistan and Iraq

FAS coordinates and provides administrative support for the Department's efforts to assist in agricultural reconstruction activities in Afghanistan and Iraq. The agricultural sectors of both these countries represent a large and important component of their economies and employ a substantial portion of their population. Reconstruction of the agricultural sectors is therefore essential to achieving long-term stability and economic growth.

The Department is providing technical advisors to the Ministry of Agriculture in Iraq, who are assisting in agricultural economics and planning, soil and water policy, extension, and food safety and animal inspection. Other advisors are serving on the Provincial Reconstruction Teams (PRTs) that are operating in the rural provinces of Afghanistan and Iraq. The PRT advisors, who serve voluntarily on temporary assignments, provide valuable technical advice needed to develop and manage projects to rehabilitate the agricultural infrastructure and strengthen the capacity of rural institutions. In order to support continued USDA participation in these activities, the budget requests $12.5 million in the Office of the Secretary to meet the costs associated with having advisors serve on these assignments.

Export Promotion and Market Development Programs

FAS also administers the Department's export promotion and market development programs that play an important role in our efforts to enhance the international competitiveness of American agriculture.

The CCC export credit guarantee programs provide payment guarantees for the commercial financing of U.S. agricultural exports. The guarantees facilitate exports to buyers in countries where credit is necessary to maintain or increase U.S. sales. For 2009, the budget projects a program level of nearly $2.7 billion for CCC export credit guarantees.

For the Department's market development programs, the CCC budget baseline assumes funding for the Market Access Program (MAP) at the current level of $200 million. However, the Administration's Farm Bill proposals recommended increased funding for MAP, and the 2009 program level could change once the new Farm Bill has been enacted.

The budget baseline does not include funding for several other market development programs, including the Foreign Market Development (Cooperator)

Program and the Technical Assistance for Specialty Crops Program (TASC). This is in keeping with an Office of Management and Budget – Congressional Budget Office scoring convention that programs with expiring authorizations and annual outlays of less than $50 million are not included in the budget baseline. However, as in the case of MAP, we expect 2009 funding levels for these programs to be established in the new Farm Bill and note that increased funding for TASC was also recommended in the Administration's Farm Bill proposals.

For the Dairy Export Incentive Program (DEIP), the budget includes a $3 million program level for 2009. U.S. dairy products have been competitive in overseas markets in recent years due to favorable world market conditions and, as a result, no DEIP bonuses have been awarded since 2004. This situation is expected to continue relatively unchanged during 2008 and 2009. However, as a contingency, the CCC budget baseline includes $3 million for DEIP in 2009, should market conditions change and reactivation of the program is warranted. In that case, the actual level of programming would reflect developments in world dairy markets and the relationship between U.S. and world market prices during the course of the programming year.

In conclusion, I again would like to express our appreciation to the Committee for the support it has provided to our mission area and programs. We look forward to working with you as you review and consider the 2009 budget proposals and will be pleased to provide whatever assistance you may require.

Thank you for the opportunity to present our 2009 budget and program proposals. The Administrators and I would be pleased to answer any questions you and other Members of the Committee may have.

FARM SERVICE AGENCY
Statement of Teresa C. Lasseter, Administrator
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Madam Chairwoman and Members of the Subcommittee, I appreciate this opportunity to discuss Farm Service Agency (FSA) issues and funding.

Our fiscal year (FY) 2009 request is a lean budget that continues our fiscally responsible approach. It funds critical program levels and essential administrative delivery expenses, including crucial information technology (IT) operational expenses and limited technology modernization priorities, while helping to restrain discretionary spending. Our budget request does not include estimates of personnel or IT costs of implementing a new Farm Bill.

AGENCY OPERATIONS

Office Structure

All 50 States and Puerto Rico have submitted their plans under the initiative I described to you last year, in which our State Executive Directors conducted independent reviews of the county office structure in their respective States. In total, 230 offices were proposed for consolidation. Of these, 75 were closed in 12 States prior to December 26, 2007, after following the public and congressional notification procedures mandated in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, and the Continuing Appropriations Resolution, 2007. Another 5 offices had the logistics of consolidation under way prior to December 26, 2007, and once complete, they will bring the number of closures to 80. One new office, in Alabama, was opened as a result of the State plan. In accordance with the provisions of the Consolidated Appropriations Act, 2008, further closure action was halted unless it involved offices with zero permanent employees as of February 7, 2007. Under that exception, 18 offices have been approved for consolidation. The structural

realignment achieved by the completed and upcoming consolidations is an important step toward maximizing agency efficiency and making best use of available resources.

Another phase in our effort to optimize agency structure is the national office review currently under way. We have engaged a contractor to conduct an independent assessment to determine where further opportunities exist for achieving greater economies and efficiencies within our structure. The review focuses primarily on the organizational structure and practices within the FSA National and State offices, and the structure and practices between the National and State offices. It will also identify how FSA can position itself to effectively integrate and implement IT modernization throughout the agency once funding is available. The data collection phase of the review is complete, and we expect to receive a preliminary report by mid to late April.

Business Processes

In addition to evaluating the agency structure, we are continuing to improve the methods by which we conduct business. A leader in this endeavor has been the Farm Loan Program area, which has implemented a number of improvements in guaranteed and emergency loans over the past few years. During 2007, the ongoing effort culminated in significant changes to streamline the administration of the direct farm loan programs. Taking into account about 1,500 public comments, we reduced the number of pages of regulations by about 80 percent and replaced nearly 40 instruction manuals with 6 handbooks. We modified program requirements to more closely conform with those used by other lenders, cut nearly in half the number of forms required, and made all forms available on line. The streamlined rules and forms became effective January 1, 2008.

Information Technology

Thanks to a supplemental appropriation of $37.5 million that Congress provided on May 25, 2007, under Pubic Law 110-28, the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, together with $24 million FSA made available by reprioritizing previously appropriated funds, we have been able to make

progress in stabilizing the operations of Web-based software systems and understanding some of the problems that plagued our program delivery a year ago. We have installed a code review laboratory that is yielding results to identify application software performance enhancements. We have installed new monitoring tools that expose inefficiencies between the application software and data base servers. We have increased in-house and contractor support, and as a result have been able to identify and in some cases prevent system downtime. Through these and other measures, we have stabilized the computing infrastructure so that program benefits such as the Tobacco Transition payments could be issued without any significant "hiccups" during the first week of January 2008. We will need to continue to devote agency resources to maintain these successful efforts.

While the stabilization efforts have been successful to date, these actions are short-term, stop-gap measures. For the long term, transition of our business delivery systems to a centralized, real-time, Web-based, program delivery model continues to be crucial to our ability to meet the future program delivery expectations of our customers and Congress. I remain committed to work with the Congress to identify a funding strategy that will move our modernization business plan to full system implementation.

Performance and Accountability

As I reported to you last year, improved statistical sampling had increased the estimated number of improper payments for FSA's high risk programs and resulted in four additional programs being declared susceptible to improper payments. In the past year, through employee commitment at all levels, we have made significant strides, bringing total improper payments in our seven high-risk programs from an estimated $2.9 billion, or 11 percent, in FY 2006 to $563 million, or 2.5 percent, in FY 2007. Agencywide training, implementation of program checklists, enhanced instructions, and factoring improper payment reduction into employee performance plans are among the measures leading to this success. Because some of our corrective actions were implemented late in the year, we expect to realize even more improvement in FY 2008.

PROGRAM UPDATES

Disaster Assistance

The Agricultural Assistance title of Public Law 110-28 authorizes disaster assistance to producers through the Crop Disaster Program (CDP), Livestock Compensation Program (LCP), Livestock Indemnity Program (LIP), Dairy Disaster Assistance Program (DDAP), and Emergency Forestry Conservation Reserve Program (EFCRP), as well as providing supplemental funding for the Emergency Conservation Program. The Consolidated Appropriations Act, 2008, extends eligibility for the CDP, LCP, and LIP.

The CDP is available to producers who suffered quantity and quality losses from natural disasters on 2005, 2006, and 2007 crops planted before December 31, 2007, as long as the producers had obtained crop insurance or coverage under the Non-Insured Crop Disaster Assistance Program. Producers who suffered losses in more than one crop year must select only one year for benefits. Because the software needed to administer quality loss payments is much more complex than that for quantity losses, and because quantity losses were more widespread, we began signup for the quantity loss component October 15, 2007, while quality loss administration was still under development. As of February 12, 2008, we have made quantity-loss payments totaling over $1.13 billion to nearly 172,000 producers.

Signup began on September 10, 2007, for both the LCP, which covers livestock feed losses, and the LIP, which covers losses of livestock, for losses resulting from natural disasters that occurred between January 1, 2005, and December 31, 2007. Both programs are available to producers in primary or contiguous counties with Secretarial or Presidential disaster declarations. Producers incurring a loss in more than one of the eligible calendar years must choose only one year for which to receive benefits. As of February 12, 2008, we have made LCP payments totaling over $150 million to about 122,000 producers, and LIP payments of nearly $7.9 million to over 1,000 producers.

The DDAP assists dairy producers who suffered dairy production losses as a result of natural disasters that occurred between January 1, 2005, and December 31, 2007. Signup was announced on December 3, 2007, but was temporarily suspended to update automation and policy to comply with the extension of the eligible period as authorized by the Consolidated Appropriations Act, 2008, as well as to make minor program modifications based on comments received during the public comment period on the proposed rule. The final program regulations are expected to be published in the *Federal Register* on March 4, 2008, and a 60-day signup period is scheduled to begin on March 5, 2008. Payments are expected to be made in spring 2008.

The EFCRP assists landowners in restoring non-industrial, private forest land damaged by one of the hurricanes that occurred in calendar year 2005. Signup began August 6, 2007, and ended December 31, 2007.

Tobacco Transition Payment Program

The Fair and Equitable Tobacco Reform Act authorized the Tobacco Transition Payment Program (TTPP), also known as the "tobacco buyout" program, which terminated the tobacco marketing quota and price support programs of more than 65 years that had restricted production and kept domestically produced tobacco prices high. The program allows producers and quota owners to sign up for 10 years of transition payments to ease the economic adjustment process.

As of February 2008, CCC had disbursed FY 2008 payments on nearly 293,000 quota holder contracts totaling about $494 million, and close to 129,000 producer contracts totaling about $210 million. Additionally, 100 percent, or 150 successor-in-interest payments for FY 2008 were paid totaling $249 million.

The successor-in-interest provision of the TTPP allows contract holders to transfer their remaining contract rights in full to a third party in return for a lump-sum payment. As of

February 2008, more than 161,000 quota holder and producer contracts valued at $2.5 billion have been sold to lump-sum providers.

TTPP assessments have been issued for FY 2005 through 2007. Annual revisions to reflect late-filed reports and revisions to previously filed reports have been issued for FY 2005 and 2006. Currently, FSA is processing the FY 2007 revisions and the first quarter assessments for FY 2008.

Commodity Credit Corporation (CCC) Stocks-for-Food Initiative

While current high commodity prices are good news for producers, they have created a problem for food aid programs by reducing the amount of products the programs are able to provide their recipients. To alleviate the shortfall, USDA called upon the resources of the CCC. Although CCC cannot transfer the proceeds of commodity sales to the food programs, it does have authority to donate commodities and to engage in barter. Therefore, beginning in FY 2007, we embarked upon a Stocks-for-Food Initiative to exchange commodities in inventory for those needed for food aid distribution. On July 6, 2007, then-Secretary Mike Johanns announced that USDA would exchange uncommitted commodity inventories then valued at approximately $50 million for agricultural products to be distributed through USDA domestic and international food assistance programs. Eighty percent of the value was targeted for domestic food assistance.

The initial barters conducted in July and August exchanged corn and soybeans for vegetable oil and corn-soy blend for the McGovern-Dole program. Subsequent barters from August 30, 2007, through January 24, 2008, exchanged CCC-owned peanuts and uncommitted wheat stocks for peanut butter and canned meats for Food and Nutrition Service (FNS) programs. A small quantity of wheat was also exchanged for vegetable oil for the McGovern-Dole Program. Title to CCC-owned cotton was transferred to the on-line marketplace The Seam as the front end of a barter to acquire processed commodities for food aid programs. To date, FNS programs have benefited by acquisitions of peanut butter and canned vegetables through this process.

On January 31, 2008, CCC transferred title to all remaining uncommitted inventories, including peanuts, rice, and wheat, to The Seam. The total value expected to be generated from CCC exchange is over $100 million in additional processed commodities for food aid programs, with about $90 million to be used in domestic feeding programs. While we recognize that the release of CCC commodities can be disadvantageous to the warehouses where they are stored, we believe it is a necessary step to address urgent humanitarian needs.

BUDGET REQUESTS

Turning now to the specifics of the 2009 Budget, I would like to highlight our proposals for the commodity and conservation programs funded by the Commodity Credit Corporation (CCC); the farm loan programs of the Agricultural Credit Insurance Fund; our other appropriated programs; and administrative support.

Commodity Credit Corporation

Domestic farm commodity price and income support programs are administered by FSA and financed through the CCC, a government corporation for which FSA provides operating personnel. Commodity support operations for corn, barley, oats, grain sorghum, wheat and wheat products, soybeans, minor oilseed crops, upland cotton and extra long staple cotton, rice, milk and milk products, honey, peanuts, pulse crops, sugar, wool and mohair are facilitated primarily through loans, payment programs, and purchase programs.

The 2002 Farm Bill and the FY 2003 through 2008 Appropriations Acts authorized CCC to transfer funds to various agencies for authorized programs in fiscal years 2002 through 2008. The FY 2009 appropriation is expected to continue this practice. It is anticipated that in FY 2008, $2.1 billion will be transferred to other agencies.

The CCC is also the source of funding for the Conservation Reserve Program administered by FSA, as well as many of the conservation programs administered by the Natural Resources Conservation Service. In addition, CCC funds many of the export programs administered by the Foreign Agricultural Service.

Program Outlays

The FY 2009 budget estimates largely reflect supply and demand assumptions for the 2008 crop, based on November 2007 data, and will primarily reflect current law, with some modifications for a new farm bill. CCC net expenditures for FY 2009 under current law assumptions are projected at $10.5 billion, down from $11 billion in FY 2007 and a record high of $32.3 billion in FY 2000. FY 2008 baseline net expenditures are estimated at $10.2 billion. The overall downward trend in net expenditures reflects higher commodity prices due primarily to growth in demand for bioenergy and increased export demand.

Reimbursement for Realized Losses

CCC is authorized to replenish its borrowing authority, as needed, through annual appropriations up to the amount of realized losses recorded in CCC's financial statements at the end of the preceding fiscal year. For FY 2007 losses, CCC was reimbursed $12.6 billion in FY 2008.

Conservation Reserve Program

The Conservation Reserve Program (CRP), administered by FSA, is in dollar terms USDA's largest conservation/environmental program. For over 20 years it has cost-effectively assisted farm owners and operators in conserving and improving soil, water, air, and wildlife resources by converting highly erodible and other environmentally sensitive farmland to a long-term resource-conserving cover. CRP participants enroll acreage for 10 to 15 years in exchange for annual rental payments as well as cost-share assistance and technical assistance to install approved conservation practices.

The 2002 Farm Bill authorized new enrollments through December 31, 2007, up to a maximum of 39.2 million acres. In FY 2006, 950,000 of the acres offered under the 2006 general signup were approved for enrollment. No general signup was held during FY 2007, but the FY 2007 Continuous and Farmable Wetlands Program (FWP) signups enrolled a combined total of 314,000 acres. As of February 1, total CRP enrollment is 34.7 million acres, about 88 percent of the 39.2 million acres authorized under the Farm Bill.

The Conservation Reserve Enhancement Program (CREP) is a major initiative under CRP that addresses recognized environmental issues of States, Tribes, and the Nation. Community-based and results-oriented, CREP is implemented through cooperation with partners such as States, Federal agencies, and private groups, and is conducted under CRP's continuous signup. FSA currently has 41 CREP agreements with 31 States, with a total of 2.27 million acres reserved for enrollment. This fall, FSA hit the 1-million-acre milestone in nationwide CREP enrollment.

The FY 2009 budget assumes general signups in fiscal years 2008 and 2009 to enroll 250,000 and up to 2.4 million acres, respectively. We also anticipate enrolling about 395,000 acres in FY 2008 and 457,000 acres in FY 2009 under continuous signup and the CREP. However, CRP enrollment is expected to gradually decline from 36.8 million acres at the end of FY 2007 to 32.9 million acres by FY 2011, since high crop prices will be an incentive for farmers to return land to production as contracts expire. Then, assuming continuation of the current program under a new farm bill, CRP acreage is expected to gradually increase, reaching full enrollment in 2017.

Farm Loan Programs

The loan programs funded through the Agricultural Credit Insurance Fund provide a variety of loans and loan guarantees to farm families who would otherwise be unable to obtain the credit they need to continue their farming operations.

The FY 2009 Budget proposes a total program level of about $3.4 billion. Of this total, over $900 million is requested for direct loans and nearly $2.5 billion for guaranteed loans offered in cooperation with private lenders. These levels should be sufficient to provide adequate funding throughout the year. While the total request is slightly below the amount available in FY 2008, it generally reflects actual usage in recent years.

For direct farm ownership loans we are requesting a loan level of $253 million. The proposed program level would enable FSA to extend credit to about 1,900 small and beginning farmers to purchase or improve a family farm. In accordance with legislative authorities, FSA has established annual participation targets for members of socially disadvantaged groups based on demographic data. Also, 70 percent of direct farm ownership loan funds are reserved for beginning farmers; over the past several years, all of the reserved funds have been used for beginning farmer loans. For direct farm operating loans we are requesting a program level of $628 million. The proposed program level would enable FSA to provide production loans to approximately 15,000 family farmers. The Agency also targets a portion of direct operating loan funding to members of socially disadvantaged groups based on demographic data, and 35 percent of the funds are reserved for beginning farmers. Over the past several years, loans made to beginning farmers have exceeded the amount of funds reserved for them. Many beginning farmers are minimally capitalized, and as a result they cannot obtain commercial credit to finance annual crop and livestock production expenses.

For guaranteed farm ownership loans in FY 2009, we are requesting a loan level of $1.22 billion. This program level will provide about 3,800 farmers the opportunity to acquire their own farm or to preserve an existing one. One critical use of guaranteed farm ownership loans is to allow real estate equity to be used to restructure short-term debt into more favorable long-term rates. For guaranteed farm operating loans we propose an FY 2009 program level of approximately $1.27 billion to assist over 6,800 producers in financing their farming operations.

This program enables private lenders to extend credit to farm customers who otherwise would not qualify for commercial loans and ultimately be forced to seek direct loans from FSA.

In addition, our budget proposes program levels of $4 million for Indian tribe land acquisition loans and $59 million for boll weevil eradication loans. For emergency disaster loans, our budget does not request an appropriation since disaster needs are unpredictable.

Other Appropriated Programs

State Mediation Grants

State Mediation Grants assist States in developing programs to deal with disputes involving a variety of agricultural issues including distressed farm loans, wetland determinations, conservation compliance, program payment eligibility, and others. Operated primarily by State universities or departments of agriculture, the program provides neutral mediators to assist producers – primarily small farmers – in resolving disputes before they culminate in litigation or bankruptcy. States with mediation programs certified by FSA may request grants of up to 70 percent of the cost of operating their programs.

For FY 2008, we expect to issue grants to between 33 and 36 States. For FY 2009, the proposed decrease of $369 thousand, to $4 million from $4.369 million in FY 2008, is not expected to significantly impact the program.

Emergency Conservation Program

Since it is impossible to predict natural disasters, it is difficult to forecast an appropriate funding level for the Emergency Conservation Program (ECP), and in recent years the program has been funded through supplemental appropriations. The FY 2009 Budget does not include a request for the ECP. The Agricultural Assistance title of Public Law 110-28 provided $16 million for the program, and an additional $2 million was made available under title V of that law to assist Kansas in recovering from tornado damage. On August 16, 2007, FSA

allocated the $16 million to 18 States. The $2 million for Kansas was allocated in October 2007. During FY 2007, a total of $45.4 million was allocated using funds carried forward from prior years and recoveries of unused prior allocations in addition to the supplemental funding. As of February 28, 2008, $6.3 million has been allocated to States during FY 2008, and $1.6 million remains available for allocation.

Dairy Indemnity Program

The Dairy Indemnity Program (DIP) compensates dairy farmers and manufacturers who, through no fault of their own, suffer income losses on milk or milk products removed from commercial markets due to residues of certain chemicals or other toxic substances. Payees are required to reimburse the Government if they recover their losses through other sources, such as litigation. DIP is an important element in the financial safety net for dairy producers in the event of a serious contamination incident. The program was authorized through 2007 by the 2002 Farm Bill.

As of February 28 we have paid FY 2008 DIP claims totaling $127 thousand in 4 States. During the last 5 years, DIP claims have averaged $331 thousand. The FY 2009 appropriation request of $100 thousand, together with unobligated carryover funds of $152 thousand expected to be available at the end of FY 2008, would cover claims during the year, provided no major contamination incidents occur.

Grassroots Source Water Protection Program

The Grassroots Source Water Protection Program (GSWPP) is a joint project by the Farm Service Agency and the nonprofit National Rural Water Association designed to help prevent surface and ground water pollution through voluntary practices installed by producers at the local level. In priority watersheds in the 37 participating States, rural source water technicians work with FSA State and county directors as well as State conservation specialists to develop water protection plans that outline pollution prevention measures producers can install on their lands.

Legislative authority for the GSWPP expired September 30, 2007. The budget requests no funding for this program.

Administrative Support

The costs of administering all FSA activities are funded by a consolidated Salaries and Expenses (S&E) account. The account comprises direct appropriations, transfers from loan programs under credit reform procedures, user fees, and advances and reimbursements from various sources.

The FY 2009 Budget requests $1.52 billion from appropriated sources including credit reform transfers, for a net increase of about $92 million over the FY 2008 enacted level. The request reflects increases in pay-related and non-pay-related costs to sustain essential program delivery as well as unavoidable increases of $8.1 million in information technology operational expenses to support legacy IT systems and maintain current IT operations during the transition to Web-based systems. It continues to include in the S&E account certain costs previously funded in the Common Computing Environment account, such as consolidated enterprise architecture and common infrastructure, the Universal Telecommunications Network, and enterprise licensing.

FSA has taken aggressive action over the past 5 years to reduce discretionary administrative expenditures and operate within available funding. The FY 2009 budget assumes that the agency will continue that trend of fiscal restraint.

Because the potential provisions of a new farm bill remained uncertain at the time of budget development, the requested funding does not include costs associated with new legislative requirements. The Department will be able to provide cost estimates for administering a new farm bill once the provisions are final.

The FY 2009 request reflects a total of 5,253 Federal staff-years and 9,425 non-Federal staff-years, unchanged from the FY 2007 and 2008 levels. Temporary non-Federal county staff-years will remain at the projected FY 2008 level of 650.

Madam Chairwoman, this concludes my statement. I will be happy to answer your questions and those of the other Subcommittee Members.

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FOREIGN AGRICULTURAL SERVICE

Statement of Michael W. Yost, Administrator
before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Members of the Subcommittee, I appreciate the opportunity to review the work of the Foreign Agricultural Service (FAS) and to present the President's budget request for FAS programs for 2009.

Introduction

Fiscal (FY) 2007 was another record-setting year for U.S. agricultural exports -- $81.9 billion. The forecast for 2008 is even better, with our exports expected to reach $101 billion. If realized, that would be $19 billion more than was exported in 2007 and an unprecedented $32.4 billion increase in exports in a 2-year period. Because imports are rising more slowly, the 2008 trade surplus surges to $24.5 billion, which is more than twice last year's figure.

FAS supported U.S. farmers and ranchers in a number of important ways last year that helped bolster our export performance. We helped successfully conclude trade agreements with Korea and Panama and provided key input and support for implementation of the Central America-Dominican Republic-United States Free Trade Agreement (CAFTA-DR). We opened additional markets to U.S. beef. We ensured a successful implementation to the North American Free Trade Agreement despite some late-breaking political opposition to it in the Mexican legislature. We helped exporters regain market access for millions of dollars of products from pork to grapes to apples. We helped feed people in more than 25 developing countries through our food aid programs.

FAS works to create economic opportunity for American farmers and ranchers by increasing export opportunities. In addition to our Washington-based staff, the Agency maintains a network of overseas attachés, counselors, and trade officers that provide critical market and policy intelligence to support our strategic goals, responds quickly and effectively in cases of market disruption, and represents U.S. agriculture in consultations with foreign governments.

In the 2009 budget, particular emphasis must be placed on maintaining FAS' overseas posts so that their representation and advocacy activities on behalf of U.S. agriculture can continue. Included in the budget is funding to pay for higher operating costs at overseas offices, including increased payments to the Department of State for non-discretionary administrative services. Recent declines in the value of the dollar, combined with overseas inflation and rising wage rates, have led to substantially higher operating costs that must be accommodated if FAS is to maintain an effective overseas presence.

FAS activities can be broadly classified into four areas – market access, trade development, trade-related technical assistance, and sanitary and phytosanitary (SPS) issues resolution. While the first two functions represent the longstanding activities of the Agency, the other two have emerged and rapidly grown in importance in recent years in support of U.S. agriculture and broader U.S. government policy goals.

Market Access

Our core objective continues to be the expansion and maintenance of overseas market opportunities for U.S. agriculture. To continue to see the record gains we have seen over the past 4 years, we must continue to expand existing and idenfity new overseas markets. There are

untapped markets around the world with rapidly growing middle classes and increasing populations.

Expanding access through the negotiation of new bilateral, regional, and multilateral trade agreements that lower tariffs and reduce trade impediments is key to seizing market opportunities. FAS provides the critical analysis, policy advice, and a seat at the negotiating table to help ensure U.S. agriculture achieves substantial benefits in ongoing trade negotiations.

Maintaining our existing market access is also critical to our producers. FAS coordinates with other trade and regulatory agencies to develop effective strategies to avoid or resolve trade-disruptive actions. We utilize the extensive expertise within USDA to pursue solutions to difficult technical issues that restrict trade, such as those related to bovine spongiform encephalopathy (BSE) and biotechnology. FAS monitors foreign compliance with trade agreements. We work closely with the Office of the U.S. Trade Representative to ensure trade agreements are enforced through formal dispute resolution mechanisms.

Trade Development

The goal of our market development programs is to help build new markets and improve the competitive position of U.S. agriculture in the global marketplace. Our price/credit risk mitigation and market development programs support U.S. firms and industries in their efforts to build and maintain overseas markets for U.S. agricultural products. FAS administers two major export development programs – the Market Access Program (MAP) and the Foreign Market Development Cooperator Program (FMD). These programs are part of a unique partnership between FAS and more than 70 industry trade organizations that has helped create, develop, and maintain export markets for a wide range of U.S. food and agricultural products in nearly every corner of the world. In 2007, these programs successfully promoted U.S. soybeans and cotton in

China and the Middle East; U.S. wheat sales to Indonesia; U.S. poultry exports to Vietnam; U.S. almond exports to the European Union (EU), India, China, and Russia; U.S. rice to Turkey, and numerous other successful projects.

Three smaller programs – Technical Assistance for Specialty Crops (TASC), the Quality Samples Program (QSP), and the Emerging Markets Program (EMP) – build on the success of MAP and FMD by providing additional help for industry-FAS joint efforts on market access and technical assistance. All of these programs combine to leverage federal and industry funds to support U.S. agricultural producers and exporters. Trade finance risk mitigation programs include the GSM-102 Export Credit Guarantee Program and the Facility Guarantee Program. They provide payment guarantees for the commercial financing of U.S. agricultural exports, and goods and services that will improve or establish agriculture-related facilities in emerging markets.

Technical Assistance

U.S. agriculture benefits from growth in global trade and a trading system that adheres to international rules and norms. Two-thirds of World Trade Organization (WTO) members are developing countries. Many of them lack the knowledge, expertise, and regulatory policy frameworks necessary to participate in the global trading system. FAS supports the U.S. trade agenda by providing technical assistance to help developing countries become better trading partners and achieve economic growth.

FAS deploys USDA's unique resources and expertise in its agricultural development activities to promote market- and science-based policies and institutions, and sustainable agricultural systems. Promoting productivity-enhancing technologies that will increase food security is a priority. To deal with immediate food security needs, FAS administers food

assistance programs to help countries experiencing humanitarian crises. Over the long term, our food aid programs help support economic development in recipient countries. Combined with trade capacity building (TCB) efforts, recipient countries can be expected to transition from food aid recipients to commercial buyers. In addition, we support agricultural reconstruction in post-conflict or post-disaster countries or regions such as Afghanistan and Iraq.

Sanitary and Phytosanitary (SPS) Issues Resolution

Countries have become increasingly reliant on SPS and technical trade barriers to protect domestic industries and deny market access. FAS works to improve market access for U.S. agricultural products by monitoring and enforcing international SPS rules and participating in the development and adoption of international standards. FAS' efforts include departmental coordination with the Animal and Plant Health Inspection Service (APHIS); Food Safety and Inspection Service; Agricultural Marketing Service; Grain Inspection, Packers and Stockyards Administration (GIPSA) along with the Food and Drug Administration (FDA) and Environmental Protection Agency. We also work with developing countries to improve their regulatory frameworks and integrate their agricultural sectors in the global economy.

Major Activities and Goals

In 2007, FAS dedicated significant effort to the ongoing Doha Development Agenda negotiations of the WTO. The United States believes the Doha Round offers a historic opportunity to not only help American farmers and ranchers export more products, but also to improve the lives of producers and consumers in the developing world. The United States has worked diligently to negotiate a fair agreement in three areas—also known as the three "pillars": export competition, domestic support, and market access. In February 2008, Ambassador Crawford Falconer, chair of the Doha agriculture negotiations, released a revised text, which is

currently being negotiated. To move the process along, Ambassador Falconer has convened a core group of 36 countries for intensive negotiations. Independently, a smaller group of WTO members is supplementing these efforts. The goal is to reach agreement on a more complete text by spring of 2008.

FAS provided critical support to assist with the implementation of CAFTA-DR. The CAFTA-DR countries represent increasingly important markets for the United States, with the combined value of U.S. agricultural exports totaling a record $2.6 billion in calendar year 2007. Under the agreement, the removal of the remaining trade barriers in the region will create a range of new export opportunities for the U.S. agricultural sector.

The agreement formally entered into force with the Dominican Republic in March 2007, which followed similar actions with El Salvador, Guatemala, Honduras, and Nicaragua in 2006. In Costa Rica, the agreement was ratified by popular referendum on October 7, 2007. However, actual entry into force of the agreement remains contingent upon the passage of implementing legislation. At this time, it is anticipated that the implementation of the agreement with Costa Rica will occur by October 1, 2008, or possibly earlier.

FAS played a key role with the Office of the U.S. Trade Representative in concluding negotiations for the Korea-U.S. Free Trade Agreement (KORUS FTA) and the Trade Promotion Agreement (TPA) with Panama. If approved by Congress, the KORUS FTA will provide America's farmers, ranchers, food processors, and businesses they support with improved access to Korea's 49 million consumers. The KORUS FTA would represent the most economically significant trade agreement for U.S. agriculture in 20 years. The KORUS FTA provides immediate elimination of duties for more than 60 percent of current U.S. agricultural exports and

gives U.S. exporters improved access to the Korean market for many more products that have been highly obstructed.

The U.S.-Panama TPA will make duty-free trade a two-way street and is another key building block in the U.S. strategy to advance free trade with the Western Hemisphere. Like the Colombia and Korea TPAs, the Panama agreement requires Congressional approval.

On December 14, 2007, President Bush signed implementing legislation approving the U.S.-Peru TPA. In CY 2007, U.S. exporters sold more than $430 million in agricultural products in Peru and, under the TPA, our agricultural producers will be well positioned to provide an expanded range of high-value and consumer-ready products to this market. The TPA will also help to keep U.S. bulk commodities competitive in Peru. We will continue working with the Peruvian Government in 2008 on implementing rules and regulations.

Under the TPA with Colombia, agricultural trade between the United States and Colombia will change from a one-way street to a two-way street. At present, no U.S. agricultural products enjoy duty-free access to the Colombian market. However, upon implementation of the agreement more than half of current U.S. farm exports to Colombia will become duty-free immediately, and most remaining tariffs will be eliminated within 15 years. On the regulatory side, Colombia has adopted import measures on meat and poultry that are consistent with international guidelines and has resolved other SPS issues that were barriers to trade. Colombia has also agreed to recognize the equivalence of the U.S. meat and poultry inspection systems. This agreement offers great potential for America's farmers and ranchers, and we urge Congress to approve it expeditiously.

Since accession to the WTO in 2001, agricultural trade with China has grown substantially, and today China ranks as the fifth largest overseas market for U.S. agricultural

products. As with any trade relationship of this magnitude, issues remain between the two countries. We participate in a variety of international fora to address and resolve agricultural trade issues. The most recent Joint Committee on Cooperation in Agriculture (JCCA), which addresses China's evolving regulatory system for biotechnology, among other issues, was held in August 2007 in Beijing and led by Farm and Foreign Agricultural Services (FFAS) Under Secretary Mark Keenum. The 18th U.S.-China Joint Commission on Commerce and Trade (JCCT) and third U.S.-China Strategic Economic Dialogue (SED) meetings were held during the week of December 10, 2007, in Beijing and covered many key agriculture-related issues between the United States and China. At these meetings, China agreed to: 1) re-list six pork processing facilities so that exports from these establishments may resume, 2) consider dropping contract reporting requirements, and 3) eliminate requirements that seed companies provide viable seeds for biotechnology testing. FAS and the FDA are partnering with the Chinese government on leadership training on food safety issues for ministry officials. These efforts will lead to a science-based approach to food safety that will improve China's ability to meet international standards.

Biofuels production and use has grown significantly in the United States and in key U.S. agricultural trading partners, resulting in substantial increases in demand for corn, oilseeds, and sugarcane. Expected increases in worldwide biofuels use will affect trade and production of feedstocks and related downstream industries, and trade in biofuels itself. FAS collects information from more than 25 countries and analyzes the world biofuels situation, as well as helps coordinate responses to international biofuels issues. In 2007, the United States signed Memoranda of Understanding (MOU) on biofuels cooperation with Brazil and China. In addition, we are engaged in a number of other international organizations to support increased

biofuels production and consumption. FAS is helping to ensure that U.S. agricultural interests are considered as the U.S. Government plans and engages in such cooperative endeavors. We will participate in the Washington International Renewable Energy Conference (WIREC 2008) in March that brought together over 3,100 government, civil society, and private business leaders from 113 countries to address the benefits and costs of a major and rapid scale-up in the global deployment of renewable energy technology. In addition, more than 4,000 attendees participated in a global business conference that included a trade exhibit showcasing the latest technology in the renewable energy field.

In 2007, we continued our efforts to re-open markets that closed as a result of the finding of BSE in the United States in December 2003. I am pleased to report that on May 22, 2007, the World Organization for Animal Health (OIE) unanimously adopted the recommendation that several countries, including the United States, be recognized as having "controlled" risk status for BSE. The OIE controlled risk classification provides objective international recognition that the science-based mitigation measures in place in the United States effectively manage any BSE risk and justify acceptance of U.S. beef, beef products, and live animals of all ages. We are pleased that progress has been made in , Indonesia, Barbados, Peru, Colombia, Panama, and the Philippines. We continue to press for access based on the OIE guidelines to the Korean, Japanese, Chinese, and Russian markets.

When regulated genetically engineered rice (LLRice601) was found in the U.S. commercial long-grain rice supply, and after the APHIS and the FDA determined its safety, FAS moved swiftly to ensure that foreign market access for U.S. rice was maintained. By providing our trading partners with information about the safety of U.S. rice, including assessments by APHIS and FDA regarding the safety of LLRice601, the impact on our overseas markets was

significantly reduced. In addition, we have worked closely with all segments of the U.S. rice sector and our trading partners to assure that exports of U.S. rice meet foreign countries' import requirements. Russia has been the only country to close officially its market to all U.S. rice and reopened its borders in March 2008. The EU, which implemented emergency sampling and testing requirements on U.S. long-grain rice that constitute a *de facto* prohibition, lifted its emergency measure in February 2008 on adoption of the USDA/GIPSA sampling and testing protocol. All other U.S. rice markets, including Mexico, Japan, Iraq, Haiti, Canada, and Ghana remain open. In calendar year 2007, total U.S. rice exports increased 10 percent.

In the area of trade development, we continue to evaluate and refine our programs to improve effectiveness and efficiency. We developed improved performance measures for our export credit guarantee programs and have taken steps to improve claims recoveries. For our market development programs, we are modifying our collection and reporting requirements so that we can better measure program performance. As a result, we will have a more consistent and systematic approach for program evaluations.

Working with the State Regional Trade Groups and other industry organizations, FAS encouraged outreach efforts that focused on facilitating export readiness for U.S. exporters. FAS' overseas offices also support industry efforts, especially in developing markets, by providing market intelligence and by helping to introduce U.S. exporters to potential foreign customers. In addition, FAS facilitated U.S. participation in a range of international trade shows.

Our Country Strategy Support Fund (CSSF), formerly called the Annual Marketing Plan (AMP), provides funds to support country strategies and focuses on the activity level to open markets for U.S. exports. The CSSF supports projects that are in line with FAS strategic priorities, including market access, communications, and other inherently governmental

activities. Overseas posts define activities within eight areas of work, which cover all of the functional areas of the new FAS structure. These include: Trade Policy/Market Access, Sanitary and Phytosanitary/Technical Barriers to Trade, Market Knowledge and Intelligence, Trade Facilitation, Trade Capacity Building, Strategic Communication, Export Programs, and Unscheduled Events. In 2007, the total amount of CSSF funding was $1.9 million.

We promote agricultural development around the globe, but let me mention just two examples. In response to the President's request for additional civilian advisors, we deployed 20 agricultural advisors to Iraq by the end of 2007. We also work to improve the capacity of the Iraqi Ministry of Agriculture to support growth in the private agricultural sector. Four USDA ministry advisors work to strengthen the Ministry's strategic planning, animal inspection and food safety programs, water and soil initiatives, and agricultural extension efforts. Technical assistance programs focus on helping the government build capacity to deliver more effective agricultural extension, animal health, statistics, and soil and water programs and services.

In Afghanistan, USDA deployed 6 agricultural advisors in 2007. In 2008, that number will increase to 13 in response to the increasing recognition of the positive role that agriculture plays in stabilizing fragile economies. USDA has provided technical assistance to help the government improve its capacity to deliver agricultural extension, animal health, biodiversity, and conservation programs and services.

Trade Capacity Building (TCB) is a critical tool to address the many technical barriers that impede access for U.S. agricultural products in markets throughout the world. By helping countries develop transparent, science-based regulations and by increasing understanding of the U.S. regulatory system, TCB can expand future access for U.S. agricultural products. Likewise, this assistance enables recipient countries to access other markets. As a result of FAS capacity

building efforts, Nicaragua has rewritten its poultry inspection laws and regulations to meet USDA requirements. U.S. poultry products will benefit because they will encounter familiar standards to access Nicaragua, and it also provides Nicaragua access to the United States without compromising U.S. import safety standards. This is just one example of how all countries gain from stronger infrastructure and regulatory systems, frameworks for monitoring and mitigating plant and animal diseases, and compliance with international norms.

TCB also assists international standards-setting bodies. FAS has helped African nations understand Codex Alimentarius food safety standards and build strategic coalitions both within the continent and with the United States to ensure African food products meet international requirements. Additionally, FAS TCB efforts have enabled Serbia to begin meeting International Plant Protection Convention reporting requirements. Adoption of international laws and standards benefits U.S. agricultural exporters and enhances the ability of developing countries to produce safe products for domestic consumption and for trade. This also leads to economic development and growth, and ultimately greater capacity to purchase U.S. products.

Under the Cochran Fellowship Program, we provided short-term training for 730 participants from 71 countries. Cochran participants meet with U.S. agribusinesses, attend policy and food safety seminars, and receive technical training related to market development and TCB. Under the Norman E. Borlaug International Agricultural Science and Technology Fellows Program, launched in 2004, nearly 100 researchers, policymakers, and university staff received short-term scientific training and research opportunities at U.S. colleges and universities in FY 2007.

Our food assistance programs have helped millions of hungry people around the world. For example, our Food for Progress Program (FFP) is targeted to countries that are making

strides toward democracy and private enterprise. The program supports agricultural and economic development projects that are implemented by private voluntary organizations and foreign governments. In 2007, assistance under the program totaled more than 250,630 metric tons of commodities, valued at $97 million, and $50 million of additional support for transportation and other non-commodity costs.

The McGovern-Dole International Food for Education and Child Nutrition Program (FFE) helps support education, child development, and food security for some of the world's poorest children. During 2007, we were able to feed more than 2.5 million people in 15 developing countries, including Cambodia, Guatemala, and Malawi, with the $99 million program level.

FAS developed and continues to refine a new annual performance measure for food aid targeting effectiveness. FAS has also provided baseline data, made improvements in program financial management areas, and taken the lead in an interagency review of food and information technology systems that will lead to further program efficiencies. In 2006, FAS began development of the Food Aid Information System (FAIS), a new database system for USDA's food aid programs. In 2007, FAS completed the design phase of the FAIS and is ready to undertake the build phase. This system will improve program accountability by providing ready access to food aid shipments at various stages, on-line access for cooperating sponsors to file reports, and cost information on commodities and transportation.

Commodity and freight costs for the USDA food aid programs increased during 2006-2008. Prices for the commodities provided as food aid increased by more than 80 percent, with a large portion of the increase occurring over the past 6 months. Average freight costs rose by about $30 per ton under the FFP program and about $50 per ton under the FFE program. To

ameliorate the effects of these increases, FAS has provided substitute lower-cost commodities and spread funding across years to limit the decline in tonnage available to these programs. The Stocks-for-Food Program also helped to limit the impact of increased costs on the FFE program. In July 2007, former Secretary Johanns authorized the exchange of uncommitted CCC-owned commodities for finished food products. Nearly 80 percent of commodities were designated for domestic programs, while 20 percent were to be provided to the FFE program. During 2007, a total of 12,823 metric tons of finished food products, valued at $9.3 million, were made available to the FFE program through commodity exchanges. The initiative is being continued in 2008 and additional food products will be made available to the FFE program.

Along with the U.S. Agency for International Development (USAID), USDA is working to improve the quality, safety, and shelf-life of food aid products by standardizing existing commodity specifications and sampling and laboratory testing protocols. In addition, we are assessing the effectiveness of the commodities currently in our food aid programs in order to enhance the nutritive quality of the food we deliver to needy populations.

In 2008, our goals include bringing the Doha Round negotiations to a successful conclusion, implementing the free trade agreements with Colombia, Korea and Panama, and monitoring existing agreements. We also will continue to press our trade partners to use science-based regulatory systems and follow international guidelines, particularly regarding BSE and products from agricultural biotechnology. Successfully implementing a project to revitalize Iraqi agricultural extension programs and providing agricultural specialists for Provincial Reconstruction Teams throughout Iraq continue to be priorities.

Budget Request

Madam Chairwoman, our 2009 budget proposes a funding level of $173 million and 1,004 staff years. The budget has been developed to ensure the Agency's continued ability to conduct its full array of activities and provide services to U.S. agriculture.

The budget proposes an increase to meet higher operating costs at FAS overseas offices. The FAS network of 101 offices covering over 130 countries is affected by macro-economic events and developments that are beyond the agency's control, but which increase operating costs. These cost increases are necessary to maintain FAS' overseas presence during 2009 so that our representation and advocacy activities on behalf of U.S. agriculture can continue. For example, reduced overseas operating budgets would limit overseas support, reduce regional coverage, and prevent hiring of locally employed staff. The 2009 increases include:

- $2.0 million to fund higher FAS overseas operating costs and activities for 2009. Declines in the value of the U.S. dollar, coupled with overseas inflation and rising wage rates, have led to significantly higher operating costs that must be accommodated in order to maintain our current overseas presence. FAS overseas offices are critical to carrying out the Agency's mission and provide essential support to U.S. exporters, as well as to the wide range of international activities carried out by USDA.
- $2.3 million for increased payments to the Department of State (State) for International Cooperative Administrative Support Services (ICASS) for 2009. State provides common administrative services at more than 200 diplomatic and consular posts overseas that FAS and other foreign affairs agencies help to pay for through the ICASS system. Increased ICASS costs are also due to declines in the value of the dollar and overseas inflation and wage increases.

- $2.5 million for an increased Capital Security Cost Share (CSCS) program assessment for 2009. In 2005, State implemented the CSCS program under which all agencies with an overseas presence in U.S. diplomatic facilities pay a proportionate share for accelerated construction of new secure, safe, and functional diplomatic facilities. These costs are allocated annually based on the number of globally authorized personnel positions. This plan is designed to generate a total of $17.5 billion to fund approximately 150 new facilities over a 14-year period. The current plan estimates the FAS payments from 2009 through 2018 will be $11.1 million annually. However, State is expected to review the costs in 3-year intervals and determine any increases or decreases. The next review will take place in 2011.
- $680,000 for overseas operating costs to fund Private Security Details in Afghanistan. In 2009, FAS will be required to meet the costs of security details previously funded by State. This estimate includes the costs to provide the security necessary to safely conduct activities inside Afghanistan. Such measures include providing the security for trips to and from the airport, supervisory trips for the FAS officer located in Pakistan who covers Afghanistan, biweekly Foreign Ministry in-town meetings, and day trips outside Kabul.

Finally, the budget provides an increase to cover higher personnel compensation costs associated with the anticipated 2009 pay raise. Pay cost increases are mandated and must be funded by the agency. Without sufficient funding, absorption of these costs in 2009 would primarily come from an extension of current hiring restrictions and possibly reductions in Agency personnel levels. This would significantly affect FAS efforts to improve access to export markets for U.S. agriculture, facilitate growth in global agricultural trade, and address expanding restrictions on U.S. exports due to SPS and other technical trade barriers.

Export Programs

Madam Chairwoman, the 2009 budget includes approximately $4.7 billion for programs administered by FAS that are designed to promote U.S. agricultural exports, develop long-term markets overseas, and foster economic growth in developing countries.

Export Credit Guarantee Programs

The budget includes a projected overall program level of $2.7 billion for export credit guarantees in 2009. Under these programs, the CCC provides payment guarantees for the commercial financing of U.S. agricultural exports and goods and services to improve or establish agriculture-related facilities in emerging markets. As in previous years, the budget estimates reflect the level of sales expected to be registered under the programs and can change depending on world financial market conditions, program demand, and other relevant factors during the course of the year. A recent independent analysis of the GSM-102 program revised assumptions on historical loan recovery and loan restructuring that resulted in reducing the estimated "subsidy" rate for the GSM-102 portfolio from over 2 percent to 0.87 percent or 87 basis points. The subsidy budget authority is provided to account for anticipated claim payments. Therefore, due to FAS' management and oversight, the 2009 guarantee programs reflect a $27 million reduction in the required budget authority from 2008 without reducing actual program levels.

Market Development Programs

Funded by CCC, FAS administers a number of programs in partnership with private sector cooperator organizations to promote the development, maintenance, and expansion of commercial export markets for U.S. agricultural commodities and products. For 2009, the program levels for the Foreign Market Development Cooperator Program, Emerging Markets Program, and Technical Assistance for Specialty Crops Program are expected to be established

in the new Farm Bill. The CCC budget baseline provides funding of $200 million for the Market Access Program, which could change as a result of congressional action on the new Farm Bill, and $2.5 million for the Quality Samples Program.

International Food Assistance

The United States continues to play a leading role in providing international food assistance. In this regard, the 2009 budget includes an overall program level for U.S. foreign food assistance of $1.8 billion consisting of:

- $1.4 billion for P.L. 480, which includes appropriated funding of $1.2 billion requested in the budget, plus projected reimbursements from the Maritime Administration for prior year cargo preference-related expenses. The budget proposes that all P.L. 480 food assistance in 2009 be provided through the Title II donations program, which is administered by USAID. In recent years, there has been significant decline in demand for food assistance provided through concessional credit financing and, accordingly, no funding is requested for Title I credit sales and grants. The budget again proposes the authority to allow up to 25 percent of Title II funding to be used to purchase commodities locally or regionally.

- $340 million for the CCC-funded FFP program. Funding at that level is projected to support approximately 400,000 metric tons of commodity assistance.

- $108 million for the McGovern-Dole FFE program. This is comprised of $100 million in appropriations and an estimated $8 million in reimbursements from the Maritime Administration. Funding at this program level will assist an estimated 2 million women and children through the donation of nearly 70,000 metric tons of commodities.

Agricultural Reconstruction Activities

FAS coordinates USDA's efforts to assist in agricultural reconstruction activities in Afghanistan and Iraq, including providing technical advisors assigned to Government Ministries in Iraq and on Provincial Reconstruction Teams (PRTs) operating in the rural provinces of Afghanistan and Iraq. The PRTs promote economic development and stability in rural areas by addressing a wide range of problems brought on by years of neglect and mismanagement. USDA advisors, who serve in temporary assignments on the PRTs, provide a variety of technical expertise in support of agricultural reconstruction and rural development activities, offer advice to non-governmental organizations, and assist local authorities in setting agricultural priorities. The 2009 budget includes $12.5 million in the Office of the Secretary to help support the costs of participating in these activities.

Dairy Export Incentive Program

FAS administers the Dairy Export Incentive Program (DEIP) through which bonus payments are made to exporters of U.S. agricultural commodities to enable them to be price competitive in overseas markets where competitor countries are subsidizing sales. Although the program has been inactive in recent years, the budget includes $3 million for DEIP, as a contingency should market conditions change that would warrant reactivation of the program. The actual level of bonuses awarded could change during the programming year depending upon market conditions and U.S. competitiveness factors.

This concludes my statement, Madam Chairwoman. I will be pleased to answer any questions.

RISK MANAGEMENT AGENCY
FEDERAL CROP INSURANCE CORPORATION

Statement of Eldon Gould, Administrator
before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies

Madam Chairwoman and members of the Subcommittee, I am pleased to present and discuss the fiscal year (FY) 2009 budget for the Risk Management Agency (RMA). This budget reflects a conservative funding level - - and modest increase - - for the discretionary Administrative and Operating (A&O) Expense Account and significant increases for the mandatory Federal Crop Insurance Corporation (FCIC) Fund. The mandatory request reflects estimated savings from the Administration's Farm Bill proposals. Also included is language to address, in a budget neutral manner, critical Agency information technology (IT) requirements.

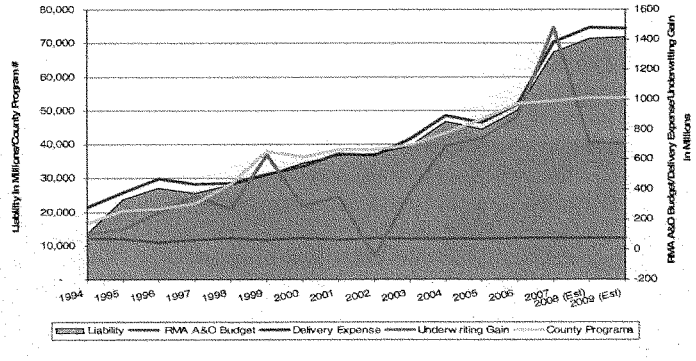
The progress of the Federal crop insurance program may be measured in several ways. Key measurements are the number of policies sold, net acres insured, the level of risk protection coverage underwritten, and the participation rate. This past crop year, over 271 million acres were insured, including acreage in all 50 states, more than 1.1 million policies earned premium, $67.3 billion in risk protection was provided, and a participation rate of 80 percent was maintained for the principal crops. The following is an overview of projected program growth in 2008 and 2009:

Program Data	Crop Year 2007 Actual	Crop Year 2008 Estimate	Crop Year 2009 Estimate
Policies	1,137,000	1,140,000	1,140,000
Acres Insured	271,400,000	284,500,000	287,800,000
Liability-Risk Protection Coverage	$67.3B	$71.3B	$71.8B
Participation Rate	80%	80%	80%

As you can see, the crop insurance program has grown significantly over the last couple of years. Even more significantly, the crop year 2009 liability, projected as $71.8 billion, is 44 percent higher than the crop year 2006 level of $49.9 billion. In part, the growth of the program can be attributed to the increase in the number and complexity of counties/programs offered as shown in the graph below.

In order for the Federal crop insurance program to support risk protection coverage of $71.8 billion in 2009, an appropriation of $6.7 billion is required. The funding level proposed for the FCIC Fund is $6.6 billion, and for the A&O Expense Account, $77.2 million.

Comparison of RMA Administrative and Operating Budget to Program Growth Indicators



A&O EXPENSES

RMA's FY 2009 request of $77.2 million for Administrative and Operating Expenses includes a net increase of $1.1 million. This net increase includes pay costs for existing employees. The 2009 request will help to maintain current staffing levels, which is critical to RMA's ability to continue to operate the Federal crop insurance program. The budget request also includes appropriation language that would allow RMA to fund critical information technology modernization through existing mandatory funding.

FCIC FUND

The FY 2009 budget proposes that under current statute "such sums as may be necessary" be appropriated to the FCIC Fund. This ensures the program is sufficiently funded to meet estimated growth based on the latest program indicators. We anticipate that 63 percent of the request, or $4.1 billion, will be needed for premium subsidy. Without subsidized crop insurance premiums, many producers, especially minority and limited-resource farmers and ranchers, likely will opt not to participate in the crop insurance program due to financial hardship, or they will reduce coverage levels; leaving them inadequately protected in the event of a crop loss. Premium subsidy encourages participation in the program and encourages producers to purchase higher levels of coverage thereby providing a viable safety net. For example, last April, the Kansas wheat crop suffered devastating losses due to freeze and excess moisture. Because over 70 percent of the insured growers in that state had purchased some form of revenue insurance, RMA and reinsured companies were able to quickly and efficiently provide growers nearly $396 million in loss payments, without additional disaster funding from Congress.

For delivery expenses paid to the reinsured companies, the FCIC budget estimate includes $1.5 billion - - 22 percent of the budget request - - to reimburse the reinsured companies for administrative expenses associated with selling and servicing crop insurance products per the Standard Reinsurance Agreement between the government and the participating companies. The budget also estimates that the participating companies

will receive about $709 million in underwriting gains. Also included in the budget are $936.1 million for excess losses above estimated producer premium and $74.5 million for Agricultural Risk Protection Act (ARPA) initiatives, which are 14 percent and one percent of the budget request, respectively. The basis for premium subsidy, delivery expenses, and excess losses stems largely from USDA's latest projections of planted acreage and expected higher market prices.

FARM BILL LEGISLATIVE PROPOSAL

The request includes mandatory savings of about $277 million resulting from the Administration's Farm Bill proposals, which include specific proposals for crop insurance. These include allowing farmers to purchase supplemental insurance that would cover their deductible in the event of a county wide loss, reducing the expected loss ratio from 1.075 to 1.000, along with a continuation of a series of crop insurance reforms that have been proposed in the past to increase program participation and at the same time control program costs.

Information Technology

RMA's existing information technology (IT) system is more than a decade old, well past its expected useful life. New plans of insurance such as revenue insurance - - livestock,

and innovative indexed programs to cover pasture, rangeland, and forage (PRF) - - have greatly increased the size and complexity of the crop insurance program. These changes place a greater burden on the aging IT system resulting in increased maintenance costs and limits RMA's ability to comply with Congressional mandates pertaining to data reconciliation with the Farm Service Agency. Recent years have seen increases in "down-time" resulting from system failures. We must update our antiquated IT systems or a catastrophic system failure will occur.

RMA has spent funds gathering information and developing the user requirements necessary to build a business case for IT modernization that is fully supported by the Office of Management and Budget and the USDA Office of the Chief Information Officer. Unfortunately, this project was suspended however additional funding would allow the continuation of the modernization project.

Funding availability for IT modernization greatly impacts our ability to implement many planned program improvements. For example, in 2006, RMA published a proposed rule that was to have replaced the Actual Production History (APH), Crop Revenue Coverage (CRC), Income Protection (IP), Indexed Income Protection (IIP), and the Revenue Assurance (RA) plans of insurance and offer producers a choice of revenue protection - - protection against loss of revenue caused by low prices, low yields, or a combination of both - - or protection for production losses only - - within a single policy. This was intended to reduce the amount of information producers must read and understand to determine the best risk management tool for their operation and to improve prevented

planting and other provisions to better meet the needs of insured producers. This combined policy would have covered nearly 85 percent of FCIC's total liability and approximately 94 percent of all policies earning premium. Funding for IT modernization would allow the completion of this project.

Further, in July 2007, the FCIC Board of Directors approved a private sector proposal to extend livestock coverage to dairy producers in over 35 States - - including the 15 underserved States - - mostly in the Northeast - - listed below. This pilot program would have provided the first meaningful protection for dairy producers. Availability of IT funding would allow implementation of this program.

Clearly, IT modernization is crucial to RMA's ability to continue operating the Federal crop insurance program. Consequently, the 2009 President's budget includes two options for securing the necessary funding. First, the budget includes a legislative proposal that would require reinsured companies to share in the cost to develop and maintain a new and efficient IT system. Companies participating in the program would be assessed a fee based on about one-quarter cent per dollar of premium sold. The fee is estimated to generate an amount not to exceed $15 million annually beginning in 2010. As noted above, participating companies receive considerable compensation from the Federal government for participating in the crop insurance program. In 2009, total compensation for delivery expenses and underwriting gains are expected to exceed $2.1 billion. This proposal asks for less than 1 percent of that amount to be used to build and maintain the IT system that makes that level of compensation possible.

Second, the 2009 President's budget includes language to expand the authorized purposes for mandatory Research & Development funds provided by the Agricultural Risk Protection Act of 2000 (ARPA). During fiscal years 2006 and 2007, RMA's data mining and data warehousing activities were funded from the discretionary appropriation provided by Congress. However, Congress encouraged USDA to find a source of mandatory funding in future years. For fiscal year 2008, Congress adopted language authorizing the use of existing mandatory funding provided by ARPA to fund both data mining and the Congressionally mandated Comprehensive Information Management System. The proposal in the 2009 budget request would further expand the authorized purposes of the ARPA funds to include the development, modernization, and enhancement of the information technology systems used to manage and deliver the crop insurance program.

PROGRAM MANAGEMENT

The following is an update on accomplishments and ongoing operations that reflect major program management activities to support our strategic goal to: "Preserve and strengthen the economic stability of America's agricultural producers by promoting and supporting the use of sound risk management tools among farmers and ranchers."

Pasture, Rangeland, and Forage Pilot Programs

FCIC now offers two new pilot Group Risk Protection risk management programs for pasture, rangeland, and forage. These innovative pilot programs are based on vegetation greenness and rainfall indices and were developed to provide livestock producers the ability to purchase insurance protection for losses on forage grazed or harvested. These programs were developed to become a risk management tool for the 588 million acres of U.S. pastureland and the 61.5 million acres of hayland. Beginning with the 2007 crop year, the pilot programs were available for testing in selected States with 9,713 policies sold covering more than 28.5 million acres. Presently, producers have been paid over $25.5 million from these pilot programs.

Livestock Risk Protection (LRP)

LRP insures against a decline in prices for cattle and swine. LRP is owned by a private company and was first introduced for swine with sales beginning on July 8, 2002, for all counties in Iowa. LRP expanded to cover feeder cattle and fed cattle with sales beginning on June 9, 2003. LRP now insures swine, feeder cattle, and fed cattle in Colorado, Indiana, Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, North Dakota, Oklahoma, Ohio, South Dakota, Texas, Utah, West Virginia, Wisconsin, and Wyoming. In addition, beginning in the fall of 2007, LRP started insuring lambs with liability over $44 million as of February 2008. LRP sales for the 2007 crop year totaled 4,564 policies with 148,309 head of livestock insured at $67.5 million in liability and $1.3 million in total premium.

Livestock Gross Margin (LGM)

LGM is a gross margin index, designed to protect profit margins for swine and cattle producers, and is based on futures contracts at the Chicago Mercantile Exchange and the Chicago Board of Trade. For the 2007 reinsurance year, LGM has provided coverage for 354,647 head of slaughter hogs for a liability of $27.1 million with a premium of $1.6 million. For the 2007 reinsurance year, LGM has provided coverage for 13,219 head of beef cattle for a liability of $15.1 million with a premium of $327 million. LGM for cattle was available for sale to producers in early 2006. As noted above, in 2007 the FCIC Board of Directors approved LGM for dairy in over 35 States; however, implementation is delayed pending modernization of the RMA information technology system.

Federal/State Loss Adjuster Licensing and Rebating Enforcement Initiatives

RMA has initiated a cooperative effort with the National Association of Insurance Commissioners to establish a uniform way to license loss adjusters as well as curb illegal rebating schemes. Involving the state departments of insurance creates a two way flow of information that did not exist concerning rebating schemes that could violate State or Federal law. Working with the States and National Crop Insurance Services - - to ensure uniform loss adjustment training and testing - - will help supply trained and licensed loss adjusters for the Federal crop insurance program.

Risk Management Education and Outreach

Through development and coordination of partnerships, RMA provided risk management education and outreach to over 49,000 agricultural producers and representatives during over 124,900 hours of RMA sponsored training at meetings and workshops throughout the United States.

RMA executed cooperative agreements in 15 underserved States - - Connecticut, Delaware, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Utah, Vermont, West Virginia, and Wyoming - - totaling $4.5 million in funding; funding 93 partnership agreements across the nation totaling $5.1 million; working with the Cooperative State Research, Education and Extension Service to fund $5 million in risk management education grants; and cooperating with the National Future Farmers of America (FFA) Foundation in operating the 11th Annual FFA Risk Management Writing Contest.

The Community Outreach Partnership Program included funding, administering, and providing substantial involvement for 65 outreach projects in 28 states, totaling over $8.3 million. These programs are aimed at providing women, and limited resource farmers and ranchers with the information and training necessary to make informed decisions regarding the use of existing and emerging risk management tools. Through Partnership Agreements, RMA sponsored a National Outreach Conference entitled "Risk

Management Strategies for Beginning and Small Farmers and Ranchers" to train users to disseminate information from the Regional Conferences entitled, "Success Strategies for Small and Limited Resource Farmers and Ranchers".

Additionally, RMA entered into a Memorandum of Understanding with the National Society of Minorities in Agriculture, Natural Resources and Related Sciences (MANRRS) to promote diversity in agriculture, natural resources and related sciences. RMA's initiatives include servicing agricultural producers through effective, market-based risk management solutions; promoting outreach efforts to diverse communities and organizations regarding the mission of RMA; and encouraging minorities and women students and professionals to consider careers with RMA. RMA has awarded $10,000 in scholarships to MANRRS for four years. RMA representatives attended the MANRRS 22nd Annual Career Fair and Training Conference. RMA also participated in the Hispanic Youth Symposium.

Compliance Activities

RMA, the Farm Service Agency (FSA) and our participating private insurance companies continued to improve program compliance and integrity through reconciling and matching data for disaster program payments, evaluating and amending procedures for referring potential crop insurance errors or abuse between FSA and RMA, and providing distance learning training packages as required by ARPA. RMA has also improved efforts to integrate ad hoc data mining projects, explore avenues to expedite the

processing of sanctions requests, and continues to improve the case management and tracking system.

The formalized alliance with FSA, along with data mining and analysis, greatly improved referral of questionable activities or conditions to and from RMA. This is attributable to the greater emphasis placed upon deterrence and prevention efforts. In order to deal with the referral activity and the responsibilities of data reconciliation with FSA, RMA has sought to manage the increase in workload by increasing emphasis on data management and computer based resources, increasing the Agencies urgent need for IT updates. RMA continues to develop strategies to increase program compliance through data mining and integration tools to evaluate, track, and improve program compliance and integrity.

CONCLUSION

This concludes my statement, Madam Chairwoman. I would be pleased to answer any questions that you and other members of the Subcommittee may have. Thank you.

Ms. DELAURO. Thank you very, very much, Dr. Keenum. I apologize for not mentioning the Stocks for Food program in my opening remarks. It is something I think is very interesting. It is a unique idea, and I commend you for looking at all of the areas in which we can continue to address and look at what we have that we might be able to engage in, in order to meet both the domestic and international food aid crisis that we have.

Let me move to the computer.

Mr. KEENUM. Yes, ma'am.

FSA INFORMATION TECHNOLOGY

Ms. DELAURO. The subcommittee has asked for many years and at many hearings what long-term plans to modernize FSA's delivery of the farm programs, including requests for funding. In fact, the long-term project called MIDAS has been in the planning stages since 2004. GAO just briefed the subcommittee staff—and there is a report in March of 2008—they briefed the subcommittee on their review of FSA's plans for stabilizing and modernizing its farm program delivery system.

This is what GAO pointed out:

Several serious flaws in how FSA has been proceeding and stabilizing and modernizing the systems. Plans you have developed do not adequately assess cost and schedule estimates by using key information such as MIDAS's business requirement, which you are just now in the process of developing.

GAO further states that you have not addressed key managerial issues, such as there are no clearly defined organizational roles and responsibilities between FSA's chief information officers and the Department's chief information officer, and no tracking system for users to report problems with the system.

In your testimony, you have suggested to Congress a proposal requesting authority to assess farm program beneficiaries in order to secure accurate resources to implement the needed technology. Your plan currently estimates a 2-year implementation schedule and that the cost of MIDAS will be $454 million, of which $62.5 million was provided in 2007 through supplemental funding and redirection of salaries and expenses funding. What basis did you use for coming up with this cost in the schedule estimate?

Mr. KEENUM. Madam Chair, we have been working very closely with our Chief Financial Officer at the Department who as taken on the responsibility of leadership for our MIDAS program. It has been a program that we have been working on, as you mentioned, for some time. We have had to engage the Office of Management and Budget to get their approval for us to be able to submit our proposals to the Congress. As you pointed out, it is a $455 million initiative, of which around $60-some-odd million has been made available through, again, supplemental appropriations and other redirecting of funds within the Agency.

All told, to get the program implemented, we will need about $392 million, and we have looked to the authorizing committees, Madam Chair, to assist us in identifying ways to come up with those funds. This is a long-term initiative. As we talked about earlier, our computers are outdated. We are using 1980s-era computer systems, and we are in desperate need to upgrade and modernize

our computer systems. And it is a tremendous challenge to FSA in meeting our delivery obligations to farm clientele because of the outmoded and outdated computer systems that we are operating with.

Ms. DELAURO. I think we are looking at estimates almost after the fact. Shouldn't they have been based on actual business requirements for MIDAS to build a reliable cost and time estimate? Can you give us an example of a modernization project of the same size as MIDAS that was able to be completed within 2 years? In your plans you assumed it would take 10 years to complete MIDAS, so——

Mr. KEENUM. If you don't mind, I will ask our Administrator to respond to that specific inquiry.

Ms. LASSETER. I would just say that technology has changed so much, FSA has gone from writing many of our own programs and developing—to moving to more off-the-shelf software. We are in the process of reviewing our business processes to see how we can streamline, and we have indeed hired an SES project manager for MIDAS who is working on this full time with the Chief Financial Officer for the Department in OCIO and our FSA OC, our financial officer and the computer specialist. So it is all tied together.

And Dr. Keenum and I get a report from the senior management oversight committee, so we feel like we are using our resources as best we can to make sure that we do what we should do.

Ms. DELAURO. I understand. I still don't get a sense, I don't get a sense of the basis that you use for coming up with cost and schedule of estimates and what are the business requirements for MIDAS so that you could build in this cost in a time estimate. Two years. What is the reality of 2 years versus prior information that said 10 years? There is a big gap.

You also made a proposal you say you are suggesting to the Congress. Have you submitted proposed legislation or a budget amendment to pay for MIDAS? What is the proposal?

Mr. KEENUM. We worked with the authorizing committee to ask the committee as they put forward their farm bill to include an assessment on farmers. We have identified mechanisms on how we can do a very nominal fee assessment on producers. We have 2 million farmers in this country——

Ms. DELAURO. Was this in the farm bill?

Mr. KEENUM. Farm bill?

Ms. DELAURO. What you are talking about, is this in the farm bill?

Mr. KEENUM. We are still working with the authorizing committees on this very topic. We are working with them and communicating with them. We have made numerous presentations, numerous presentations to the Members, to the Chairman, the Ranking Member and our members of the committee and senior staff. Yesterday, we were talking with the committee staff on this very initiative.

Ms. DELAURO. What is the proposal?

Mr. KEENUM. Well, the proposal is that we do an assessment—we proposed assessing a $50 fee on all producers who are recipients of farm program benefits. And that fee would be used to help——

Ms. DELAURO. A user fee?

Mr. KEENUM. A user fee, that is correct.

Ms. DELAURO. What is the likelihood of getting a user fee?

Mr. KEENUM. Well——

Ms. DELAURO. Is it slim and none, and slim left town? I mean I don't know. Proposals for user fees——

Mr. KEENUM. I wouldn't characterize it as that, Madam Chair, because the members of the authorizing committees, the chairmen of both committees, really understand the needs and the challenges we are facing because of our IT situation. Will they do a user fee? I don't know. And we have told them and we are working with them and we have provided language to them on this topic. We have told them we are willing to negotiate, work with them to find a reasonable way to assess farmers in a way that really is so nominal that when a farmer gets a $40,000 payment, a direct payment—and we are talking about as much as $50—it is not a very big assessment to a farmer.

But having said that, there are opportunities to look to other ways through offsets and spending and other areas to come up with the needed moneys that we are looking at.

Mr. BOYD. Madam Chair, would you yield?

Ms. DELAURO. Go ahead.

Mr. BOYD. What about a farmer that gets a $500 payment, is he going to pay $50 just the same as the $40,000 or——

Mr. KEENUM. Congressman Boyd, that is a good question. Part of our negotiation is we have identified the fact that there are farmers who get very small payments, and we were looking at doing a de minimis exemption or waiver that farmers who make small payments should not be required to make this kind of a contribution.

Ms. DELAURO. But none of this is sorted out. What happens with the farm bill? The deadline is not in there. I am hopeful that by the 18th we will have a bill; but at the moment, it is not here. What happens? Are you coming back? What is your plan if it is not in the farm bill?

Mr. KEENUM. Well, Madam Chair, that is a very good question and——

Ms. DELAURO. And it needs a very good answer.

Mr. KEENUM. Well, we are working with the authorizers to try to get the funding. And to come to you all to say we need $392 million, we know the challenges that that presents. And so our hope is that we will be able to prevail upon——

Ms. DELAURO. Well, that is why—right, hope is wonderful, we all—I am from a place called hope, but hope is not reality. But the very fact of the matter is that this is—it is critically important, and that is why I asked my prior questions about what the estimates were based on and what the costs were based on, because if you are going to come to this committee with the $392 million request, I think I can speak up for both sides of the aisle here, saying you better have it nailed down, chapter and verse, as to what it is about, what it is based on, what are the estimates, have you looked at other systems. All of the questions that we are going to ask because of due diligence.

We know that this is a problem, but what I don't get a sense of—and I just say this before you come before this subcommittee ask-

ing for a go-ahead here—you really need to be dealing with a business plan that is a business plan and not just, you know, some hope.

Mr. KEENUM. Well, I agree with that. We feel that the business plan that has been prepared by our Chief Financial Officer, working with our officials in FSA clear through the Office of Management and Budget, is very detailed. And it has been provided. I know it has been provided to members of this—committee staff have been briefed on this, but I will turn to our Administrators to add additional comments.

Ms. LASSETER. We actually have been working on the business plan for 2 years. It was approved by OMB in November of 2007. It was not in time to be in this budget. And in putting together that plan, this team did review comparable projects at RAS, at USDA and at Department of Defense.

Ms. DELAURO. Are NRCS and RMA going to be able to communicate with these systems with what you are doing, or are we going to wind up with a situation where we have agencies who can't communicate because of the nature of the software or whatever. I am going to wrap up, my friends here, but I want to get to the end of this conversation.

Ms. LASSETER. I cannot answer to you today the extent of the communication. I don't know exactly if you are talking about us just communicating or actually sharing all of our——

Ms. DELAURO. No, the related systems are going to be able to communicate with what you are doing—the interoperability, which is a wonderful word we have used for Homeland Security. Are all these agencies and their computer systems going to be—I am coming kicking and screaming into the 21st century here, so I am not a maven in the technology, but there are others here who are. You know, are we stovepiping here, and then we have this one over here that we spent a ton of money on, and the other agencies, RMA or NRCS, can't communicate with you.

Ms. LASSETER. I am told no stovepipe. We will communicate.

Ms. DELAURO. Final question. Are you addressing the managerial issues raised in the GAO report, because that will be critical as to whether or not we deal with serious funding.

Ms. LASSETER. Yes. And there were indeed nine pages of comments given back to GAO on that report. Of course, we don't agree with everything they said, and we made comments.

Ms. DELAURO. We also will be looking at what the timetable is as to readdressing the problems that GAO laid out. So we know if we move in this direction we are standing on solid fiscal ground. Thank you.

Mr. Alexander.

Mr. ALEXANDER. No.

Ms. DELAURO. Ms. Emerson.

FOOD AIR COST INCREASES

Mrs. EMERSON. Thank you, Madam Chair.

I am not going to talk about computers, although one wants to after that discussion.

Dr. Keenum, the administration managed in its budget to actually budget for higher commodity prices, so you all showed sharp

decline in marketing assistance loans and countercyclical payments. Tell me how you all have budgeted for the impact that the same commodity prices will have on the effectiveness of our food aid programs.

Mr. KEENUM. Well, I think as Madam Chair mentioned earlier about the increases that we have seen in our food commodities according to USAID and challenges that they face and are facing—and we are all facing in our food aid programs—the biggest increases that we have seen in and these commodity prices have occurred since the beginning of this fiscal year, October of last year. We have seen a huge surge or spike in commodity prices that really no one could foresee, particularly in putting together the budget for fiscal year 2009.

When we submitted our budget earlier, we did look at challenges that we are facing. Particularly when we looked at our farm bill proposals, we did take into consideration the challenges that we face in anticipation of higher shipping costs. This is an issue that is a big issue with us: meeting our food aid obligations as the commodity price increases. We have seen the average shipping costs for shipping our food products increased by over $30 a ton, and that is for our bulk commodities. And products we see under McGovern-Dole, we have seen the shipping costs increase by nearly $50 a ton. So those have big impacts on all of our food aid programs and our ability to meet our humanitarian obligations.

Mrs. EMERSON. Obviously, higher prices just in general from whatever means that we are going to have less food for emergency programs. So you know, the decisions about where do the cuts come from, do we cut rations, cut participants, or the aid intended to prevent emergencies from happening in the first place? Those are tough questions.

STOCKS-FOR-FOOD PROGRAM

Mr. KEENUM. Those are tough questions. And I think when we were looking at last summer our situation with our surplus commodities in CCC inventory, one of the things we did realize is that we were going to have more demands on our food aid programs and challenges because of these higher costs of shipping and also higher commodity prices. That is one of the reasons we did get so engaged in trying to meet those needs with our Stocks-for-Food program by providing over—actually, since July, will have provided and committed over $20 million of assistance. And our technical staff that worked with the McGovern-Dole program has informed me that that will help us mitigate these added costs for food and transportation so that we will not have to cut rations, as you mentioned, or have to take participants off the rolls for the McGovern-Dole program.

INTERNATIONAL HUNGER RELIEF SUPPLEMENTAL

Mrs. EMERSON. And I appreciate all that you have done to try to mitigate some of the challenges that we face.

Recently the Chairwoman and Congressman LaHood, me, and several of our colleagues wrote a letter to the President seeking additional resources for international hunger relief. We have received the traditional $350 million supplemental budget request, but there

is that funding gap that still remains. And I think the last request I saw was about $500 million that we were short.

In regard to that supplemental request, what rule do you all have at USDA as compared to USAID or OMB in deciding what the size of that might be?

Mr. KEENUM. Well, obviously USAID is the lead agency for making recommendations for supplemental requests, working with OMB. We do have an interagency Food Assistance Policy Council that we participate in. We rely on the leadership of USAID to make the determinations, because these moneys are going to the Title II Program, which is a program that they have oversight over, and they know best what their international needs and obligations are going to be.

Mrs. EMERSON. In our letter to—let me just mention that we suggested the possible use of the Bill Emerson Humanitarian Trust in fiscal year 2008. How do you all, who obviously administer that trust, view its use to meet any projected current food aid shortfalls?

Mr. KEENUM. Well, just to give you a perspective, the Bill Emerson Trust today has 915,000 metric tons of wheat; that is 33.6 million bushels. It has a current value of around $326 million. Plus we have $117 million of cash in the Bill Emerson Trust, so that is almost $450 million of value that is in the Bill Emerson Trust right now that could be used for any supplemental humanitarian food aid needs. And one thing about that is that any commodities that are drawn out of the Bill Emerson Trust for the purposes of humanitarian aid, Title II, the shipping cost is paid out of CCC. We estimate that to be about $500 million.

Mrs. EMERSON. So the shipping U.S. Made it 500 million?

Mr. KEENUM. Five hundred million for shipping costs. So the total value of the Bill Emerson Trust is just shy of a billion dollars in value that could be used for humanitarian food aid needs. And as you mentioned, there is a $350 million supplemental before the Congress. We are going to continue, if we receive those funds, working with USAID, to monitor the needs that we are facing. And we do have this Emerson Trust, and characterize it as somewhat of a safety blanket that we can draw from. Since 1985, we have tapped the Emerson Trust 12 times. So it is a wonderful resource to have at our disposal if it is determined to be in fact needed.

Mrs. EMERSON. I appreciate that. I am embarrassed to admit that I don't know—are there minimal levels that we are required to keep in the trust?

Mr. KEENUM. It is 4 million metric tons. That is the cap. It is not the minimum, it is the maximum.

Mrs. EMERSON. Okay. But we don't have a minimum?

Mr. KEENUM. No, ma'am.

Mrs. EMERSON. So we do have the ability to tap into whatever we need from that if the need arises?

Mr. KEENUM. That is correct.

Mrs. EMERSON. Thank you. Thank you, Madam Chair.

Ms. DELAURO. Mr. Jackson.

P.L. 480 LOCAL PURCHASE PROPOSAL

Mr. JACKSON. Thank you, Madam Chair, and thank you, members of the panel. Last year the panelists discussed a proposal by

the administration that will allow up to 25 percent of Title II funding to be used for the purchase of foreign agricultural products. Instead of giving food, the United States will give a check. While I understand both sides of the argument, I am very concerned about potential job loss in the city of Chicago. The Port of Chicago has a major involvement in the food aid program. Approximately 25 percent of all Title II food is loaded onto shipping containers at that port. These are very labor-intensive and very good paying jobs. As many as 250 workers are employed at the Port of Chicago to handle cargo, operate forklifts, and provide trucking and rail service.

If the administration's proposal is adopted, those 250 good paying jobs are at risk. While I am aware of reports of wasteful spending and inefficient practices, the food aid programs are successful because of the broad support from agriculture and the maritime industries. If these jobs are lost and money given in place for food, support for these critical programs will obviously dwindle.

I ask the panelists to consider these good paying jobs that are at risk when they discuss potential changes to the food aid program.

Would you care to share with the panel what is the status of the administration's recommendation of changing Title II or using up to 25 percent of Title II funding for the purchase of foreign agricultural products? Instead of giving food we are now giving a check.

Mr. KEENUM. Thank you. You described the situation very well. The status is that this was a proposal that we made to the authorizing committees for consideration in the farm bill, and the farm bill that passed the House of Representatives did not include the local purchase provision.

And the bill that passed the Senate had a pilot project that was far less than the 25 percent that we had recommended. It is in the conference. As you know, they are meeting this morning—conferees.

I don't know what will come out of the conference on this particular provision, but I would like to address a couple of points that you made and to put a little bit in perspective the magnitude of the 25 percent and the rationale behind why it was proposed to start with.

If you consider the fact that commercially the United States, we export in the commercial markets about 146 million metric tons of grains and cereals and oilseeds. That is what is in the commercial pipeline that is exported. It creates the jobs for export trade that you alluded to.

We as a country contribute to international food aid from grains and cereals and oilseeds about 3 million metric tons. The commercial environment is 146 million. We contribute 3 million, and we were talking about up to 25 percent of that 3 million. So if you put it in a commercial perspective, we are talking about one-half of 1 percent of all the grains and cereals and oilseeds that we export would be affected by that. One-half of 1 percent.

So from the effects on industry and trade and commodity farmers it is very minuscule, and we are only proposing up to 25 percent local purchase. When there is an emergency, when people's lives are at stake—the local purchase would only occur if commodities

are in that region or in that area. And so we look at it as an option and an opportunity to help us address humanitarian needs to help save lives. Just as simple as that.

Also, another advantage of this is with the higher shipping costs and fuel costs we are faced with, that is a portion that we would not have to ship; we would be able to go in and buy locally to address those humanitarian needs.

Mr. JACKSON. Thank you, Mr. Chairman

Mr. HINCHEY [presiding]. Mr. Latham.

Mr. LATHAM. Thank you.

Mr. HINCHEY. Did you say, Madam Chairman?

FSA OPERATIONS UNDER A CONTINUING RESOLUTION

Mr. LATHAM. I did not, but if you put a skirt on, I'll gladly—anyway, it has become very evident I think to everyone around here that, while the House is going to do their work this year as far as passing appropriation bills, the Senate has publicly announced, basically leadership over there, that they are not going to do anything. And you had a long discussion about the changes as far as information technology and your needs on that, but I would be curious if you had done any preparation for a continuing resolution that would freeze everything going forward; you are talking probably at least until March of next year. What does that do to your program?

Mr. KEENUM. Well, needless to say, Congressman, that is a good point. I mean we have had to deal with continuing resolutions, obviously, many times in the past and we will find a way to get through the process and meet our obligations, but it will have a tremendous drain.

As you know, our fiscal year 2008 budget for FSA is about $98 million less than what was requested by the President. That has caused a strain on our operating ability for FSA and we have asked for increases. That is why we asked for a $96 million increase just to cover our increased cost, expenses that we will be incurring in this coming fiscal year. And to not be able to get the additional funding that we need to meet our personnel, our pay obligations, to pay our rents, you know, we have a lot of fixed expenses that we have to pay just to operate the Agency.

And then if we get a farm bill implemented and we are hopeful again—use the word "hope"—then that is all we have right now is hope. We can request and present the facts and outline why we have the needs, but the actual decisions rest with you, the Members of the Congress, members of the authorizing committee, as to whether or not they will provide additional moneys for us to implement the new farm bill. We are going to have more challenges and, obviously, to not be able to get any increases for whatever period of time we operate under a continuing resolution will put a strain on all the agencies.

Mr. LATHAM. Ms. Lasseter, say hi to Willard for me, please.

Ms. LASSETER. I will do that.

CROP INSURANCE PROVISIONS OF FARM BILL

Mr. LATHAM. I don't know if you have any other comments as far as the effects of the CR. If you do, fine. If not, I have a question

as far as that proposals in the farm bill are to make, in my mind, draconian cuts to profit-sharing.

I just wondered, Mr. Gould, if you have studied those proposals, the crop insurance program, obviously, with the higher value of crops today, with what we have seen certainly in history, the effect that that is going to have and what—have you studied and can you give us some insight as to what you see the effects of those cuts will be in the farm bill?

Mr. GOULD. Well, we have looked at those. As you said, in the last 2 years commodity prices have increased by a factor of 2 and it looks like our insured liability is going to be similar to that. The liability has doubled in the last two years.

About half of the risk management program is in the heart of the Midwest, with corn, soybeans and wheat, where the increased commodity prices are the most dramatic. At the same time, the companies are paid—or because of those higher commodity prices, premium prices have gone up dramatically. We not only insure yield, but price. And in the last 2 years, volatility has been a large factor in the pricing of the premiums. As the premiums go up, companies' compensation goes up and so the companies will be generating more income.

The other side of that is the companies are going to have huge price risk. In fact, being back in Illinois two weeks ago, farmers and lenders alike were talking about at that time soybeans being "in the money." So it is a dramatic risk.

Back to your question of the cuts being draconian, I think, at least the last report that I saw, they were less than draconian, at least some of them were. At the same time, we are concerned about the financial stability of the companies, and while they are making good money today I think in any insurance program you have to look at the long-term perspective. And while things are rosy for the 2006 indemnity payments, and 2007 was even better, it is hard to predict what 2008—and now we are talking about the 2009 budget—will predict, will come to fruition.

Mr. LATHAM. Are you saying that the financial stability of insurance companies could be put in jeopardy with the cuts?

Mr. GOULD. We don't think so. We take an in-depth look at the financial health of the companies. They have to be able to withstand huge loses for 2 years before we approve their plan of operations. Some of the companies came forth as recently as the first of the year, looking for ways that they could increase their capacity as they saw the increase in commodity prices affect their capacity. Again, the financial health of the companies is something we take seriously, and at least the last cuts that were proposed in the farm bill that I saw I would not consider draconian, and today would probably be acceptable; and from what we have heard from companies and agents alike would be palatable to them.

Mr. LATHAM. Thank you, Mr. Chairman.

Mr. HINCHEY. Thank you.

Mr. Boyd.

FARM BILL FUNDING

Mr. BOYD. Thank you, Mr. Chairman. Dr. Keenum, Ms. Lasseter, Mr. Yost, Mr. Gould, welcome. Thank you for your service to farmers and to our country.

Dr. Keenum, you have been around this process for a long time. I think you know as well as everybody sitting at the table that the user fee proposal won't fly. Never has. It probably didn't with your previous bosses when you were in the other body, and you know it is a non-starter over here. And we get somewhat amused, and I guess cynical, when we see these proposals.

And you know, I think, I like many others who have to deal with the farm community understand the IT issue, how important it is and how we have to solve it. So I hope we can come to some solutions.

I want to remind the committee that the farm bill is bogged down in many ways because of this administration's persistence on not finding ways to pay for the proposals that the House and Senate have put forward and even some the administration has put forward. And I hope that we can get past that, because some of those offset proposals are—we are using some pretty onerous loopholes in the current Tax Code. That is an argument for another day, but I just want to remind us where we are.

USDA REORGANIZATION

Now, I want to get to a pertinent question about the future of the Department of Agriculture, particularly the Farm Service Agency and the other agencies in the USDA that serve our farmers.

Dr. Keenum, your staff on your right has a wealth of experience, life experience that serves I think all of our farmers and the Nation very well. Ms. Lasseter has spent all of her career in FSA and in a rural community; by the way, not too far from where I live. I've known Ms. Lasseter and her husband for a long time, and Mr. Yost and Mr. Gould with their experiences in the farm community using the FSA programs and the farm programs, USDA programs.

My question really goes to—I would like to draw on that wealth of experience to answer this question. There are some folks here in Congress, particularly the authorizing chairman here in the House, Collin Peterson, talking a great deal about reorganization and restructuring.

Maybe if I could ask Ms. Lasseter to answer this question: Has the USDA on the FSA side begun to think about reorganization restructure; and given your life experience, Ms. Lasseter, what would your recommendations be for that restructure as it relates to FSA, NRCS and how we do some of these things.

Ms. LASSETER. You are right, I have worked for the Agency out there in the county office when we had some shared responsibilities, or more shared responsibilities than we do today, and whatever we have been given out there, the county office people have been able to make it work.

I have not been a part of discussions for the administration as to whether or not reorganization should or should not happen. I guess we would have to see exactly what we are talking about in

the reorganization to know if it would be a better plan. I have been focused on FSA and what our present operations are today, our responsibilities and how we can do a better job of delivering to those of you who use our offices out there. I really believe that in the last 2 years we have made significant progress with our delivery.

Mr. BOYD. Well, I understand your reluctance maybe to step out in front. And maybe it is an unfair question, but I thought maybe I would ask permission for Dr. Keenum, for these folks who have spent their entire life using the farm program system and now have a chance to make a difference, how are we drawing on their experience?

And I would like for them to tell the committee the FSA and NRCS are two distinctly different groups, agencies, when it comes to the way they operate. One is from the top down and the other is from the bottom up, and they operate differently as a result of that.

Mr. Yost, you have spent a little time in the FSA and spent your life as a beneficiary of these agencies. Would you care to comment?

Mr. YOST. Congressman Boyd, in the last year we have completed our reorganization on Agricultural Service, and it takes an enormous amount of time developing the concepts, talking to employees, talking to stakeholders. It is a relatively small Agency compared to the Farm Service Agency.

Mr. BOYD. Right. I know you served some FSA time also. I really wanted to see you speak to that more than FAS.

Mr. YOST. There is a lot of work that needs to be done. There is a lot of discussion with employees across the country, farmers across the country about what needs to be done. What we are trying to accomplish takes a lot of buy-in so that everyone realizes what the end goal is. I just want to make that statement because I think it is critically important. We felt strongly that the Foreign Agricultural Service needed to be reorganized to reflect 21st century agriculture.

I think there needs to be some work done in the Farm Service Agency to also reflect 21st century agriculture. What that exactly is I wouldn't really care to comment, but mindsets have to change, people that work there and people that use the services. They have to think about how we can incorporate 21st century technology in our structure top to bottom, what we are going to do for producers to improve service by doing anything of that magnitude, what we are going to do for employees.

I throw those issues out because I think you have to start at the very highest level thinking about what needs to be done before you can get down to any details, and, quite frankly, take a lot of input from a lot of people.

Mr. BOYD. Mr. Chairman, I know my time has run out. I apologize to the panel for asking them to step out into an area, and obviously I didn't get very far with the answers, but I think it is important to highlight. Mr. Gould I see you pulling——

Mr. GOULD. Well, as long as your time ran out, I want to end this on a positive note. At the Agency level, I don't know if I have any comments on reorganization. But I would like to comment on the cooperation just by the nature of the programs at the Risk Management Agency and the Farm Service Agency; cooperate to-

gether on disaster payments, linkage between disaster and crop insurance.

We do cooperate with FSA and RMA dramatically.

The common information management system is coming on board and has been implemented at a minimal level. It will come forth with more States on board sometime this summer, hopefully by the 1st of June, and that will increase information sharing between the two agencies.

And then in addition, a lot of our programs depend upon the information that comes from the Statistics Service, NASS. We are exploring opportunities to work with them to build a more robust data set that combines information that each agency has. So, again, I want to leave you with the impression that—maybe "reorganization" is not the right word, but an opportunity of cooperation. And increasingly so.

Mr. BOYD. Mr. Chairman, there is a lot of work to be done to bring us into the 21st century and the way we deliver our services to our customers—and that is the farmer—and be accountable to the taxpayer. We need to draw—and I hope in the 9 months that are left in this administration that there will be some discussions about what kind of recommendations we leave for the next administration in terms of how we reorganize these agencies. Thank you.

Mr. HINCHEY. Thank you. Mr. Kingston.

Mr. KINGSTON. I wanted to say, Mr. Gould and Mr. Yost, you talk about there will be cooperation. The taxpayers have to—that is the bottom line. Certainly there is going to be cooperation. That is not what we hope, that the Federal bureaucracy cooperates. It is damn right you will; that is your job.

And so to me it is not a matter of tiptoeing around the FSA offices and asking these people, hey, we have a new law out; will we follow it? I think Mr. Boyd touched on something very important. But to me the only question is will it be more efficient to the farmers.

FARM PROGRAM DELIVERY

And I wanted to ask my friend, Ms. Lasseter—and you are my friend—she is a constituent so I have to underscore it a little bit more—the question really is: With this administration pushing payment limitations on conservation programs and so forth and the NRCS and FSA both having a paperwork role, is that going to be inefficient and cumbersome to the farmer?

By the way I want to say, Mr. Gould, I am not picking on you at all for that, but I just want to make sure that we in the Ag family know that cooperation isn't the issue here; it is efficiency ineffectiveness. And you weren't saying that it is either. Okay, I am tired of being nice to you.

Ms. LASSETER. Congressman, I would hope that we can make things work, that it is not cumbersome to the farmer. They presently use the FSA office to file their plan of operation and to give us their certification as to their gross income. And FSA is the face for the Department now for gathering that information and making the determination on that information. So I would say we can make it work.

I am not sure if this question is leading back to once upon a time FSA administered conservation programs as far as taking the application, making the payments, and that change was made and there are questions as to whether or not it would work.

Mr. KINGSTON. As you know, the ones out in the field are ready to resume that role again and are certainly capable. I just think the real question is no matter what comes out of this conference committee, is we have to make it work for efficiency and effectiveness for the farmer.

Ms. LASSETER. I think we are all for that.

HARVESTING PINE STRAW ON CRP ACRES

Mr. KINGSTON. I do want to say I think you guys have done a great job on patiently waiting in mid-air to see. I know the FSA particularly has a lot of balls in the air since last year, but waiting on this farm bill, I know, has been frustrating.

We have had some conversations, and I know Dr. Keenum you and I have had conversation about CRP and the idea that under CRP you can only get rental for taking the land out of cultivation. And yet there is a growing push that utilize profit centers, if you will, on the farm. And a lot of landowners have asked us after 10 years, when it is not a nutrition for the tree issue, could they opt out of the rental portion of CRP and sell their pine straw? Not cut the trees or anything, but sell their pine straw; or would that be seen as hey, you know, we paid you for one thing, and now you want to switch to another?

I do think there is a potential market out there. I know there is for the farmers. It could be a way to save money as a government. It could be a way to help the farmers of the rural economy.

Mr. KEENUM. Thank you, Congressman. I tell you, with your encouragement, we have had several conversations on this topic, and I know it is of significant importance to you in particular. And based on the dialogues that we have had, and our offices have had, and discussions you had with the Secretary of Agriculture on this topic, we have engaged on this and we are beginning to work with University of Georgia——

Mr. KINGSTON. That is a great choice.

Mr. KEENUM. I was hoping you would think so.

To look at how we can address those very points that you outline. It is our policy to be able to effectively utilize our CRP lands without hampering the environmental benefits and the wildlife benefits that have occurred from the conservation program, CRP.

And that is why we need to reach out to the technical people, to scientists, researchers in this field, to understand wildlife and the environment.

So the point is we engaged in dialogue with the University of Georgia to initiate a research project to address this very point. We have also implemented or begun to work on addressing NEPA requirements that will have to be addressed on this as well. And our hope is that we can have the research and the review done on pine straw harvest on CRP land—done within 3 to 6 months. And again, this is because of your leadership and what you have brought, bringing this issue to our attention, that we have been focused and engaged on this very important topic.

Mr. KINGSTON. Thank you. I am out of time. I did have some other questions. Maybe the next round.

Mr. HINCHEY. Continue if you would like.

Mr. KINGSTON. I want to thank you for doing what you are doing—you are doing it very slowly and very carefully for environmental purposes, and also for the spirit of what CRP is really about. And we also need to be able to answer to constituents, We didn't pay these folks to take land out of cultivation to maximize profit in a different way; we have to address the subsidy. I think you guys are doing a very good job of walking that line.

CROP INSURANCE

Mr. Gould, just for my own background purposes, how many insurance companies are involved in crop insurance and how many reinsurance companies, do you know?

Mr. GOULD. We have 16 proved insurance providers. I am not sure how many reinsurance companies there are. I want to guess a half a dozen, but that is only a guess. That is a handful.

Mr. HINCHEY. A handful, five to start with.

Mr. KINGSTON. The subsidy, is it on the premium or on the underwriting cost or on the underwriting loss?

Mr. GOULD. Are you talking about the approved insurance companies or the reinsurance?

Mr. KINGSTON. I know it is not actuarially sound. Would that be an accurate description?

Mr. GOULD. No.

Mr. KINGSTON. If it was, the Federal Government could get out of it completely, correct? If the private sector could consistently make a buck selling crop insurance then we would have no need for a Federal program.

Mr. GOULD. Oh, I see. If you do not have to subsidize the producer premium.

Mr. KINGSTON. Yes.

Mr. GOULD. Our history shows that if we, the Federal Government, don't do that, we have a limited participation from the farmer level.

Mr. KINGSTON. But after we subsidize their premium, there is no further subsidy on the crop end in terms of paying an underwriting loss or in terms of the underwriting cost of acquisition of the account and processing the paperwork.

Mr. GOULD. No. That is all provided by the insurance companies to the reinsurance companies, and there is a gazillion different arrangements that they have. At the same time, I don't want to mislead you and say that—there is further subsidy to the insurance companies in the fact that the Federal Government pays the insurance providers an administrative and operating expense for delivery of the program.

Mr. KINGSTON. Okay. So that is a second.

Mr. GOULD. That is a second item.

Mr. KINGSTON. And then if there is a disaster that goes beyond the value of the insured land, how does that work? Do you have a—can you give me——

Mr. GOULD. Well, without getting into a lot of detail, there are three different funds that approved insurance providers can place

their risk with the Federal Government to the extent that we share—typically we expect to get the high-risk funds, and they keep the good—the good business. So obviously that enhanced their rate of return on their book of business. Ironically for the 2007 crop year, and we just learned this this morning, that, in fact, the Federal Government had more gains on reinsurance than the companies did. Again, it was a result of a good crop year, and the bad book of business that we inherited from the companies turned out to be a good book of business.

Mr. KINGSTON. If I just heard what you said, there is a quasi-reinsurance mechanism to the Federal Government.

Mr. GOULD. Yes. We have a 5 percent quota share at the moment, and hopefully through our administration proposal in our farm bill to increase that quota share so the government would be a bigger player in the reinsurance business.

Mr. KINGSTON. All right. Then last question I hope, Mr. Chairman. On an acre of insured cropland, if there is a disaster, is that producer eligible for any payment from the disaster outside of insurance at all?

Mr. GOULD. Well, it obviously would depend on how the disaster bill is written. For the most part—at least certainly in recent disaster bills, there is a linkage between crop insurance and disaster. So if, in fact, the producer has crop insurance, then he is entitled to some level of disaster coverage.

Mr. KINGSTON. Okay. But if he doesn't have insurance, he doesn't get anything, is that——

Mr. GOULD. That is correct.

Mr. KINGSTON. Except for other——

Mr. GOULD. And as a producer, I think that is the way it should be.

Mr. KINGSTON. Because, frankly, the disaster bills are so murky over the years that, you know, even on the committee that is doing it, you often just need to reclarify that and reeducate yourselves. So, thanks.

WORLD FOOD SUPPLY

Mr. HINCHEY. Thank you. It has been a very interesting discussion. And I just want to express my appreciation for all of you for not just the discussion today, but for all of the work that you do.

We have some votes coming up now, but I think I am the last one to ask a question or two. So if you don't mind.

Again, thank you. It has been an interesting discussion. I appreciate the response to the questions. I think you are engaged in one of the most fascinating and one of the most significant issues that we have to confront not just as a Nation, but as a species globally.

Circumstances around the world on food are getting more and more difficult almost every day. There was an interesting editorial in The New York Times today, which, among other things, talks about how the World Bank president has just estimated that there are at least 33 countries in the world that are on the edge of social unrest because of the increasing price of food and, one has to assume, that in addition to the increasing price, the decline in the availability of food. We know that hunger is growing, and it is growing fast.

We are not one of those 33 nations yet, but it is interesting that we have such a dramatically increasing number of people on food stamps in our country, almost 28 million right at the moment, and that number is going up. And when you look at the situation in schools, school lunch programs, school breakfast programs, growing demand for that and the ability of the schools to deal with that is also going down. Very, very difficult.

We have a complex set of circumstances here to confront. There is nothing more important for our species to deal with than food and fiber. That is one of the reasons why we all sit on this committee, because it is—you know, it is the basic ingredient of life. Without it, you can't continue.

So this farm bill that is coming up has been very contentious, and I think that a lot of the contention has to deal with a lot of these complex circumstances, situations in which we are dealing with. And there is a lot of ways people are trying to answer these questions, and you get a lot of answers depending on who you are talking to.

So one of the responsibilities of this committee, of course, is to look out for big producers of agriculture in our country, farmers, but at the same time we are facing some interesting situations in that regard. For example, the amount of corn that is now being used in biofuel is estimated to—somewhere in the neighborhood of have doubled price of various elements of food not just here in the United States, but around the world because of the huge amounts of corn that are being put into biofuel and the large amounts of other food products that are now not being produced. People are rushing to try to start planting corn because there is a lot bigger profit to be made from the corn.

So I am wondering if you might have any ideas about this set of circumstances, what we might be doing more constructively. What are the things that we should be engaging in? There is no question because of—the ability of people to get adequate nutrition in our own country is going down, but in a lot of countries, like Haiti, for example, which is very close to us, most of the countries in sub-Saharan Africa and a number of other countries around the world, including Vietnam and other places where dangerous, difficult circumstances are beginning to prevail because of the lack of food.

What do we have in terms of storage? I used to take note of the huge storage amounts that we had for various kinds of food. What is the storage situation now?

STOCKS-FOR-FOOD PROGRAM

Mr. KEENUM. Well, Congressman Hinchey, in my earlier comments when we were talking about our Stocks-for-Food Program, I made a point that we no longer own any CCC surplus stocks. We have converted all of our CCC surplus stocks into food to address many of the points that you just highlighted. And I appreciate your comments.

Mr. HINCHEY. You turned the stocks into food?

Mr. KEENUM. That is correct.

Mr. HINCHEY. What does that mean?

Mr. KEENUM. Well, we——

Mr. HINCHEY. Stocks were food. They always were food or potential for food.

Mr. KEENUM. Right. For example, we took a bale of cotton that we own in our CCC inventory.

Mr. HINCHEY. Pardon me?

Mr. KEENUM. Cotton. We own I don't know how many thousands of bales of cotton.

Mr. HINCHEY. Let's just talk about wheat and corn and soybeans.

Mr. KEENUM. Sure. We own wheat and corn and soybeans and peanuts and rice and cotton.

Mr. HINCHEY. Who owns those stocks now?

Mr. KEENUM. Well, the U.S. Government had those stocks.

Mr. HINCHEY. Now they are in private hands? They are in corporate hands now?

Mr. KEENUM. Rather than sell those commodities and have the proceeds—

Mr. HINCHEY. When was that change made, back in the 1980s?

Mr. KEENUM. July of last year. We are responding to those points that you highlighted. What we tried to do was say that—you know, we have got these surplus commodities. When a farmer takes out a loan from the government, and he puts his crop up for collateral, and so rather than pay back the government, a lot of farmers just forfeit their commodity to us, and we own it.

Mr. HINCHEY. Who are the main owners of those stocks now?

Mr. KEENUM. Well——

Mr. HINCHEY. Which corporations own them?

Mr. KEENUM. Well, sir——

Mr. KINGSTON. Dr. Keenum, if you don't mind me interjecting myself.

Mr. HINCHEY. I do mind you interjecting yourself. Wait a minute, wait a minute, Mr. Kingston. Just relax. Your time is up.

Mr. KINGSTON. This is such a friendly comment, you will be so happy.

Mr. HINCHEY. Your time is up. Don't interrupt me. Your time is up.

Mr. KINGSTON. I don't think you can have a hearing with one person here. Your hearing is over because you can't have a hearing without anybody here.

Mr. HINCHEY. Thanks very much. Thanks for leaving.

So what were you saying?

Mr. KEENUM. Well, with the commodities that we obtain through a farmer forfeiting his commodities to us, our job is to dispose of those commodities because we have to pay storage on those commodities that we own. That is the way the program is structured. But rather than selling those commodities, what we do was we looked at the law and we determined that we could swap or barter those commodities for processed foods. We could take bushels of wheat and exchange them for canned vegetables or canned meats, stews.

Mr. HINCHEY. Who do you exchange them with?

Mr. KEENUM. Food companies that come in who want to—

Mr. HINCHEY. Which are the major food companies that own the major foodstocks in the country now?

Mr. KEENUM. These are major companies. ConAgra, Cargill, Louis Dreyfus are just some of the major companies that come to mind. But it is an opportunity we saw——

Mr. HINCHEY. Why aren't those companies dealing with the growing problem of malnutrition in America?

Mr. KEENUM. Hmm, I can't——

Mr. HINCHEY. What kind of intervention could we engage in to ensure that those corporations, which now control the surplus agricultural commodities for America, begin to look at the situation and begin to deal with it in ways that are not just in corporate interests, but in the interests of the country?

Mr. KEENUM. Well, Congressman, I don't know the answer to that. You pose somewhat of a philosophical question.

Mr. HINCHEY. Do you think it might be reversing that process of getting the corporations out of the ownership of those huge stocks and putting it back in the hands of the Agriculture Department so that decisions like that can be made on the basic interest of the population of the country rather than corporate interests?

Mr. KEENUM. Again, we are talking about dealing with farmers, farmers who have forfeited their commodities to us. And rather than just simply sell these commodities, we have tried to put them to a constructive use to address our international humanitarian needs and our domestic food programs.

You mentioned about the humanitarian needs in this country, TEFAP, which is The Emergency Food Assistance Program. But TEFAP, which is a very important program, has a budget of $140 million, and by these actions that we took as an initiative, we are putting more than $100 million into TEFAP. Again, it is a $140 million budget. We are taking our commodity, a bulk commodity, and converting it into a food that a needy American can utilize for their families. And we have a lot of families in need in this country. We saw some of the points that you outlined in your comments, and we took an action to address those concerns and those needs both here domestically and internationally, as you pointed out about a lot of countries that are on the verge of very serious problems. And this is an attempt by the Department of Agriculture to address all of these humanitarian needs. We are obviously, as you can tell, very pleased with this program.

Mr. HINCHEY. Yeah. Well, thanks very much. We have some votes on now, and I think maybe we will try to keep this open, if you don't mind staying with us for a little while.

Mr. KEENUM. Absolutely.

Mr. HINCHEY. Appreciate it.

Mr. KEENUM. Yes, sir.

Mr. HINCHEY. I think these issues that you have been talking about, I think, are very critical, and they are critical not just domestically, but they are critical internationally. And the set of circumstances that are prevailing around the world and growing are increasingly dangerous.

Mr. KEENUM. I agree.

Mr. HINCHEY. And thanks. Thank you very much.

Mr. KEENUM. Thank you, Congressman.

[Recess.]

FARM BILL CONFERENCE

Ms. DELAURO [presiding]. Again, my apologies. I will report that there was the opening session of the conference, House and Senate. It is the largest conference I think I have ever seen. It is in the Russell Building, 345. So there was opening statements, and the House made its formal proposal to the Senate. The Senate is taking a look at that. And then obviously there will be the deliberations amongst the finance people, Mr. Rangel, Mr. Baucus, Mr. McCrery. And actually, the leadership of the conference laid out its positions, and there isn't anything different than any of us in this room know about. So that is where we are, and we are recessed subject to the call of the Chair. There we are.

FARM BILL IMPLEMENTATION COSTS

Let us get back under way. Thank you again for your patience here. Let me just—this goes actually to the farm bill again. In order to implement—the budget request or the farm bill proposal doesn't include funds to implement the 2008 farm bill. And the testimony says, Secretary, then I quote, we will evaluate the necessary administrative resource requirements and work with the appropriate authorizing committees to implement the new and reauthorized programs and policies once the specific provisions and operational requirements have been determined.

I am trying to get a sense here of how you would expect to know what funding is necessary to fix your IT problems and to implement the new farm bill. When you put together your farm bill proposals, why did you not include an estimate at that time of what administrative expenses would be necessary to implement your own proposal? And when do you plan to work with the appropriate authorizing committees after the farm bill has passed? It seems a little late in that context of doing that.

And then again, this isn't the first agency or agencies that I have asked this question. You know, you never get everything you want out of a conference. It always winds up being less than you anticipated. And again, our hope is that we will have a farm bill in the next week or so. So, you know, did you include an estimate at the time of your administrative expenses and what it was going to take to implement your own proposals? And what is the status of your working and your continued work with the authorizing committees? Where are we?

Mr. KEENUM. Yes, ma'am. To my knowledge, we did not submit an implementation budget proposal when we submitted our farm bill policy ideas to the Congress, but we have subsequently—since presenting our policy ideas to the Congress, we have followed up with the leadership of both committees and their pertinent staff to inform them of what we would need to implement the farm bill. And what we did was we waited until the House actually passed their farm bill, and we had a chance to evaluate the bill. And our estimates on implementing the House-passed farm bill would be roughly $217 million. We have since evaluated the Senate bill. And just the Senate bill itself, without a disaster component, our staff has informed me and we have informed the committees that it would cost $320 million to implement the Senate farm bill. And if

you have the disaster provision that was in the original Senate bill, the total cost would be about $360 million.

Now, when we put that in perspective, when the 2002 farm bill was enacted, the authorizers provided $50 million to the Department to implement the farm bill. We wound up spending about $157 million to implement it. But the appropriators came back in fiscal year 2003 and provided the Department with another $60 million. So all told in the 2002 farm bill, the Department received from the Congress $110 million for implementation. But an actual——

Ms. DELAURO. It is hard to get the money if you don't request it. You know, I mean, I just think that——

Mr. KEENUM. But we are requesting it, Madam Chair.

Ms. DELAURO. Then you didn't put anything——

Mr. KEENUM. We have given it to the authorizing committee members and their staff, and we have made it very clear what our needs are.

Ms. DELAURO. Okay. We will have to figure it out. As far as I know, we do not have copies of what your—what you listed and what they are, et cetera. So actually that——

Mr. KEENUM. Madam Chair, I think it would be very appropriate for us to provide that information to you, absolutely.

NATIONAL AGRICULTURE IMAGERY PROGRAM

Ms. DELAURO. Let me ask a quick question about the NAIP. I have got other questions, but we will go back and forth here for a while.

Let me just say, fiscal year 2007 FSA did not spend the $24 million for NAIP even though under the continuing resolution terms and conditions of the 2000 conference report were applicable in 2007, not the National Agriculture Imagery Program. Some of those funds were redirected to pay for the stabilization of the farm program delivery systems. Fiscal year 2008 House report also contained language; $24 million was provided for NAIP, and this language was not contradicted in the conference report.

How much did you spend on NAIP in fiscal year 2007? How much do you plan to spend in 2008? And what amount is assumed in the fiscal year 2009 budget request? And the other piece is, are you redirecting the funds in 2008 from NAIP to stabilize the farm program delivery system?

Mr. KEENUM. Madam Chair, in 2007, the FSA provided $6.3 million to NAIP. As you recall, last year when we were facing a lot of challenges with our IT system, we had to come up with some additional funds to make sure that our computers at the time did not completely collapse, and we had to make a very difficult decision to redirect moneys. And the only moneys, working with our budget office, that we could identify that we could fill those needs for our IT systems was out of the NAIP funds. That was a decision we made internally to fulfill our IT commitments.

For fiscal year 2008, we are projected to spend $10.1 million. And we have partners with us that will contribute another $2.4 million, and we are negotiating another $1.5 million from a partnership.

Ms. DELAURO. When you talk about partners, who are these partners?

Mr. KEENUM. Partners are the ones on the ground who are actually implementing the NAIP program. The State of Missouri, for example.

Ms. LASSETER. Geological Survey, State government, the Forest Service, NRCS.

Mr. KEENUM. So we are expecting this year to spend roughly around $14 million on NAIP. And the 2009 budget has $10.1 million in the budget request for NAIP.

Ms. DELAURO. So are you redirecting the funds in 2008 from NAIP to stabilize the farm program delivery system? Are you going to take any money from that program again to do——

Mr. KEENUM. No, ma'am. That is not what our intentions are this time, no.

Ms. DELAURO. Well, what I need to do is to see—because it was $24 million. You used $6 million in 2007. You used the balance of that for the IT system?

Mr. KEENUM. Yes, ma'am.

Ms. DELAURO. But you used the $24 million; 6 of it was for the NAIP program. Is that right?

Ms. LASSETER. Well, we used the $20 million——

Ms. DELAURO. Twenty-four.

Ms. LASSETER. Okay. But that was not all of our money that we had, that we were going to use for NAIP. So we still used the 2007; it was $6.3 FSA contributed or spent on NAIP. And my records show $4 million from our partners. So it was a total of $10 million in 2007.

Now, in the 2008 budget, there is the earmark. But the President's Budget, as I understand, did not have that much for NAIP.

Ms. DELAURO. Can somebody get to me what we did here on the numbers with the NAIP program, 2007, 2008? We have got a request for 2009 for $10.1. I mean, we had 24. How much went to the IT program? There has got to be some accounting here someplace.

Ms. LASSETER. Can we give you that?

Ms. DELAURO. Sure. In a timely way. I don't want to wait. I really do want to find out.

Mr. KEENUM. Sure.

[The information follows:]

FARM SERVICE AGENCY
National Agriculture Imagery Program (NAIP) Funding

Fiscal Year	(dollars in millions) President's Budget	FSA Expenditures	Notes
2007 actual	$26.5	$6.3	To respond to the program delivery crisis being experienced during FY 2007, FSA made the difficult decision to redirect $20 million from NAIP to IT stabilization. Another $4 million for IT stabilization came from carryover funding from the Common Computing Environment account. These actions were taken before the supplemental appropriation was enacted that provided $37.5 million for stabilization. Total program expenditures for NAIP in 2007 were $9.05 million, including over $2.7 million from other Federal and State government partners.
2008 estimated	12.7	10.1	The budget request reflects the current constrained funding environment. The reduction in estimated expenditures compared to the budget is one of the measures enabling the agency to operate within a Salaries & Expenses appropriation below the budget request while absorbing an enacted pay raise above the budgeted level. Total NAIP program expenditures in 2008 total over $14.3 million, including over $4.2 million in other Federal and State government partnership contributions.
2009 estimated	10.1	10.1	To meet agency imagery requirements and stabilize NAIP funding for future years, FSA is revising the program's overall acquisition strategy. Annual 2 meter resolution imagery will no longer be collected. Under development are provisions for a new 3 year acquisition cycle that would provide for 1 meter imagery collection on 1/3 of agricultural program lands each year. Additional options under development would allow for extending to full state coverage and increased frequency based on other Federal, State or local partnership participation in NAIP.
TOTAL FSA	$49.3	$26.5	NAIP partners have contributed funds to enlarge areas of collection and ensure full state coverage. The Forest Service, Natural Resources Conservation Service,US Geologic Survey, Bureau of Land Management and others have traditionally contributed at the Federal level. Partnerships at the State level have been consortiums of State and local groups that include agricultural and natural resource agencies, county governments, water resource boards and others. Partnership contributions in 2007 and 2008 totalled over $7 million.

Ms. DELAURO. If you bear with us again? And I promise you if we cannot finish up today, I am committed to try to finish up by 1:00, and we will have to ask you to come back. But if you just bear with me for a few minutes.

[Recess.]

Ms. DELAURO. Ladies and gentlemen, let me just tell you what I have concluded is that we are going to reschedule. And there are a number of questions that I have. I think other Members do as well. And it actually may in the long run serve us well because many of the committees are finishing up today with what they are doing. And there are some areas that we didn't get an opportunity to cover that I know are important areas. I know some of the food aid efforts have been covered, from, you know, my point of view. It is about, you know, again FSA and NCRS working together, and some other areas which I think merit a conversation with folks, and where we are with some of the crop efforts, crop insurance, et cetera.

So I thank you again for your patience and apologize because I know your schedules are busy as well. So we will reschedule at another time. And the hearing is concluded. Thank you very, very much.

Mr. KEENUM. Thank you, Madam Chair.

Thank you, Congressman.

Mr. HINCHEY. Thank you very much.

Fiscal Year 2009 Hearing Questions

Foreign Agricultural Service

Administrative Expenses

Ms. DeLauro: How much did FAS pay in FY 2008 for overseas rental expenses and how did that compare to FY 2007 costs?

Response: FAS paid $6.2 million for overseas rental and related expenses for overseas offices and residences. Actual overseas rental and related expenses for fiscal year 2007 were $5.7 million. The FY 2008 increase includes additional expenses for one new Agricultural Trade office in Chengdu, China and establishing a presence in Shenyang, China.

Ms. DeLauro: How much did the FAS transfer to the State Department for leasing services in FYs 2007 and 2008, and what are the estimated amounts for each of FY 2009?

Response: FAS transferred $128,773 during FY 2007 and $90,754 during FY 2008 to the State Department through International Cooperative Administrative Support Services (ICASS) for the administration of leasing services. The current estimate for fiscal year 2009 is $101,281.

Ms. DeLauro: Please provide a history of USDA funding for the Capital Security Cost Share program, by agency. Include amounts and units of how costs are allocated. What are future estimates for the program? What is the final year of the program?

Response: Capital Security Cost Share (CSCS) charges are based on the number and character of an agency's authorized positions overseas under the authority of a U.S. Chief of Mission. The program is designed to end in FY 2018. All USDA agencies in the table below have an overseas presence. Any agency with a negative charge is the result of an actual or anticipated rent credit that exceeds the cost of their positions. In this situation, FAS absorbs the rent credit and transfers the credit to the appropriate agency within USDA. The following factors are considered in calculating the CSCS program charges for each agency:

1) Existing Positions Charge - per authorized position;
2) ICASS Pass-through Charge - ICASS positions are the joint responsibility of the participating agencies;
3) Projected Staff Growth Charge - planned positions based on space requirement plans; and
4) Rent Credit - credit for net rent paid for office space outside of the Embassy.

USDA has no controlled access area space. The unit costs for the two types of non-controlled access area (non-CAA) allocated to USDA agencies are:

[The information follows:]

Charge per Authorized Position

Category	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009-2010	FY 2011-2018 (projected)
Non-CAA Desk	$5,626	$11,258	$16,886	$16,391	$20,488	$19,344
Non-Office	988	1,976	2,964	2,837	3,546	3,450

CSCS Actual and Projected charges:

Agency	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010-2018 (projected)
Foreign Agricultural Service	$515,569	$2,624,713	$5,538,589	$7,072,597	$9,545,358	$9,919,882
Agricultural Research Service	$0	$110,161	$182,859	$178,222	$199,782	$199,948
Rural Development	$0	$25,860	$59,212	$51,442	$-4,559	$-901
Animal and Plant Health Inspection Service	$0	$1,070,114	$3,034,742	$2,476,699	$3,273,712	$3,406,129
Natural Resources Conservation Service	$0	$55,884	$152,611	$36,488	$51,496	$55,721
Grain Inspection Packers and Stockyards Administration	$0	$27,942	$0	$7,074	$0	$0
Forest Service	$0	$0	$0	$0	$56,385	$56,542
TOTAL	$515,569	$3,914,674	$8,968,013	$9,822,522	$13,122,174	$13,637,321

Ms. DeLauro: What is the current estimate of AID reimbursable funding for FY 2009? How much was reimbursed in FYs 2007 and 2008? For what purpose are these reimbursements provided? In your response, please provide details as to what constitutes agriculturally-related technical assistance in developing countries.

Response: The current estimate for AID reimbursable funding totals $35 million for FY 2009. The actual amount reimbursed for FY 2007 was $44 million and $38.9 million for FY 2008.

Reimbursements are provided for implementation of agricultural technical assistance activities in developing countries. USDA has a long tradition of providing technical assistance and capacity building to help other countries develop a productive agricultural sector in cooperation with host governments, producers, and markets. USDA's expertise and institutional resources, which serve as a reference for other countries and are among the most sophisticated in the world, have been deployed to help countries strengthen food security since the

United States first engaged in foreign assistance. Further, USDA's institutional ties with agribusiness, land grant universities, extension services, and agricultural research centers are fully utilized in providing international technical assistance for agricultural and rural development.

USDA trade and development programs assist foreign governments to adopt productivity-enhancing technologies, reconstruct the agricultural sector in post-conflict or disaster areas, develop sustainable natural resource management systems, and strengthen agricultural research and extension programs. USDA also works with foreign counterparts to advance market-based policies and institutions and expand international trade through trade capacity building. The focus is to help countries meet their World Trade Organization (WTO) obligations, avoid or eliminate barriers to trade, and strengthen policy and regulatory frameworks.

Ms. DeLauro: Please describe the program under which the Department reimburses the Department of State for certain expenses overseas, and update the table that appears in last year's hearing record to include FYs 2001 through 2009. How are these costs calculated? For the 2008 enacted bill and the 2009 request, please disaggregate and itemize the reimbursements to the State Department.

Response: FAS, as well as other agencies, rely on the Department of State to provide in-country administrative support services including such functions as fiscal, personnel, building maintenance, motor pool, and security. Agencies receiving these services reimburse The Department of State (DOS) through the ICASS program. A basic principle of ICASS is to distribute costs in a transparent, fair, and equitable manner. Any costs that can be attributed to a specific agency are directly charged to that agency; not via ICASS. Costs that cannot be easily attributed to an agency are distributed via ICASS using one of the following four methods:

(1) Straight capitation: Charge for services provided based on head count.

(2) Modified capitation: An agency population can be "weighted" using the following standard distribution levels:

1.0 = full service
.6 = mid level
.3 = low level

(3) Workload: Costs are distributed based on workload factors - square feet, miles driven, vouchers processed, etc.

(4) Modified workload: This is the workload method described above but with the flexibility to reduce actual workload statistics to reflect partial usage as follows.

1.0 = full service
.6 = mid level
.3 = low level

FAS COST SUMMARY

REIMBURSEMENT TO STATE DEPARTMENT

Fiscal Year	Total Costs ($000)	FY 2008/2009 Reimbursable Agreements					
		AAO*	AIO*	FODAG*	USEU*	SEC 108*	Other
2001	$9,156	—	—	—	—	—	—
2002	$9,905	—	—	—	—	—	—
2003	$10,372	—	—	—	—	—	—
2004	$10,763	—	—	—	—	—	—
2005	$11,451	—	—	—	—	—	—
2006	$12,875	—	—	—	—	—	—
2007	$13,927	—	—	—	—	—	—
2008	$15,508	9,728	1,406	251	749	12	3,361
2009	$16,526	10,367	1,498	267	798	13	3,582

*Note: AAO - Agricultural Affairs Office; AIO - Agricultural Trade Office; FODAG - Food and Agriculture; USEU - U.S. European Union; Sec. 108 - Section 108; Other - Includes Administrative and Misc. Reimbursable Agreements.

Ms. DeLauro: Please provide a list of all countries where the FAS or attaches have foreign currency accounts and the current dollar value of each account. For what purposes are these funds being used? Please cite the authority in law that permits use of these currencies.

Response: As of October 1, 2008, FAS has unobligated Section 108 foreign currency accounts in the following countries:

Country	U.S. Dollar Equivalents
Costa Rica	$131,803
Tunisia	$13,234,958

Section 108 foreign currencies are used for activities that are intended to result in the development, maintenance, and expansion of long-term export markets for U.S. agricultural products. These funds will help to foster and encourage the development of private enterprise institutions, and infrastructure in developing countries. Section 416 of the Agricultural Trade Development and Assistance Act of 1954, as amended, 7 U.S.C. 1736g.3, authorizes the Secretary to use local currencies, generated under pre-1990 Title I agreements, for market development and agricultural technical assistance activities. "Section 108" refers to section 108 of P.L. 480 as added by section 1111(h) of the Food Security Act of 1985, P.L. 99-198.

Ms. DeLauro: What impact has foreign currency funds had on the development, maintenance, and expansion of long-term export markets for

U.S. agricultural products? Please be specific and provide recent examples of how FAS used funds from Section 108 accounts.

Response: Please find below examples of how Section 108 funds are being used to develop, maintain, and expand long-term export markets for U.S. agricultural products.

Algeria

U.S. Wheat Associates (USW) developed technical outreach under P.L. 480, Section 108, to educate more than 200 Algerian port inspectors and laboratory technicians about the integrity of the U.S. grain inspection, grading and certification system. The *Office Algerian Interprofessional de Cereales* bought more than 125,200 metric tons (MT) of U.S. wheat during the program and 615,000 MT more U.S. wheat in 2007/2008 than the annual average over 3 years before. The incremental sales, at an average of $300 per metric ton, were worth $184.5 million.

Moroccan Milling School

USW had used P.L.480, Section 108, funds and Quality Samples Program (QSP) funding to support the Moroccan milling school in Casablanca. The activities helped students improve skills as they learn about the functional qualities of U.S. wheat. This effort has helped build incremental U.S. wheat sales since 2004/2005. In 2007/2008, Morocco imported 417,000 MT more U.S. wheat, valued at an additional $125 million to the U.S. wheat industry, than in 2006/2007.

Tunisia

USW has built a strong relationship with Tunisia's Office of Cereals (OCT) through P.L. 480, Section 108, activities. In 2007/2008, OCT and Tunisian millers asked USW's Tunis office to provide neutral, third party expertise to address a technical supply issue. Based on the plan USW proposed, OCT bought an additional $55 million of U.S. spring wheat and durum in 2007/2008 compared to 2006/2007.

Ms.DeLauro: From what budget authority does FAS fund the Section 108 accounts?

Response: The Section 108 program uses funds accruing from the local currency repayment provision of the U.S. Department of Agriculture's food aid program (Title I, P.L. 480) under agreements that financed the sale and exportation of agricultural commodities to Costa Rica, the Dominican Republic, Guatemala, Jamaica, Morocco, Sri Lanka, and Tunisia. The 7 U.S.C. 1736g-3 authorizes the Secretary to use local currencies, generated under pre-1990 Title I agreements, for market development and related activities. Thus, the Section 108 law provides independent authority to use Section 108 funds for activities in addition to, and without offsetting, any other funds available for this purpose.

Ms. DeLauro: For FYs 2007 and 2008, please provide a table that details the obligated and unobligated balances for each country where FAS has established Section 108 accounts.

Response: The information is submitted for the record.
[The information follows:]

Obligated Section 108 Balances as of October 1, 2008
(local currency converted to U.S. Dollars)

Country	Balance
Dominican Republic	$368,812
Jamaica	105,992
Morocco	4,117,211
Tunisia	3,294,616
Total	$7,886,631

Unobligated Section 108 Balances as of October 1, 2008
(local currency converted to U.S. Dollars)

Country	Balance
Costa Rica	$131,803
Tunisia	13,234,958
Total	$13,366,761

Note: Section 108 funds are not reported on a FY basis.

Arrearages

Ms. DeLauro: Please update the table that appears in last year's hearing record listing all of the countries that are in arrears in their payments.

Response: The information is submitted for the record.
[The information follows:]

ARREARS REPORT
as of September 30, 2008

	Not Pending Rescheduling		Pending Rescheduling			
Country / Obligor	P.L.-480 Principal Arrears	P.L.-480 Interest Arrears	P.L.-480 Principal Arrears	P.L.-480 Interest Arrears	Total	Arrears
Angola	413	-	-	-		413
Armenia	-	3,642	-	-		3,642
Cambodia	72,457,123	27,008,583	77,413,482	90,563,534		267,442,723
Congo-Brazzaville	1,626,948	78,625	135,806	22,451		1,863,830
Cote D' Ivoire	33,053,598	14,062,984	-	-		47,116,582
Croatia	179	-	-	-		179
Democratic Republic of Congo (Zaire)	57,360,467	28,196,895	-	-		85,557,362

ARREARS REPORT
as of September 30, 2008

	Not Pending Rescheduling		Pending Rescheduling		
Country / Obligor	P.L.-480 Principal Arrears	P.L.-480 Interest Arrears	P.L.-480 Principal Arrears	P.L.-480 Interest Arrears	Total Arrears
Dominican Republic	9,537	398	-	-	9,935
Ecuador	-	424	-	-	424
Eritrea	1,545,348	691,261	-	-	2,236,609
Indonesia (PANGANMAS)	2,685,521	147,734	-	-	2,833,255
Indonesia (SRIBOGA)	3,252,718	174	-	-	3,252,892
Korea	424	-	-	-	424
Macedonia	648	-	-	-	648
Moldova	-	45,274	-	-	45,274
Romania	782,095	-	-	-	782,095
Sierra Leone	3,269,931	2,128,858	-	-	5,398,789
Somali Republic	79,673,793	62,792,182	-	-	142,465,975
Sudan	175,146,357	169,876,729	-	-	345,023,086
Syrian Arab Rep.	54,091,649	12,093,218	-	-	66,184,867
Ukraine	280	444	-	-	724
Uzbekistan	1,480,465	358,601	-	-	1,839,066
Yemen	44,848	171,458	-	-	216,306
Zimbabwe	19,552,229	11,839,323	-	-	31,391,552
Grand Total	$506,034,571	$329,496,805	$77,549,289	$90,585,985	$1,003,666,652

Ms. DeLauro: Please provide a table showing how much CCC has paid out, by country, on loans that are in arrears and what recoveries were made in 2007 and 2008.

Response: The information is submitted for the record.

[The information follows:]

COMMODITY CREDIT CORPORATION

GSM-102, GSM-103, AND SCGP CLAIMS, RECOVERY & RESCHEDULING ACTIVITY

January 1, 2007 to September 30, 2008

Country	GSM Claims Paid	GSM Recoveries Received	GSM Rescheduling	GSM Write-Offs	Subtotal of Years Activity	Outstanding Balance as of 09/30/2008
Argentina	-	-	-	$6,773,506	$6,773,506	$76,853,010
Brazil	$1,530,517	-	-	-	1,530,517	8,979,285
Bulgaria	-	-	-	-	-	585,654
China	-	-		14,971	14,971	440,170
Colombia	-	-	-	403,254	403,254	-
Dominican Republic	-	-	-	-	-	59,757,242
Egypt	-	-	-	-	-	1,140,746
El Salvador	-	-	-	-	-	174,807
Ghana	-	-	-	-	-	1,272,357
Guatemala	(234,832)	60,062	432,774	159,117	417,121	486,612
Guyana	-	-	-	48,477	48,477	-
Hong Kong	-	-	-	-	-	130,862
India	-	-	-	-	-	931,782
Indonesia	-	460,382	40,995,214	-	41,455,596	72,503,858
Jamaica	-	-	-	-	-	2,169,746
Korea	-	-	-	-	-	893,075
Lithuania	-	-	-	54,714	54,714	-
Mexico	-	-	-	1,047,498	1,047,498	120,655,537
Nigeria	-	-	2,629,326		2,629,326	140,398
Peru	-	-	-	3,049,674	3,049,674	1,136,325
Philippines	-	-	-	-	-	1,295,493
Romania	-	-	-	23,759	23,759	-
Russia	-	-	-	774,227	774,227	13,595,183
Singapore	-	-	-	-	-	18,344
Sudan	-	-	-	-	-	61,213,646
Suriname	-	-	-	-	-	14,481,396
Thailand	-	-	-	-	-	5,330,254
Turkey	-	-	-	-	-	2,308,938
Uganda	-	-	-	-	-	12,135,399
Venezuela	-	-	-	-	-	2,507,482
Yemen	-	1,673,956	-	-	1,673,956	2,825,942
Totals	$1,295,685	$2,194,400	$44,057,314	$12,349,197	$59,896,596	$463,963,543

Agricultural Knowledge Initiative with India

Ms. DeLauro: Please describe FAS activities supporting the Agricultural Knowledge Initiative with India. How much was funded in FY 2007 and 2008? What is the estimate for 2009? How, if any, are other USDA agencies involved in this initiative?

Response: FAS has sponsored dozens of activities since FY 2006 to support the U.S.-India Agricultural Knowledge Initiative (AKI) in partnership with the U.S. Agency for International Development (USAID), the U.S. Trade Development Agency, and the Department of State (DOS). FAS also works very closely with USDA's Cooperative State Research, Education, and Extension Service in implementing AKI projects. Activities fall under the four main focus areas: cooperation in university capacity-building, biotechnology, water resource management, and agro-processing and marketing. Principal activities funded by FAS include the Cochran Fellowship and Borlaug Fellows programs and trade capacity building projects in FYs 2007 and 2008. Examples of activities include collaboration in the areas of food safety, contract farming, and water resource management. There have also been an unprecedented number of U.S.-India university partnerships in the four main focus areas. FAS spending on AKI-related projects in FY 2007 and FY 2008 were $415,000 and $1.2 million respectively. In FY 2009, we anticipate implementing projects valued at $675,000.

Overseas Offices

Ms. DeLauro: For all FAS overseas offices, please provide a table organized by region and country that provides the following information: the type of office, the number of American and foreign national staff located at the office, the annual cost to operate the office, and the number of years FAS has operated that office.

Response: Below is a table of FAS overseas offices for FY 2008 organized by region (Africa/Middle East, Western Hemisphere, South and West Asia, Europe and North Asia), city and country and the number of American and foreign national staff assigned to those offices, the annual cost to operate each office, and the number of years FAS has operated that office. Please note FAS is following the State Department practice of replacing Foreign Service Nationals (FSN) with Locally Employed Staff (LES). FSNs are considered employees while LESs are considered contract employees hired under Personal Service Agreements. As FSNs leave/retire they are replaced with LESs, which is a cost savings measure for FAS.

[The information follows:]

CITY	COUNTRY	OAA/ ATO	AMERICAN STAFF	FSN/LES STAFF	ANNUAL COST	YEARS
Accra	Ghana	OAA	0	1	$38,500	[17]
Algiers	Algeria	OAA	0	3	54,972	24
Amman	Jordon	OAA	0	1	30,700	[17]
Baghdad	Iraq	OAA	2	1	67,565	14
Cairo	Egypt	OAA	3	5	411,479	53
Dakar	Senegal	OAA	1	3	230,760	4
Damascus	Syria	OAA	0	1	49,317	33

CITY	COUNTRY	OAA/ ATO	AMERICAN STAFF	FSN/LES STAFF	ANNUAL COST	YEARS
Dubai	United Arab Emirates (UAE)	ATO	1	4	368,564	15
Lagos	Nigeria	OAA	2	4	591,772	48
Nairobi	Kenya	OAA	2	4	300,906	52
Pretoria	South Africa	OAA	3	5	683,295	53
Rabat	Morocco	OAA	1	3	275,275	51
Riyadh	Saudi Arabia	ATO	1	2	191,231	18
Sanaa	Yemen	OAA	0	0	22,800	[17]
Tel Aviv	Israel	OAA	0	3	216,847	49
Tunis	Tunisia	OAA	0	3	86,689	27
Bogota	Colombia	OAA	2	5	670,323	53
Brasilia	Brazil	OAA	3	2	768,271	36
Buenos Aires	Argentina	OAA	2	5	421,891	54
Caracas	Venezuela	OAA	1	5	502,040	52
Guatemala City	Guatemala	OAA	2	4	318,462	52
Kingston	Jamaica	OAA	0	1	54,703	[17]
Lima	Peru	OAA	2	5	435,413	53
Managua	Nicaragua	OAA	0	2	60,246	[17]
Mexico City	Mexico	ATO	2	4	506,617	16
Mexico City	Mexico	OAA	4	7	848,636	53
Miami	Caribbean Basin	ATO	3	0	40,700	10
Monterrey	Mexico	ATO	1	4	423,198	7
Ottawa	Canada	OAA	2	4	548,166	54
Panama City	Panama	OAA	0	2	119,795	17
Quito	Ecuador	OAA	0	2	321,824	53
San Salvador	El Salvador	OAA	0	2	110,836	53
Santiago	Chile	OAA	1	4	424,636	54
Santo Domingo	Dominican Republic	OAA	1	4	366,367	51
San Jose	Costa Rica	OAA	2	4	268,634	53
Sao Paulo	Brazil	ATO	1	5	616,172	54
Tegucigalpa	Honduras	OAA	0	2	66,247	[17]
Toronto	Canada	OAA	0	1	61,430	[17]
Bangkok	Thailand	OAA	2	7	486,949	52
Canberra	Australia	OAA	1	3	406,333	53
Dhaka	Bangladesh	OAA	0	2	47,720	35
Hanoi	Vietnam	OAA	2	4	272,806	12
Ho Chi Minh City	Vietnam	OAA	1	3	180,834	8
Islamabad	Pakistan	OAA	1	4	136,112	41
Jakarta	Indonesia	OAA	2	7	293,099	53
Kuala Lumpur	Malaysia	OAA	1	5	316,306	53
Manila	Philippines	OAA	2	7	446,730	47
Manila	Philippines [27]	ATO	1	4	256,088	6
New Delhi	India	OAA	3	8	566,235	53
Rangoon	Burma	OAA	0	1	23,888	54
Wellington	New Zealand	OAA	1	2	189,621	54
Almaty	Kazakhstan	OAA	0	0	20,030	14
Ankara	Turkey	OAA	2	3	423,897	53
Athens	Greece	OAA	0	2	210,870	52
Belgrade	Serbia-	OAA	0	2	134,250	10

CITY	COUNTRY	OAA/ ATO	AMERICAN STAFF	FSN/LES STAFF	ANNUAL COST	YEARS
	Montenegro					
Berlin	Germany	OAA	2	3	563,045	18
Bonn	Germany	OAA	0	1	174,190	53
Brussels USEU	Belgium	OAA	4	7	1,471,463	48
Bucharest	Romania	OAA	0	2	93,435	29
Budapest	Hungary	OAA	0	1	21,381	53
Copenhagen	Denmark	OAA	0	1	168,383	54
Dublin	Ireland	OAA	0	1	201,146	53
Geneva (USTR)	Switzerland	OAA	3	1	623,387	46
Istanbul	Turkey	OAA	0	2	147,900	23
Kiev	Ukraine	OAA	1	3	203,370	10
London	United Kingdom	OAA	1	4	697,206	54
Madrid	Spain	OAA	1	2	272,507	53
Moscow	Russia	OAA	3	7	825,013	53
Moscow	Russia	ATO	1	3	209,543	11
Paris	France	OAA	2	4	901,394	53
Prague	Czech Republic	OAA	0	2	134,339	[1/]
Rome (USUN)	Italy	OAA	1	1	250,469	30
Rome	Italy	OAA	2	3	805,441	53
Sarajevo	Bosnia/ Herzegovina	OAA	0	1	58,103	[1/]
Sofia	Bulgaria	OAA	1	2	244,581	16
Stockholm	Sweden	OAA	0	2	224,246	53
St. Petersburg	Russia	ATO	0	1	58,462	13
Tashkent	Uzbekistan	OAA	0	1	34,900	[1/]
The Hague	Netherlands	OAA	1	3	478,320	54
Vienna	Austria	OAA	0	2	552,912	54
Vladivostok	Russia	ATO	0	1	45,734	13
Warsaw	Poland	OAA	2	3	524,100	49
Zagreb	Croatia	OAA	0	1	94,593	[1/]
Beijing	China	OAA	5	10	1,142,298	32
Beijing	China	ATO	1	5	545,738	37
Chengdu	China	ATO	1	3	324,446	1
Guangzhou	China	ATO	1	7	431,770	23
Hong Kong	Hong Kong	ATO	2	5	720,738	49
Osaka	Japan	ATO	0	1	389,795	16
Seoul	Korea	ATO	1	6	783,976	28
Seoul	Korea	OAA	3	6	671,431	52
Shanghai	China	ATO	2	8	728,822	13
Shenyang [3/]	China	ATO	1	0	78,707	8 mths
Singapore	Singapore	OAA	0	2	198,451	29
Taipei	Taiwan	ATO	1	4	867,384	16
Taipei	Taiwan	OAA	2	3	129,609	40
Tokyo	Japan	OAA	4	8	1,134,333	53
Tokyo	Japan	ATO	1	6	678,575	22

[1/] FAS has not had an American officer at Posts; and therefore is unable to provide the number of years post has been operational.

[2/] The Philippines, Manila ATO office reflects costs for less than a full year due to its closing in June 2008.

[3/] The expenses are associated with establishing a presence in FY 2008 with an official office scheduled to open in FY 2009.

OAA - Office of Agricultural Affairs; ATO - Agricultural Trade Office.

Agricultural Trade Offices (ATOs)

Ms. DeLauro: What are your plans for FY 2009 for your ATOs? Did you close or open any in FY 2007 or 2008? Do you have any plans to do so in fiscal year 2009?

Response: FAS expects to continue to operate Agricultural Trade Offices (ATOs) as we have in the past with an added emphasis on market access. FAS did not close or open any ATO's in FY 2007. FAS opened one ATO in FY 2008 in Chengdu, China (November 2007); and one ATO will open FY 2009 in Shenyang, China (January 2009) that was originally scheduled to open in FY 2008. FAS did establish a presence in FY 2008 in Shenyang, China, as scheduled; however, it could not open the office due to problems securing its physical location. FAS closed one ATO in Philippines, Manila (June 2008). All of the ATO's functions in Manila were transferred to the FAS Office of Agricultural Affairs in Manila.

Ms. DeLauro: Please list for the record the location of each ATO, the numbers of FAS and foreign nationals assigned to each and the annual cost to operate each of those offices.

Response: The information is submitted for the record:
[The information follows:]

AGRICULTURAL TRADE OFFICES

Fiscal Year 2008
On-Board Employees

LOCATION	AMERICAN	FSN/LES	ANNUAL COST
SAO PAULO, Brazil	1	5	$616,172
BEIJING, China	1	5	545,738
CHEGNDU, China	1	3	324,446
GUANGZHOU, China	1	7	431,770
SHANGHAI, China	2	8	728,822
SHENYANG, China [1/]	1	0	78,707
HONG KONG	2	5	720,738
TOKYO, Japan	1	6	678,575
OSAKA, Japan	0	1	389,795
SEOUL, Korea	1	6	783,976
PHILIPPINES, Manila	1	4	256,088
MEXICO CITY, Mexico	2	4	506,617
MONTERREY, Mexico	1	4	423,198
MOSCOW, Russia	1	3	209,543
ST. PETERSBURG, Russia	0	1	58,462
VLADIVOSTOK, Russia	0	1	45,734
RIYADH, Saudi Arabia	1	2	191,231
TAIPEI, Taiwan	1	4	1,078,512
DUBAI, U.A.E.	1	4	368,564
CARIBBEAN BASIN, USA	3	0	40,700
TOTAL	22	73	$8,477,388

[1/] The information reported is associated with establishing a presence in Shenyang, China in FY 2008. An official office opening is scheduled for FY 2009.

NOTE: FAS is following the State Department practice of switching from Foreign Service Nationals (FSN) to Locally Employed Staff (LES). FSNs are considered employees while LES are considered contract employees hired under Personal Service Agreements. As FSNs leave/retire they are replaced with LES, which is a cost saving measure for FAS.

Bill Emerson Humanitarian Trust

Ms. DeLauro: What commodities were released from the Bill Emerson Humanitarian Trust (the Trust) in FYs 2007 and 2008?

Response: In FY 2008, USDA converted 915,349 metric tons of wheat in the Trust to cash. USDA used part of the cash in the Trust to purchase $143 million of commodities that were used in P.L. 480, Title II programs in Afghanistan, Ethiopia, Kenya, North Korea, and Zimbabwe. Commodities purchased for these programs are shown in the following table.

Commodity	Metric Tons	Commodity Cost ($ Million)
Beans	4,800	$5.4
Bulgur	32,540	14.8
Corn	101,000	28.6
Corn Soy Blend	15,470	8.9
Cornmeal	11,760	5.1
Peas	17,530	10.6
Sorghum	77,380	21.0
Soybeans	5,060	2.3
Vegetable Oil	16,520	30.0
Wheat	41,760	16.4
Total	323,820	$143.1

Ms. DeLauro: As of the start of FY 2009, what is the cash balance held by the Trust?

Response: The cash balance of the Trust was $314.9 million at the beginning of FY 2009.

Ms. DeLauro: At the end of the current agreement for food aid operations in North Korea, what will be the estimated remaining cash holdings in the Trust?

Response: The additional resources in the Trust necessary to complete the North Korea operation will depend on the exact commodities ordered and the prices for those commodities at that time. Our current estimate is that the balance of the Trust is expected to range between $175 million and $195 million after the current operations are complete.

Ms. DeLauro: Please provide a five-year table that reports the reimbursements and/or replenishments to the Trust. What are FAS's plans to replenish the Trust in FY 2009?

Response: No reimbursements or replenishments of the Trust are planned in FY 2009. Please see the table below for a listing of reimbursements during the last 5 years. No replenishments occurred during the 5-year period.

[The information follows:]

Fiscal Year	Amount of Reimbursements ($ Million)
2004	$20
2005	20
2006	0
2007	10 [a/]
2008	100 [a/]

[a/] Funding provided through supplemental appropriations.

Binational Agricultural Research and Development Fund (BARD)

Ms. DeLauro: What is the total amount of U.S. funding provided to the United States-Israel BARD and in what years have the funds been provided?

Response: Since 1979, total funding provided to the U.S.-Israel BARD is $70,220,056, with funding averaging just over $500,000 per year since 2002.

The information is submitted for the record.
[The information follows:]

Fiscal Year	U.S. Contribution
1979	$40 Million
1985	15 Million
1993	2.5 Million
1994	>2 Million
1995	>2 Million
1996	>2 Million
1997	2 Million
1998	500,000
1999	400,000
2000	320,000
2001	390,000
2002	520,000
2003	515,746
2004	512,082
2005	505,385
2006	528,843
2007	528,000
Total	$70,220,056

Ms. DeLauro: What research grants were awarded by BARD in FYs 2007 and 2008?

Response: The following information is for research grants awarded during FY 2007 and FY 2008.
[The information follows:]

FY	Research Grant
2007	Unstable Flow in Repellent and Sub-critically Repellent Soils: Theory and Management Implications
2007	The Fate of Phosphorus Originated from Treated Wastewater and Biosolids in Soils: Speciation, Transport, and Accumulation
2007	Replication Defective Cyprinid Herpes Virus-3 (CyHV-3) as a Combined Prophylactic Vaccine in Carp
2007	Use of Oocyte and Embryo Survival Factors to Enhance Fertility of Heat-stressed Dairy Cattle
2007	Deciphering the Luteal Transcriptome: Insights into the Mechanisms Regulating Corpus Luteum Regression
2007	Enhancing Sustainability of Cattle Production Systems through Discovery of Biomarkers for Feed Efficiency
2007	Molecular Mechanisms of Sex Determination in Cultured Tilapias
2007	Genetic Basis of Cyprinid Herpes Virus-3 Resistance in Common Carp
2007	Simultaneous Treatment of Odorants and Pathogens Emitted from Confined Animal Feeding Operations (CAFOs) by Advanced Oxidation Technologies
2007	Development of Agricultural Sensors Based on Conductive Polymers
2007	Developing Simulation Tool for the Prediction of Cohesive Behavior Agricultural Materials Using Discrete Element Modeling
2007	Sugar and Acid Homeostasis in Citrus Fruit
2007	Regulation of Tomato Fruit Development by Interacting MYB Proteins
2007	Molecular and Anatomical Characterization of Sweet Potato Storage Root Formation
2007	Role of Polyploidy in Vine Cacti Speciation and Crop Domestication
2007	Characterization and Manipulation of the Primary Components in Gibberellin Signaling in the Grape Berry
2007	Map-based Cloning of High-temperature Adult Plant Stripe Rust Resistance Gene Yr36 from Wheat
2007	A Biological Systems Approach to Developing Mealiness-free Peach and Nectarine Fruit
2007	The Molecular and *in vivo* Functions of the Chloroplast Chaperonins

FY	Research Grant
2007	Elucidating Mechanisms that Connect Activation of ROP GTPases, Membrane Dynamics and Signaling in Cell Growth and Stress Responses
2007	MicroRNA Targeted Transcription Factors for Fruit Quality Improvement
2007	Studies of Novel Cytoskeletal Regulatory Proteins that are Involved in Abiotic Stress Signaling
2007	Modulation of the Redox Climate and Phosphatase Signaling in a Necrotroph: an Axis for Inter- and Intra-cellular Communication that Regulates Development and Pathogenicity
2007	Molecular Interactions of *Clavibacter michiganensis subsp. michiganensis* with Tomato
2007	Characterization and Chemistry of Sexual Communication in Two Psyllid Pests of Pears (Homoptera: Psyllidae)
2007	Dissection of Whitefly-geminivirus Interactions at the Transcriptomic, Proteomic, and Cellular Levels
2007	The Unexpected Specificity of a Sea Anemone Small Toxin for Insect Na-channels and its Synergic Effects with Various Insecticidal Ligands: A New Model to Mimic
2007	Genomic Approaches for Understanding Virulence and Resistance in the Sunflower-Orobanche Host-Parasite Interaction
2007	Do Saponins Present in Model Systems and Legume Bread Modulate Cholesterol Absorption *in vitro* and *in vivo*?
2007	Molecular Studies of Postharvest Leaf and Flower Senescence
2008	Physiological and Biochemical Characterization of the Effects of Oxidant Air Pollutants, Ozone and Gas-phase Nitric Acid, on Plants and Lichens for their Use as Early Warning Biomonitors of these Air Pollutant
2008	Development of Predictive Tools for Contaminant Transport through Variably-Saturated Heterogeneous Composite Porous Formations
2008	The Use of Branding and Sampling in Agricultural Fresh Produce
2008	Characterization and Control Strategies of Low Pathogenic Avian Influenza Virus H9N2
2008	Exploration of the Epidemiology of a Newly Emerging Cattle-Epizootic Hemorrhagic Disease Virus in Israel

FY	Research Grant
2008	Genomic and Organismal Studies to Elucidate the Mechanisms of Infectivity of Entomopathogenic Fungi to Ticks
2008	Nutrition of the Developing Chick Embryo: Nutrient Uptake Systems of the Yolk Sac Membrane and Embryonic Intestine
2008	Development and Use of Leptin Receptor Antagonists to Increase Appetite and Adaptive Metabolism in Ruminants
2008	Enhanced Climate Control of Semi-arid and Arid Greenhouses Equipped with Fogging Systems
2008	The Molecular and Biochemical Basis of Terpenoid Aroma Formation in Tomato
2008	Genetic Linkage Mapping of Basil (*Ocimum basilicum*) Field Crops & Hort.
2008	Identification and Allelic Variation of Genes Involved in the Potato Glycoalkaloid Biosynthetic Pathway
2008	Population Genomics and Association Mapping of Disease Resistance Genes in Israeli Populations of Wild Relatives of Wheat, *Triticum dicoccoides* and *Aegilops speltoides*
2008	The Role of GOBLET and Auxin in Controlling Organ Development and Patterning
2008	A Novel Lectin Controls Wound-responses in Arabidopsis
2008	Studying the Involvement of the Linker Protein CWLP and its Homologue in Cytoskeleton-plasma Membrane-cell Wall Continuum and in Drought Tolerance
2008	Controlling Early Stages of DNA Repair for Gene-targeting Enhancement in Plants
2008	Integrated Studies of Chloroplast Ribonucleases
2008	One Host, Two Associated Pests: Responses of Tomato Plants to Whiteflies and Broad Mites
2008	Broad-spectrum Resistance to Root-Knot Nematodes in Transgenic Cucurbits
2008	MAP Kinase Cascades Activated by SlMAPKKKε and their Involvement in Tomato Resistance to Bacterial Pathogens
2008	Molecular Characterization of PBAN G-protein Coupled Receptors in Moth Pest Species: Design of Antagonists

FY	Research Grant
2008	Post-transcriptional Regulation of Host Genes Involved with Symptom Expression in Potyviral Infections
2008	Fungal Iron Acquisition, Oxidative Stress and Virulence in the Cochliobolus-maize Interaction
2008	*thaliana* Defense Genes to Phloem-feeding Insects
2008	Study of the Physiological, Molecular, and Genetic Factors Associated with Postharvest Water Loss in Pepper Fruit
2008	Analysis of Small RNAs Associated with Plant Senescence
2008	Application of Pre-storage Short Anaerobiosis to Alleviate Superficial Scald and Bitter Pit in Granny Smith Apples

Buyout Authority

Ms DeLauro: Did FAS exercise any buyout authority in FY 2007 or 2008? Does FAS plan to exercise any buyout authority in FY 2009?

Response: FAS did not exercise any authorities for buyouts in FYs 2007 and 2008. FAS does not plan to exercise buyout authority in FY 2009.

China

Ms DeLauro: Provide a current update on how China's accession to the WTO affected U.S. agricultural imports and exports.

Response: China formally acceded to the World Trade Organization (WTO) on December 11, 2001. The access conditions for China's agricultural products coming into the U.S. market effectively did not change as a result of that country's accession to the WTO. That development, however, did lead to the removal of the Jackson-Vanik requirement in the case of China and the granting of Permanent Normal Trade Relations by the President on January 1, 2002. In 2007, U.S. imports of agricultural products from China totaled $2.9 billion, compared to $816 million in 2001. Meanwhile, China's accession agreement did provide for concessions (e.g., tariff reductions, expanded tariff-rate quotas) providing improved market access for a range of U.S. products. In 2001, U.S. agricultural exports to China totaled $1.94 billion. By 2007, U.S. exports had more than quadrupled, totaling $8.3 billion.

Cochran Fellowship Program

Ms. DeLauro: Please explain the purpose and recent accomplishments for the Cochran Fellowship Program. How many students, and from what countries, were selected to participate in the program during FY 2007 and 2008? What is the status of the 2009 program? How many students will be selected and what countries will be involved?

Response: Since its start in 1984, the Cochran Fellowship Program has provided U.S.-based training for over 13,400 international participants from 105 countries worldwide. Recent accomplishments include the training of 549 participants from 69 countries during FY 2008 and the implementation of 131 training programs that have enhanced technical capacities in agriculture, helped resolve technical barriers to trade, improved U.S. market access, generated sales opportunities for American agricultural commodities and products, and built goodwill within Cochran countries. During FY 2007, 732 individuals from 72 countries were selected and trained. In FY 2009, approximately 600 to 625 participants will be selected and trained in about 140 to 150 programs. The following countries are targeted as recipients of the Cochran Program during FY 2009:

- Africa & Middle East: Afghanistan, Algeria, Botswana, Egypt, Ghana, Iraq, Jordan, Kenya, Lesotho, Madagascar, Morocco, Namibia, Nigeria, Oman, Senegal, South Africa, Tanzania, Tunisia, Uganda, and Yemen;
- Asia: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, and Vietnam;
- Latin America & Caribbean: Argentina, Brazil, Caribbean Islands, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, and Venezuela;
- Eastern Europe & Eurasia: Albania, Armenia, Azerbaijan, Bosnia-Herzegovina, Croatia, Georgia, Kazakhstan, Kyrgyz Republic, Macedonia, Moldova, Montenegro, Serbia (includes Kosovo), Tajikistan, Turkey, Turkmenistan, Uzbekistan, and Ukraine

Information on countries and their number of fellows is submitted for the record.
[The information follows:]

FY 2007 Participants and Countries

Asia - 164 participants from 9 countries

China	61	Pakistan	1	Vietnam	22
India	8	Philippines	23		
Indonesia	11	Sri Lanka	11		
Malaysia	9	Thailand	18		

Eastern Europe and Eurasia- 180 participants from 20 countries

Albania	10	Kazakhstan	4	Serbia	9
Armenia	10	Kosovo	13	Tajikistan	8
Azerbaijan	1	Kyrgyz Republic	8	Turkey	17
Bosnia and Herzegovina	11	Macedonia	18	Turkmenistan	8
Bulgaria	9	Moldova	8	Ukraine	10
Croatia	11	Romania	9	Uzbekistan	7
Georgia	2	Russia	7		

Latin America and the Caribbean - 224 participants from 21 countries

Antigua and Barbuda	1	Dominican Republic	3	Panama	6
Argentina	20	Ecuador	9	Paraguay	2
Brazil	38	El Salvador	5	Peru	12
Chile	18	Guatemala	13	Trinidad and Tobago	2
Colombia	16	Honduras	13	St. Vincent and the Grenadines	1
Costa Rica	10	Mexico	5	Uruguay	18
Dominica	1	Nicaragua	7	Venezuela	24

Africa and the Middle East - 164 participants from 22 countries

Afghanistan	2	Madagascar	9	Swaziland	1
Algeria	6	Mauritius	1	Tanzania	10
Angola	1	Morocco	4	Tunisia	8
Botswana	5	Namibia	5	Uganda	8
Egypt	9	Nigeria	20	Yemen	11
Ghana	8	Oman	7	Zambia	2
Iraq	3	Senegal	1		
Kenya	22	South Africa	21		

FY 2008 Participants and Countries

Asia - 105 participants from 10 countries

Bangladesh	4	Indonesia	11	Philippines	7
China	36	Malaysia	5	Sri Lanka	3
India	12	Pakistan	4	Thailand	16
Vietnam	7				

Eastern Europe & Eurasia - 151 participants from 18 Countries

Albania	7	Kazakhstan	3	Serbia	9
Armenia	10	Kosovo	3	Tajikistan	7
Azerbaijan	7	Kyrgyz Republic	9	Turkey	20
Bosnia /Herzegovina	8	Macedonia	9	Turkmenistan	7
Croatia	5	Moldova	17	Ukraine	8
Georgia	8	Montenegro	1	Uzbekistan	13

Latin America and the Caribbean - 128 participants from 18 countries

Argentina	8	Ecuador	4	Panama	5
Brazil	15	El Salvador	4	Peru	8
Caribbean	10	Guatemala	11	Uruguay	1
Chile	8	Honduras	10	Venezuela	9
Colombia	16	Jamaica	3		
Costa Rica	5	Mexico	1		
Dominican Republic	5	Nicaragua	5		

Africa and the Middle East - 165 participants from 23 countries

Afghanistan	8	Iraq	19	Oman	7
Algeria	7	Jordan	4	Senegal	12
Benin	6	Kenya	9	South Africa	12
Bot'swana	5	Madagascar	4	Tanzania	11
Burkina Faso	9	Mali	5	Tunisia	5
Chad	3	Morocco	7	Uganda	6
Egypt	5	Namibia	3	Yemen	7
Ghana	5	Nigeria	6		

Ms. DeLauro: Please provide a funding history for the program for the last five years, including funding sources. Is there a carryover in this program and if so, why?

Response: The Cochran Fellowship Program had a very modest carry-over at the end of FY 2008, the bulk of which allows the program to operate uninterrupted during the first quarter of each fiscal year. The information is submitted for the record.

[The information follows:]

Source of funds	FY 2008	FY 2007	FY 2006	FY 2005	FY 2004
Cochran Appropriation	$3,425,000	$3,960,000	$3,960,000	$3,750,000	$4,000,000
Freedom Support Act	0	1,070,000	1,207,000	1,094,000	1,405,000
Emerging Markets Program (EMP)	0	0	200,000	710,000	923,000
Other (USAID, State, Middle East Partnership Initiative)	0	380,000	182,000	0	26,000
Total	$3,425,000	$5,410,000	$5,549,000	$5,554,000	$6,354,000

Ms. DeLauro: Please provide the allocations for this program for FYs 2007 and 2008.

Response: The allocation for FY 2007 was $3.96 million, and the allocation for FY 2008 was $3.425 million.

Conferences

Ms. DeLauro: What FAS conferences took place in FY 2007 and 2008 and where were they held? Please provide details on cost, number of attendees, and purpose.

Response: The information is submitted for the record.
[The information follows:]

FOREIGN AGRICULTURAL SERVICE

FY 2007/2008 LIST OF AGENCY SPONSORED CONFERENCES

Conference Name	Location	Number of Attendees	Agency Justification for Conference	FAS Cost
2007				
Agricultural Trade Office Strategy Meeting	Japan	8	Strategic planning	$1,200
Biotechnology Conference	Turkey	14	Cooperator activity oversight	13,251
Canada Concepts Marketing Workshop	California	5	Annual strategic marketing planning session with cooperators/states	6,933
European Union Consolidated Reporting Meeting, Dairy	Poland	3	Create EU-wide workplan & report for community.	50
FAS-Mexico Strategic Planning Conference	Mexico	12	Strategic planning for FAS Mexico	9,597
Food Safety - HACCP seminar	Romania	1	U.S. food safety control system and HACCP application in U.S. supermarket operations	3,171
General Sales Manager GSM-102 Seminar	Jamaica	3	Discussed risks in international trade through export programs such as GSM-102.	1,728
Global Attaché Conference	Washington, DC	10	Update FAS Attaches Overseas on the FAS issues, along with policy changes and headquarters policy initiatives.	23,809
U.S. Agricultural Export Development Council (USAEDC) Annual Workshop	Maryland	97	Provides a forum for FAS Washington-based staff and members of the U.S. agricultural community to discuss U.S. agricultural trade strategy, learn more about other trade-related topics, and exchange information on specific aspects of the FAS-administered export market development programs.	49,950
U.S. Agricultural Export Development	Washington, DC	231	Provides an opportunity for USAEDC members, FAS	44,208

FOREIGN AGRICULTURAL SERVICE

FY 2007/2008 LIST OF AGENCY SPONSORED CONFERENCES

Conference Name	Location	Number of Attendees	Agency Justification for Conference	FAS Cost
2007				
Council (USAEDC) Annual Attaché Seminar			agricultural counselors and attachés to meet and discuss agricultural trade issues that affect their respective countries of responsibility.	
World Trade Organization Accession	Russia	1	The United States supports Iraq's accession to the World Trade Organization	2,672
Subtotal, FY 2007		385		$156,569
2008				
International Food Aid Conference	Missouri	20	Annual conference for all stakeholders involved in food aid.	$28,646
U.S. Agricultural Export Development Council Workshop (USAEDC) Annual Workshop	Washington, DC	112	Provides an opportunity for USAEDC members, FAS agricultural counselors and attachés to meet and discuss agricultural trade issues that affect their respective countries of responsibility.	31,910
U.S. Agricultural Export Development Council (USAEDC) Annual Attaché Seminar	Maryland	210	Provides a forum for FAS Washington-based staff and members of the U.S. agricultural community to discuss U.S. agricultural trade strategy, learn more about other trade-related topics, and exchange information on specific aspects of the FAS-administered export market development programs.	40,975
Subtotal, FY 2008		342		101,531
Total		727		$258,100

Ms. DeLauro: According to the agency's response to questions for the record, in FY 2006 FAS spent almost $118,000 for 66 staff on one line item and almost $10,000 for 4 staff on another line item to attend an "Administrative Conference" in Miami, Florida. In addition, FAS spent over $20,000 for 11 staff on one line item and almost $1,400 for one staff on another line item to attend an "International Administrative Conference" also in Miami, Florida. Please provide descriptions of these Miami conferences and rationales for their significant cost. What were the conferences' benefits and how did they demonstrably improve the agency's administrative performance?

Response: During FY 2006, FAS only conducted one Administrative Conference. FAS conducted a 5-day International Administrative Conference, "Meeting Tomorrow's Administrative Challenges With Solutions Today!" from June 12 to 16, 2006, in Miami, Florida. The participants included 80 overseas administrative assistants for our overseas posts and 11 FAS/Washington staff who provided the training. The cost included airfare, lodging, meals and incidental expenses, as well as insurance for the overseas participants. The program included topics with direct financial and operational impacts on our overseas offices, including contracting/procurement, ICASS, budget management, debit and credit cards, records management, post management reports, compliance review/audits, and reporting. It is critical that this type of conference be held on a routine basis in an effort to improve financial management and keep USDA and ICASS costs to a minimum.

Ms. DeLauro: Also in FY 2006, FAS spent over $162,000 for 129 staff to attend a 'Global Attaché" Conference" in Washington, DC. What was the purpose of the conference and what accounts for the significant cost to attend a conference in Washington?

Response: The conference held July 15-19, 2006, was a week-long internal conference for approximately 115 U.S. Foreign Service (agricultural) officers from FAS and APHIS entitled "Ahead of the Curve: The Future FAS Overseas." These "global" conferences serve to build organizational cohesion and strengthen the ability of the agency to successfully implement USDA programs around the globe in a variety of challenging environments. Global Attaché Conferences of this size usually take place every 4 years or so and serve to update and inform officers stationed overseas of the latest developments in agency programs and policies (and training on the best methods of delivering our message to their overseas counterparts), and provide the best venue to exchange ideas and develop our global strategy. The program included a town-hall meeting with the Secretary of Agriculture and other senior USDA officials and numerous group and individual meetings with industry representatives, industry and national media, FAS/Washington officials, and other agency representatives. The primary costs of the event were the international travel and per diem expenses for the returning Foreign Service Officers, hotel facilities expenses, and related conference costs including document preparation.

Ms. DeLauro: For the "U.S. Agricultural Export Development Council Annual Workshop," FAS reported total costs of $37,800 for 126 staff in Falls Church, VA, and $26,220 for 138 staff in Washington, DC. Why did FAS report two separate locations for this annual workshop, along with varying costs and attending staff for each location? What

was the purpose of the conference and what accounts for the significant cost to attend a conference in the Washington region?

Response: The U.S. Agricultural Export Development Council (USAEDC) is a non-profit private sector trade association, representing approximately 80 U.S. commodity trade groups, farmer cooperatives, and state regional trade groups from around the country. The costs reported represent registration fees for two separate USAEDC events.

The USAEDC Annual Workshop, which is a 2-day event held in November, provides a forum for FAS Washington-based staff and members of the U.S. agricultural community to discuss U.S. agricultural trade strategy, learn more about other trade-related topics, and exchange information on specific aspects of the FAS-administered export market development programs. The USAEDC Annual Attaché Seminar, which is a 1-day event held in July in conjunction with the FAS Annual Attaché Conference, offers an opportunity for USAEDC members, FAS agricultural counselors and attachés to meet and discuss agricultural trade issues that affect their respective countries of responsibility. Both of these events offer unique opportunities to discuss issues and programs of critical importance to help maintain the strong positive U.S. agricultural trade balance.

Dairy Export Incentive Program (DEIP)

Ms. DeLauro: Please describe any changes you have made in the Export Enhancement Program or the Dairy Export Incentive Program (DEIP) since last year. What was the annual cost of the DEIP in each of FYs 2003-2008, and what is the estimate for FY 2009?

Response: The Food, Conservation, and Energy Act of 2008 repealed EEP and reauthorized DEIP.

Total bonuses awarded under the DEIP were $31.5 million for fiscal year 2003; $2.7 million for FY 2004; $0 for FY 2005, FY 2006, FY 2007, FY 2008, and $0 estimated for FY 2009.

Ms. DeLauro: Please provide a list of the countries that participated in the DEIP program and the amount of product they received in FYs 2007 and 2008.

Response: Due to the prevailing domestic and international market situation, CCC did not issue any invitations or award any bonuses under the DEIP in fiscal years 2007 and 2008.

Ms. DeLauro: How much barter was done in FYs 2005 through 2008?

Response: CCC did not participate in any direct barter arrangements with foreign countries in fiscal years 2005, 2006, 2007, or 2008.

Emerging Markets Program

Ms. DeLauro: Please tell the Committee how funding for the Emerging Markets Program is allocated. Has funding been allocated each year? How is the effectiveness of this program measured? Please

provide examples of how FAS used program evaluations to improve the performance of individual projects and the programs as a whole.

Response: The Emerging Markets Program (EMP) is authorized by Section 1542(d) of the Food, Agriculture, Conservation, and Trade Act of 1990, as amended, to provide funding for technical assistance activities that develop, maintain, or expand the export of U.S. agricultural commodities to overseas emerging markets. Funds have been allocated each year and are authorized to fund both private sector and government initiatives. Applications for EMP funding undergo a multi-phase review by FAS staff and a private sector advisory committee. Among the review criteria considered: evidence of an experienced U.S.-based staff to effectively manage the project; level of commitment on the part of the applicant to contribute matching resources, including cash, goods and services; applicant's demonstrated understanding of the conditions affecting U.S. exports and market share; degree to which the proposed project is likely to contribute to the development, maintenance, or expansion of U.S. agricultural exports to emerging markets; and demonstration of how the proposed project will benefit a particular U.S. industry as a whole. EMP participants must file project progress reports, and a final report must be submitted at completion of the project. This final report should detail the project's success in overcoming the identified trade constraint or opportunity, increases in export sales, and other quantifiable results. In addition to the EMP participant reports, FAS staff may also conduct project evaluations. As many of the EMP projects are one-time events, the feedback from such evaluations may be used by FAS staff to review similar project proposals from other applicants. However, for some multi-year projects, FAS evaluation has provided useful feedback to improve specific aspects of these projects. One example is the Minority Exporter Training Program, which benefited from evaluation and feedback by FAS staff to help make the project more responsive to trainee needs. Finally, all EMP projects are subject to FAS compliance review to ensure that funds are being used in strict accordance with program regulations.

Employee Management Retreats

Ms. DeLauro: Has FAS held any employee management retreats during the past 24 months? If so, where and what was the cost for each location? What was the purpose of the retreats?

Response: FAS had four employee management retreats held at headquarters and in FAS' overseas offices during the last 24 months. The retreats provide FAS the opportunity to assist management in improving internal and external working relationships and policies. FAS' overseas staff held various retreats to strategically coordinate regional activities for the fiscal year. FAS held retreats in Washington, DC and overseas facilities located in China and Kenya. The costs for FY 2007 retreats totaled approximately $37,000 for travel, facilities, and translation services. The costs for the two retreats held in FY 2008 totaled $2,760 to cover facilitator fees and local travel expenses.

Export assistance and promotion

Ms. DeLauro: How much does FAS spend in all export assistance and promotion on alcoholic products, including wines, beers, and distilled spirits?

Response: As of October 22, 2008, the following funds for fiscal years 2006, 2007, and 2008 have been allocated for export assistance and promotion of alcoholic products under the Market Access Program (MAP), the Foreign Market Development (Cooperator) Program, and the EMP.

The information is submitted for the record.
[The information follows:]

Participant	2006	2007	2008
Brewers Association	$195,282	$221,697	$322,454
Distilled Spirits Council	93,196	86,686	153,328
Food Export USA NE	10,000	0	0
Mid-America International Agri-Trade Council	5,000	0	0
New York Wine and Grape Foundation	329,322	233,435	334,955
Northwest Wine Promotion Coalition	842,413	993,034	905,895
Southern United States Trade Association	87,600	57,246	95,104
Wine Institute	6,751,256	8,500,941	7,280,280
Total	$8,314,069	$10,093,039	$9,092,016

Export Enhancement Program (EEP)

Ms DeLauro: Please describe any changes you have made in EEP since last year.

Response: The statutory authority to operate the program was repealed in the Food, Conservation, and Energy Act of 2008.

Ms. DeLauro: Please describe what market conditions would precipitate a large-scale use of the Export Enhancement Program. How much is available in FY 2009 for this purpose and does FAS anticipate using these authorities?

Response: The statutory authority to operate the program was repealed in the Food, Conservation, and Energy Act of 2008.

Facilities Guarantee Program

Ms. DeLauro: Are you forecasting any activities in the Facilities Guarantee Program for FY 2009? Was this program used in FYs 2007 or 2008?

Response: The Food, Conservation, and Energy Act of 2008 amended the provisions of the Facility Guarantee Program (FGP) which requires regulation changes. A program level of $75 million is assumed in the FY 2009 CCC baseline for the FGP; however, it is difficult to project the level of participation. The program was not used in fiscal years 2007 or 2008.

Food Shows

Ms. DeLauro: What international or national food shows were sponsored by FAS during FY 2007 and 2008, and what shows are currently scheduled for FY 2009? Also indicate the location, dates, and purpose of each show. What is the actual and estimated cost for sponsoring the food shows for FYs 2007 through 2009?

Response: The information is submitted for the record. [The information follows:]

FY 2007 SHOWS

EVENT	DATE	LOCATION
WESTERN HEMISPHERE		
Americas Food & Beverage Show	November 8-10, 2006	Miami, Florida
Canadian Food & Beverage	February 18-20, 2007	Toronto, Ontario
ANTAD	March 14-16, 2007	Guadalajara, Mexico
SIAL Montreal	March 28-30, 2007	Montreal, Canada
Expo Alimentos	April 14-15, 2007	San Juan, Puerto Rico
U.S. Food Export Showcase (Food Marketing Institute/FMI)	May 6-8, 2007	Chicago, Illinois
American Food Fair (National Restaurant Association/NRA)	May 19-22, 2007	Chicago, Illinois
Alimentaria Mexico	June 5-7, 2007	Mexico City, Mexico
EXPHOTEL	June 13-15, 2007	Cancun, Mexico
SIAL Mercosur	August 28-31, 2007	Buenos Aires, Argentina
ASIA		
Health Ingredients Japan (Hi Japan)	October 4-6, 2006	Tokyo, Japan
Food & Hotel China, Shanghai	Nov. 30-Dec. 2, 2006	Shanghai, China
FOODEX	March 13-16, 2007	Tokyo, Japan
Seoul Food & Hotel Korea	April 24-27, 2007	Seoul, Korea
SIAL China	May 10-12, 2007	Shanghai, China
HOFEX	May 13-16, 2007	Hong Kong
International Food Ingredients & Additives Exhibition (IFIA)	May 30-June 1, 2007	Tokyo, Japan
Food & Hotel China, Beijing	June 13-15, 2007	Beijing, China
Food Taipei	June 21-24, 2007	Taipei, Taiwan
Asia Food Expo	September 5-8, 2007	Manila, Philippines
Food Ingredients Asia (Fi Asia)	September 26-28, 2007	Bangkok, Thailand
AUSTRALIA		
Fine Food Australia (NEW!)	September 24-27, 2007	Sydney, Australia
EUROPE/RUSSIA		
SIAL Paris	October 22-26, 2006	Paris, France
Health Ingredients Europe (Hi Europe)	November 14-16, 2006	Frankfurt, Germany
Ingredients Russia	December 5-8, 2006	Moscow, Russia
Sirha	January 20-24, 2007	Lyon, France
Fruit Logistica	February 8-10, 2007	Berlin, Germany

BioFach (organics)	February 15-18, 2007	Nuremberg, Germany
International Food & Drink Exhibition (IFE) London	March 18-21, 2007	London, United Kingdom
European Seafood Exposition	April 24-26, 2007	Brussels, Belgium
World Food Moscow	September 18-21, 2007	Moscow, Russia
AFRICA/MIDDLE EAST		
ISRAFOOD (American Café)	November 20-22, 2006	Tel Aviv, Israel
Gulfood	February 19-22, 2007	Dubai, United Arab Emirates
Alimenticia Angola	May 3-6, 2007	Luanda, Angola
Morocco (American Café)	June 4-6, 2007	Casablanca, Morocco

FY 2008 SHOWS

EVENT	DATE	LOCATION
WESTERN HEMISPHERE		
Abastur	October 3-5, 2007	Mexico City, Mexico
Americas Food & Beverage	October 29-31, 2007	Miami, Florida
The Canadian Food & Beverage Show and HostEx	March 2-4, 2008	Toronto, Ontario
ANTAD	March 5-7, 2008	Guadalajara, Mexico
Expo Alimentos	April 5-6, 2008	San Juan, Puerto Rico
SIAL Montreal	April 23-25, 2008	Montreal, Canada
Global Food & Style Expo(NEW)	April 27-29, 2008	Chicago, Illinois
American Food Fair (National Restaurant Association/NRA)	May 17-20, 2008	Chicago, Illinois
EXPHOTEL	June 11-13, 2008	Cancun, Mexico
Alimentec	August 12-16, 2008	Bogota, Colombia
SIAL Mercosur	September 16-18, 2008	Buenos Aires, Argentina
IFE Americas Food & Beverage	September 24-26, 2008	Miami, Florida
Abastur	September 10-12, 2008	Mexico City, Mexico
ASIA		
Food & Hotel Vietnam	Oct. 30-Nov. 1, 2007	Ho Chi Minh City,Vietnam
Food & Hotel China, Shanghai	November 14-16, 2007	Shanghai, China
Health Ingredients Japan (Hi Japan)	November 20-22, 2007	Tokyo, Japan
FOODEX Japan	March 11-14, 2008	Tokyo, Japan
Food & Hotel Asia	April 22-25, 2008	Singapore, Singapore
SIAL China	May 14-16, 2008	Shanghai, China
International Food Ingredients & Additives Exhibition (IFIA)	May 21-22, 2008	Tokyo, Japan
Food Taipei	June 18-21, 2008	Taipei, Taiwan
Food Ingredients Asia (FI Asia)	September 24-26, 2008	Bangkok, Thailand
AUSTRALIA		
Fine Food Australia	September 8-11, 2008	Melbourne, Australia
EUROPE/RUSSIA		
ANUGA	October 13-17, 2007	Cologne, Germany
Food Ingredients Europe		

(Fi Europe)	Oct. 30- Nov. 1, 2007	London, United Kingdom
Fruit Logistica	February 7-9, 2008	Berlin, Germany
BioFach (organics)	February 21-24, 2008	Nuremberg, Germany
Alimentaria Barcelona	March 10-14, 2008	Barcelona, Spain
European Seafood Exposition	April 22-24, 2008	Brussels, Belgium
World Food Moscow	September 23-26, 2008	Moscow, Russia
AFRICA/MIDDLE EAST		
Libya	December 3-5, 2007	Tripoli, Libya
Gulfood	February 24-27, 2008	Dubai, United Arab Emirates
Alimenticia Angola	June 5-8, 2008	Luanda, Angola
Morocco (American Café)	June 2008	Casablanca, Morocco

FY 2009 SHOWS (Planned)

EVENT	DATE	LOCATION
WESTERN HEMISPHERE		
Canadian Food & Beverage Show and HostEx	March 1-3, 2009	Toronto, Ontario
ANTAD	March 10-13, 2009	Guadalajara, Mexico
SIAL Montreal	April 1-3, 2009	Montreal, Canada
Expo Alimentos	April 17-18, 2009	San Juan, Puerto Rico
American Food Fair (National Restaurant Association/NRA)	May 14-19, 2009	Chicago, Illinois
Alimentaria Mexico	June 2-4, 2009	Mexico City, Mexico
EXPHOTEL	June 10-12, 2009	Cancun, Mexico
SIAL Mercosur	September 2009	Buenos Aires, Argentina
Abastur	Sept 30-Oct 2, 2009	Mexico City, Mexico
ASIA		
Health Ingredients Japan (HI Japan)	October 15-17, 2008	Tokyo, Japan
Food & Hotel China, Shanghai	November 11-13, 2008	Shanghai, China
AAHAR	March, 2009	New Delhi, India
FOODEX	March 3-6, 2009	Tokyo, Japan
Food and Hotel Indonesia (American Café)	April 1-4, 2009	Jakarta, Indonesia
Seoul Food & Hotel Korea	May 26-29, 2009	Seoul, Korea
SIAL China	May 19-21, 2009	Shanghai, China
HOFEX	May 6-9, 2009	Hong Kong
International Food Ingredients & Additives Exhibition (IFIA)	May 2009	Tokyo, Japan
Food & Hotel China, Beijing (Tentative)	June 9-11, 2009	Beijing, China
Food Taipei	June 17-20, 2009	Taipei, Taiwan
AFEX Plus (Tentative)	July 2009	Manila, Philippines
Food Ingredients Asia (FI Asia)	September 2009	Bangkok, Thailand
AUSTRALIA		
Fine Food Australia	September 7-10, 2009	Sydney, Australia
EUROPE/RUSSIA		
SIAL Paris	October 19-23, 2008	Paris, France

Health Ingredients Europe (Hi Europe)	November 11-13, 2008	Paris, France
Sirha	January 23-27, 2009	Lyon, France
Fruit Logistica	February 5-7, 2009	Berlin, Germany
BioFach (organics)	February 19-22, 2009	Nuremberg, Germany
International Food & Drink Exhibition (IFE) London	March 15-18, 2009	London, United Kingdom
European Seafood Exposition	April 28-30, 2009	Brussels, Belgium
World Food Moscow	September 2009	Moscow, Russia
AFRICA/MIDDLE EAST		
Libya	December, 2008	Tripoli, Libya
FI Africa	January 2009	Johannesburg, South Africa
Gulfood	February 19-22, 2009	Dubai, United Arab Emirates
Alimenticia Angola	April 2009	Luanda, Angola
Morocco (American Café)	June 2009	Casablanca, Morocco

FAS Trade Show Costs

	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate
Trade Shows	$27,852	$69,515	$80,000

FAS has streamlined its involvement in trade shows, shifting the agency's focus to an inherently governmental role. FAS no longer manages every detail of trade shows, such as direct recruitment and mass mailings. It relies on show organizers, primarily private firms, for all logistics. FAS partners with organizers to ensure quality service for U.S. exporters in the U.S. Pavilions. The organizers also bare the financial risk of the shows.

FAS direct costs involve local servicing of exhibitors, inviting buyers, providing a reception or hospitality event, and in some cases booth fees.

Foreign Market Development (FMD)

Ms. DeLauro: Please update the table in last year's hearing record of actual and estimated costs for the Foreign Market Development (FMD) program.

Response: The information is submitted for the record.
[The information follows:]

Foreign Market Development Cooperator Program					
	($Millions)				
	2004	2005	2006	2007	2008
	Actual	Actual	Actual	Actual	Actual
Marketing Plans	$38.9	$38.6	$38.0	$38.0	$38.0
Program Availability:					
Carryover Balance from Prior Years	10.7	9.2	7.1	6.1	4.7
New Allocation	34.5	34.5	34.5	34.5	34.5
Total Available	45.2	43.7	41.6	40.6	39.2
Program Expenditure:					
Actual Cash Expended	36.0	36.7	35.4	35.9	28.8[1/]
Carryover Balance to Following Year	$9.2	$7.1	$6.1	$4.7	[1/]

[1/]Expenditures are not yet complete for FY 2008.

Ms DeLauro: Please update the tables in last year's hearing record identifying each participant in the FMD/Cooperator program through FY 2008, the overseas location of each participant, the total U.S. contribution to each and a breakdown of that contribution into categories such as travel, housing, office expenses, etc.

Response: The information is submitted for the record.
[The information follows:]

Foreign Market Development (Cooperator) Program 2008 Contribution Estimates by Cost Category									
Participant Name	Compensation/ Allowances	Contractor Payments	International Travel	Trade Promotion	Rent and Supplies	Sales & Trade Relations	Shows	Technical Assistance	Total Contribution
American Forest & Paper Association	$1,062,105	$0	$311,160	$164,575	$398,803	$0	$86,127	$487,083	$2,509,853
American Peanut Council	448,393	39,866	162,847	778,360	601,366	1,599	0	152,396	2,184,827
American Seed Trade Association	216,717	50,270	38,670	52,357	146,562	0	0	14,740	519,316
American Sheep Industry Association	177,605	0	0	98,855	61,933	0	0	296,024	634,417
American Soybean Association	2,074,027	3,630,165	990,430	2,717,770	832,480	93,230	0	502,017	10,840,119
Cotton Council International	2,040,575	0	437,581	248,094	869,897	93,918	0	60,401	3,750,466
Leather Industries of America	59,038	0	793,811	128,500	46,068	0	367,774	0	1,395,191
Mohair Council of America	62,377	3,235	2,777	0	3,945	0	0	0	72,334
National Hay Association	0	0	41,935	69,078	0	36,680	0	18,125	165,818
National Renderers Association	307,216	0	94,726	77,585	155,133	426	8,075	286,773	929,934
National Sunflower Association	50,775	9,978	4,154	16,160	25,722	1,063	0	369,087	476,939
North American Millers Association	173,730	3,386	2,967	2,170	39,876	7,790	0	515	230,434
U.S. Dairy Export Council	605,682	0	0	114,700	256,134	0	31,428	586,284	1,594,228
U.S. Dry Bean Council	43,033	51,142	29,902	3,338	5,677	0	1,359	1,246	135,697
U.S. Grains Council	2,090,673	0	2,286,714	0	462,207	16,979	0	1,299,596	6,156,169
U.S. Hide, Skin and Leather Association	169,473	205,558	198,696	21,871	45,891	0	439,765	11,105	1,092,359
U.S. Livestock Genetics	0	93,361	936,169	234,935	1,181	17,892	105,266	122,038	1,510,842
U.S. Meat Export Federation	1,083,787	25,103	71,379	79,473	420,384	0	12,818	313,669	2,006,613
U.S. Wheat Associates	2,448,947	0	344,008	1,540,228	856,586	40,346	0	2,002,724	7,232,839
USA Dry Pea and Lentil Council	75,164	0	20,494	0	29,473	0	0	110,323	235,454
USA Poultry and Egg Export Council	269,499	0	0	689,150	537,841	0	0	224,985	1,721,475
USA Rice Federation/US Rice Producers	1,504,533	110,056	131,357	1,591,923	82,594	13,601	7,000	0	3,441,064
Total	$14,963,349	$4,222,120	$6,899,777	$8,629,122	$5,879,753	$323,524	$1,059,612	$6,859,131	$48,836,388

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
Alaska Seafood Marketing Institute	Shanghai Shengming Trade Company	29G, Shanghai Pufa Tower	588 South Pudong Road		Pudong	China, Peoples Republic of
Alaska Seafood Marketing Institute	Markonsult	58 Rue Pottier	78150		Le Chesnay	France
Alaska Seafood Marketing Institute	R&L Associates Inc.	5-31-2 #410Kasuga-cho			Nerima-ku, Tokyo	Japan
Alaska Seafood Marketing Institute	D. McClellan, S.L.	C/Borrell 7 - Local 19	St. Cugat del Valles		Barcelona	Spain
Alaska Seafood Marketing Institute	Andrew Brown Associates	P.O. Box 14			Giuldford	United Kingdom
Almond Board of California	PR Consultants Limited	Unit D, 14 Floor Vulcan House	21-23 Leighton Road		Hong Kong	Hong Kong
Almond Board of California	18 Efremova Street, Bld. 41	119048			Moscow	Russian Federation
Almond Board of California	3/F, #31 Lane 33	Section 1 Chien-kuo N. Road	104		Taipei	Taiwan
Almond Board of California	c/o Ketcham	35-41 Folgate Street	E1 6BX		London	United Kingdom
American Forest & Paper Association	Rm 3703, Bldg 1st, Great Grandway Center	No. 1, Hong Qiao Road,			Hong Qiao	China, Peoples Republic of
American Forest & Paper Association	Rm605, CITIC Building	No. 19 Jianguomenwai Dajie	100004		Beijing	China, Peoples Republic of
American Forest & Paper Association	528 W Wing, New World Office Building	20 Salisbury Road	Tsimshatsui		Hong Kong	Hong Kong
American Forest & Paper Association	1st Floor KOWA #9 Building Annex	6-7 Akasaka 1-chome			Tokyo	Japan
American Forest & Paper Association	Room #303, Leema Building	146-1 Susong-dong, Chongro-Ku			Seoul	Korea, Republic of
American Forest & Paper Association	Sierra Candela No. 111 Int. 507/508	Col. Lomas De Chapultepec,	CP 11000, D.F.		Mexico City	Mexico
American Forest & Paper Association	AF&PA/AHEC - London	3 St. Michael's Alley	EC3V 9DS		London	United Kingdom

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
American Hardwood Export Council	Rm. 3703, Bldg 1st,Great Grandway Center	No. 1 Hong Qiao Road			Shanghai	China, Peoples Republic of
American Hardwood Export Council	3 St. Michael's Alley	EC3V 9DS			London	UK
American Hardwood Export Council	c/o American Consulate General	2-11-5 Nishitenma	Kita-ku		Osaka	Japan
American Hardwood Export Council	U.S. ATO, Room #303, Leema Building	146-1, Susong-dong Chongro-ku			Seoul	Korea, Republic of
American Hardwood Export Council	Sierra Candela No. 111 - 507	Col. Los Morales Polanco			Mexico City	Mexico
American Hardwood Export Council	Room 528, AIA Tower	New World Center, 20 Salisbury Road	Tsimshatsui		Kowloon	Hong Kong
American Peanut Council	Grosvenor Gardens House	35-37 Grosvenor Gardens			London	United Kingdom
American Seafood Institute	Baekgaardsvej 1	DK-2640			Hedehusene	Denmark
American Seafood Institute	R&L Associates Inc.	5-31-2 #410	Kasuga-cho		Tokyo	Japan
American Soybean Association	Rue du Luxembourg 16b				Brussels	Belgium
American Soybean Association	Suite 902, China World Tower 2	No. 1 Jianguomenwai Avenue			Beijing	China, Peoples Republic of
American Soybean Association	149 Jor Bagh				New Delhi	India
American Soybean Association`	Toshin Tameike Building, 4th Floor	1-6-19 Akasaka			Tokyo	Japan
American Soybean Association	11th Fl. Press Center	25, Taepyung-ro 1Ga	Chung-gu		Seoul	Korea, Republic of
American Soybean Association	Ave. Mariano Otero No. 1249	Torre Pacifico Int. B 171M	Col. Rinconada del Bosque		Guadalajara	Mexico
American Soybean Association	541 Orchard Road	#11-03 Liat Towers	238881		Singapore	Singapore
American Soybean Association	6 Fl., #27, Chang An East Road	Section 1			Taipei	Taiwan

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Participant	Address1	Address2	Address3	Address4	City	Country
American Soybean Association	BJK Plaza, Suleyman Seba Cad No. 92	A-Blok, Kat-8 No. 85/86	80680 Besiktas		Istanbul	Turkey
APA-The Engineered Wood Association	RM. 3703, Building 1, Grand Gateway, #1	Hongqiao Road	200030		Shanghai	China, Peoples Republic of
APA-The Engineered Wood Association	Room 605 CITIC Building Tower A	No. 19, Jianguomenwai Daije	100004		Beijing	China, Peoples Republic of
APA-The Engineered Wood Association	Toranomon 40MT Bldg. 4F	5-13-1 Toranomon, Minato-ku	105-0001		Tokyo	Japan
APA-The Engineered Wood Association	Mecma S.A. de C.V	KM 3.5 Caarr Coatepec Las Trancas	Coatepec		Veracruz	Mexico
APA-The Engineered Wood Association	Siera Candela #111, #507	Lomas de Chapultepec	11100		Mexico City	Mexico
Blue Diamond Growers	Eastern Zone Company	21-A Chaiwan Industrial Centre	20 Lee Chung Street		Chai Wan	Hong Kong
Blue Diamond Growers	Godrej Foods Limited	L.M. Nadkarni Marg	Near M.P.T. Hospital, Wadala (E)		Mumbai	India
Blue Diamond Growers	Toranomon NS Building 3F	22-25 Toranomon 1-Chome	Minato-ku		Tokyo	Japan
Blue Diamond Growers	Furnei Company	11th Floor, No. 88	Section 2, hsin Yi Road		Taipei	Taiwan
Blue Diamond Growers	Heritage Murgerbon Corp Ltd.	34/1 Soi Mooban Malee	Putthamonthon Sai 4 Road	Sampran 73220	Nakornpathom	Thailand
California Ag Export Council	Louis Ng and Associates Ltd.	Suite B 3rd Floor	Luen Wai Commercial Building	93-97 Des Voeux Road	West Hong Kong	Hong Kong
California Ag Export Council	J. Brain, Inc.	Kohyo Bldg. 7F, Honcho 5-49	Naka-ku, Yokohama-shi	231	Kanagawa	Japan
California Ag Export Council	Yamano & Associates	Residence Viscountess, Suite 310	1-11-36 Akasaka	Minato-ku, 107	Tokyo	Japan
California Ag Export Council	California Office of Trade and Investmen	Paseo de la Reforma 265, 14th Floor	Colonia Cuauhtemoc	06500	Mexico City	Mexico
California Asparagus Commission	Ken Berger Sales	1054 Centre Street	Suite 221	Ontario L4J 8E5	Thornhill	Canada

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
California Asparagus Commission	Milton Group, Inc.	Moto Akasaka Building 9F	9-1-7-581 Akasaka	Minato-ku 107-0052	Tokyo	Japan
California Asparagus Commission	Steven Chu & Associates Co., Ltd.	10F-3, No. 508, Chung Hsiao E. Road	Sec. 5 110		Taipei	Taiwan
California Cherry Advisory Board	22 Daymer Gardens	Pinner HA5 2HP			Middlesex	United Kingdom
California Cling Peach Advisory Board	Grupo PM S.A. de C.V.	Sol Esquina Mercurio No. 24	Colonia Jardines de Cuernavaca	Morelos CP 62360 Mexico	Cuernavaca	Mexico
California Dried Prune Board	7B Yi Cui Court, Crest Garden	97 Song Lin Road, Pudong	200120		Shanghai	China, Peoples Republic of
California Dried Prune Board	Euro-American Marketing Services	The Old Chapel	41 Main Street Lubenham		Leiscestershire	United Kingdom
California Dried Prune Board	K-3/17 DLF Phase II				Gurgaon	India
California Dried Prune Board	Uniflex Marketing, Inc.	Pacific Bldg., 3 Fl.	1-5-3, Higashiazabu, Minato-ku		Tokyo	Japan
California Dried Prune Board	Arab Marketing & Finane, Inc. (AMFI)	Tabbara Bldg. 4th Floor, Manara Ras Beir	P.O. Box 113-5028		Beirut	Lebanon
California Dried Prune Board	Grupo PM S.A. de C.V.	Brisas De Tampico No. 14	Las. Brisas de Cuernavaca	Morelos C.P. 62580	Temixco	Mexico
California Fig Advisory Board	Milton Consultants, Ltd	867-6 Kita Imaizumi	Chiba 299-32		Oamishirasato	Japan
California Kiwifruit Commission	Faye Clack Marketing & Communications	5025 Orbiter Drive	Ontario L4W 4Y5		Mississauga	Canada
California Kiwifruit Commission	Sohn's Market Makers	Room 1506-1507 Hansuh Building 11-11	Yoido-dong, Youngdeungpo-ku		Seoul	Korea, Republic of
California Kiwifruit Commission	Atlanta #143	Colonia Noche Buena			Mexico City	Mexico
California Kiwifruit Commission	Steven Chu & Associates Co., Ltd.	13F, No. 102, Civil Boulevard, Sec 4			Taipei	Taiwan

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
California Pear Advisory Board	Faye Clack Marketing & Communications	5025 Orbiter Drive	Ontario L4W 4Y5		Mississauga	Canada
California Strawberry Commission	Suite B, 3rd Floor	Luen Wai Commercial Building	93-97 Des Voeux Road West		Hong Kong	Hong Kong
California Strawberry Commission	Uniflex Marketing, Inc.	Pacific Bldg., 3 Fl.	1-5-3, Higashiazabu, Minato-ku		Tokyo	Japan
California Strawberry Commission	Grupo PM S.A. de C.V.	Sol Esquina Mercurio No. 24	Colonia Jardines de Cuernavaca	Morelos C.P. 62360	Cuernavaca	Mexico
California Table Grape Commission	Rua Mourato Coelho, 299 Suite 2	Cj. 2 - Pinheiros	CEP. 05417 010		Sao Paulo	Brazil
California Table Grape Commission	Bai Yun Hotel, Room 720	367 Huanshi Dong Road 510060			Guangzhou	China, Peoples Republic of
California Table Grape Commission	Room 415, No. 266	Xi Kang Road, 200040			Shanghai	China, Peoples Republic of
California Table Grape Commission	Louis Ng and Associates Ltd.	Suite B 3rd Floor	Luen Wai Commercial Building	93-97 Des Voeux Road	West Hong Kong	Hong Kong
California Table Grape Commission	PEKA Consult.Inc.	Jalan Kemang Raya No. 1	12730		Jakarta	Indonesia
California Table Grape Commission	J. Brain, Inc.	Kohyo Bldg. 7F, Honcho 5-49	Naka-ku, Yokohama-shi		Kanagawa	Japan
California Table Grape Commission	Sohn's Market Makers	Room 1506-1507 Hansuh Building 11-11	Yoido-dong, Youngdeungpo-ku		Seoul	Korea, Republic of
California Table Grape Commission	DB Consultancy	26 Jalan Assunta	46050 Petaling Jaya		Selango Darul Ehsan	Malaysia
California Table Grape Commission	Grupo PM S.A. de C.V.	Brisas De Tampico No. 14	Las. Brisas de Cuernavaca	Morelos C.P. 62580	Temixco	Mexico
California Table Grape Commission	The Marketing Department	P.O. Box 56512/Dominion Road	1 Locarno Avenue	Sandringham	Auckland	New Zealand
California Table Grape Commission	Suite 910 West Tower	Philippines Stock Exchange Building	Ortigas Center		Pasig City	Philippines
California Table Grape	Lieu Marketing Associates	Block 138	150138		Singapore	Singapore

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
Commission	Pte., Ltd	Alexandra Road #01-221				
California Table Grape Commission	Steven Chu & Associates Co., Ltd.	13F, No. 102, Civil Boulevard, Sec 4			Taipei	Taiwan
California Table Grape Commission	Andrew Brown Associates	P.O. Box 14	Surrey GU1 2RH		Guildford	United Kingdom
California Tree Fruit Agreement	Michael Wong and Company, LTD	7C Queen's Centre	58-64 Queen's Road East		Wanchai	Hong Kong
California Tree Fruit Agreement	J. Brain, Inc.	Kohyo Building 7F	Honcho 5-49 Naka-Ku Yokahama-shi,		Kanaga	Japan
California Tree Fruit Agreement	Grupo PM S.A. de C.V.	Mercurio y Sol No. 24	Colonia Jardines de Cuernavaca	Morelos C.P. 62580	Cuernavaca	Mexico
California Tree Fruit Agreement	The Marketing Department	P.O. Box 56512/Dominion Road	1 Locarno Avenue	Sandringham	Auckland	New Zealand
California Tree Fruit Agreement	Lieu Marketing Associates Pte., Ltd	Block 3, Unit #08-22	Alexandra Distripark	Pasir Panjang Road 118483	Singapore	Singapore
California Tree Fruit Agreement	Steven Chu & Associates Co., Ltd.	10F-3, No. 508, Chung Hsiao E. Rd.			Taipei	Taiwan
California Walnut Commission	Viamonte 675, piso 11 A	1053			Buenos Aires	Argentina
California Walnut Commission	McAlpine & Company	12 Valdemar Court	3187 Victory		East Brighton	Australia
California Walnut Commission	Rua Mourato Coelho, 299 Suite 2	Cj. 2 - Pinheiros	CEP. 05417 010		Sao Paulo	Brazil
California Walnut Commission	Maria Kraus Marketing & Kommunikation	Hinter Hoben 13	53129		Bonn	Germany
California Walnut Commission	MS& P	88 Gordon Street	64389		Tel Aviv	Israel
California Walnut Commission	Access S.A.S.	Via Enrico Glori, 30	00137		Rome	Italy
California Walnut Commission	MK Netmark, Inc.	Suite 201, Alasaka TM Flat	7-6-16 Akasaka Minato-ku	107	Tokyo	Japan
California Walnut Commission	Sohn's Market Makers	Room 1506-1507 Hansuh Building 11-	Yoido-dong, Youngdeungpo-ku	150-010	Seoul	Korea, Republic of

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Participant	Address1	Address2	Address3	Address4	City	Country
		11				
California Walnut Commission	Alta Definicion & Washington Olivetto	Avda. Diagonal, 407 Bis, Planta 11	08008 Barcelona Spain			Spain
California Walnut Commission	Nicholas Lin Marketing Services	1, Alley 38, Lane 209	Kung Kuan Road	Peitou 112	Taipei	Taiwan
Cherry Marketing Institute	Tangstedter Chaussee 12	25462			Rellingen	Germany
Cherry Marketing Institute	Moto Akasaka Building 9F	9-1-7-581 Akasaka	Minato-ku,		Tokyo	Japan
Cotton Council International	Zoroastrian Building, 20th Floor	101 Leighton Road			Causeway Bay	Hong Kong
Cotton Council International	Leema Building, Suite 303	146-1 Soosong-Dong, Chongro-ku	110-140		Seoul	Korea, Republic of
Cotton Council International	Empire House 5th Floor	175 Piccadilly	W1J 9EN		London	United Kingdom
Florida Department of Citrus	137 River Oaks Boulevard, West	Oakville, Ontario L6H 3S7 Canada				Canada
Florida Department of Citrus	Room 1305, Guo Li Building	1465, Biejing Road West	200040		Shanghai	China, Peoples Republic of
Florida Department of Citrus	International Ag Market Development Co.	310 rue de la Tour, Centra 114	94566 Cedex		Rungis	France
Florida Department of Citrus	Louis Ng & Associates Ltd.	Suite B, 3rd Floor	Luen Wai Commercial Building	93-97 Des Voeus Road	West Hong Kong	Hong Kong
Hawaii Papaya Industry Association	Koyo Advertising, Ltd.	11-8, Sekiya-cho, Adachi-ku			Tokyo	Japan
National Hay Association	1010-1302 Imachon, 101 Imadong, Bundung-	Kyunggi-Do, 463-901			Sungman-Shi	Korea, Republic of
National Honey Board	Arab Marketing & Finane, Inc. (AMFI)	Tabbara Bldg. 4th Floor, Manara Ras Beir	P.O. Box 113-5028		Beirut	Lebanon

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Participant	Address1	Address2	Address3	Address4	City	Country
National Potato Promotion Board/United States Potato Board	Michael Wong and Company, LTD	3B Harvard Commercial Building	105 Thomson Road		Wanchai	Hong Kong
National Potato Promotion Board/United States Potato Board	Market Makers, Inc.	Seibunkan Building 5F	5-9 Lidabashi, 1-Chome, Chiyoda-ku		Tokyo	Japan
National Potato Promotion Board/United States Potato Board	Yamano & Associates	Residence Viscountess, Suite 310	1-11-36 Akasaka	Minato-ku	Tokyo	Japan
National Potato Promotion Board/United States Potato Board	Sohn's Market Makers	Room 1506-1507 Hansuh Building 11-11	Yoido-dong, Youngdeungpo-ku	150-010	Seoul	Korea, Republic of
National Potato Promotion Board/United States Potato Board	Grupo PM S.A. de C.V.	Brisas De Tampico No. 14	Las. Brisas de Cuernavaca	Morelos C.P. 62580	Temixco	Mexico
National Potato Promotion Board/United States Potato Board	Lieu Marketing Associates	Block 4, Unit 09-11	Pasir Panjang Road	0511	Singapore	Singapore
National Potato Promotion Board/United States Potato Board	Steven Chu & Associates Co., Ltd.	13F, No. 102, Civil Boulevard, Sec 4			Taipei	Taiwan
National Renderers Association	21/Fl., Causeway Bay	1-5 Sugar Street			Hong Kong	Hong Kong
National Renderers Association	Sierra Candela No. 111 Office 501	Lomas de Chapultepec			Mexico City	Mexico
New York Wine and Grape Foundation	Ketchin Sales & Marketing	74 Hurontario Street, Suite 206	Ontario L9Y 2L8		Collingwood	Canada
New York Wine and Grape Foundation	Cateador Food & Beverage	Rusthallarev agen 2B	S-191 78		Sollentuna	Sweden
Northwest Wine Coalition	The Forefront Communications, inc.	30 Tresillian Road	Ontario M3H 1L6		Toronto	Canada
Northwest Wine Coalition	Westbury Blake Mrktg & Communication	3 Imperial Studios, Imperial Road	SW6 3AG		London	United Kingdom
Ocean Spray Cranberries, Inc.	2nd Floor, Riversdell	HouseGuildfo rd Street Chertsey	KT16 9AU		Surrey	United Kingdom
Pear Bureau of Northwest	International Ag Markt Devel Co (IAMDC)	416 Avenue Louise, Bte 16	1050		Brussels	Belgium

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Participant	Address1	Address2	Address3	Address4	City	Country
Pear Bureau of Northwest	Produce Mkt Comunicacao	Rua Mourato Coelho, 798	CJ 121 Pinheiros	CEP 05417-001	Sao Paulo	Brazil
Pear Bureau of Northwest	Faye Clack Marketing & Communications	5025 Orbiter Drive	Ontario L4W 4Y5		Mississauga	Canada
Pear Bureau of Northwest	International Ag Market Development Co.	Stadtdelch 27, 2nd Floor	20097		Hamburg	Germany
Pear Bureau of Northwest	Louis Ng and Associates Ltd.	Suite B 3rd Floor	Luen Wai Commercial Building	93-97 Des Voeux Road	West Hong Kong	Hong Kong
Pear Bureau of Northwest	PEKA Consult.Inc.	Jalan Kemang Raya NO. 1	12730		Jakarta	Indonesia
Pear Bureau of Northwest	Grupo PM S.A. de C.V.	Brisas De Tampico No. 14	Las. Brisas de Cuernavaca	Morelos C.P. 62580	Temixco	Mexico
Pear Bureau of Northwest	Nekrasovskaya, Rm 88, 4th Floor,	Office 302, Box 305	Vladivostok 690002 Russia, UI			Russian Federation
Pear Bureau of Northwest	Arab Circle Marketing	P.O. Box 503	Jeddah 21421 Saudi Arabia			Saudi Arabia
Pear Bureau of Northwest	Lieu Marketing Associates	Block 4, Unit 09-11	Pasir Panjang Road	0511	Singapore	Singapore
Pear Bureau of Northwest	Steven Chu & Associates Co., Ltd.	13F, No. 102, Civil Boulevard, Sec 4			Taipei	Taiwan
Pear Bureau of Northwest	Andrew Brown Associates	P.O. Box 14	Surrey GU1 2RH		Guildford	United Kingdom
Pet Food Institute	NES Bldf. 2F	PRAP Japan, Inc. Sakuragaoka-cho	Shibuya-ku, 150		Tokyo	Japan
Pet Food Institute	Bosque de Duraznos No. 61 - 4 Piso	Bosques de las Lomas	11700 Mexico, D.F.		Mexico City	Mexico
Pet Food Institute	4 Pudovkina str.	119285			Moscow	Russian Federation
Raisin Administrative Committee	Louis Ng and Associates Ltd.	Rm 1301-4, Hua Fu Comm. Bldg.	111 Queen's Road West		Hong Kong	Hong Kong
Raisin Administrative Committee	H-1124	Deres u. 10/D			Budapest	Hungary
Raisin Administrative Committee	Market Makers, Inc.	Seibunkan Building 5F	5-9 Lidabashi, 1-Chome, Chiyoda-ku		Tokyo	Japan

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Participant	Address1	Address2	Address3	Address4	City	Country
Raisin Administrative Committee	Lieu Marketing Associates Pte., Ltd	Block 3 Alexandra Distripark	United 08-22 Pasir Panjang Road	118483	Singapore	Singapore
Raisin Administrative Committee	c/Borrell 7-Local 19	08190 St. Cugat de Valles			Barcelona	Spain
Raisin Administrative Committee	Steven Chu & Associates Co., Ltd.	10F-3, No. 508, Chung Hsiao E. Road	Sec. 5, 110		Taipei	Taiwan
Raisin Administrative Committee	78-80 Glentham Road	Barnes SW13 9JJ			London	United Kingdom
Softwood Export Council	#605A CITIC Building Tower A	19, Jianguomenwai Street	100005 China		Beijing	China, Peoples Republic of
Softwood Export Council	25 Castle Street	Bucks	HP13 6RU		High Wycombe	United Kingdom
Softwood Export Council	Toranomon 40MT Bldg. 4F	5-13-1 Toranomon, Minato-ku,	105-0001		Tokyo	Japan
Softwood Export Council	Leema Building # 303	146-1- Susong-dong, Chongro-ku	110-140		Seoul	Korea, Republic of
Softwood Export Council	KM 3.5 Carr Coatepec Las Trancas	Xalapa, Veracruz 9100 Mexico	Veracruz CP 91500		Coatepec	Mexico
Softwood Export Council	Siera Candela #111, # 507	Lomas de Chapultepec	11100 D.F		Mexico City	Mexico
Softwood Export Council	Opalo 30	28224 Pozuelo de Alarcon			Madrid	Spain
Southern Forest Products Association (SFPA) and Southern Pine Council (SPC)	25 Castle Street	Bucks	HP13 6RU		High Wycombe	United Kingdom
Southern Forest Products Association (SFPA) and Southern Pine Council (SPC)	Toranomon 40MT Bldg. 4F	5-13-1 Toranomon, Minato-ku,	105-0001		Tokyo	Japan
Southern Forest Products Association (SFPA) and Southern Pine Council (SPC)	Mecma S.A. de C.V., Apartado Post 459	Veracruz 9100			Xalapa	Mexico

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Participant	Address1	Address2	Address3	Address4	City	Country
Southern Forest Products Association (SFPA) and Southern Pine Council (SPC)	Siera Candela #111, # 507	Lomas de Chapultepec	11100		Mexico City	Mexico
Southern Forest Products Association (SFPA) and Southern Pine Council (SPC)	Avda. de Europa, 42, Local A	28224 Pozuelo de Alarc¢n			Madrid	Spain
Texas Produce Export Association	Uniflex Marketing, Inc.	Pacific Building, 3rd Floor	1-5-3, Higashiazabu, Minato-ku	Tokyo 106 Japan		Japan
The Catfish Institute (TCI)	1054 Centre Street	Suite 221		Thornhill, Ontario L4J 8E5		Canada
U.S. Apple Export Council	22 Daymer Gardens	Pinner, Middlesex HA5 2HP	United Kingdom			United Kingdom
U.S. Dairy Export Council	Contacts International	Av. Lins de Vasconcelos	3282 - cj. 31/32		Sau Paulo - SP	Brazil
U.S. Dairy Export Council	PR Consultants, Ltd.	Shanghai Centre East Tower, Suite 436	1376 Nanjing Xi Lu		Shanghai	China, Peoples Republic of
U.S. Dairy Export Council	PR Consultants, Ltd	Suite 1406B Maiden Court	46 Cloudview Road, North Point		Hong Kong	Hong Kong
U.S. Dairy Export Council	Market Makers, Inc.	Seibunkan Building 5F	5-9, Iidabashi 1-chome	Chiyoda-ku	Tokyo	Japan
U.S. Dairy Export Council	IntNet	2nd Floor, Yuhan Building	591-14, Shinsa-dong	Kangnam-gu	Seoul	Korea, Republic of
U.S. Dairy Export Council	AMFI	P.O. Box 113-5028	Tabbara Bldg., Manara		Beirut	Lebanon
U.S. Dairy Export Council	AMMEX - Mexico City	Matanzas 733-B	Col. Lindavista Deleg. G.A. Madero		Mexico City	Mexico
U.S. Dairy Export Council	AMMEX - Queretaro	Regules #2 esquina Madero Interior 3	colonia Centro, Codigo Postal		Queretaro	Mexico
U.S. Dairy Export Council	PR Consultants, Ltd.	Suite 7D-07, Taipei World Trade Centre	No. 5, Section 5, Hsin Yi Road		Taipei	Taiwan
U.S. Dairy Export Council	Pacrim Associates Ltd.	11/14 Soi Ruam Rudee	Wireless Road		Bangkok	Thailand

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Participant	Address1	Address2	Address3	Address4	City	Country
U.S. Dairy Export Council	Mistral Group	Staplehurst Office Centre	Weston on the Green		Oxfordshire	United Kingdom
U.S. Grains Council	Room 901 China World Tower 2	No. 1 Jianguomenwai Avenue			Beijing	China, Peoples Republic of
U.S. Grains Council	8 Abd El Rahman El Rafei Street	8th Floor, Flat 804 Mohandessin			Cairo	Egypt
U.S. Grains Council	4th Floor, KY Tameike Building	1-6-19, Akasaka, Minato-ku			Tokyo	Japan
U.S. Grains Council	# 303 Leema Building	146-1 Susong-dong, Chongro-ku			Seoul	Korea, Republic of
U.S. Grains Council	Suite 3B-7-3A, Block 3B, Level 7	Plaza Sentral, Jalan Stesen Sentral 5	50470		Kuala Lumpur	Malaysia
U.S. Grains Council	Jaime Balmes 8-602	Col. Los Morales Polanco	11510		Mexico City	Mexico
U.S. Grains Council	Denezhnyi peroulek 7	Building 2	119002		Moscow	Russian Federation
U.S. Grains Council	7th Floor, 157 Nanking East Road	Section 2			Taipei	Taiwan
U.S. Grains Council	9 bis Ave. Louis Braille, #A3	1002 Tunis-Belvedere			Tunis	Tunisia
U.S. Grains Council	U.S. Grains Council	P.O. Box 5285			Dubai	United Arab Emirates
U.S. Meat Export Federation	A/19F Junhui Bldg, No. 7, Tiyu Rd. West	Tianhe District	510620		Guangzhou	China, Peoples Republic of
U.S. Meat Export Federation	East Ocean Center	A-24 Jianguomenwai Road, Suite 505	Chao Yang District, 100004		Beijing	China, Peoples Republic of
U.S. Meat Export Federation	Room 1010, Shanghai Central Plaza	227 Huangpi Bei Lu, Hugnapu Distrct	200003		Shanghai	China, Peoples Republic of
U.S. Meat Export Federation	Room 4-4-2	100 Yan He Street, HuangGu District	110036		Shenyang	China, Peoples Republic of

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Participant	Address1	Address2	Address3	Address4	City	Country
U.S. Meat Export Federation	18 St. Mary's Street	Oxfordshire	OX10 0EW		Wallingford	United Kingdom
U.S. Meat Export Federation	Zoroastrian Building, 8th Floor	101 Leighton Road			Causeway Bay	Hong Kong
U.S. Meat Export Federation	5th Floor KY Tameike Building	6-19 Akasaka, 1-chrome	Minato-ku, 107-0052		Tokyo	Japan
U.S. Meat Export Federation	Room 303, Leema Building	146-1 Soosong-dong, Seoul, Chongro-ku	110-140		Seoul	Korea, Republic of
U.S. Meat Export Federation	P.O. Box 113-5028	Manara, Hamra	1103-2010		Beirut	Lebanon
U.S. Meat Export Federation	Blvd Diaz Ordaz No. 140, Piso 7 Torre II	Colonia Santa Maria	Nuevo Leon 64650		Monterrey	Mexico
U.S. Meat Export Federation	Jaime Balmes 8, Piso 6 Despacho 602 C	Col. Los Morales Polanco	11510		Mexico City	Mexico
U.S. Meat Export Federation	Business Center	The Atrium at Nevsky 25, 25 Nevsky Prosp	191186		St. Petersburg	Russian Federation
U.S. Meat Export Federation	Business Center, 9th Floor	Leninsky Prospekt, 2	119049		Moscow	Russian Federation
U.S. Meat Export Federation	39 Tyrwhitt Road	3rd Floor Suite	207538		Singapore	Singapore
U.S. Meat Export Federation	12F-1, No. 23, Sec. 2, Keelung Rd.	Hsin-Yi District	110		Taipei	Taiwan
U.S. Wheat Associates	Contact US Wheat For Their Address					Chile
U.S. Wheat Associates	Contact US Wheat For Their Address					China, Peoples Republic of
U.S. Wheat Associates	Contact US Wheat For Their Address					Egypt
U.S. Wheat Associates	Contact US Wheat For Their Address					Hong Kong
U.S. Wheat Associates	Contact US Wheat For Their Address					Japan
U.S. Wheat Associates	Contact US Wheat For Their Address					Korea, Republic of
U.S. Wheat Associates	Contact US Wheat For Their Address					Mexico
U.S. Wheat Associates	Contact US Wheat For Their Address					Morocco

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Participant	Address1	Address2	Address3	Address4	City	Country
U.S. Wheat Associates	Contact US Wheat For Their Address					Netherlands
U.S. Wheat Associates	Contact US Wheat For Their Address					Nigeria
U.S. Wheat Associates	Contact US Wheat For Their Address					Philippines
U.S. Wheat Associates	Contact U.S. Wheat For Their Address					Russian Federation
U.S. Wheat Associates	Contact US Wheat For Their Address					Singapore
U.S. Wheat Associates	Contact US Wheat For Their Address					South Africa, Republic of
U.S. Wheat Associates	Contact US Wheat For Their Address					Taiwan
USA Dry Pea And Lentil Council	107, Avenue La Bourdonnais	75007 Paris, France				France
USA Dry Pea And Lentil Council	PR Consultants Limited	Unit D, 14 Floor Vulcan House	21-23 Leighton Road		Hong Kong	Hong Kong
USA Dry Pea And Lentil Council	B-408, SDB Chamber 1	5, Bhika Ji Cama Place	110066		New Delhi	India
USA Dry Pea And Lentil Council	Toyoda Corporation	3-3-17, Kudan Minami, Chiyoda-Ku	102		Tokyo	Japan
USA Dry Pea And Lentil Council	Marketing Solutions Firm	San Juam de los Lagos 52	Mexico		Santa Monica	Mexico
USA Dry Pea And Lentil Council	Commodity Consulting	Avda. Montseny, 32 - La Floresta	08190 St. Cugat del Valles		Barcelona	Spain
USA Dry Pea And Lentil Council	Ambassador's Court, 4th Floor, No. 416	761 Soi Lang Suan, Ploenchit Road	10330		Bangkok	Thailand
USA Poultry & Egg Export Council	AMFI Azerbaijan	Nizami St. 91, Suite 44, Postal Code 370	P.O. Box 189		Baku	Azerbaijan, Republic of
USA Poultry & Egg Export Council	1809 -1810 Overseas Chinese Mansion	129 Yanan Road West	200040		Shanghai	China, Peoples Republic of

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
USA Poultry & Egg Export Council	Room 419, Building A	Heqiao Mansion, No. 8A Ghuanghua Road,	Chaoyang District, 100026		Beijing	China, Peoples Republic of
USA Poultry & Egg Export Council	2010 Hang Lung Centre	2-20 Paterson Street	Hong Kong		Causeway Bay	Hong Kong
USA Poultry & Egg Export Council	Albergo Nogizaka Suite 702	9-6-28 Akasaka, Minato-ku	1070052		Tokyo	Japan
USA Poultry & Egg Export Council	4th Floor, The House Building	128-25 Chungdam-dong, Kangnam-ku	135-100		Seoul	Korea, Republic of
USA Poultry & Egg Export Council	Ras Beirut, Manara, Tabbara Bldg. 4th Fl	P.O. Box 113-5028, Harma Beirut 1103-201			Beirut	Lebanon
USA Poultry & Egg Export Council	Agricultural Trade Office	Blvd. Diaz Ordaz #140-Piso7			Monterrey	Mexico
USA Poultry & Egg Export Council	Mexico City Office	Col. Lomas de Chapultepec			Mexico City	Mexico
USA Poultry & Egg Export Council	Bldg. 1A,	20 Kulakova St.	123592		Moscow	Russian Federation
USA Poultry & Egg Export Council	Al Bandriah Centre, 5th Floor, Suite 501	28th St. Pepsi Cola St, P.O. Box 3492	31952		Al-Khobar	Saudi Arabia
USA Poultry & Egg Export Council	541 Orchard Road	Suite 15-04 Liat Towers	238881		Singapore	Singapore
USA Poultry & Egg Export Council	Zodiac Marketing,	6 Dieu Donna, Pinotage St., Meyersdahl,	1448		Johannesburg	South Africa, Republic of
USA Rice Federation	Alsterufer 28	20354 Hamburg Germany				Germany
USA Rice Federation	Dawson Meadows	78-80 Glentham Road	Barnes, SW13 9JJ		London	United Kingdom
Washington State Apple Commission	Rua Mourato Coelho, 798	CJ 121 Pinheiros	CEP:05417-001		Sao Paulo	Brazil

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
Washington State Apple Commission	Bonesko S. en C.	Calle 86-A No. 13-57 Office 702			Santa fe de Bogota	Colombia
Washington State Apple Commission	Hernando de la Cruz #600	Yulloa			Quito	Ecuador
Washington State Apple Commission	Hong Kong & PRC	Marketing Channels	Room 2107, Progress Commercial Bldg	9 Irving Street	Causeway Bay	Hong Kong
Washington State Apple Commission	PEKA Consult.Inc	Jalan Kemang Raya No. 1	12730		Jakarta	Indonesia
Washington State Apple Commission	J. Brain, Inc.	Kohyo Bldg. 7F, Honcho 5-49	Naka-ku, Yokohama-shi	231 Japan	Kanagawa	Japan
Washington State Apple Commission	DLG Communications	No. 8C, 3rd Floor, Jalan Angsoka			Kuala Lumpur	Malaysia
Washington State Apple Commission	Mision de Tilaco 31C	Colinas del Bosque	Qro 76900		Queretaro	Mexico
Washington State Apple Commission	PCN/Promopro, Inc.	2213-B F. Zobel Street	San Miquel Village, Makati		Metro Manila	Philippines
Washington State Apple Commission	Rm 11, 3d Floor, 52-A, Nekrasovskaya St.	690014			Vladivostok	Russian Federation
Washington State Apple Commission	Steven Chu & Associates Co., Ltd.	13F, No. 102, Civil Boulevard, Sec 4			Taipei	Taiwan
Washington State Apple Commission	PT & Tatch Ltd.	208 Soi Ram-Indra	19 Ram-Indra Road Anusawaree	Bangkhen, 10220	Bangkok	Thailand
Washington State Apple Commission	2nd Floor, Titan Court	3 Bishop Square	AL10 9NA		Hatfield	United Kingdom
Wash State Fruit Com/Calif Cherry	Hong Kong & PRC	Marketing Channels	Room 2107, Progress Commercial Bldg	9 Irving Street	Causeway Bay	Hong Kong
Wash State Fruit Com/Calif Cherry	J. Brain, Inc.	Kohyo Bldg. 7F, Honcho 5-49	Naka-ku, Yokohama-shi	231	Kanagawa	Japan
Wash State Fruit Com/Calif Cherry	Milton Consultants, Ltd	867-6 Kita Imaizumi	Chiba 299-32		Oamishirasato	Japan
Wash State Fruit Com/Calif Cherry	Mision de Tilaco 31C	Colinas del Bosque	Oro 76900		Queretaro	Mexico

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
Wash State Fruit Com/Calif Cherry	Bozell Advertising	14F, No. 44	Chung Shan North Road., Section.2		Taipei	Taiwan
Wash State Fruit Com/Calif Cherry	2nd Floor, Titan Court	3 Bishop Square	Hatfield AL10 9NA United Kingdom			United Kingdom
Welch's Food	15th Floor JDH Center	2 On Ping Street	Siu Lek Yuen		Shaten	Hong Kong
Welch's Food	Pt. Mulia Multi Mandiri	Jl. Prof. Dr. Soepomo SH	No. 44, Jakarta 12870 Indonesia			Indonesia
Welch's Food	Welch's Foods of Japan Co., Ltd.	Kyowa Building, No. 202	1-16-26 Ebisu	Shibuya-Ku 105	Tokyo	Japan
Welch's Food	Nong Shim Co., Ltd.	6th Floor, Nong Shim Building	370 Shindaebang-Dong, Dongjak-Ku		Seoul	Korea, Republic of
Welch's Food	Harpers Trading (Singapore) PTE. Ltd.	34 Boon Leat Terrace	Pasir Panjang Post Office, PO Box 86	0511	Singapore	Singapore
Welch's Food	Inchcape Taiwan Limited	7/F National Enterprise Center	188 Nanking East Road, Section 5.		Taipei	Taiwan
Wine Institute	4145 North Service Rd., Suite 200	Ontario L7L 6A3			Burlington	Canada
Wine Institute	Room 2F, 2nd Floor	No. 886 Tian Bao Road	200086		Shanghai	China, Peoples Republic of
Wine Institute	Vinens Hus	Magstraed 7	1204 K		Copenhagen	Denmark
Wine Institute	Rheingaustrabe 85	65203			Wiesbaden	Germany
Wine Institute	Silk Tamagawa 403	2-24-6 Tamagawa	Setagaya-ku 158-0094		Tokyo	Japan
Wine Institute	5th Floor, Chungboo Building	118-4 Chungdam-dong	Knagnam-gu		Seoul	Korea, Republic of
Wine Institute	Sur 75 #4415	Col. Viaducto Piedad	08200		Mexico City	Mexico
Wine Institute	Prins Bernhardlaan 14P	Postbus 208	2400 AE Alphen a/d		Rijn	Netherlands
Wine Institute	08-22, Block 3	Alexandra Distripark	Pasir Panjang Road 118483		Singapore	Singapore
Wine Institute	P.O. Box 2843	SE-187 28			Taby	Sweden
Wine Institute	Suite 7D-07 Taipei World	No. 5,	110 Taiwan		Taipei	Taiwan

Foreign Market Development Program Foreign Office Directory

Participant	Address1	Address2	Address3	Address4	City	Country
	Trade Centre	Section 5, Hsin Yi Road				
Wine Institute	Vigilant House	120 Wilton Road	SW1V1JZ		London	United Kingdom

Office of Capacity Building and Development

Ms. DeLauro: What is the program level for the Office of Capacity Building and Development and how much of this is provided by reimbursements? How much does each agency reimburse the program? Where does the money come from for the program level that is not reimbursed?

Response: The estimated total FY 2008 program level for the Office of Capacity Building and Development activities was $94.8 million (excluding McGovern-Dole). Of this, $74.9 million or 79 percent of the total is an estimated reimbursement. The USAID has the largest portion of the reimbursement at an estimated $38.9 million; Department of State is an estimated $20.4 million; other Federal agencies are estimated at $4.9 million; other USDA agencies are estimated at $10.2 million; and an estimated $.5 million is from non-Federal sources. The remaining $19.9 million is funded via annual FAS appropriations.

Remote Sensing

Ms. DeLauro: How does FAS use the satellite imagery it purchases annually? Please be specific and detail the purposes and uses for FY 2008.

Response: FAS uses satellite imagery products as an independent, reliable, and timely information resource for global food supply monitoring through crop condition assessments and international food supply reporting oversight. These crop production estimates are a critical component of the Department's monthly supply and demand estimates. In order to provide unbiased assessments of potential food supply disruptions, FAS uses satellite imagery analysis to validate crop production reports from major food producing nations. Also, this information sometimes provides the only land observations to help verify early warning reports from food insecure nations, food aid organizations, U.S. government national security and intelligence organizations, and the United Nations.

Specific examples:

(1) Iraq wheat shortage, an example of land observations to help verify early warning reports from food insecure nations. Serious drought conditions damaged Iraq's domestic grain prospects in 2008. Wheat production for all 18 provinces in market year (MY) 2008/2009 is forecast at 1.5 mmt, down 36 percent from last year's estimated harvest of 2.3 mmt. The predominately rain-fed barley crop is expected to fall even more precipitously (60 percent) with the 2008 crop forecast at 450,000 MT. FAS used satellite imagery products to provide early warning of the drought's effect on production. FAS briefed the US Ambassador several months prior to the harvest. FAS used satellite imagery products to estimate crop area for wheat and barley at the province level. The location-specific drought damage assessment is critical information for allocating the $1.16 billion drought mitigation effort currently underway.

(2) Ukraine wheat increase, an example of validating crop production reports from major food producing nations. USDA

estimated Ukraine wheat production for 2008/2009 at 21.0 million tons, up 50 percent from last year. The winter wheat crop benefited from excellent weather throughout the growing season, and the estimated yield of 3.09 tons per hectare is among the highest of the past fifteen years. The current USDA yield estimate is based chiefly on the analysis of satellite imagery: satellite-derived vegetative indices such as the normalized-difference vegetation index (NDVI) have proven to be a reasonably reliable indicator of wheat yield in both Ukraine and the neighboring winter-wheat region of southern Russia. Higher NDVI typically indicate greater vegetative biomass or, in the case of cropland, higher potential yield.

(3) Burma cyclone damage to rice crop, is an example of disaster assessment and estimation of regional-scale damage to agricultural production capacity while providing early warning of potential food insecurity. Tropical cyclone Nargis struck the heart of Burma's rice growing region in the low-lying Ayeyarwady delta on May 2nd, causing extensive damage to agricultural lands, infrastructure, livestock, and stored food grains. The affected region normally accounts for roughly 60 percent of the nation's rice production. The USDA conducted a post-flood assessment using MODIS satellite imagery to analyze the extent of damage to major rice producing areas, classifying and estimating inundated lands. This assessment indicated that as of May 30, 2008, flood waters had receded over a sizable area. However, a month after the cyclone approximately 1.35 million hectares or 77 percent of the original flooded area was still affected by some degree of flooding. Approximately 870,000 hectares had shown no improvement. As a result of lasting flood conditions and the fast-closing planting window for rice, USDA estimated that approximately 400,000 hectares would go unsown in the main monsoon season, thereby reducing overall rice area in 2008/2009. USDA currently estimates 2008/2009 Burma rice production at 9.8 million tons (milled basis), down 9 percent from last year. In addition, USDA estimates that approximately 1.0 million tons of rice (milled rice equivalent) from the 2007/2008 harvest was lost or destroyed by the storm surge and subsequent flooding. These stocks were largely held on-farm and by local millers and warehouses. The USDA provided this satellite-based analysis information to United Nations disaster recovery teams, as well as the Food and Agriculture Organization (FAO), the World Food Program (WFP), USAID, and other non-government organizations (NGOs) participating in recovery efforts.

Ms. DeLauro: From all fund sources, what was the total cost of all satellite imagery purchased by FAS in FYs 2007 through 2009?

Response: The information is submitted for the record.

[The information follows:]

FAS Satellite Imagery Products

Fiscal Year	Amount in Millions
2007	$5.02
2008	$5.36
2009 Estimate	$5.50

Ms. DeLauro: How much did you receive from the CCC in FYs 2007 and 2008 for the purchase of remote sensing data, and what are your plans for FY 2009? What has FAS done to make effective use of these funds?

Response: FAS received $4.75 million for satellite imagery products in FY 2007 and FY 2008. In FY 2009 FAS requested $5.50 million to address the eroding imagery coverage of countries in global food crisis and support for the catastrophic drought in the Middle East and South Asia, as well as Africa.

FAS continues to save USDA more than $3.5 million annually by providing domestic imagery to other USDA imagery users. This cost savings does not include the impact of the satellite imagery on a variety of agricultural missions (e.g. California Forest Fire burned area assessments). FAS leverages partnerships (cost-sharing and data-sharing) with National Aeronautics and Space Administration (NASA), U.S. Intelligence Community and Department of Defense (DOD) (e.g. Iraqi crop production assessments), and other USDA agencies to remove redundancy and reduce cost through volume discounts. FAS partners with other nations by sharing satellite imagery products to gain better access to ground truth information. FAS partners with the private sector through Small Business Innovative Research and technology transfer agreements to sponsor and share data to stimulate private sector satellite analysis solutions.

In FY 2009 FAS expects to begin a research partnering program in which any land-grant university in the nation that is performing USDA sponsored research can gain access to FAS satellite imagery and analysis products.

Ms. DeLauro: Which agencies are users of FAS-purchased satellite imagery?

Response: FAS centralizes USDA's satellite imagery acquisitions so agencies can cost-effectively acquire satellite imagery to support their missions. USDA agencies who receive satellite imagery from FAS include: Farm Service Agency (FSA), Risk Management Agency (RMA), Natural Resources Conservation Service (NRCS), Forest Service (FS), Agriculture Research Service (ARS), Animal and Plant Health Inspection Service (APHIS), National Agricultural Statistics Service (NASS), and, of course, FAS. Through data-sharing and cost-sharing agreements with DOD, NASA, U.S. Agency for International Development (USAID), and U.S. Geological Survey (USGS), FAS shares satellite imagery acquisitions to reduce redundancies and leverage resources only available from these partner agencies.

Language Training

Ms. DeLauro: Ms. DeLauro: How much did you spend on language training during FY 2007 and 2008 and what is your estimate for 2009? During FYs 2007 and 2008, how many FAS employees were enrolled in language training, by language?

Response: During FYs 2007 and 2008, $386,100 and $478,356 respectively was spent on language training. For FY 2009, the estimated expenditure for foreign language training is $700,000. There were 24 employees enrolled in language training during FY 2007 and 23 in 2008. A list of languages with the number of employees per language is provided for the record.

[The information follows:]

FAS EMPLOYEES IN LANGUAGE TRAINING

LANGUAGE	FY 2007	FY 2008	FY 2009
Arabic	2	3	2
Chinese	6	3	9
Bulgarian	0	1	0
French	2	1	4
German	0	0	2
Indonesian	1	0	1
Italian	0	2	1
Japanese	1	3	1
Korean	0	0	2
Malay	1	0	0
Polish	1	0	0
Portuguese	0	1	3
Russian	4	1	1
Spanish	5	4	5
Thai	0	0	1
Turkish	1	1	1
Vietnamese	0	3	0
Total	24	23	33

Market access compliance

Ms DeLauro: How much did USDA spend on market access compliance in FY 2007 and 2008? What are your estimates for FY 2009?

Response: Between our overseas offices and our Washington-based monitoring and enforcement staff, FAS spent $2.5 million in FY 2007 and $2.4 million in FY 2008, and expects to spend $2.7 million for FY 2009, to monitor compliance with trade agreements and enforce related U.S. trading rights. The agency's priority focus in this area was reflected in the creation of a new Monitoring and Enforcement Division within FAS as part of the agency's reorganization. In addition to continuing to support current staffing levels of the Monitoring and Enforcement Division, which coordinates closely with other FAS program areas, overseas offices, and other agencies, we are considering the appropriate staffing levels for this function to manage an expanding workload, including that related to the implementation and enforcement of recently concluded trade agreements. All of this reflects the fact that market access remains a top priority for FAS. In addition, other USDA agencies, such as APHIS and the Food Safety and Inspection Service

(FSIS), devote significant resources to working with regulatory agencies in foreign governments to remove technical barriers to U.S. agricultural exports.

Market Access Program (MAP)

Ms. DeLauro: How many new participants joined the MAP program in FYs 2005 through 2008 and how many either dropped out or were removed? Which ones? Please explain the process by which participants are chosen or removed. Please provide a list of all organizations and companies that received funds in each of FYs 2005 through 2008 and the amount each received.

Response: Two new organizations, California Pistachio Export Council/Cal-Pure Pistachio, Inc., and the Specialty Coffee of Puerto Rico received funding in FY 2008. Three organizations, the California Tomato Commission, the California Pistachio Commission, and the U.S. Highbush Blueberry Council were dissolved by their membership. The California Fresh Tomato Growers, in a joint program conducted with the Florida Tomato Committee, replaced the California Tomato Commission.

The procedure used to award funding to an organization is based on an allocation process that is comprised of three phases. They are:

1) Sufficiency Review for Regulatory Requirements. FAS determines the eligibility of the applicants and the completeness of the applications based upon the MAP regulations. Among the information to be provided by applicants are: amount of funds requested (generic and/or brand); description of organization; membership and managerial capability; export promotion experience; dollars applicant will contribute; description of world market situation for promoted product; description of foreign competition; historical export data; statement of projected export goals; and applicants' plans for monitoring and evaluating performance.

2) Review with Recommendations for Funding Levels. FAS recommends program funding levels for each applicant after reviewing the strategic plan and other factors such as the applicant's management and administrative capability, effective use of results-oriented management concepts and evaluations, attaché comments, targeted markets, general administrative costs, availability and coordination of funding through other USDA export programs, and export effectiveness.

3) Competitive Review (The Formula). Using the funding recommendations, applicants are subjected to a transparent competitive review that compares the relative performance of each applicant based on four weighted criteria: contributions (40%), export performance (30%), export goals (15%), and accuracy of past projected export goals (15%).

Information on program participants for FYs 2005 through 2008 will be provided for the record.

[The information follows:]

MARKET ACCESS PROGRAM ALLOCATION HISTORY				
Participant	2005 MAP Allocation	2006 MAP Allocation	2007 MAP Allocation	2008 MAP Allocation
Alaska Seafood Marketing Institute	$3,454,121	$5,116,061	$5,557,794	$5,009,685
American Forest & Paper Association	7,675,622	12,197,854	8,822,028	9,309,336
American Peanut Council	1,407,852	1,973,810	2,309,130	2,477,734
American Seed Trade Association	9,353	13,482	99,403	41,601
American Sheep Industry Association	389,697	395,713	479,927	333,074
American Soybean Association	5,102,079	4,623,364	7,849,268	4,443,480
Blue Diamond Growers/Almond Board of California	1,772,823	2,327,044	2,237,329	2,852,709
Brewers Association	127,219	195,282	156,697	313,279
California Agricultural Export Council/Western Growers Association	1,025,198	1,317,235	981,929	1,024,711
California Asparagus Commission	271,270	240,835	292,736	232,103
California Cherry Advisory Board	250,639	537,580	459,295	373,298
California Cling Peach Growers Advisory Board	391,890	419,070	812,745	237,705
California Dried Plum Board	2,362,903	1,824,791	3,338,691	3,103,144
California Fresh Tomato Growers/Florida Tomato Committee	0	0	1,492,216	373,620
California Kiwifruit Commission	143,398	138,449	176,629	321,800
California Pear Advisory Board	146,577	480,170	280,452	178,474
California Pistachio Export Council/Cal-Pure Pistachio, Inc.	0	0	0	830,800
California Pistachio Commission	949,679	1,298,037	1,003,723	0
California Strawberry Commission	727,896	874,105	903,472	1,019,816
California Table Grape Commission	2,574,810	5,793,964	3,334,372	3,595,571
California Tomato Commission/Florida Tomato Committee	753,821	684,906	0	0
California Tree Fruit Agreement	1,347,254	2,689,884	1,904,697	2,488,136
California Walnut Commission	3,350,278	4,440,311	3,502,195	4,087,466
Cherry Marketing Institute	153,468	188,861	277,495	275,436
Cotton Council International	10,759,253	16,702,650	23,661,572	20,660,669

MARKET ACCESS PROGRAM ALLOCATION HISTORY				
Participant	2005 MAP Allocation	2006 MAP Allocation	2007 MAP Allocation	2008 MAP Allocation
Cranberry Marketing Committee	918,802	1,806,608	1,237,602	1,626,014
Distilled Spirits Council	78,305	93,196	86,686	147,692
Florida Department of Citrus	3,769,708	3,869,511	8,819,854	5,962,365
Food Export Association of the Midwest USA	7,628,987	8,046,096	8,431,959	10,230,370
Food Export USA Northeast	6,434,945	6,620,306	7,032,872	8,368,422
Ginseng Board of Wisconsin	60,053	114,754	110,663	351,393
Hawaii Papaya Industry Association	49,301	64,494	100,309	135,900
Hop Growers of America	89,440	38,912	99,503	50,756
Intertribal Agriculture Council	343,542	484,299	588,865	766,386
Mohair Council of America	43,584	128,723	146,630	38,123
National Association of State Departments of Agriculture	2,023,614	2,713,554	2,631,337	4,026,501
National Confectioners Association	1,225,740	1,311,062	1,684,263	1,473,067
National Honey Board	122,509	206,145	151,339	207,030
National Renderers Association	395,099	860,149	673,176	896,074
National Sunflower Association	1,055,610	982,636	1,028,393	1,226,303
National Watermelon Promotion Board	150,589	174,090	194,592	169,098
New York Wine and Grape Foundation	209,055	329,322	233,435	301,770
North American Export Grain Association	40,549	0	0	0
Northwest Wine Promotion Coalition	542,107	752,413	926,534	881,845
Organic Trade Association	323,604	301,896	301,525	363,113
Pear Bureau Northwest	1,876,356	2,967,351	3,882,140	3,577,866
Pet Food Institute	1,106,601	1,493,158	1,121,864	1,434,572
Raisin Administrative Committee	2,191,064	2,378,825	3,564,358	3,037,738
Southern U.S. Trade Association	5,634,251	8,265,669	8,220,415	6,905,241
Specialty Coffee Association of Puerto Rico	0	0	0	62,000
Sunkist Growers, Inc. (Cooperative)	2,105,527	3,613,372	3,499,997	4,202,886
Texas Produce Export Association	69,853	87,145	162,194	112,831
The Catfish Institute	336,646	406,886	338,357	289,419
The Popcorn Board	309,179	271,737	341,081	177,928

MARKET ACCESS PROGRAM ALLOCATION HISTORY				
Participant	2005 MAP Allocation	2006 MAP Allocation	2007 MAP Allocation	2008 MAP Allocation
U.S. Apple Export Council	471,062	811,697	817,364	892,157
U.S. Dairy Export Council	3,824,617	5,528,848	4,051,416	4,511,398
U.S. Dry Bean Council	779,380	1,236,347	1,028,682	1,112,097
U.S. Grains Council	5,112,638	7,671,058	7,313,245	8,191,306
U.S. Highbush Blueberry Council	148,755	217,452	96,502	0
U.S. Livestock Genetics, Inc.	880,263	1,630,893	1,115,949	866,640
U.S. Meat Export Federation	12,055,587	18,089,139	13,725,552	15,351,211
U.S. Potato Board	3,248,573	6,091,366	6,042,938	5,184,364
U.S. Wheat Associates	3,374,852	6,299,107	4,176,296	6,531,290
USA Dry Pea & Lentil Council	754,073	879,266	919,206	999,299
USA Poultry and Egg Export Council	3,392,217	4,953,751	4,444,548	5,379,580
USA Rice Federation/U.S. Rice Producers Association	3,343,573	4,667,954	3,799,107	4,665,156
Washington Apple Commission	2,486,334	4,082,167	5,299,376	4,834,387
Washington State Fruit Commission	737,057	650,280	791,226	1,021,992
Welch's Foods	667,270	1,017,074	709,235	967,687
Western U.S. Agricultural Trade Association	8,335,493	13,057,609	11,224,679	10,676,049
Wine Institute	4,606,536	6,751,256	8,450,941	7,481,814
Reserved by CCC	1,500,000	3,508,969	450,000	727,223
GRAND TOTAL	$140,000,000	$200,000,000	$200,000,000	$200,000,000

Ms. DeLauro: How many companies participating in MAP fit the definition of small businesses of the Small Business Administration?

Response: In program year 2005, 722 companies were approved for MAP funding; 17 were agricultural cooperatives and 705 were small companies. In 2006, CCC modified the program year for MAP to improve program efficiency. During this transition, the 2006 program year was eliminated, and the 2005 and 2007 program years were lengthened. In fiscal year 2007, 634 companies were approved for MAP funding; 15 were agricultural cooperatives and 619 were small businesses.

Export Incentive Program

Ms. DeLauro: In FYs 2007 and 2008, of the MAP agreements, how much was for the Export Incentive Program?

Response: In FY 2007, the CCC allocated a total of $6,446,561 to three agricultural cooperatives: Blue Diamond Growers; Sunkist Growers, Inc.; and Welch's Foods for the Export Incentive Program. In FY 2008, CCC allocated a total of $8,023,282 to the same organizations.

McGovern-Dole

Ms. DeLauro: Provide a county-by-county breakout of the numbers of children and mothers who benefited from the FY 2007 and 2008 McGovern-Dole program. What is the estimated participation in 2009?

Response: In FY 2009, 2.3 million beneficiaries are already approved through the multi-year agreement process. FAS is currently considering approving additional agreements and adding more than 1.7 million beneficiaries to the program. The extra $84 million provided in the Food, Conservation, and Energy Act of 2008 accounts for the increase in expected beneficiaries in FY 2009.

The information regarding FY 2007 and 2008 is submitted for the record.

[The information follows:]

FY 2007 McGovern Dole Food for Education and Child Program Beneficiaries	
Country	Number of Beneficiaries
Afghanistan	72,600
Bangladesh	350,000
Benin	13,000
Bolivia	150,000
Cambodia	731,146
Congo, Republic of	135,000
Guatemala	162,000
Guinea	193,928
Kenya	1,100,000
Malawi	410,000
Nicaragua	13,000
Pakistan	259,000
Senegal	19,574
TOTAL	3,609,248

FY 2008 McGovern Dole Food for Education and Child Program Beneficiaries	
Country	Number of Beneficiaries
Bangladesh	350,000
Cambodia	168,264
Cameroon	36,000
Chad	103,500
Congo, Republic of	70,000
Ethiopia	160,391
Guatemala	172,300
Kenya	1,100,000
Kyrgyzstan	31,920
Malawi	410,000
Mozambique	200,000
Nicaragua	13,000
Pakistan	259,000
Rwanda	300,000
Senegal	19,574
Sierra Leone	36,800
TOTAL	3,430,749

Overseas Offices/Costs

Ms. DeLauro: Provide a listing of all overseas offices where FAS is located, and the annual operating cost of each office.

Response: The location of FAS overseas offices and the operating costs for FY 2008 are as follows:

[The information follows:]

LOCATION	OPERATING COST
ALGIERS, Algeria	$54,972
BUENOS AIRES, Argentina	421,891
CANBERRA, Australia	406,333
VIENNA, Austria	552,912
DHAKA, Bangladesh	47,720
BRUSSELS, Belgium, USEU	1,471,463
SARAJEVO, Bosnia/Herzegovina	58,103
BRASILIA, Brazil	768,271
SOFIA, Bulgaria	244,581
RANGOON, Burma	23,888
OTTAWA, Canada	548,166
TORONTO, Canada	61,430
SANTIAGO, Chile	424,636
BEIJING, China	1,142,298
BOGOTA, Colombia	670,323
SAN JOSE, Costa Rica	268,634
ZAGREB, Croatia	94,593
PRAGUE, Czech Republic	134,339
COPENHAGEN, Denmark	168,383
SANTO DOMINGO, Dominican Republic	366,367
QUITO, Ecuador	321,824
CAIRO, Egypt	411,479
SAN SALVADOR, El Salvador	110,836
PARIS, France	901,394
BERLIN, Germany	563,045
BONN, Germany	174,190
ACCRA, Ghana	38,500
ATHENS, Greece	210,870
GUATEMALA CITY, Guatemala	318,462
TEGUCIGALPA, Honduras	66,247
BUDAPEST, Hungary	21,381
NEW DELHI, India	566,235
JAKARTA, Indonesia	293,099
BAGHDAD, Iraq	67,565
DUBLIN, Ireland	201,146
TEL AVIV, Israel	216,847
UN MISSION, Italy (Rome)	250,469
ROME, Italy	805,441
KINGSTON, Jamaica	54,703
TOKYO, Japan	1,134,333
AMMAN, Jordon	30,700
ALMATY, Kazakhstan	20,030
NAIROBI, Kenya	300,906
SEOUL, Korea	671,431
KUALA LUMPUR, Malaysia	316,306
MEXICO CITY, Mexico	848,636
RABAT, Morocco	275,275
THE HAGUE, Netherlands	478,320
WELLINGTON, New Zealand	189,621
LAGOS, Nigeria	591,772
MANAGUA, Nicaragua	60,246
ISLAMABAD, Pakistan	136,112
PANAMA CITY, Panama	119,795
LIMA, Peru	435,413
MANILA, Philippines	446,730

LOCATION	OPERATING COST
WARSAW, Poland	524,100
BUCHAREST, Romania	93,435
MOSCOW, Russia	825,103
DAKAR, Senegal	230,760
BELGRADE, Serbia/Montenegro	134,250
SINGAPORE, Singapore	198,451
PRETORIA, South Africa	683,295
MADRID, Spain	272,507
STOCKHOLM, Sweden	224,246
GENEVA, Switzerland	623,387
DAMASCUS, Syria	49,317
BANGKOK, Thailand	486,949
TUNIS, Tunisia	86,689
ANKARA, Turkey	423,897
ISTANBUL, Turkey	147,900
KIEV, Ukraine	203,370
LONDON, United Kingdom	697,206
TASHKENT, Uzbekistan	34,900
CARACAS, Venezuela	502,040
HANOI, Vietnam	272,806
HO CHI MINH CITY, Vietnam	180,834
SANAA, Yemen	22,800
TOTAL	$26,496,904

Ms. DeLauro: What is the average annual cost, per FAS overseas employee, for ICASS for each of FYs 2005 through 2008 and estimate for 2009?

Response: The average annual cost, per FAS overseas employee, for ICASS in FYs 2005, 2006, 2007, and 2008 were $28,854; $25,809; $30,765; and $34,884 respectively. The estimated average annual cost in FY 2009 is $38,377. ICASS costs are based on actual and estimated workload counts. The workload count is calculated by head count or actual workload, depending on the cost center. Some workload counts may be modified if an agency does not utilize the full range of services.

Ms. DeLauro: Why does FAS fund and operate both a UN Mission based in Rome, Italy, as well as a separate Italian mission office also based in Rome? Are the two offices co-located? Do the separate missions require separate staff?

Response: FAS funds and operates two offices in Rome with very separate goals and objectives. Our United Nations (U.N.) Office of Agricultural Affairs (OAA) is co-located with and reports to the Ambassador at the U.S. Mission to the U.N., serving as USDA's representative at three U.N. organizations—the FAO, which includes the standard setting bodies of Codex Alimentarius and the International Plant Protection Convention, the World Food Program, and the International Fund for Agricultural Development. The office is staffed with one American officer and one local employee who together advance U.S. interests including global food security, combating avian influenza, and developing science-based international standards on food safety and plant protection.

The OAA, located in the U.S. bilateral mission building, serves under our bilateral U.S. Ambassador, has a staff of two Americans and three LESs, and in addition to Italy, has regional responsibility for coverage of Albania, Bosnia, Croatia, Greece, and Malta. This office promotes U.S. agricultural, fishery, and forestry exports, reports on agricultural conditions, combats trade barriers, and advocates a wide range of U.S. Government/USDA trade policies including biotech and our World Trade Organization Doha Round position, and assists with trade capacity building in the non-EU countries of Albania, Bosnia, and Croatia.

PL 480

Ms. DeLauro: What are the total arrearages for P.L. 480 and Commodity Credit Corporation (CCC)?

Response: Arrearages under the P.L. 480, Title I program total $1.003 billion and $329 million for CCC export credit guarantees. This amount includes arrearages of both principal and interest.

Ms. DeLauro: Please list all of the Title I agreements with concessional sales activity during FYs 2007 and 2008, including the country, the commodity, the dollar value and the terms of these agreements.

Response: There were no Title I agreements with concessional sales activity during this period.

Ms. DeLauro: Please provide the allocations by country for FY 2008 Title I funded Food for Progress projects.

Response: These allocations were provided to the World Food Program to implement programs in East-Timor and Tajikistan. The information is submitted for the record.

[The information follows:]

Food for Progress Agreements
Title I Funded
Fiscal Year 2008

Country	Commodity	Metric Tons	Total Value *
East-Timor	Corn-Soy Blend	1,600	
	Rice	900	
	Beans	850	
	Vegetable Oil	260	
Total:		3,610	$4,987,300
Tajikistan	Wheat	7,000	
	Vegetable Oil	320	
Total:		7,320	$7,926,498

* Includes commodity, freight, and administrative costs.

Ms. DeLauro: What was the ocean freight differential for FY 2007 and 2008, and what is your estimate for FY 2009?

Response: The ocean freight differential (OFD) for FY 2007 was approximately $102 million. For FYs 2008 and 2009, OFD is estimated at

$150 million and $175 million, respectively. These figures are inclusive of P.L. 480 Title I and Title II.

Ms. DeLauro: Please list the commodities and countries in the Title II program for FYs 2007 and 2008. Please provide a list of the sponsors with the acronyms spelled out.

Response: The information is submitted for the record.
[The information follows:]

P.L. 480 Commodity Mix (metric tons)

Group	Commodity	FY 2007	FY 2008
Wheat/Wheat Products	Bulgur	145,474	97,970
	Soy Fortified Bulgur	22,720	18,860
	Wheat Flour	62,340	44,860
	Wheat Flour Bread	16,560	6,510
	Wheat Soya Blend	2,400	0
	Wheat Hard Red Spring	1,530	0
	Wheat Hard Red Winter Bag	6,510	16,040
	Wheat Hard Red Winter Bag	335,020	420,890
	Wheat Hard Red Winter Bulk	135,400	151,730
	Wheat North Spring Bulk	98,740	12,470
	Wheat North Spring Dark Bags	4,500	0
	Wheat North Spring Dark Bulk	11,520	9,500
	Wheat Soft Red Winter Bag	5,120	4,110
	Wheat Soft Red Winter Bnt	14,980	0
	Wheat Soft Red Winter Bulk	0	14,890
	Wheat Soft White Bag	1,940	0
	Wheat Soft White bnt	101,350	80,510
	Wheat Soft White Bulk	45,330	29,130
	Subtotal	1,011,434	907,470
Feed Grains	Corn Soya Blend	105,907	137,322
	Cornmeal	179,777	105,540
	Corn, Bagged	720	3,900
	Corn Bulk w/bnt	16,920	81,000
	Sorghum, Bagged	10,910	18,160
	Sorghum, Bulk bnt	400,550	891,820
	S.F. Cornmeal	5,141	5,160
	S.F. Sorghum Grits	4,140	970
	Subtotal	724,065	1,243,782
Pulses	Beans	41,245	46,010
	Peas	102,150	135,780
	Lentils	46,300	76,250
	Subtotal	189,695	258,040
Vegetable Oil	4 Liter	101,570	161,807

P.L. 480 Commodity Mix (metric tons)

Group	Commodity	FY 2007	FY 2008
	20 Liter	9,020	2,810
	Bulk	14,290	0
	Crude De-Gummed	23,270	8,470
	Subtotal	148,150	173,087
Other	Potatoes (Flakes)	140	70
	Rice, Bagged	54,230	76,950
	Rice, Bulk bnt	0	4,800
	Defatted Soy Flour	90	0
	Subtotal	54,460	81,820
Total		2,127,804	2,664,199

Countries that Received Title II Contributions FY 2007-2008

FY 2007	FY 2008
Afghanistan	Afghanistan
Bangladesh	Algeria
Bolivia	Bangladesh
Burkina Faso	Bolivia
Burundi	Burkina Faso
Cameroon	Burma
Central African Republic	Burundi
Chad	Cameroon
Colombia	Central African Republic
Congo, Republic of (Brazzaville)	Chad
Congo, Democratic Republic of	Colombia
Cote d'Ivoire	Congo, Democratic Republic of
Djibouti	Democratic People's Republic of North Korea
East Timor	Djibouti
El Salvador	East Timor
Ethiopia	Ecuador
Ghana	Ethiopia
Guatemala	Gambia
Guinea	Ghana
Haiti	Guatemala
Honduras	Guinea
India	Haiti
Indonesia	Honduras
Kenya	India
Lebanon	Iraq
Lesotho	Kenya
Liberia	Liberia
Madagascar	Madagascar
Malawi	Malawi
Mali	Mali
Mauritania	Mauritania

Countries that Received Title II Contributions FY 2007-2008	
FY 2007	FY 2008
Mozambique	Mozambique
Nepal	Nepal
Nicaragua	Nicaragua
Niger	Niger
Peru	Pakistan
Rwanda	Rwanda
Senegal	Senegal
Sierra Leone	Sierra Leone
Somalia	Somalia
Southern Africa Region	Sri Lanka
Sri Lanka	Sudan
Sudan	Syria
Syria	Tajikistan
Tajikistan	Tanzania
Tanzania	Uganda
Uganda	Yemen
West Bank/Gaza	Zambia
Zambia	Zimbabwe

The following organizations implemented Title II food assistance programs in FY 2007:

ACDI/VOCA	Agriculture Cooperative Development International/ Volunteers in Overseas Cooperative Assistance
ADRA	Adventist Development and Relief Agency International, Inc.
Africare	Africare
Caritas	Caritas
CARE	Cooperative for Assistance and Relief Everywhere, Inc.
CPI	Counterpart International
CRS	Catholic Relief Services
FHI	Food for the Hungry International
LOL	Land O'Lakes
MCI	Mercy Corps International
NPA	Norwegian People's Aid
OICI	Opportunities Industrialization Centers International
PCI	Project Concern International
PRISMA	Asociación Benéfica PRISMA
REST	Relief Society of Tigray
SCF	Save the Children Federation
SCF-UK	Save the Children United Kingdom
SHARE	SHARE Guatemala
WFP	United Nations World Food Programme
WVUS	World Vision (U.S.)

The following organizations implemented Title II food assistance programs in FY 2008:

ACDI/VOCA	Agriculture Cooperative Development International/ Volunteers in Overseas Cooperative Assistance
ADRA	Adventist Development and Relief Agency International, Inc.
Africare	Africare
CARE	Cooperative for Assistance and Relief Everywhere, Inc.
CPI	Counterpart International
CRS	Catholic Relief Services
FHI	Food for the Hungry International
LOL	Land O'Lakes
MCI	Mercy Corps International
NPA	Norwegian People's Aid
OICI	Opportunities Industrialization Centers International
PCI	Project Concern International
REST	Relief Society of Tigray
SCF	Save the Children Federation
SCF-UK	Save the Children UK
SHARE	SHARE Guatemala
WFP	United Nations World Food Programme
WVUS	World Vision (U.S.)

Ms. DeLauro: What was the cost of internal transportation during FYs 2007 and 2008, and what is the estimate for 2009?

Response: In FY 2007, Title II approved $443 million for internal transport, storage, distribution and handling costs (ITSH), and $556 million for ITSH in FY 2008. In addition, for inland transportation costs, Title II approved $124 million in FY 2007 and $160 million in FY 2008. Inland transportation costs are incurred when commodities move from a port of discharge to an inland destination for a land-locked country, such as Chad. ITSH costs are incurred within the recipient country where the commodity is distributed. We do not have an estimate for FY 2009.

No estimates can be made at this time because the costs of two other major components (commodities and ocean freight) are changing significantly. With a certain level of funding, all three must be balanced. Also, most Title II food aid is for emergencies, and it is too early to predict where the major funding will be provided.

Ms. DeLauro: What was the cost of external transportation during FYs 2007 and 2008, and what is the estimate for 2009?

Response: USAID approved $296 million in ocean transportation costs in FY 2007 and $418 million to date in FY 2008. We do not have an estimate for FY 2009.

Ms. DeLauro: What was the cost of administration for the Title II program for FYs 2007 and 2008, and what is the estimate for 2009? Please disaggregate the federal and non-federal administration costs to deliver the program. For the federal administration costs, please identify the USDA and USAID costs.

Response: USDA's actual expenses to administer the Title II program were $6.147 million for FY 2007 and $6.329 million for FY 2008. The estimated cost for USDA to administer the Title II program is $6.511 million for FY 2009. USAID has also committed administrative costs to the Title II program during FY 2007 and FY 2008; estimates for FY 2009 are not available at this time.

Ms. DeLauro: To put it another way, for every dollar of federal funding for the Title II program, how much is spent on administration, how much is spent on transportation, and how much is for on-the-ground food aid?

Response: Below is a breakdown of USAID Title II funding (expenditures) for FYs 2007 and 2008, divided into commodity costs; ocean freight; inland transportation; ITSH; 202(e) costs; and administrative costs.

	FY 2007	(%)	FY 2008	(%)
Commodity	$836,630,727	45%	$1,038,748,956	43%
Ocean	347,435,893	19%	499,645,097	21%
Inland	127,143,129	7%	152,437,720	6%
ITSH	455,949,173	24%	545,085,601	22%
202(e)	93,272,125	5%	155,524,506	6%
Admin	6,159,629	0.33%	8,327,099	0.34%
TOTAL	$1,866,590,676		$2,399,768,979	

Ms. DeLauro: What was the last fiscal year in which any agreements were signed under Title III?

Response: FY 2000 was the last FY in which any agreements were signed under Title III.

Ms. DeLauro: Please provide for the record a five-year table including FYs 2007 and 2008 that shows unobligated balances in each of P.L. 480-Titles I, II, and III. What are the current estimates for FY 2009?

Response: The information is submitted for the record for Titles I and II. Title III has not existed as an account since the 1990's.

[The information follows:]

P.L. 480 Unobligated Balances as of End of the Fiscal Year
(In Millions of Dollars)

	Account Type	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Title I	Title I Program Account	236.74	87.82	39.47	18.47	15.47
	Title I Ocean Freight Differential	53.56	37.23	16.71	19.72	9.72
Title II	Title II Grants	304.8	50.69	80.01	269.92	27.00(est.)

Ms. DeLauro: Please list any transfers among Titles I, II and III in FYs 2007 and 2008.

Response: There were no transfers among Titles I, II, and III in FYs 2007 and 2008.

Ms. DeLauro: Were you able to carry into the FYs 2007 and 2008 P.L. 480 Title I program, the policy of requiring Title I recipient countries to arrange and pay for shipping commodities after discharge? How much?

Response: There were no concessional sales programs for FYs 2007 and 2008.

Ms. DeLauro: What is the total that USDA/CCC spent on maritime costs for each of the past five years for food aid programs? How much was paid by USDA/CCC and how much was paid by the U.S. Maritime Administration?

Response: The information is submitted for the record.

[The information follows:]

TRANSPORTATION COSTS FOR FOOD AID PROGRAMS
(in Millions of Dollars)

Fiscal Year	Total Cost of Ocean Transportation	Maritime Administration (MARAD) Cost**	Ocean Transportation USDA/CCC Cost
2003	$493.1	$35.9	$457.2
2004	444.2	39.0	405.2
2005	412.5	18.3	394.2
2006	447.6	35.2	412.4
2007	383.0	33.2	349.8
2008*	548.3	45.6	502.7

*Figures for FY 2008 are preliminary.

**MARAD costs do not include 20 percent payments which apply when freight costs exceed 20 percent of the combined total of commodity and freight costs.

Ms. DeLauro: Did any countries graduate from food aid to GSM programs in FYs 2007 or 2008?

Response: No countries graduated from food aid to Export Credit Guarantee (GSM) programs during FYs 2007 and 2008.

Food for Progress

Ms. DeLauro: Please provide a table that lists the five-year funding history for the Food for Progress program through the FY 2009 estimate. The table should account for both CCC and PL 480 funds. For each FY, please identify FAS's cost to implement FFP. Please identify the sources and amounts used to cover the administrative costs.

Response: During FY 2004 to FY 2008, FAS has implemented the Food for Progress program with about 15 FTEs that were covered by the FAS appropriation for salaries and expenses. The total cost to FAS in FY 2008 for those costs was about $1.7 million. The program costs for Food for Progress are shown below. The information is submitted for the record.

[The information follows:]

Food for Progress
Fiscal Years 2004-2009

Fiscal Year	Funding Source	Total Program Costs (millions)
2004	CCC	$137.9
	Title I	105.4
2005	CCC	113.2
	Title I	81.9
2006	CCC	123.0
	Title I	116.0
2007	CCC	102.8
	Title I	16.7
2008	CCC	155.3
	Title I	12.9
2009 (estimates)	CCC	227.9
	Title I	7.0

Provincial Reconstruction Teams

Ms. DeLauro: Please describe in detail the involvement by FAS with the PRT. Provide a detailed history of FAS funding, including all sources of funding, whether inside or outside USDA.

Response: Within USDA, FAS coordinates and administers the recruitment, deployment and support of the Department's program that provides technical advisors to the two countries (Iraq and Afghanistan) for 12-month assignments. Since 2003, 53 advisors from 10 USDA agencies have served on PRTs in Afghanistan, while in Iraq, since 2006, 36 advisors from 8 USDA agencies have served on PRTs. The advisors play a critical role in developing projects on a local level that contribute to ongoing reconstruction and stabilization efforts in diverse areas such as livestock health, sanitary-phytosanitary (SPS) and food safety issues, soil and water conservation; irrigation and water management; grain and seed storage; post-harvest loss reduction; market system; agricultural extension; and management and protection of forests, rangelands, and watersheds. As a result of these efforts, State Department, USAID, and the military have all solicited continued additional USDA support in the reconstruction efforts in Iraq and Afghanistan.

As of November 2008, USDA has 14 PRT advisors in Afghanistan and 25 PRT advisors in Iraq. In direct response to requests for expansion of PRT advisors from Department of State (DOS) and Department of Defense (DOD), USDA has pledged to increase the number of advisors deployed to Iraq to 30 PRT advisors in FY 2009. In addition, USDA is committed to maintain 14 advisors in Afghanistan in FY 2009.

From 2003-2005 FAS received funding for PRT activities in Afghanistan through the FAS Emerging Markets Program (EMP). EMP-funding was used to cover travel, training, and per diem for PRT advisors. During those years, each agency that provided volunteer advisors covered the salaries, benefits and special allowances for these employees through their annual appropriations. FAS covered the administrative costs associated with the activities.

In FY 2006, FAS received $1 million from USAID to support PRTs in Afghanistan including travel, training, per diem, and special salary allowances. As in years prior, home agencies paid for basic salary and benefits from their respective appropriations, and FAS covered the administrative costs.

In FY 2007, FAS began covering all costs associated with the program, including salary and benefits; these costs were approximately $6.7 million. Other USDA agencies were no longer required to cover salary and benefits for their advisors while deployed overseas. In addition, USDA received $1 million from USAID for PRT related expenses in Afghanistan.

In FY 2008, FAS again covered all USDA costs associated with the PRT program; other USDA agencies did not have to pay salary and benefits for their advisors while deployed overseas. In addition, DOS provided USDA with $5 million to support PRT advisors in Iraq. This combined funding (totaling $15 million) allowed USDA to place a total of 39 PRT advisors (25 PRT advisors in Iraq and 14 PRT advisors in Afghanistan).

For FY 2009, to ensure continuity of operations, FAS is again committing $10 million in funding to support the PRT programs.

The projected financial commitment needed to sustain a total of 44 PRT advisors (30 in Iraq and 14 in Afghanistan) in FY 2009 is $15.5 million. USDA anticipates continued reimbursements from the Department of State to cover salaries, travel, benefits and allowances for PRT advisors deployed to Iraq. The requested funding will be used to meet the costs of the PRT advisors serving in these positions. Such costs include salaries, benefits and associated expenses, such as danger pay and post differential allowances; medical exams; security clearances; travel; recruitment and training; communications; equipment; and supplies.

Quality Samples Program (QSP)

Ms. DeLauro: Please describe the QSP. Provide a history of funding for the last five years, including sources of funds.

Response: Established in 1999, the QSP helps U.S. exporters provide samples of American commodities to foreign buyers who have not previously used them to encourage new purchases. The program is funded through CCC under the authority of the CCC Charter Act.

[The information follows:]

Quality Samples Program 5-Year Funding History

Fiscal Year 2008

QSP Participant	Allocation
Alaska Seafood Marketing Institute	$28,000
American Sheep Industry Association	370,000
American Soybean Association	190,000
California Tomato Export Group	30,000
Cherry Marketing Institute	30,000
Cranberry Marketing Committee	72,000
Ginseng Board of Wisconsin	70,000
Hop Growers of America	2,500
Mohair Council of America	196,000
National Potato Promotion Board	295,000
U.S. Grains Council	19,800
U.S. Livestock Genetics Export, Inc.	121,750
U.S. Wheat Associates	46,000
Total Allocation	$1,471,050

Fiscal Year 2007

QSP Participant	Allocation
Alaska Seafood Marketing Institute	$38,000
American Sheep Industry Association	395,000
California Tomato Export Group	80,000
Far East Puerto Rico Trade and Investment Group, LLC	25,000
Ginseng Board of Wisconsin	200,000
Mohair Council of America	140,000
National Hay Association	60,000
National Potato Promotion Board	335,000
U.S. Rice Producers Association	75,000
Total Allocation	$1,348,000

Fiscal Year 2006

QSP Participant	Allocation
Alaska Seafood Marketing Institute	$43,000
American Sheep Industry Association	305,000
American Soybean Association	50,000
California Agriculture Export Council	30,000
California Tomato Export Group	100,000
Cherry Marketing Institute	63,000
Cranberry Marketing Committee	24,000
Ginseng Board of Wisconsin	60,000
Mohair Council of America	231,000
National Confectioners Association	10,000
National Hay Association	75,000
National Potato Promotion Board	478,000
Pear Bureau Northwest	2,000
Raisin Administrative Committee	30,000
U.S. Dairy Export Council	50,600
U.S. Grains Council	161,000

U.S. Wheat Associates	90,600
Total Allocation	$1,803,200

Fiscal Year 2005

QSP Participant	Allocation
Alaska Seafood Marketing Institute	$30,000
American Sheep Industry Association	340,000
American Soybean Association	50,000
California Table Grape Commission	45,000
California Walnut Commission	25,000
Cherry Marketing Institute	30,000
Cranberry Marketing Committee	30,000
Hop Growers of America	2,500
Missouri Department of Agriculture	84,500
Mohair Council of America	118,000
National Potato Promotion Board	305,000
National Renderers Association	45,000
U.S. Livestock Genetics, Inc.	68,000
U.S. Wheat Associates	421,800
USA Dry Pea and Lentil Council	2,500
WE CO., 1991, Inc.	45,525
Western U.S. Agricultural Trade Association	35,000
Total Allocation	$1,677,825

Fiscal Year 2004

QSP Participant	Allocation
Alaska Seafood Marketing Institute	$30,000
Almond Board of California	30,000
American Forest & Paper Association	180,000
American Sheep Industry Association	330,000
California Agricultural Export Council	45,000
California Table Grape Commission	45,000
California Walnut Commission	75,000
Cherry Marketing Institute	30,000
Cranberry Marketing Committee	22,000
Florida Department of Citrus	10,000
Hop Growers of America*	2,500*
Mohair Council of America	98,000
National Dry Bean Council	90,000
National Potato Promotion Board	215,000
U.S. Dairy Export Council	12,000
U.S. Grains Council	139,000
U.S. Livestock Genetics Export, Inc.	56,000
U.S. Wheat Associates	320,500
USA Rice Federation/U.S. Rice Producers Association	206,580
WE CO, Inc.	40,450
* Although Hop Growers were allocated $40,000, only $2,500 was signed up.	
Total Allocation	$1,977,030

Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) issues

Ms. DeLauro: Please describe FAS's activities in resolving SPS and TBT issues. Include information on how many SPS and TBT measures were reviewed by FAS in FYs 2007 and 2008, the results of those reviews, and a list by country of the measures that did not comply with World Trade Organization standards.

Response: The FAS strategic plan lists three principal goals, one of which is "to reduce technical trade barriers and restrictive SPS measures" that hinder U.S. exports of food and agricultural products. We rely heavily on our network of overseas offices and our extensive contact with private sector trade associations to help set priorities and evaluate the impact of foreign regulatory actions. FAS plays a vital role in the following areas:

- leading the U.S. effort to monitor foreign regulatory changes to evaluate the impact of such changes on U.S. agricultural exports;
- helping set interagency priorities for SPS- and TBT-related market access discussions affecting agriculture;
- coordinating technical expertise from across the U.S. Government in support of U.S. market access strategies for agriculture;
- facilitating communication with foreign officials through formal and informal exchanges;
- ensuring export interests are represented in the development of international standards to help resolve or prevent trade disputes;
- training foreign government officials on international standards; WTO, SPS, and TBT obligations; and the principles upon which they are based (such as sound science and transparency); and
- supporting U.S. Trade Representative in the negotiation and enforcement of trade agreements.

Each year FAS supports the creation and maintenance of billions of dollars in U.S. agricultural exports by insisting on transparency and sound science in foreign regulatory practices. In this process, legal determinations of compliance are complex and are generally secondary to the question of whether the issue presents a problem to our exporters. One part of that process is the FAS-managed formal interagency review of foreign measures notified to the WTO SPS Committee and those notifications to the TBT Committee that affect agriculture. This includes the distribution of a list of new foreign notifications to over 400 interested U.S. Government and private-sector stakeholders on a weekly basis; the collection of comments from interested parties; the oversight of the internal U.S. Government review process to identify new regulations of concern; and the drafting and finalization of formal comments for submission to the WTO Secretariat and foreign government. The process includes a general review of consistency with the principles imbedded in the WTO, SPS, and TBT agreements. In FY 2007 we reviewed 893 foreign measures and provided comments on 101. In FY 2008 we reviewed 1,205 foreign measures and provided U.S. comments on 226, more than double the prior year's record. [The information follows:]

Section 416(b)

Ms. DeLauro: Please list the total amount of section 416(b) commodities donated, by fiscal year, since FY 1996. Please estimate the market value of those commodities for each fiscal year.

Response: The information is submitted for the record.
[The information follows:]

SECTION 416(B) FOREIGN DONATIONS
Fiscal Years 1996 - 2008

TOTAL TONNAGE/VALUE

Fiscal Years	Metric Tons	Thousand Dollars
1996	--	--
1997	--	--
1998	--	--
1999	5,407,089	739,020
2000	3,145,090	501,503
2001	3,038,730	629,989
2002	1,641,850	410,016
2003	249,600	159,000
2004	80,450	153,302
2005	25,420	46,738
2006	--	--
2007	--	--
2008	--	--
TOTAL	13,588,229	2,639,568

Note: The values above do not include transportation or administrative costs.

GSM Program

Ms. DeLauro: What has been the annual cost over the last five fiscal years to CCC to guarantee the export credits? What has been the default rates over the past five years, and how do these rates compare with USDA's other credit guarantee programs?

Response: The annual cost from FY 2003 through FY 2008, as represented by subsidy obligations net of re-estimates, is shown in the following table. This table represents total obligations for the fiscal years shown. Obligations were incurred for GSM-102, GSM-103 and Supplier Credit in FY 2003, GSM-102 and Supplier Credit in FY 2004 and FY 2005, and GSM-102 only in FY 2006 through FY 2008. Total re-estimates does not include interest on the re-estimates.

[The information follows:]

GSM Program ($ in millions)			
Cohort	Original Subsidy Obligations	Total a/ Re-estimates	Subsidy Net of Re-estimates
2003	170	-109	61
2004	457	-276	181
2005	152	-34	118
2006	71	-53	18
2007	39	-20	19
2008	86	0	0
Total	975	-492	397

a/ Includes re-estimates through FY 2008. Further re-estimates will occur until each fiscal year cohort is closed.

The default component of budgeted subsidy for each of those years is displayed below. It should be noted that no claims (defaults) have been paid for any cohort later than 2004. The budgeted default rate is based on government-wide country ratings and default rates developed by OMB for use by all international programs. As such, it is not possible to compare the budgeted default rates with other USDA credit guarantee programs. In terms of actual performance, export credit guarantees have performed better than other USDA programs, which also generally perform well but do have some defaults.

Default Rate (Weighted Average Subsidy Rate Budgeted)	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
GSM	7.48	7.48	N/A	N/A	N/A
GSM 102	Disaggregated Program Data Not Available		0.00	0.00	0.00
Facilities			8.18	4.57	4.12
Supplier Credit			0.83	0.96	N/A

Ms. DeLauro: Please provide a ten-year table that reports the annual default rate and annual budget authority required to cover defaults for the GSM-102 program.

Response: The following are the actual default rates and annual budget authority for program years 1999 through 2008 for the GSM-102 program. The Annual Budget Authorities are the Original Subsidy Estimates from the U.S. Government Annual Budget Appendices. The Default Rates are calculated as the ratio of Claim Payments to the Guaranteed Value of the registrations. At the close of FY 2008, no claims (defaults) have been paid on any cohort after 2004.

[The information follows:]

Program Year	Guaranteed Value	Claim Payments	Default Rates *	Annual Budget Authority **
1999	2,816,225,451	13,331,041	0.47%	158,000,000
2000	2,899,934,707	3,692,576	0.13%	195,000,000
2001	2,846,225,259	218,465,991	7.68%	103,000,000
2002	2,854,285,950	4,612,194	0.16%	97,000,000
2003	2,500,831,730	0	0.00%	170,000,000
2004	2,879,342,925	13,789,673	0.48%	457,000,000
2005	2,170,833,377	0	0.00%	142,000,000
2006	1,359,810,921	0	0.00%	71,000,000
2007	1,484,472,033	0	0.00%	39,000,000
2008	3,133,641,602	0	0.00%	86,000,000
Totals / Average%	24,945,603,955	253,891,475	1.02%	1,518,000,000

Ms. DeLauro: How does FAS determine which countries are allocated export credit guarantees? What is the selection process? How does FAS determine the amount of the annual allocation to each country or region?

Response: Interested parties, including U.S. exporters, foreign buyers, and banks may request that the CCC establish a GSM-102 program for a country or region. Prior to announcing the availability of guarantees, CCC evaluates the ability of each country and foreign bank to service CCC-guaranteed debt. New countries or banks may be added or levels of approval for others increased or decreased as information becomes available.

By examining a number of factors, including CCC's experience in the operation of the program in the particular country, CCC assigns a numeric risk category (zero to six, lowest to highest risk). The risk category (along with other factors) determines country eligibility. The amount announced or "allocated" annually to each country or region is based on country risk, bank risk, demand from the U.S exporter and/or U.S. bank, and CCC's appetite for risk tolerance.

Ms. DeLauro: Why does the projected default rate fall significantly in the 2009 estimate?

Response: The default rate falls significantly in the 2009 estimate due to the fact that for the first time, the agency used program-specific recovery data to adjust the default estimates prescribed by OMB. Gross default rates are still provided by OMB, but the default rate net of recoveries substantially reduces our projected costs. This should bring our original subsidy estimates more in line with program experience and should also serve to reduce the size of our downward re-estimates over the life of each fiscal year cohort.

Ms. DeLauro: Please provide a table for the 2005 cohort of GSM-102 loan guarantees that includes by region or country the announced allocation, the exporter applications received, the three-year default

rate, and the total budget authority required to subsidize the guarantees.

Response: There have been no reported defaults for the GSM-102 program cohort for FY 2005. As of October 18, 2008 there is a remaining contingent liability of $9 million.

[The information follows:]

Country / Region	Announced Allocations FY 2005 ($000)	Exporter Applications Received ($000)
Algeria	$8,000	$8,000
Baltic Region	15,000	0
Caribbean Region	300,000	74,900
Central Europe Region	505,000	283,400
Central Europe Region	10,000	0
China / Hong Kong	300,000	146,400
India	25,000	0
Kazakhstan	10,000	10,000
Korea	800,000	325,000
Mexico	230,000	63,200
Middle East Region	155,000	17,800
Poland	30,000	0
Russia	303,000	294,700
South America Region	900,000	354,400
South East Asia Region	300,000	132,700
Southeast Balkan Region	25,000	610
Southeast Europe Region	25,000	0
Southern Africa Region	51,000	0
Sri Lanka	35,000	0
Tunisia	40,000	3,700
Turkey	455,000	455,000
West Africa Region	15,000	0
Totals	$4,537,000	$2,169,810
Budget Authority	$142,000,000	

Ms. DeLauro: The GSM-102 program guarantees 98 percent of the loan. What is the justification for this high guarantee rate? How is this rate determined?

Response: CCC established GSM-102 principal coverage of 98 percent several decades ago to ensure coverage sufficient to promote trade to emerging markets and to balance risk assumed by GSM-102 participating U.S. banks or financial institutions. Also, the GSM-102 program covers only a portion of interest outstanding, and the U.S. bank and financial institution assumes the balance of risk on the uncovered portion of the interest. This level of coverage has been sufficient over the past decades to induce U.S. banks or financial institutions using the GSM-102 to perform due diligence on the foreign bank obligors. U.S. banks or financial institutions have made decisions to avoid riskier markets because of their principal and

interest liability under the GSM-102 program. This measure has also allowed CCC to keep losses at acceptable private sector standards.

DeLauro: Why has the dollar value of the export applications received been consistently and significantly less (on average less than 50 percent over the last five years) than the total GSM-102 allocations?

Response: Over the last 5 years, the average percentage of exporter applications received within announced allocations was 56 percent. In FY 2004, registrations amounted to nearly $3 billion of the $4.48 billion announced. The disciplines imposed as a result of findings by the WTO dispute panel along with the increased liquidity at that time in the global market, combined to have an adverse effect on program participation in FYs 2005 through 2007. Registration levels fell as a result of the aforementioned factors. In FY 2008, however, CCC announced $3.36 billion under the GSM-102 program of which $3.11 billion or 93 percent was received as registrations.

FY	Announced (billion $)	Registrations (billion $)	Usage (%)
2008	3.36	3.11	93
2007	3.69	1.44	39
2006	3.80	1.36	36
2005	4.54	2.16	48
2004	4.48	2.92	65

Ms. DeLauro: The Federal Credit Supplement reports 14 years of subsidy re-estimates for GSM-102. If these are loan guarantees for up to three years, why is FAS re-estimating subsidy costs from 1992? Over 14 years, why has the original subsidy estimate vastly exceeded the actual re-estimated subsidy rate in every year?

Response: GSM re-estimates are performed on an annual basis based on the status of either outstanding loan guarantees or outstanding rescheduled loan agreements in each cohort. Although the guarantees are originally made for 3 years, once a loan defaults and a claim is paid, the U.S. government takes over the outstanding debt essentially as a direct loan. The terms of these rescheduled agreements vary, are generally brokered by Paris Club agreements, sometimes involve other political considerations, and often extend many years beyond the original loan term. For instance, the FY 1992 cohort had rescheduled agreements that extended to FY 2016. Those particular rescheduled agreements were entirely repaid (prepaid for all outstanding balances) in FY 2007. The latest date for an existing rescheduled agreement is November 30, 2024, for the 1996 and 1997 cohorts. When GSM agreements are rescheduled, substantial interest penalties are incurred by the borrower that generally, at a minimum, compensate for the loss of net present value based on the length of the agreement.

The original subsidy estimates for all cohorts, with the exception of those for FY 2009, were based on default and recovery estimates prescribed by multi-agency Interagency Country Risk Assessment System (ICRAS) net default rates. Use of these default

estimates was required by OMB for many years to be applied consistently across all international U.S. government credit agreements. Therefore, they were not tailored to the experience or the actual risk characteristics of the individual programs. GSM specific program experience has differed significantly from the original assumptions and, combined with the rescheduled agreements, has consequently resulted in large downward re-estimates.

Effective with the FY 2007 re-estimates, OMB directed agencies to estimate recovery assumptions based on individual program experience and projected performance. OMB has recently provided agencies the option to either use OMB approved gross default rates or to estimate defaults based on program history and risk characteristics, but they do not currently require agencies to incorporate a change to program-specific default assumptions. Because CCC's risk history has historically proven better than the ICRAS net default rate estimates, for the FY 2009 budget, CCC incorporated revised assumptions in its original subsidy estimates resulting in an approximate 60 percent reduction in the FY 2009 budget estimates. CCC expects to incorporate GSM program-specific default assumptions for the FY 2010 budget estimates and for the re-estimates for the fiscal year ending on September 30, 2009.

Ms. DeLauro: Please update the tables from last year's hearing record showing the countries that received GSM-102 guarantees during FYs 2007 and 2008 and the amount of the guarantee and what commodities were sold. Please explain the difference between the "announced allocation" and the "exporters applications received."

Response: An "announced allocation" is the amount of guarantee coverage offered by CCC for a particular country or region. "Exporter applications received" represents the amount of guarantee coverage CCC committed to as of a particular date based on exporter sales registrations. The information on FY 2007 and FY 2008 programming is submitted for the record.

[The information follows:]

Ms. DeLauro: During FYs 2007 or 2008, did you have any cases where exporters falsely certified that the commodities they were selling were not entirely of U.S. origin?

Response: USDA is not aware of any cases during FY 2007 and FY 2008 where exporters falsely certified that the commodities they were selling did not meet the definition of U.S. agricultural products as defined in the CCC Export Credit Guarantee Program regulations.

Ms. DeLauro: Of the amount available for the short-term credit guarantee program, how much do you actually expect to use in FY 2009?

Response: We announced allocations of $3.5 billion at the beginning of the fiscal year and expect that amount will increase as we move through the fiscal year.

Ms. DeLauro: Please discuss the benefits to U.S. exporters of the Supplier Credit Guarantee Program.

Response: The statutory authority to operate the Supplier Credit Guarantee Program was repealed in the Food, Conservation, and Energy Act of 2008.

Table

Ms. DeLauro: Please update the table that appears on page 389 in last year's hearing record concerning the use of certain funds in the past five years.

Response: The information is submitted for the record.
[The information follows:]

Fiscal Year	GSM-102 Allocations ($ millions)	Export Applications Received ($ millions)
2004	$4,484	$2,926
2005	4,546	2,170
2006	3,800	1,363
2007	3,630	1,445
2008	3,366	3,115

Technical Assistance for Specialty Crops

Ms. DeLauro: Please describe the Technical Assistance for Specialty Crops program. Provide a history of funding for the last five years, including sources of funds.

Response: The Technical Assistance for Specialty Crops (TASC) Program is designed to assist U.S. organizations by providing funding for projects that address sanitary, phytosanitary, or related technical barriers that prohibit or threaten the export of U.S. specialty crops. U.S. specialty crops, for the purpose of the TASC Program, are defined to include all cultivated plants, or the products thereof, produced in the United States except wheat, feed grains, oilseeds, cotton, rice, peanuts, sugar, and tobacco. As a general matter, TASC Program projects are designed to accomplish the following goals:

- Projects should address a sanitary, phytosanitary, or related technical barrier that prohibits or threatens the export of U.S. specialty crops;

- Projects should demonstrably benefit the represented industry and not a specific company or brand; and

- Projects must address barriers to U.S. specialty crops that are currently available on a commercial basis and for which barrier removal would predominantly benefit U.S. exports.

Examples of expenses that may be reimbursed under the TASC Program include, but are not limited to: initial pre-clearance programs, export protocol and work plan support, seminars and workshops, study tours, field surveys, development of pest lists, pest and disease research, database development, reasonable logistical and administrative support, and travel and per diem expenses. The information submitted provides a history of funding for the last five years and its sources.

History of Funding for TASC (5 years)		
Year	**Funding Source**	**Amount**
2008	2008 Farm Bill	$4,000,000
2007	2002 Farm Bill	2,000,000
2006	2002 Farm Bill	2,787,248
2005	2002 Farm Bill	2,595,200
2004	2002 Farm Bill	2,000,000

Ms. DeLauro: How does FAS evaluate the effectiveness of the TASC Program? How does FAS ensure that taxpayers are receiving appropriate value from TASC grants?

Response: As part of the approval process, FAS evaluates the potential trade impact of the proposed project on market retention, market access, and market expansion. This includes the potential for expanding commercial sales in the targeted market, expected benefits to the represented industry, and the justification for the need for Federal funding. In addition, FAS requires a benchmark performance measure for the year prior to the year that the project would begin and performance measures for the next 3 years which can be used to measure the effectiveness of the project.

FAS requires each recipient to provide written interim reports and a final report each of which documents the outcomes of approved activities. The final report is due no later than 30 calendar days following the completion of the project. The final report is used to determine whether the project was appropriate and effective in achieving the expected outcomes and goals specified in proposal. The outcomes reported are used in the evaluation of future funding requests.

Ms. DeLauro: Is TASC cost effective? If so, how does FAS determine/evaluate cost effectiveness?

Response: There is strong evidence that activities funded under TASC have been effective in meeting program objectives. U.S. producer organizations have cited TASC-funded activities that have helped reduce or eliminate trade barriers and bans, allowing improved market access for U.S. specialty crops. FAS agricultural attaches in the target countries where activities have been conducted also have reported that such activities are important in supporting their diplomatic efforts to improve market access for U.S. specialty crops. When applying for TASC funds, applicants must clearly identify a specific market access issue, provide clear goals and objectives for the project, and establish appropriate performance measures. Applications must also demonstrate that the applicant has the technical and administrative capacity to carry out the project and that the project will broadly benefit the affected U.S. specialty crop sector. These applications are then subjected to a competitive review and funding allocation process. The successful TASC recipient must also document results in reports filed with FAS. The TASC program requires matching industry contributions in the form of cash, goods, or other services to ensure that TASC funds are more effectively leveraged. Applications supported by higher contributions are more likely to receive funding. Finally, all projects are subject to compliance review to ensure that funds are being used in accordance with program regulations.

Ms. DeLauro: Why does TASC provide grants to public entities, such as the University of Maryland, the Regents of the University of California, the California Department of Food and Agriculture, and USDA's Agricultural Research Service?

Response: The TASC program provides direct assistance through private and public sector projects and technical assistance to remove, resolve, or mitigate sanitary and phytosanitary and related barriers to trade. The program allows any United States organization, private or government, with a demonstrated role or interest in exporting U.S. agricultural commodities to submit a proposal. Government organizations consist of Federal, State, and local agencies. Private organizations include non-profit trade associations, universities, agricultural cooperatives, state regional trade groups, and private companies. TASC proposals undergo a competitive review process and funds are rewarded to applicants that demonstrate how their project will overcome trade barriers resulting in market access, retention, and expansion of specialty crops.

Trade capacity building

Ms. DeLauro: Please describe FAS activities in trade capacity building. How much was funded in FYs 2007 and 2008 and how much is estimated for 2009? How do these activities complement those by APHIS and FSIS?

Response: FAS trade capacity building (TCB) efforts address a broad spectrum of policy and regulatory issues that consider the entire agricultural trade regime of a recipient country. FAS TCB efforts address countries' lack of understanding and acceptance of the U.S. regulatory systems, including the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA); international standard setting bodies (International Organization of Animal Health, IPPC, and

Codex Alimentarius); and broader free trade agreement (FTA) and WTO Agreement issues.

For example, FAS is collaborating closely with FSIS and the U.S. industry on a food safety TCB program to reduce China's trade barriers on U.S. meat and poultry exports. In another project, FAS is leading an interagency TCB effort that includes APHIS, FSIS, and FDA to facilitate resolution of numerous trade barriers that India imposes on U.S. agricultural exports. Further, FAS provides TCB to countries with which the United States negotiated or is negotiating FTAs, or which have recently acceded or are in the process of acceding to the WTO. These FAS TCB programs help countries better understand and implement their new FTA and WTO commitments, which reduces trade barriers and provides greater market access for U.S. agricultural exports.

FAS works closely with APHIS and FSIS to ensure that priorities are clear and that TCB efforts are not duplicative. FAS and APHIS have made great strides in the past year in the coordination of joint TCB activities. FAS, APHIS, and FSIS have established formal lines of communication through working groups and other functional groups to discuss TCB efforts both at the policy and operational levels. FAS receives funding for TCB activities under reimbursable agreements with other Federal agencies and through appropriations. FAS direct funding of TCB activities has primarily been limited to Cochran Fellowship Program training and the China Scientific Cooperative Exchange Program. FAS expenditures on these TCB activities were $4.22 million in FY 2007 and $3.73 million FY 2008. Regarding FY 2009, funding is expected to decline given the current budget situation.

USTR and USAID

Ms DeLauro: Describe the interaction between FAS and the U.S. Trade Representative, and between FAS and the U.S. Agency for International Development.

Response: FAS is an active participant in the inter-agency trade policy coordination process which is led by the USTR office. This coordination is accomplished through existing formal mechanisms (e.g., Trade Policy Staff Committee, Trade Policy Review Group) and also through ongoing interaction between FAS staff and USTR counterparts on agricultural trade policy issues. Frequently, FAS is the linchpin between USTR and U.S. food and fiber producers and processors, both domestically and in international markets, where our network of Attaches provides on-the-ground support and advice to USTR negotiators. FAS also takes an active role in coordination between USDA scientific and regulatory agencies and USTR negotiators in seeking the removal of foreign SPS barriers to U.S. agricultural exports.

Since passage of the Foreign Assistance Act that created USAID in 1961, FAS and USAID have maintained a close, cooperative working relationship, primarily through Participating Agency Service Agreements in which USAID reimburses USDA for participating in foreign assistance programs at USAID's request. Both agencies are strong partners in the delivery of agriculture-related technical assistance and TCB activities worldwide, collaborating both at headquarters in Washington and at

USAID missions overseas. FAS and USAID also cooperate to ensure that U.S. Government activities with developing countries are targeted to address the needs of beneficiary countries and are consistent with U.S. foreign policy objectives. The FAS and USAID partnership also extends to food aid, as both agencies routinely collaborate on all matters related to the delivery of food assistance around the world.

THURSDAY, JULY 10, 2007.

COMMODITY FUTURES TRADING COMMISSION (CFTC)

WITNESSES

WALTER LUKKEN, ACTING CHAIRMAN, CFTC
MARK COOPER, DIRECTOR OF RESEARCH, CONSUMER FEDERATION OF AMERICA
TOM DEVINE, INDEPENDENT CONNECTICUT PETROLEUM ASSOCIATION AND THE NEW ENGLAND FUEL INSTITUTE
MICHAEL GREENBERGER, LAW SCHOOL PROFESSOR AND DIRECTOR, CENTER FOR HEALTH AND HOMELAND SECURITY, UNIVERSITY OF MARYLAND
JOHNATHAN SHORT, SENIOR VICE PRESIDENT, GENERAL COUNSEL AND CORPORATE SECRETARY, INTERCONTINENTAL EXCHANGE, INC.

Ms. DELAURO. The hearing will come to order. Thank you to Ranking Member Kingston and the members of the subcommittee for taking part in this important hearing this morning.

Actually, this is the first oversight hearing on the Commodity Futures Trading Commission that this subcommittee has held in 9 years.

I also want to say thank you to today's witnesses for sharing their testimony and for answering our questions today.

We are here to address the concerns of millions of Americans, families and farmers who simply feel powerless at the gas station and at the grocery store, sensing that something more than supply and demand is going on to produce breathtakingly high prices.

The goal of this hearing is to take a hard look at the Commodity Futures Trading Commission to examine its mission and its funding to determine whether excessive energy speculation is driving up energy prices, making it harder for so many families just to get by.

Let me give a brief definition of excessive speculation. It occurs when market price for a given commodity no longer accurately reflects the forces of supply and demand. This is basically the definition of excessive speculation that CFTC is charged with policing and preventing under the Commodities Exchange Act.

This is a complex issue, but our responsibility as a Congress and a Nation is serious. We are in a crisis, and as such, we need to look at every aspect that could potentially affect energy prices.

Of course, we must take into account factors such as a weak dollar, strong demand from an emerging economy, geopolitical tensions in oil-producing regions and supply disruption. But we must also do everything in our power to protect consumers from improper market manipulation and excessive energy speculation.

It has not even been 7 years since Enron filed for bankruptcy, the lives of thousands of workers and retirees devastated, and the

so-called "smartest guys in the room" shown to have taken advantage of special influence and deregulated energy markets.

Now the American people wonder if it is déjà vu all over again. Today we will hear from people on the front line, like Tom Devine of the New England Fuel Institute, who suggest that we can no longer have faith in the power of our energy futures markets to provide realistic pricing or manage risk. Instead, loopholes and exceptions have grown, and experts point to interested parties with special access or information improperly speculating on the price of energy without much oversight.

Of course, the American people have seen this movie before, and they know how it ends. From the savings and loans, the dot-com bubble, from the Enron debacle to an ongoing subprime mortgage crisis, speculative bubbles emerge. Regulators do nothing in the name of letting markets do their magic. The bubble bursts, and the consumers and the taxpayers pay the bill.

We go from one financial crisis to another but do not ever seem to learn from the lesson.

Today the consequences are as grave as they have ever been. Our most basic needs are at stake, fuel and food. We know that soaring gas prices are shattering everyone's budget, killing middle class families trying to make ends meet, farmers harvesting their crops, truckers battling on our highways.

To be sure, this Congress is not going to be uncovering every intricacy of the marketplace during one hearing, but I do believe that the marketplace has a whole host of problems. And we have a responsibility to investigate and to respond, to bring oversight and enforcement to our market.

Again, no one wants to see wholesale price controls or the elimination of strong market incentives to deal with long-term issues of supply and demand. But when one sees prices weaving down the road as erratically as they have been, it may make sense to give the market a sobriety test. The amplitude of these swings does not appear to make sense. Ultimately, the one thing we know for sure is that we do not know enough.

With so much at stake, transparent and efficient trading systems are essential, and, yet, we may not have the data to make that possible. According to a July 2007 Government Accountability Office report, some observers, and I quote, believe that higher energy prices were the result of supply and demand fundamentals, while all others believe that increased futures activity may also have contributed to higher pricing.

But the effect on energy prices on individual change in these markets is unclear. At that time, the average price for a gallon of regular self-serve gas was $2.97. Just this Monday, with the price of gas now at $4.11 a gallon, the Congressional Research Service reported that, and I quote, Very little information is available about over-the-counter commodity markets, end quote.

How much longer are we going to wait? So this is where we turn to you, the Commodity Futures Trading Commission, the agency charged with ensuring that our markets run effectively and our consumers are protected.

According to its mission, the CFTC's primary function is to, and I quote, Protect market users and the public from fraud, manipula-

tion, and abusive practices related to the sale of commodity and financial futures and options, and to foster open, competitive and financially sound futures and options market, end quote.

But a regulatory agency cannot do its job without adequate resources and staff. The Agriculture Appropriations bill, the subcommittee's recommendation included greater resources than the President's proposal to help the CFTC make the needed down payment and begin recovering from years of underinvestment.

I also understand the agency has already taken on a series of initiatives in order to meet these basic regulatory responsibilities: requiring ICE Futures Europe to match the current U.S. reporting requirements and to provide daily position reports; requiring traders in the energy markets to provide monthly reports of their index rating; and three, reviewing the trading practices for index traders in the future markets to determine the impact of futures trading on the price discovery process.

But, I must wonder if all of this is too little, too late. I am glad the CFTC is moving aggressively to investigate the issue of swaps. But when the agency promises to present its report to Congress by September 15 of this year, it begs the question, how high will the price of oil have climbed at that point?

We have more to do to ensure excessive speculation is not distorting energy prices. Since 2000, the Commodity Futures Modernization Act placed large segments of the commodities future market outside the CFTC jurisdiction and allowed for virtually unregulated over-the-counter and electronic trading of many commodities.

We must bring transparency to the over-the-counter markets and foreign boards of trade, which today remain so obscure, and fully close the so-controlled Enron loophole. For too long, the CFTC has acted only when pushed hard by Congress. Another example, like the FDA, OSHA and the Consumer Product Safety Commission, of this administration's failure to meet its regulatory responsibilities.

Ultimately, this is part of something bigger, and our response must be bigger as well. The U.S. dollar is threatened, and people do not have confidence in the U.S. economy. Speculators are landing in commodities because they see few other places to go, and we are paying the price for neglecting our economic fortunes at home for 8 long years.

Getting back on track will require broad and wholesale change, and the American people agree that we cannot afford to do anything less, and we can begin immediately and empower the CFTC to do its regulatory job.

With that, let me turn the microphone over to Congressman Kingston before we move on to our first witness.

OPENING STATEMENT

Mr. KINGSTON. I thank the Chairwoman for having this very important hearing. I think it is serious. It is something that is on the mind of the American people.

And thank you, Mr. Lukken, for being here today.

I do have an opening statement.

The speculation is the target today, as it has been in the past, with plenty of history to support the philosophy. There have been

a number of times that speculation has resulted in manipulation and collapse followed. We need to look no further than in the 1970s, when the Hunt brothers cornered the market on silver.

The point here is not that speculation in itself is bad. It is that speculation is bad when speculators illegally manipulate the prices. And this is the question with the Hunt brothers. They were able to hoard silver physically in warehouses.

Is someone doing that with oil? Is that possible to do it with oil? Does somebody have tanks and tanks that they are sitting on in the manner that the Hunt brothers were sitting on silver? I would like to know that.

I am for finding out if a few speculators have bonded together in collusion to manipulate the price and impose great harm on our consumers. So far I have heard about pension plans administered by unions and State and city government; Fairfax County, Virginia, being an example. I understand that they have done well by buying some of these future contracts. I don't know that they were colluding with each other. It would be interesting to know if they were colluding with each other. Maybe some of the witnesses today could enlighten us on that.

I am opposed to attacking perfectly legal and essential speculation, including buying and selling of future contracts. Future contracts are essential ways that hedge risk and ensure the availability of a commodity at set price. They are bought and sold for people that actually have a stake, such as oil producers and the airlines.

I want to read from an article about onions in Fortune Magazine that was just published this June 30th by Jon Birger, that he points out that onions do not have future contracts on it. And I am just going to a quote part of that, and it says: With no traders to blame, the volatility in onion prices makes the swings in oil and corn look tame. It diminishes the belief that future trading diminishes price swings.

Listen to this: 2006, since 2006, oil prices have risen 100 percent; corn is up 300 percent. You can buy futures on those. But onions went up 400 percent, and you can't buy futures on onions. And that was just since October of 2006 and April of 2007 when weather reduced the crops, according to the USDA. Then they crashed by 96 percent in March of 2008 because of overproduction and then rebounded this past April 300 percent.

So, speculation can stabilize prices, and that is why there are future contracts. Onions don't have it. Corn does, but both of them swing a lot. Onions, though, probably more than them.

The future of market is about the future, months and years down the road. It is not about the spot price of today or tomorrow. Speculators are on the movement of price, either it goes up or down, and they do not have any interest in buying or selling quantities of oil or narrowly—if they do, I want to know that again. They own barrels only on paper, as I understand it.

Whatever the outcome of speculators, speculators have no impact on the price of spot oil, as I understand it. That oil is set by those who have the oil physically and sell it only to people who actually use the oil. Importantly, speculators lose money if they bet the

wrong way, so absent any physical control over oil, they do not have an incentive to move the price of oil upward.

The only way that speculators can influence the price of oil is to directly turn their papers into real barrels, take the oil off the market entirely, for example, and try to force prices to rise like the Hunt brothers did when they started hoarding silver. This is what I understand, and I may be wrong in that, but I would like to know more about it.

So as we move forward to ferret out the bad guys, we also should look to see if there are any other reasons for the rise in price. It is hard to imagine, but perhaps the demand for oil has risen 9 million barrels per day, and the supply has not kept up; that maybe we have a supply and demand issue here.

More importantly, and I will say this, interestingly, I was in Saudi Arabia with Chairman Nick Rahall of the Natural Resources Committee, and we asked the folks over in the Middle East about the prices. And their reply to us, one of the oil ministers said, How dare you come to the Middle East to whine about oil prices when you won't drill and you won't build refineries?

And having traveled all the way to the Middle East, it is true; why should we blame our oil prices on somebody else? We are unwilling to drill, unwilling to build refineries, unwilling to use our own resources.

People need to remember that the number one producer for American oil is America, and then Canada and then Mexico. It is not Saudi Arabia and Venezuela and all the bad guys. They are on the list, but they are further down than we think. We need to look at long-term supply and long-term production since it is clear that the price of oil today is based not only on the supplies of today but what expectations there are for future supplies. We need to move immediately to increase in supplies in America.

We can take a big step forward in doing this by restarting the appropriations process. Recently we had a motion to bring up the Interior Appropriations bill, which would have given Members an opportunity simply to vote on offshore drilling. That is something that I think we should be doing. We may be ending this session of Congress, going into an August recess, without moving one Appropriation bill on the floor because of the fear of the Speaker that we could bring up offshore drilling.

I feel strongly that that should be debated vigorously in Congress, but it needs to be on the House floor, not just something that we talk about in talk shows.

The price of oil is also, though, because of the weak dollar. There is also evidence to show that the rise in prices in the U.S. has been greater and faster than other countries with healthier currencies, the dollar to the euro, for example. This is a big factor. The Chairwoman mentioned it. I don't know that we have anything that we can talk about today that would control that, but it is something that we need to keep in mind.

We should also look at the fundamental economic issues that actually make the difference. If the futures markets were sending the correct prices about the future, eliminating speculation could actually make matters worse in the market by not allowing us to adapt

to the future and making markets more volatile than they are today.

With that, Madam Chair, I pass.

Ms. DELAURO. I thank the ranking member.

Now we will move to testimony and to our first this morning. We are pleased to welcome our first witness. Walter Lukken—the acting chair—I thought he had been confirmed yesterday, so I am sorry, acting chair of the Commodities Futures Trading Commission. Mr. Lukken was appointed as acting chair in June 2007 and was first appointed commissioner in 2002.

He has testified several times before Congress, represents the agency as part of the President's Working Group on Financial Markets. He also represents the commission before international organizations and forums, serves as the chair of the CFTC Energy Market Advisory Committee, which was created by the commission in 2008 to address regulatory issues connected to the role of the futures market, for discovering prices and managing energy price risks.

Prior to joining the CFTC, Acting Chairman Lukken served for 5 years as counsel on the professional staff of the U.S. Senate Agriculture Committee under Chairman Richard Lugar, specializing in futures and derivatives markets.

Chairman, please, understand that the full testimony will be made part of the record, so you are free to summarize it. Thank you.

OPENING STATEMENT

Mr. LUKKEN. Thank you, Madam Chairwoman and Congressman Kingston and other distinguished Members of the Committee. Thank you for inviting me to testify on behalf of the CFTC and its role in overseeing the futures markets.

The CFTC's mission, as the Chairwoman mentioned, is twofold. First is protecting the public and the market users from manipulation, fraud and abusive trading practices; and second is promoting open, competitive, and financially sound markets for commodity futures and options. These mandates are crucial because prices in the futures markets impact the cost of a loaf of bread, the price of a gallon of gas and the interest rate on a student loan. If the futures markets fail to work properly, all consumers will be impacted.

We are quite aware that prices in these markets have been reflecting high, putting a considerable strain on American families, farmers and businesses. Although the Commodity Exchange Act does not give the agency the ability to set prices, our people work extremely hard to ensure that the futures markets are working properly, and that prices are reflecting economic factors rather than manipulative forces.

As you know, the futures markets have changed dramatically in the last decade. Since 2000, volume on U.S. futures exchanges has grown sixfold as traders increasingly seek the price certainty and clearing benefits of the regulated futures marketplace.

The growth in the regulated marketplace has been scrutinized lately, and appropriately so, as prices in crude oil and agricultural commodities have climbed. Specifically, concerns have been raised

recently regarding the role of speculators and index traders in commodity markets.

Speculation has played a crucial role in the functioning of the U.S. futures market since their founding more than 150 years ago. Without speculators, the futures markets would not be able to work properly. Commercial participants cannot hedge their activities without someone willing to take the other side of that transaction. In the futures markets, this opposite role is often taken by speculators.

The liquidity provided by speculators has tended to lower the costs of hedging to the benefit of the commercial participants in the markets. Nevertheless, our agency recognizes that any participant in the markets with enough power, including speculators, can detrimentally affect the functioning of the markets.

Accordingly, our act requires all traders of sufficiently large size to report their futures positions daily to the CFTC. This information enables our surveillance economists to monitor large traders, to ensure that no one is attempting to manipulate the futures markets.

The amount and detail of the trade data collected by the CFTC is unique among regulatory agencies, and this system has proven very effective in the proper policing of our markets.

As the futures markets have changed, the CFTC has evolved to meet new challenges. In light of the recent developments and the impact of high prices on consumers, the CFTC has embarked upon a series of steps to ensure greater transparency, implement tighter controls and gather more energy market information. The commission recently announced an agreement with the U.K. Financial Services Authority to expand information sharing concerning crude oil contacts on ICE Futures Europe and London that is linked to the U.S. NYMEX crude oil benchmark.

The CFTC also has required the imposition of position limits and accountability levels on these products that are equivalent to U.S. standards. Additionally, we called for additional information from swaps dealers regarding their index trading and a review of whether additional controls or classifications of these traders are needed. And the agency also announced the existence of an ongoing 7–month old nationwide crude oil investigation.

More recently, the CFTC formed an interagency working group with the Federal Reserve, the Department of the Treasury, the SEC, the Department of Energy and other agencies to study investor practices, fundamental supply and demand factors and the role of speculators and index traders in the commodity markets. This group is making significant progress on completing a report to Congress, and we hope to provide an interim report on the crude oil markets in the coming weeks.

Regulatory evolution and informed responses to market conditions are keys to effective market oversight and these challenging global conditions. The CFTC and its regulatory approach have evolved along with the futures markets, and the agency has pursued its mission while operating at historically low staffing levels.

Over the last year, the CFTC worked with Congress to legislatively close the so-called “Enron loophole” as part of the Farm Bill

that provides the agency with the data and the authority to oversee these electronic energy markets.

This is clearly a busy and challenging time for the CFTC, and I believe the agency has risen to the occasion, but we simply cannot sustain the current work load, let alone what is likely in the future, without some budgetary limitations being changed.

I am appreciative of this Subcommittee approving an appropriation of $135 million for the CFTC in fiscal year 2009. This is a strong step during these tight budgetary times.

With the passage of new authorities over exempt markets and additional responsibilities currently being considered for the agency, the Senate Appropriations Subcommittee yesterday approved a mark of $157 million to meet these growing oversight needs.

I look forward to working with this Committee and Congress to ensure the proper functioning of these important markets, and I appreciate being asked to come here today, and I certainly want to answer any questions that you may have.

Thank you very much.

[The statement of Mr. Lukken follows:]

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Testimony

Written Testimony of Acting Chairman Walter Lukken Before the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

July 10, 2008

Chairwoman DeLauro, Ranking Member Kingston, and other distinguished Members, thank you for inviting me to testify before this Subcommittee about the Commodity Futures Trading Commission's (CFTC or Commission) FY09 budget request and the role of the agency in overseeing the dynamic futures and options markets.

The CFTC's mission is twofold: 1) protecting the public and market users from manipulation, fraud, and abusive practices and 2) promoting open, competitive and financially sound markets for commodity futures and options. These mandates are crucial because prices in the futures markets impact the cost of a loaf of bread, the price of a gallon of gas, and the interest rate on a student loan. If the futures markets fail to work properly, all consumers are impacted.

Futures markets help participants efficiently bring supply and demand expectations from many sources to a central and transparent location to "discover" prices for a given commodity. Akin to a thermometer that reflects - rather than sets - temperatures, properly functioning futures exchanges are the messenger for prices. Lately these markets have been reflecting prices that are putting a considerable strain on American families and businesses. It is this agency's mission to ensure that the futures markets are working properly and that prices are reflecting economic factors rather than manipulative forces.

Evolving with Change

The futures markets have changed dramatically in the last decade. Member-owned exchanges conducting open-outcry have largely been replaced by technology-driven corporations that trade electronically all around the globe. Approximately $5 trillion of notional transactions flow through these U.S. exchanges and clearing houses daily.

Since 2000, volume on U.S. exchanges has grown six-fold as traders increasingly seek the price certainty and clearing benefits of the regulated futures markets.

The growth in the regulated marketplace has been scrutinized lately—and appropriately so—as prices in crude oil and agricultural commodities have risen to historic levels. Specifically, concerns have been raised recently regarding the role of speculators and index traders in commodity markets. Speculation has played a crucial role in the functioning of the U.S. futures markets since their founding more than 150 years ago. Without speculators, the futures markets would not be able to operate properly. Commercial participants cannot hedge their activities without someone willing to take the other side of the transaction. In futures markets, this counterparty role is often taken by speculators. The liquidity provided by speculators has tended to lower the costs of hedging to the benefit of commercial participants in the markets.

Nevertheless, this agency recognizes that all market participants, including speculators, can detrimentally affect the functioning of the markets. Accordingly, the Commodity Exchange Act requires all traders of size to report their futures positions to the CFTC daily. This information enables our surveillance economists to monitor large traders to ensure that no one is attempting to manipulate the futures markets. The amount and detail of trade data collected and analyzed at the CFTC is unique among financial regulatory agencies and this system has proven to be extremely effective in the proper policing of this market.

As the futures markets have changed, the CFTC has evolved to meet new challenges. In light of the recent market developments and the impact of high prices on consumers, the CFTC has embarked upon a series of initiatives and unprecedented steps to ensure greater transparency, implement tighter controls, and gather more energy market information. For example, the Commission recently announced several energy initiatives, including: (1) an agreement with the United Kingdom Financial Services Authority (FSA) to expand information-sharing concerning energy commodity contracts with U.S. delivery points that trade on both the New York Mercantile Exchange and ICE Futures Europe in London, as well as the imposition of position limits and accountability levels on these products equivalent to U.S. standards; (2) a call for additional information from swaps dealers regarding their index trading and a review of whether additional controls or classifications for these traders are needed; and (3) the existence of an ongoing seven-month nationwide crude oil investigation.

The CFTC is committed to ensuring that our nation's futures markets operate fairly and efficiently, and that the prices of commodities are determined by the fundamental forces of supply and demand, rather than abusive or manipulative practices. Regulatory evolution and thoughtful responses to market conditions are keys to effective market oversight in a dynamic and challenging global marketplace. The CFTC and its regulatory approach have evolved along with the futures markets, and the agency has pursued its mission while operating at historic low staffing levels. This is clearly a challenging time for the CFTC and I believe the agency has risen to the occasion – but we simply cannot sustain the current workload – let alone what is likely in the future – under our current budgetary limitations.

Recent Timeline

During the last year, the Commission has worked to address the structural changes occurring in these markets, which have been brought on by globalization, electronic trading, and other factors. Using the flexibility of the agency's principles-based regulatory framework, the agency is evolving with the markets and responding to structural changes. I'd like to walk you through that evolutionary timeline.

July 2007

- After an investigation spanning several months, the CFTC charged hedge fund Amaranth and its former head energy trader, Brian Hunter, with attempted manipulation of the price of natural gas futures on the New York Mercantile Exchange on February 24 and April 26, 2006.

August 2007

- The Commission announced that it filed and settled charges against Marathon Petroleum Company for attempting to manipulate the crude oil market. The Commission must complement robust market surveillance with a strong enforcement effort. The agency's Division of Enforcement has been extremely effective in areas as diverse as internet fraud, foreign currency scams, energy market manipulation and hedge fund fraud.

September 2007

- In September 2007, the Commission convened a public hearing to examine the oversight of energy trading on Exempt Commercial Markets (ECMs). Recognized by Congress in 2000, ECMs increased competition and lowered costs for derivatives trading, but over time, certain energy contracts offered on ECMs evolved to function as virtual substitutes for contracts listed on regulated exchanges, with tight correlation and linking of prices and participants. This evolution required the Commission's regulation of these markets to evolve in kind. During the September hearing, Commission staff, exchanges, ECMs, industry groups, and consumer organizations testified before the Commission in a productive debate.

October 2007

- Based on the agency's ECM hearing, in October, the Commission presented a report to Congress detailing the Commission's findings and recommendations regarding these energy markets. The report also recommended the creation of a new Energy Markets Advisory Committee to further examine energy issues.

- The Commission convened a meeting of its Global Markets Advisory Committee focusing on issues affecting new exchanges and clearing structures in the U.S., and the European Union's ongoing review of commodity derivatives regulation and possible changes to its regulatory approach.

- The CFTC's Division of Enforcement hosted its first annual international enforcement conference focused on commodity market manipulation. The two-day conference brought international regulators together to examine trends in the

on-exchange, cash, and over-the-counter commodity markets. Given the global nature of the futures markets, it is crucial for regulators to work cooperatively across borders to achieve the shared goals of detecting and deterring misconduct affecting commodity markets.

- The agency continued its aggressive enforcement efforts and announced in late October that BP would pay a total of $303 million in sanctions to settle charges of manipulation and attempted manipulation in the propane market. Since December 2002, the Commission has filed 41 enforcement actions charging a total of 66 defendants with violations involving the energy markets. The agency has assessed almost half a billion dollars in civil monetary penalties in settlement of these enforcement actions.

November 2007

- After sending the agency's ECM recommendations to Congress, during the fall and winter of 2007 and into early 2008, Commission staff provided technical assistance to Congressional staff as they considered CFTC reauthorization legislation.

December 2007

- The agency convened an Agricultural Advisory Committee meeting to examine agriculture market issues. Commissioner Michael Dunn led this hearing that involved industry discussion of changes in price discovery and market structure, the role of speculation in agricultural futures markets, and the role of agricultural over-the-counter markets.

February 2008

- The CFTC and the China Securities Regulatory Commission (CSRC) announced that the agencies agreed to hold regular meetings to promote enhanced cooperation and collaboration. These meetings will be designed to promote investor protection, market integrity, and the supervision of derivatives trading occurring on a cross-border basis between China and the U.S.

- Following up on the agency's Fall 2007 ECM report to Congress, the CFTC announced the creation of its new Energy Markets Advisory Committee (EMAC). The EMAC provides a public forum to examine emerging issues related to the energy markets and the CFTC's role in these markets under the Commodity Exchange Act. It is charged with conducting public meetings, submitting reports and recommendations to the CFTC, and serving as a vehicle for discussion on matters of concern to exchanges, firms, end users and regulators regarding energy markets and their regulation by the CFTC.

March 2008

- The CFTC and the Securities Exchange Commission signed a ground-breaking mutual cooperation agreement to establish a closer working relationship between the agencies. The agreement establishes a permanent regulatory liaison

between the agencies, provides for enhanced information sharing, and sets forth several key principles guiding their consideration of novel financial products that may reflect elements of both securities and commodity futures or options. As innovation blurs financial sector lines and markets evolve, this agreement provides regulatory synergies between the agencies for the benefit of the public.

April 2008

- In early 2008, agriculture commodity prices, broadly, began trading at historically high levels. On April 22, following up on the agency's December Agriculture Advisory Committee meeting, the CFTC convened a day-long public roundtable to examine the extraordinary times in the agricultural markets. The agency brought together a broad cross-section of agricultural market participants in an effort to share experience and help to form a collective understanding of what is occurring. More than 2,800 individuals watched the forum over the Internet. The topics discussed included price discovery, the role of speculators, index funds and hedgers, transparency, hedging, the role of agriculture swaps and risk management tools, the role of margin and the clearing system in the futures markets, and credit availability.

May 2008

- After years of work and bipartisan efforts, Congress enacted the CFTC reauthorization legislation, as part of the Farm Bill, which makes several improvements to the agency's statutory authorities. Specifically, the legislation:
    - Closes the so-called "Enron Loophole" to require, for ECMs that trade contracts linked to regulated U.S. futures contracts or that otherwise perform a significant price discovery function, that the CFTC be provided with large trader reports and that the ECM impose position and accountability limits on such products.
    - Increases penalties for manipulation.
    - Clarifies anti-fraud authority for principal to principal energy trades.
    - Clarifies retail foreign currency fraud authority.
    - Reauthorizes CFTC through 2013.
- A week after reauthorization enactment, the CFTC announced multiple energy market initiatives, including:
    - Confirmation of a six-month ongoing national crude oil investigation.
    - An agreement to receive enhanced data from ICE Futures Europe in London on certain of its crude oil markets to match our current information requirements for domestic exchanges. This allows the CFTC to see U.S. and foreign participants in the London market that the CFTC would not normally oversee.

- Requiring more detailed information from index traders and swaps dealers in the futures markets, including the energy markets, and reviewing whether classification of these types of traders can be improved for regulatory and reporting purposes.

June 2008

- In the first week of June, the CFTC announced several policy initiatives aimed at addressing agricultural futures markets concerns that were raised at its April 22nd roundtable, including, among other things:

  - The CFTC's ongoing investigation of the February/March 2008 price run-up in the cotton futures markets.

  - Requiring more detailed information from index traders and swaps dealers in the futures markets, including the agriculture markets, and reviewing whether classification of these types of traders can be improved for regulatory and reporting purposes.

  - A Commission vote to withdraw proposed rulemakings to increase the Federal speculative position limits on certain agricultural futures contracts and create a risk management hedge exemption from the Federal speculative position limits for agricultural futures and option contracts.

- The initiatives announced in late May and June that were designed to improve the transparency of index traders and swaps dealers in the energy and agriculture markets require further explanation, as they represent a critical piece of the agency's ongoing efforts to ensure the proper functioning of the futures markets. There is public concern about the amount of index money flowing into the futures markets. Pensions, endowments, and other long-term investors increasingly are investing a portion of their portfolios in a broad mix of commodities in order to diversify their holdings and reduce volatility and risk. Unlike traditional speculative trading by hedge funds and other managed money, index investors are typically non-leveraged entities utilizing a long-term buy and hold strategy. Most of this type of investment comes through major Wall Street swaps dealers that sell their clients broad exposure to the commodity markets through an over-the-counter (OTC) commodity index contract. After aggregating these transactions, swaps dealers then face a net commodity price risk and must utilize the futures markets to manage their own remaining exposure. This "netting out" of risk by swaps dealers before coming to the futures markets makes it difficult for regulators to determine the total amount of index trading occurring in the energy markets.

  As a result, the Commission decided to issue special calls for information about commodity index trading, principally to swaps dealers through whom most of this trading takes place in the OTC market. Some market commentary has pointed to long-only index trading as part of the reason for the sharp increases in energy prices. Through its large trader reporting system, the Commission has highly accurate information on all swaps dealer positions in all regulated U.S. futures markets, including energy futures markets. However, swaps dealers' futures

positions can represent hedges of very complex "books" of many different types of OTC derivative and cash transactions. Therefore, swaps dealers' futures positions do not necessarily correspond accurately with the amount of index trading that is occurring in the OTC market. In order to better understand the extent and possible impact of index trading, the Commission has issued special calls to swaps dealers requiring them to provide information on commodity index transactions.

- In late June, the CFTC hosted its first EMAC meeting to examine the issue of transparency in the energy markets, as well as the role of index trading and energy trading on foreign boards of trade.

- The CFTC formed an interagency working group with the Federal Reserve, Treasury Department, Securities and Exchange Commission, Department of Energy, Department of Agriculture, Federal Trade Commission, and Federal Energy Regulatory Commission to study investor practices, fundamental supply and demand factors, and the role of speculators and index traders in the commodity markets. The group has already met and is working expeditiously toward completing its public report.

- Following up on the success of our first international enforcement conference in October 2007, in June 2008, the CFTC hosted its 2nd annual international regulators enforcement meeting in Washington DC with 10 different nations participating to discuss on-going manipulation cases and practices.

- The CFTC announced further modifications to its direct access process for foreign boards of trade. After consultation with the U.K. FSA, the CFTC conditioned ICE Futures Europe's direct access to U.S. customers on implementation of equivalent position limits and accountability levels on its linked crude oil contract. Pursuant to the further modifications, ICE Futures Europe also will adopt hedge exemption requirements similar to those in the U.S. and report any violations of those requirements to the CFTC. The CFTC staff has amended ICE Futures Europe's direct access letter to reflect this change.

- Following up on the May-June energy and agriculture initiatives to get further information about index traders and swaps dealers in the futures markets, this month, the CFTC also announced it will report to Congress as soon as practicable, and no later than September 15, 2008 regarding the scope of commodity index trading in the futures markets and recommendations for improved practices and controls, should they be required.

July 2008

- The CFTC announced that Commission staff has amended the May 27, 2007, "no-action relief letter" under which the Dubai Mercantile Exchange (DME) is permitted to make its electronic trading and order matching system available to DME members in the United States. The new conditions are designed to help the Commission carry out its market surveillance responsibilities and maintain the integrity of prices established on CFTC-regulated exchanges in light of the

fact that the DME may list for trading a cash-settled contract that settles on the price of a contract traded on a CFTC-regulated exchange.

- CFTC is in the midst of implementing its the new authorities resulting from CFTC reauthorization – staff is currently drafting proposed rules for the ECM legislation and will meet the deadlines as outlined in statute.

- On July 15, the agency's Global Markets Advisory Committee, led by Commissioner Jill Sommers, will convene to get information from industry and market users regarding the risks and benefits of direct market access by customers trading on exchanges and whether there is a need for industry-wide guidance.

- On July 29, the agency's Agricultural Advisory Committee, led by Commissioner Michael Dunn, will meet to continue to develop solutions with the agricultural market participants to issues surrounding price convergence, margin requirements, financing, and alternatives to existing risk management tools.

Looking back at the CFTC's actions during the course of the year, both our agency and the marketplace we oversee are moving at an incredible pace. Based on our continual examination of futures industry issues, the CFTC is implementing a number of initiatives to tighten controls, increase transparency and improve the overall functioning of the markets. We have increased regulation and transparency of trading on Exempt Commercial Markets, and for Foreign Boards of Trade that have trading screens here in the U.S., and we are in the midst of bringing greater transparency to swaps dealers and institutional investors.

It is important to remember that the actions listed above are on top of the Commission's ongoing regular activities. For example, the Division of Enforcement continues to investigate and litigate violations of the CEA. The Division of Market Oversight continues to oversee exchange operations, examine the compliance programs of Self-Regulatory Organizations, review exchange rules, products and procedures, and most significant, conduct routine surveillance of the nation's futures markets during this extraordinary period. The Division of Clearing and Intermediary Oversight continues its audit and review programs directed at clearing houses and intermediaries, all in an effort to protect customers and assure financial integrity.

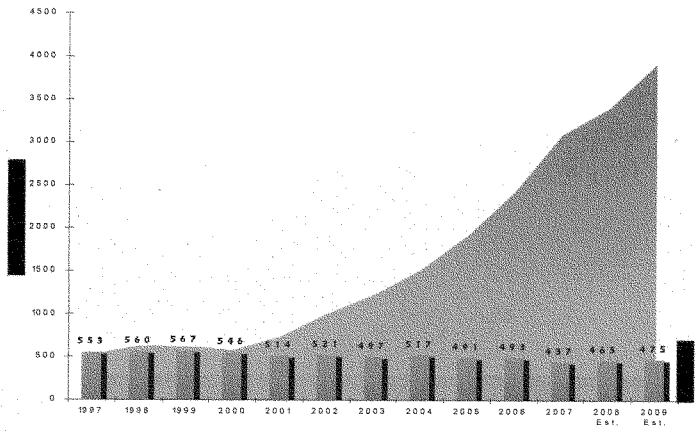
These efforts – both the daily work of overseeing the markets as well as new initiatives – are carried out each and every day by a Commission and staff dedicated to upholding the agency's mission of ensuring the integrity of the futures and options markets.

CFTC Funding

Since the CFTC opened its doors 33 years ago, the volume on futures exchanges has grown 8,000 percent while the CFTC's staffing numbers have fallen 12 percent. The following chart shows the exponential growth in contract volume, compared to CFTC staff numbers.

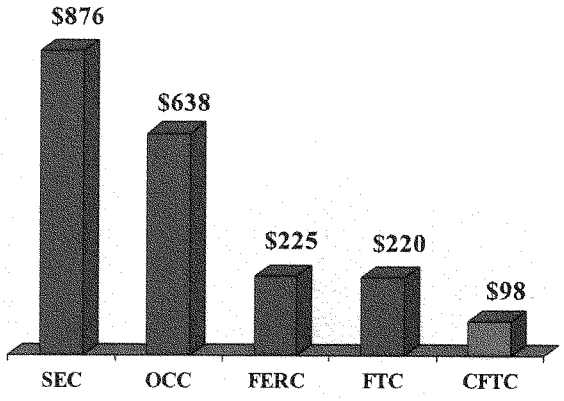
Growth in Volume of Futures & Option Contracts Traded

& CFTC Staffing Levels

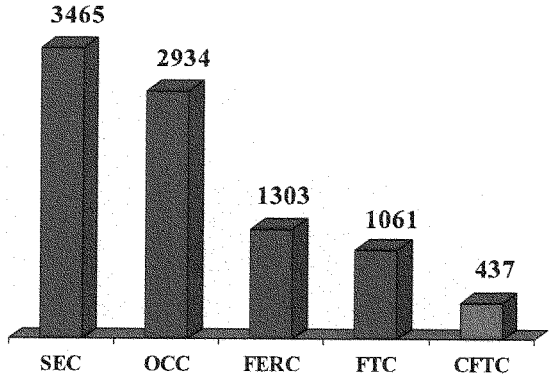


The CFTC's resources simply have not kept pace with the growth of the markets and the growth of similar financial regulators. As you can see in the following charts, the CFTC lags other comparable agencies in funding levels by substantial margins. This agency's lack of funding over the course of many years has had a negative impact on our staffing situation, rendering it unsustainable for the long run.

FY 2007 Budget ($M)



FY 2007 FTEs



The agency appreciates the increased funding from Congress of about $111 million for FY 2008 – that funding is being put to use now on priority hiring and making long-overdue major technological investments. For example, last spring, the CFTC announced a major technology purchase that will modernize our trade practice surveillance system to enhance basic trade surveillance and permit nearly real-time analyses of all trading activity – funding will allow for the completion of this project more quickly. Investments in technology and personnel are critical for the CFTC to sort through the millions of pieces of information generated by these electronic markets daily.

The dedicated and skilled individuals at the CFTC are working tirelessly to ensure the integrity of the markets. However, as the agency embarks on new authorities and initiatives in order to respond to changing market conditions, it is imperative that the CFTC receive additional funding.

As you are aware, the Administration has proposed for the Commission a budget of $130,000,000 for FY 2009. The Commission is very appreciative of the budget proposal – which reinforces the reversal of an almost two-decade-long downward trend in real funding. The $130,000,000 is greatly needed to continue the implementation of the long-delayed information technology modernization initiative first begun in FY 2008, and enables us to take continued steps to address our staffing shortage. In addition, last month, this Subcommittee marked up a funding bill that included $135,000,000 for the agency for FY 2009, which is deeply appreciated. We recognize the overall tight budgetary situation and appreciate the funding levels above the President's budget.

However, given these new authorities and the unprecedented market conditions of the day—conditions that could not have been anticipated when the FY 2009 budget was first formulated last summer—we welcome this hearing at a critical and opportune time. After reviewing the impact of recent initiatives and the projections associated with legislative changes, the Commission estimates it will require an additional $27,000,000 -

- above the President's FY 2009 budget of $130,000,000 and 475 FTEs -- for a total of $157,000,000 and 596 FTEs.

The additional $27,000,000 is comprised of $21,000,000 and 92 FTEs originally requested last September in our FY 2009 Budget Estimate submitted to Office of Management and Budget – and to Congress as required by the Commodity Exchange Act – as well as an additional $6,000,000 to undertake new responsibilities as mandated in the Farm Bill of 2008. In making this request, the Commission is mindful of the need to maintain fiscal restraint in appropriations and the competing needs of other parts of the Federal Government. However, we believe that the proposed funding level of $157,000,000 is the appropriate level of resources required to fulfill our immediate responsibilities. The increase will restore staffing to a level last sustained almost two decades ago when market volume, innovation, and complexity were significantly less than today and when the agency did not yet have to face the expanded workload brought on by globalization of the marketplace and the emergence and widespread use of derivatives and hedge funds.

In summary, I want to thank the Subcommittee for inviting me to testify today. The Commission shares the Subcommittee's concern about current conditions in the energy markets and over the effects of high crude oil and gas prices on American consumers, workers, and businesses. These are difficult times in the futures markets, and the Commission recognizes the need to respond accordingly. I am deeply proud of our highly skilled and productive staff. This small Federal agency is working hard to protect the public and the market users from manipulation, fraud, and abusive practices in order to ensure that the futures markets are working properly.

Thank you for the opportunity to appear before you today on behalf of the CFTC. I would be happy to answer any questions you may have.

Ms. DELAURO. Thank you.

What I am going to do with the questioning, because we have a full subcommittee here today, is hold myself and others to the 5-minute rule so we can have an opportunity to get in several rounds of questioning, and everybody gets an opportunity to raise questions, and you have an opportunity to respond.

BUDGET

Let me, first of all, let me just review a bit of budget history quickly. During this administration through the House mark 2009, Congress has provided 98.6 percent of the funding requested by the President. In and of itself, this is fairly remarkable because we have had a tight budget every year, and there are many priorities; more remarkable when you consider that this includes providing discretionary funding in 2007, when the President's budget proposed to fund the agency entirely through user fees. Since the fees were not enacted, we had to come up with the funds ourselves.

The funds you received last year were nearly 14 percent higher than your 2007 level, and the 2009 request as submitted by the President is another 14 percent over that. You have told the Senate that you need more for 2009, and, yesterday, in their mark, they talked about $157 million this year. This was about a 29 percent increase over 2008.

However, we have not received, this subcommittee has not received any kind of an official request for this, despite your having testified before the Senate asking for the increase.

I have two questions with regard to this. Also, why now? Why is the CFTC coming to us in this last year of the administration seeking such a massive increase in 1 year? What is the sudden urgency that demands a 29 percent increase in your budget? You claimed that flat funding, you know, over the years, has resulted in an erosion in the staffing. You say the workforce shrunk by 4 positions, over 16 percent of the commission's workforce, in 2002 and 2007.

The flat budget requests, they have apparently, they have resulted in erosion in your staff. Why have you not come forward earlier in coming to us? And you haven't come to us yet to ask us for the funding. The administration has not come to us asking for additional funding.

This committee has no official request for additional funds for the CFTC.

Mr. LUKKEN. Well, the CFTC, under its law, submits its request to the OMB for funding. This year, we submitted a request for $151 million, which we did, and under our law, we are also required to share that with our Appropriations staff, so we did share the $151 million request with this subcommittee last fall.

And in addition to that, in the meantime, the farm bill was passed, and we shared with these committees that we need an additional $6 million as part of implementing the farm bill, which gets us to our $157 million request. OMB did come back with a $130 million mark and provided that to this Committee and to the Senate Committee. And that certainly is a good increase over last year's mark. But this is the original mark that we have shared

with this committee—of $151 plus the $6 million for the farm bill, and gets us to the $157 million.

So we felt that this was something that was shared with this Committee, and, certainly, over the last several months, with increases in commodity prices and the workload exponentially increasing at the agency, we felt it was important to, again, reiterate those requests with the Senate Appropriations Committee recently.

Ms. DELAURO. I just might, for the record, note, that with regard to the $6 million from the farm bill, we received an e-mail request, nothing terribly formal, just an e-mail, you know, and the issue is, why, why now? All along you have talked erosion; it doesn't occur overnight. Where have you been in addressing the serious mission that your agency has in letting us here know on both sides of the Capitol of the need to be able to address these issues? What is moving you and pressing you now to do that, and when—what would you deal with in terms of cuts? The Senate did $157 million.

What should we cut in our bill to pay for the additional funding that you seek, the FDA, WIC, agricultural research, rural, water, sewer programs? What's your view of how we address your need?

Mr. LUKKEN. Well, again, this is something that we have been requesting since several years back. The President's budget request was at $127 million in 2007. We received $98 million that year as part of the CR, so we have that gap of $30 million——

Ms. DELAURO. As I understand that, that was going to be funded totally by user fees; so that was the user fee number, I have just been informed.

Mr. LUKKEN. Correct, but there was a request for needs for the agency, and we supported those needs for the agency of $127 million.

Again, this last year, we asked for $151 million, and then, in the meantime, we had the farm bill passed with additional authorities.

So those have been our requests over the years. We have been asking for more money, but we certainly appreciate this subcommittee making a strong step in getting us these additional funds in tight budgetary times.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chairman.

Mr. Lukken, you are a smart guy. You graduated from business school with honors. You have a law degree. You have worked for the Senate Ag Committee, and you have been serving in this capacity since 2002.

PRICE OF OIL

So based on what you know, do you believe that the price of oil is being set fairly on the market, supply and demand, or do you believe that there is illegal activity or just plain old price manipulation going on? Some say that speculators have added between $15 and $70 to a barrel of oil. To what extent do you believe this occurred? Is it true, or is it not true?

Mr. LUKKEN. Well, the CFTC looks at this in two ways. First we look at the data we receive from our market participants, and you talked about this earlier in your opening statement. We are trying to see if people are colluding together to illegally manipulate the markets, and we do see that on occasion. We have brought cases

against Amaranth, and the Hunt brothers, as you mentioned, in the past where they have tried to corner and squeeze the market by holding on and hoarding supply.

So that is what our mission is, to prevent that from occurring. We don't see systematically, in the current environment, people trying to drive up prices, working all together. I don't think that has been the allegation of anybody.

I think the concern is whether somehow new money coming in from the financial markets has somehow created an asset bubble. But we certainly have not seen it being manipulation.

We work closely with our sister agencies, like the Department of Energy, to look at the data that they have. Just Tuesday they came out with a report showing that the markets are very tight, that production over the last 3 years has been flat. There is basically no spare capacity, 1.2 billion or million barrels a day. That is all held by Saudi Arabia in very sour crude. A lot of it is stuff that is not useful for our refineries.

At the same time, we have non-OECD, China, India, growing at 1.3 million barrels a day, even though there has been some decline in the developing world. We see about 660,000 or 760,000 barrels less a day from the developing world.

But demand is still growing while supplies are flat. So our markets are reflecting that, and we feel very comfortable—we have not seen market participants driving this, but we do see supply and demand causing all of these price changes.

Mr. KINGSTON. Are there any suppliers that are hoarding inventory, maybe overseas, or any buyers hoarding inventory, and would that be possible to hoard inventory? I mean, I can see where Saudi Arabia might be able to do that, but they are really not, I don't think they are choking off the flow right now.

Mr. LUKKEN. We do have a nationwide crude oil investigation that we look for people who try to hoard oil or for people who try to take oil off the markets, so this is something we also try to work with the Department of Energy on if we see any evidence of hoarding. We haven't seen that to date, but we will certainly continue to look whether somebody is doing that, but we have no evidence that people are hoarding oil.

OFF-SHORE DRILL

Mr. KINGSTON. If the President made an executive decision to drill for oil offshore, what would happen, in your opinion, to the price of oil immediately?

Mr. LUKKEN. Well, it is difficult for us to tell, but our markets are predictive markets. So they take future decisions in mind in determining what the prices may be, so it is not just simply a current supply-demand; they look to the future. I will give a good example. The carbon markets, we have a carbon futures market right now, the Chicago Climate Exchange. The day Super Tuesday happened, and the only candidates left were Senator Clinton, Senator Obama and Senator McCain, all in favor of cap-and-trade carbon market systems, the price of carbon shot up, not because there was less carbon or more demand for carbon but because they knew it was reflecting future events that may happen in those markets. It shot up from $2.50 to near $7 for a unit.

So these markets are reflecting future events, and certainly drilling would be a part of that.

Mr. KINGSTON. But if I am hearing you right, speculators drove up the price of carbon, and that would be just betting on the come.

Mr. LUKKEN. Well, there are commercials in those markets, too, just like the futures markets. There are people who are hedging, and there are commercial businesses.

PRICE OF CARBON

Mr. KINGSTON. Perfectly legal, and it is not out of control. It is not a run-away train. What is the price of carbon now? Has it come back down——

Mr. LUKKEN. I think it has come off slightly, but we can check for you where the price of carbon currently is.

Mr. KINGSTON. All right, I have got about 10 seconds, I think, but your energy group, the Energy Markets Advisory Committee, did you guys get behind the ball on that? Should you have been doing that 5 years ago? I think you just started that; it was created in February.

Mr. LUKKEN. Well, it is something that came out of our recommendations. We held a hearing in September to talk to industry groups about energy markets, and that was a recommendation of Congress that we would form that, so that developed as a result of that. But that shouldn't mean that, I don't want anybody to misunderstand that we haven't been on top of energy issues. We talk about this every week in our surveillance meetings. We have other advisory committees that deal with energy and have in the past, but we felt this was so important that we needed to distinguish and have a separate group in looking at these issues.

Mr. KINGSTON. Well, thank you, I am out of time.

Ms. DELAURO. Mr. Hinchey.

Mr. HINCHEY. Thank you very much, Madam Chairman.

Mr. CHAIRMAN, it is nice to have you here.

There is a lot of speculation about the amount of the price of energy that has been driven up by conspiratorial speculation out in the market, and if I am correct, I have heard you say that that isn't really a significant part of the issue here, that that kind of speculation isn't having much of an effect.

Mr. LUKKEN. Well, we are certainly looking to see if it is.

Mr. HINCHEY. I know you are, and you have mentioned a couple of things way in the past, but you haven't mentioned anything recently, so I am assuming that you are not doing anything recently to look into this.

There are a number of operations called bilateral trades, foreign boards of trade, swaps loophole, the bona fide hedging exemption. All of those are involved in these kinds of speculation.

BILATERAL TRADES

For example, the bilateral trades, they are made between two individuals and are not negotiating on a trading market, and have no oversight. Foreign boards of trade, the petroleum contracts offered on the Intercontinental Exchange. This is the largest dark market, and they are cleared by a farm board of trade in London, completely in the dark.

You have got bona fide hedging exemption, an exemption that allows businesses to hedge their legitimate anticipated business need.

So the fact is, you have got a number of transactions involving oil futures. For example, on the New York Mercantile Exchange, which is the biggest market for oil, and almost triple since 2004, and the price of oil has tripled over the same period. I am sure that is just not a coincidence. There is a direct relationship to the way in which this financial operation is being manipulated and the way in which the price of oil is being driven up.

Let me give you a couple of examples. There is the director of the Public Citizens' Energy Program on May 7th of this year, just a short time ago, he estimated roughly $0.70 of the price of a gallon of gasoline is the direct result of investor speculation on the unregulated market. Well, you might anticipate that the director of Public Citizens' Energy Programs might say something like that, but he is backed up by the IMF. The IMF has said, meaning, speculation has played a significant role in driving up the price of energy. Producers, in particular, argue that fundamental would yield an oil price of about $80 a barrel. Now, this is dated March 14, just a few months ago, yield an oil price of about $80 a barrel with the rest being of speculative activity.

In summary, in this IMF report, which came out on May 14th, it appears that speculation has played a significant role in the run-up in oil prices as the U.S. dollar has weakened and investors have looked for a hedge in oil futures.

So, it is very clear, when this is being looked at objectively and openly, a lot of this big price increase in oil is driven by speculation. So why aren't you driving into this to tell us who these speculators are and what the effect is as it is being done?

Mr. LUKKEN. Well, certainly we have been looking at this since I became the chairman a year ago, first starting with exempt commercial markets, and you mentioned bilateral transaction, swap contracts. This is something that concerned us, whether these transactions were actually price discovering or whether they were influencing the price of natural gas, in particular.

So we held a hearing last September, and Congress held hearings about this, and we made recommendations to Congress to close this loophole.

ENRON LOOPHOLE

Mr. HINCHEY. Close the loophole that you made a recommendation on?

Mr. LUKKEN. This is the so-called "Enron loophole." So this is ensuring that these types of swap, energy swap transactions, when they start to influence prices, that is when we will put certain regulations on them, reporting requirements.

Mr. HINCHEY. So then you are agreeing that there is speculation, that there is this kind of conspiratorial speculation out there, and that is helping to drive up these prices significantly?

Mr. LUKKEN. Well, I am saying that we are addressing concerns there were with certain markets. You mentioned foreign boards of trade.

Mr. HINCHEY. But how are you addressing them? You are not addressing them in any real way. You said you held a hearing, and you said the Enron problem should be addressed, that is being addressed by this Congress, this House of Representatives has been addressing it very aggressively.

But the fact is that we need your operation to be much clearer about this, and the investigations that you are capable of carrying off, with the huge amount of money that you are being given, should be informing this Congress how much speculation is driving up the price of oil.

Mr. LUKKEN. And we provided legislative language to our authorizing committees to close the "Enron loophole", and they did, as part of the farm bill. And we are also asking for additional information about swaps, you mentioned. We have asked for additional information for foreign boards of trade. We have imposed position limits on those foreign boards of trade. We have been taking action on all the issues that you have raised.

Mr. HINCHEY. Well, my time is up, but I don't see any result of your allegation of taking action. There hasn't been any assertion. In fact, you have denied that there is any impact on speculation driving up the price. Now I know that you are driven by the administration, because the administration doesn't want to admit that the speculation is driving up the price either.

So I know that your statements today are directly influenced by the administration, but there is a direct inconsistency between that and what you are just trying to tell us and make us believe.

Ms. DELAURO. There is a significant difference of opinion as to whether or not the Enron loophole has been closed, so we will get to that.

Mr. Alexander.

Mr. ALEXANDER. Thank you, Madam Chairman.

COTTON MARKET

I wanted to talk just a little bit about cotton. Of course, oil is important to the State of Louisiana, but back in the early part of the year, there was some disturbances on the cotton market. So my question is, is CFTC conducting a thorough investigation of the events in the cotton market in early March?

Mr. LUKKEN. We disclosed in, I guess it was in early June, that we have an open investigation of that price run-up in March, an enforcement investigation.

Mr. ALEXANDER. So would you be issuing some kind of report to us at some point?

Mr. LUKKEN. At some point, if we find criminal activity, we will make charges in that area. And if we don't, we may, we have the option of providing a report of what actually happened during that price run-up, just as we did when natural gas spiked a few years back. So we will certainly keep Congress informed of that situation.

Mr. ALEXANDER. Do you think there will be a recommendation of any legislative action that needs to be taken?

Mr. LUKKEN. Well, I can't get into the details of the enforcement action, but one of the concerns, I think, at the time was what the influence of index trading may have been during that run-up. And so we are certainly looking across the board at the role of index

traders at all commodities, so that would influence the cotton situation, what our recommendations will be there. But we will certainly keep you informed as far as the enforcement investigation as well.

Mr. ALEXANDER. Is there any evidence that traditional hedgers are returning to the futures market?

Mr. LUKKEN. We have seen, of late, commercials, yes, during price run-ups because they need to hedge their risk. It depends on the markets, but certainly we have seen commercials returning to the markets in order to hedge their risk.

Mr. ALEXANDER. Okay.

That is all.

Ms. DELAURO. Mr. Bishop.

Mr. BISHOP. Thank you very much.

Following up on Mr. Alexander's questions regarding the cotton industry. There remains concern about the volatility in the market and the disconnection between cash and futures markets. For example, in the past few weeks, December futures have fallen from a low of $0.80 range to a low of $0.70 range with no significant change in the market fundamentals. Have you or your staff any insight about the reasons for the continued volatility and the lack of convergence between the cash and the futures markets?

Mr. LUKKEN. Well, we closely, we have economists that follow that in the cotton markets. I can't tell you specifically what caused that fall, but we can certainly have our economists follow up with you on the economics, the specifics of what is happening there.

I do know that the New York Board of Trade, ICE Futures U.S., the trades, cotton, recently took some action to try to stabilize how they set margins in that area. I believe that they are no longer going to set it against the synthetic futures price, which is something I think the cotton merchants were supportive of, and so I think they are taking steps to ensure that the clearing house is protected through the use of margins but that there is also certainty of how margin is set.

And so this is something we have been working with the merchants and the Exchange to try to promote.

Mr. BISHOP. Thank you.

One of my primary interests in today's hearing is to learn if there are any substantive ideas on potential solutions to the challenges that we face as a result of the out-of-control commodity market.

REGULATION OF SECURITIES AND COMMODITIES

As you know, in March, Secretary of the Treasury Paulson proposed a new Federal role and a plan for regulation of the securities and commodities.

His plan will combine the Securities and Exchange Commission, which regulates equities and debt markets, with the Commodity Futures Trading Commission, the CFTC, which regulates exchanges, trading commodities and financial futures. The two commissions have very different regulatory approaches, with the SEC favoring direct regulation and a rules-based approach and the CFTC favoring a principle-based approach that relies heavily on self-regulation by the commodities and future exchanges.

Given our experience, that is Congress's experience and our government's experience with the Department of Homeland Security in measures, our track record is not very good.

What is your position on this proposal?

Mr. LUKKEN. The blueprint that the Treasury Department proposed, certainly recognized that there is need for additional collaboration between regulatory agencies, both domestically and abroad. My worry with the blueprint was that somehow our expertise, the role that we provide in what we are talking about here today, would be lost in that transition, that somehow the commodity markets would not be, wouldn't be the top priority of that organization that might come out of the unification.

So we have had a good successful track record over our existence to ensure the markets are being protected. And certainly we want to make sure that these markets have a front-line regulator going forward. And that was my concern when that proposal came out.

Mr. BISHOP. The CFTC has traditionally delegated much of its regulatory oversight to its Designated Self-Regulatory Organization, the DSRO, of which the most prominent of the National Futures Association are the Chicago Board of Trade and the New York Mercantile Exchange. Has this self-regulatory process really been effective in working, and should we, given what we are facing today, now move to a more direct oversight and more direct control with more regulatory examples such as the CFTC does?

Mr. LUKKEN. Well, we have two layers of regulation. I wouldn't say it has been delegated, because there are several things that we actually duplicate with the exchanges. For example, surveillance of the marketplace, what we are talking about today, the exchanges do this on their own, and it is because they are the front line of trading. They get to see it, they know their participants. They know who is trading, so they do this. But we also get the data and do this as well.

There is duplication there, because this is important to ensure that manipulation is not occurring. There are certain functions we do delegate to the NFA and to others, including registration of traders and certain administrative functions.

But certain things we want to make sure that we keep to ourselves and that there is duplication of effort. I think it has been a good balance of ensuring that the exchanges are doing the front-line regulating, but we are overseeing them and duplicating areas in a certain way.

Mr. BISHOP. Well, you know, we are complaining now that we are seeing what is actually happening, and it appears that it is not really working.

Mr. LUKKEN. But, again, the things that we have delegated, like registration, aren't really what we are talking about here today. We certainly could register and audit firms more as an agency, that doesn't really affect sort of the manipulation and the price issues that we are dealing with today.

That would require more resources, so we would have to come talk to this committee about how many additional resources that might require. So it is trying to find that balance.

Mr. BISHOP. Thank you.

My time is up.

Ms. DELAURO. Ms. Emerson.

Mrs. EMERSON. Thanks, Chairman.

I appreciate you being here today, Mr. Lukken.

Thanks, Chairwoman DeLauro, for scheduling this hearing today.

The high energy price that Americans are faced with today certainly demands our attention, and I believe that we have got to look at every possible cause, every possible solution.

I think that we may end up finding out, you never know, that this is a supply-and-demand issue, and with some manipulation, or we don't know. But one thing is clear, that we need to have a long-term national energy policy in this country.

But with that being say, I am going to take this first round of questions and deal with agriculture, if that is all right with you.

You know, Chairman Lukken, I generally agree with your thermometer analogy. However, in regard to the grain markets, I would also ask whether that thermometer might be broken.

FUTURES MARKETS

Just as an example that I am sure you are aware of, Toledo, Ohio, is the delivery point for the Chicago Board of Trade wheat contracts, and under the thermometer analogy, the price of wheat in Toledo should, not necessarily perfectly, mirror the futures prices on the Chicago Board of Trade at the end of the contract month.

Now, the basis yesterday, the difference for those of us who aren't aggies in here, the difference between the price a farmer receives at the grain elevator in Toledo and the price set for the July contract on the futures market was negative $1.20 to $1.30. Now put that pretty simply, the thermometer seems to be reflecting the actual temperature.

So, do you have an explanation for the lack of convergence?

Mr. LUKKEN. This is something that the convergence between the cash and futures price, which, then, again, is a separate issue with sort of what we are talking about, the high prices today, but——

Mrs. EMERSON. Well, except for the fact that the prices are high on grain, and our basises are inflated.

Mr. LUKKEN. Right. It depends on where you are delivering the contract. Sometimes we have weak basis sometimes, we have strong basis, depending on where you are delivering. But as you said, a well-functioning futures market is when the prices converge at delivery. And that ensures that people who want to hedge can properly hedge in the markets.

And so this is something we have been trying to figure out over the last year of why there has been a divergence and convergence on those agricultural products.

On April 22, we held an agricultural forum in Washington. And we brought in people from the University of Illinois that have studied this and others to try to figure out, is there some way, either in product design or other ways, that we can try to address this?

Commissioner Mike Dunn who heads up our Agricultural Advisory Committee, went out to Chicago recently and met with the exchanges and others to try to get at the root of what is causing this lack of convergence.

He is also holding a hearing on this at the end of July. So I wish there was a simple answer of why the futures and cash markets aren't converging as they have prior to 2006. We are looking into it. We are trying to figure out if product design or load-out fees may have to be exchanged in order to help with this proposition.

Mrs. EMERSON. So you would have to admit that there is some kind of a problem here, correct?

Mr. LUKKEN. With convergence, absolutely.

Mr. BOYD. Would the gentle lady yield?

Mrs. EMERSON. I certainly will.

Mr. BOYD. Just to follow up, because it relates to your point, in certain parts of the country, are you aware that farmers can't even get a cash contract, for instance, in my part of the country? And I wanted to ask if you might respond to that.

Mrs. EMERSON. Please, go ahead, because that was the case, that has been the case in our neck of the woods as well.

Mr. LUKKEN. Well, we have been talking with a lot of farm groups recently. It sounds like some forward contracting is starting to happen again, but part of this was due to the rise in margins as a result of high prices, that there was uncertainty as a result of not being, having the credit lines in place to forward hedge on some of this, of these issues. Some of it, again, gets to the convergence issue that, how can you lend money when you don't know if this is converged and this hedge is going to work or not?

So we are trying to bring that certainty back to the market so that there can be forward contracting. Some of it is coming around, is my understanding from talking to farm groups, but we are working on that exact issue.

Mrs. EMERSON. You say, you say, Mr. Lukken, that, on July 29th, when you have this next Agricultural Advisory Committee meeting, that Commissioner Dunn will be leading, that you will need to continue to develop solutions to this agricultural situation.

And so I am hopeful that the solutions will happen, and we are not going to continue to study and study and study.

Mrs. EMERSON. Because I will tell you that my producers, I must get 20 calls a day at not only in my district office, but here from producers who, number one can't afford contract, or it is spotty whether they can depending on where they are. And so gathering of information analyses are all great. But we need some kind of solutions. And so I'm hopeful that we will be getting some, but ultimately, I think that the fact that we're having trouble on this end, which is a little bit more explainable worries me and doesn't inspire a whole bunch of confidence in CFTC's ability to regulate other markets, such as energy.

And so I just I hope that we are going to see some conclusions here, and I am out of time, but we will get back to this on the next round, thanks, Madam Chair.

Ms. DELAURO. Mr. Rothman.

Mr. ROTHMAN. Thank you, Madam Chairman. I would like to thank you, Madam Chairman, for holding this very important and timely hearing. I think I would like to thank you, Mr. Chairman, for being here and subjecting yourself to our questions.

PRICE OF OIL

Mr. Chairman, it has been said by people in the administration who have testified for the Senate that speculation in oil was currently adding as much as 10 percent to the price of oil, others who have testified from the private sector before the Congress have said that speculation in oil could be adding inflating the price to consumers by as much as 100 percent. What is your view on the amount of speculation that oil, that the effect of speculation in terms of the cost of gasoline and oil to consumers?

Mr. LUKKEN. Well, we have tried to talk to those people with their estimates. I think we have called all of them, in fact, our economists, to try and figure out if this is based on certain models or data that they have and tried to reach out, because we want the best information available to understand where they are getting their estimates and to date, we have not gotten any new information or different information from what we currently have as we look at this.

So we get all the participant data to see what speculators are doing, what swap dealers are doing, who are bringing in this index trading. We are trying to run analysis on whether they are driving prices or following prices. So far, we haven't seen evidence that seem to be driving prices. The fundamentals seem to explain these price moves. But we are going to start getting additional over-the-counter data now from swap dealers to see if that is potentially having an influence on prices. So we are looking, but to date, we have not seen evidence that speculation is broadly driving these prices.

Mr. ROTHMAN. So it is your view as of today there is no speculation driving these prices or distorting the market?

Mr. LUKKEN. Distorting the market. You know, speculators are a part of our markets and certainly on a day, they take positions but it is important to remember too——

Mr. ROTHMAN. Mr. Chairman, forgive me. I only have 5 minutes. If I think I got your gist, I will move to to my next question. So you disagree with those who have testified before the House and Senate who said that the price of oil has been raised by these speculators?

Mr. LUKKEN. Yes.

Mr. ROTHMAN. But you continue to look into it?

Mr. LUKKEN. Absolutely. It is our job.

Mr. ROTHMAN. That is also your testimony.

With regards to, so then the, Mr. Kingston's question about the hoarding is not one perhaps then that resonates with you because you don't see anything untoward going on out there, just normal market fluctuations, is that right?

Mr. LUKKEN. Well, we look at to look for evidence of hoarding. That would be a key determinant on whether there is a speculative bubble occurring. So that is something we are looking for. We have an open nationwide crude oil investigation, and our economists look for this, and DOE looks for this and, so far, though, we haven't seen evidence of significant hoarding.

Mr. ROTHMAN. I did want to point out then, specifically, Guy Caruso, the administrator of the energy information information testi-

fied on March 4, 2008, before the Senate and he was the one who had said that 10 percent of the price of oil was affected as, increased by speculation, and you specifically disagree with that as well?

Mr. LUKKEN. Well, Guy is a part of our Energy Market Advisory Committee, so we want his input on what is going on in the markets. He is also a part of our interagency task force that we are conducting with the DOE and other organizations, the Fed and the SEC and Treasury, so his input will be a part of those reports and those discussions. I am not familiar with that statement, but certainly we have not, at the CFTC, found evidence that speculation is——

Mr. ROTHMAN. With regards to the models and other bases upon which the individuals who testified that there was a significant price effect coming from speculation in oil markets, have you found their models or other bases to be without merit or are you still analyzing them?

Mr. LUKKEN. Well we haven't gotten significant data from a lot of these individuals. Most of the reaction is "this is based on 35 years of experience" or "this is sort of gut feels" or "it is that" sort of evidence that we are getting. We haven't, we are still looking through some of the organizations, we are still looking through some of their data.

Mr. ROTHMAN. With regards to a proposal that would allow you to say that one couldn't speculate in oil, for example, without showing an ability to take delivery, would that be something you would be interested in pursuing or do you have an opinion on that?

Mr. LUKKEN. Well, no one, hardly any of our traders, 99 percent of our traders never take delivery. Again, they are transacting on the expected price of crude oil. They are not trading physical oil, so that would significantly limit who could participate in our markets. And many of them, commercial businesses, that don't necessarily take delivery of these products. Recent months, we have had some months where no one has taken delivery of crude oil products. So I think it is important to remember that these markets are financial paper markets, they are not physical crude oil markets.

Mr. ROTHMAN. Would you be taking a position today to oppose that or you just want to point out those elements of for consideration?

Mr. LUKKEN. I would just say that that would be—significantly limit the liquidity of the marketplace which could potentially harm the price discovery function.

Mr. ROTHMAN. I understand that, but does that mean you would be opposed to it or you just want us to consider——

Mr. LUKKEN. Yes, I think that would be problematic. Yes.

Mr. ROTHMAN. Thank you, Madam Chairman, thank you, Mr. Chairman.

Ms. DELAURO. I think in later conversations what we need to do is talk through what the critics see that you don't see with regard to speculation, because there is a substantial amount of information from the IMF and other very reputable organizations who do believe that speculation is playing some role in this effort, and it really is quite disturbing that you don't even make that com-

mentary in your testimony. You don't address that issue at all. And nor do you, and, that potentially begs the question as to whether or not you really are looking at that issue in a way that others are. Sorry, Mr. Latham.

PRICE DISCOVERY PROCESS

Mr. LATHAM. Thank you, Madam Chairman, and welcome, Mr. Chairman. This is an issue I think that cumulatively Congress knows less about than any other issue that I have ever seen around here in my 14 years and it is just incredible some of the statements that are being made. Can you just give us kind of a first grade level, what makes price, is it supply demand inflation?

Mr. LUKKEN. Well fundamentally, people are trading on information, all sorts of information, supply, demand, expectations of inflation, value of the dollar, all these things come into the price discovery process.

Mr. LATHAM. And we all want an open totally transport marketplace out there, and I will tell you in my background, maybe it is because I grew up in agriculture and had a family business where we could not have existed if it were not for the ability to hedge because as in the seed business, you buy from your growers, and if you haven't sold that to your customer already you have to find a way to lay off that risk. And without a speculator in the market, I would not be able to hedge my risk. Is that normally the case? A true hedge, a speculator normally is on the other side of that?

Mr. LUKKEN. Absolutely.

OIL SPECULATION

Mr. LATHAM. Can you tell us in the oil market what side the speculators are on today?

Mr. LUKKEN. Well, surprisingly they have been almost equally long and short. We came out with this data recently that they are about 4 percent net long, which means there is slightly more longs than there are shorts in the futures markets, so there as many that would benefit from the price going down, I mean in crude oil as they are with the price going up.

Mr. LATHAM. And that normally is the case with an open transparent market you have people in that and speculators are part of making price?

Mr. LUKKEN. They make money going up or down.

Mr. LATHAM. Right, and also if you are going to hedge as we have to in our business, or if an airline has to in their business to cover theirs, their costs to know what their costs are going to be for the future and work on a margin and not speculate on those things you have to have the speculators in the market?

Mr. LUKKEN. Yes.

Mr. LATHAM. If in fact we were to shut out in our U.S. market speculators, where would the marketplace go? Would it be to unregulated markets like to Dubai and places like that?

Mr. LUKKEN. Potentially, there is a vibrant crude oil market in London as we have talked about on the foreign boards of trade.

Mr. LATHAM. Which is not as regulated as ours is.

Mr. LUKKEN. Well it is regulated by a different regulator but it would be outside of the CFTC's surveillance. We would no longer

get to see, if the Brent crude oil contract all of a sudden became the benchmark and not the WTI contract, we would no longer see that as a regulator or it could go to unregulated over-the-counter markets or as you mentioned to other jurisdictions.

Mr. LATHAM. There is a very good article today in the Wall Street Journal if anybody in opinion section that talks about what we need to do on a bipartisan basis around here to actually address the issue that is out there. On the one side, certainly and our feeling is that we need to drill, we need to go out and explore and get the resources we have here, and also on the our side, the other side we need to put a huge new investment as far as basic research, as far as trying to find alternatives for the future, things like that but we need to work together. And one interesting point in here is that in the past, any kind of spikes in oil prices, at the pump, whatever, obviously affects that, has been a short-term interruption in the marketplace where the futures out 3 or 4 years were not affected because it was a short-term spike.

It is today's spot price. What is different today is that the futures market out 3 or 4 years is the same as what the spot market is today. And could you tell us if, in fact, we were to tell the world today that we are going to have energy, much more energy supply in this country in 3 or 4 years, what would that do to those markets out 3 or 4 years from now as far as the futures market, and what affect would that have on the spot market today?

Mr. LUKKEN. Well, it would likely come down and the futures market predict, are predictive in nature, so any sort of additional certainty of supply in the future or conservation on the demand side would be reflected in those markets. And I think what is lost in sort of the debate about the additional speculators you mentioned coming into the markets, they are also providing longer term the ability of hedgers to go out longer term. It used be you could only hedge a year or 2 in the futures markets. You can now go beyond 8 years, so we can lock in prices as a business far down the road and that is very helpful for businesses for planning purposes. So this has been useful, this additional liquidity, but it still requires us to keep looking into it.

Mr. LATHAM. But the point is if we would start today and it wasn't going to come on until 5 years from now, it would have an affect on price today?

Mr. LUKKEN. Absolutely.

Mr. LATHAM. Thank you.

Ms. DELAURO. Mr. Jackson.

Mr. Farr.

Mr. FARR. Thank you very much, Madam Chair, I am just struck by the fact that, Mr. Lukken, you have created a whole new interest in Congress. We have had exchange under our jurisdiction for a long time, but I can never remember having a hearing that gets as substantively involved in this. And I would like to thank the Chair for doing this. It is an upgrading of our experience in a rather esoteric field and I was just reading a little bit about the history here, the number of just the activity in the exchange over the last few years. I mean, this is essentially involved with the electronic capability of being a global community, and your job is to protect the public and the markets' users from manipulation, fraud, abuse

in practice, at the same time, to promote open competitive and financially sound markets for the commodities futures options. As I understand it, approximately $5 trillion of transactions flow through the U.S. exchanges daily.

LONDON LOOPHOLE PROBLEM

And I don't understand the system much. But how do you—and you have ability and there are other markets around, there are other exchanges around the world, and you allow those exchanges to be, or we allow them to bid on our exchange, what is the essentially the London loophole problem? How do you protect the public and market users from manipulation, fraud and abuse practices that go on in other exchanges? And how do you, I think, part of this hoarding you are talking about you are looking at whether people are hoarding supply, how do you know that that, how do you look at that? How do you understand that particularly when these actions can go on in other exchanges which we give electronic terminals in the U.S. so people can get access to those exchanges?

Mr. LUKKEN. In the United States and this dates back about since about 1996 the CFTC users in the markets, institutions, wanted access, electronic direct electronic access to foreign exchanges. These were some of our registrants. They were able to get access by picking up the phone or going through foreign affiliates, but they wanted to actually put a trading screen in the U.S. to allow them access to those foreign exchanges. And so the CFTC, since 1996, has allowed these institutions access to those markets but they required certain things.

They required us to do an analysis of the regulatory authority to make sure that they were comparable, regulatory objectives, and we do that whenever somebody asks for access to those markets. But we also then look at the exchange itself to make sure that it has the rules in place, the controls in place that we normally look for in our exchanges. And once that is done, we would allow U.S. participants access to that market.

Mr. FARR. But there is not a common playing field around the globe of information—

Mr. LUKKEN. These were normally foreign products, so if I was a U.S. institution and I wanted to trade the German bond interest rate contract, bond contract, I could trade these foreign products by placing a screen in the United States. What recently happened in 2006 is that somebody started to list a product in direct competition with our crude oil benchmark, and they linked it off of our benchmark, and in 2006 we realized—well that had the ability to influence our price, our regulatory authority.

And so at that time, we held a hearing, we went to the Federal Register for comment, and we decided that it was necessary to get additional information on the traders in those markets, not just U.S. traders but foreign traders as well that we normally would not see. And so we started to get that information in 2006. Since then, we have decided to improve on that information and make it equivalent to the information we get for our traders, and that was done in conjunction with negotiations with the U.K. Regulatory authority and then recently we applied position limits on those participants as well.

So now we have the equivalent position limits and information in order to surveil the marketplace so we can protect our pricing structure and that is the policy going forward for this agency.

Mr. FARR. How about hoarding?

HOARDING

Mr. LUKKEN. Hoarding, this is something, hoarding is a cash market, we have jurisdiction in the futures markets but our manipulation authority allows us to go out and investigate hoarding wherever it may be so our manipulation authority goes to the cash market, the over-the-counter markets, if people are manipulating overseas. We went after Sumitomo overseas a few years back for manipulation, so we have ability to police for hoarding that leads to manipulation.

Mr. FARR. Thank you, Madam Chair.

Ms. DELAURO. Mr. LaHood.

Mr. LAHOOD. Mr. Chairman, what do you tell common ordinary citizens or simple-minded Members of Congress or your own family members, how do you answer the question, why are gas prices high? Why are they $4 or more a gallon? What do you tell them? What is your answer?

Mr. LUKKEN. Well, my Mom calls me up and asks me those questions too.

Mr. LAHOOD. I wasn't referring to your mother as simple-minded.

Mr. LUKKEN. I know. I know she is the smarter one of the family. We look closely like everybody is looking to try and find whether it is supply and demand or whether this is market participants that are driving this. And so we see production as flat around the world. Demand is growing, while production remains flat, and that is driving up prices. So again, at the same time, we are looking at market participants to ensure no one is artificially driving prices up.

Mr. LAHOOD. Give me a much simpler answer. I can't believe you are telling your mother about all these technical terms. What do you, is that really the way you explain it to her?

Mr. LUKKEN. We are not, we are consuming more than we are producing.

EFFECT OF DRILLING ON GAS PRICES

Mr. LAHOOD. And your answer to Mr. Latham very specifically, if the Congress passed a bill that allowed for drilling somewhere in this country, you name the place, we will just name a place, and the President signed it, would that send a loud message to these speculators and that would that then drive down the cost of a gallon of gasoline almost immediately?

Mr. LUKKEN. Well, there is—it would be a factor in the price discovery process.

Mr. LAHOOD. Do you think gasoline would come down if the Congress and the President enacted a law like that pretty immediately?

Mr. LUKKEN. It is hard for me to tell, but certainly those signals are helpful to drive down prices.

Mr. LAHOOD. So it is quite possible that a gallon of gasoline might come down if Congress took that kind of action?

Mr. LUKKEN. Quite possible.

BIOFUELS

Mr. LAHOOD. Do you believe that the enormous influx of biofuels, primarily ethanol, has driven up the cost of gasoline?

Mr. LUKKEN. It certainly had impact on the price of corn and other agricultural products. Our economists have looked at this.

Mr. LAHOOD. I know that. I know that I am not talking about the price of food or the price of corn. I am asking you, if you think that ethanol has driven up the price of a gallon of gasoline because some people have said that.

Mr. LUKKEN. I don't think so. Actually it probably had some bearish factors on gasoline, in that I think it is helping with the supply of fuel. Alternative fuel. Thank you.

Mr. LAHOOD. Those are my questions. Thank you. Thank you for your answers.

Ms. DELAURO. I will just make one point. It would take a lot of years for that drilling to come on line and refiners are not dealing are what they already have and we are sitting on 68 million acres of land for which there are leases and where there hasn't been any drilling today. And maybe that is a piece of this hoarding effort in which we are just sitting on it and continuing to drive the price and continue to drive price. Is that possible?

Mr. LUKKEN. Well, all these factors would be a part of the price discovery process.

Ms. DELAURO. Mr. LaHood did a very interesting thing, and Mr. Latham said something as well before, it is a very complex issue, very complex and a few people who understand it. On the other hand, we have agencies that are supposed to understand and are supposed to do something about it, and the fact of the matter is that the agencies charged with doing something about it and understanding it and being able to explain it and bring the kind of people together that we need to address the issue are not doing the job. Are not doing the job. That is your responsibility. And it was those smart guys at Enron who put us into the place we are now, with what happened there, and we are beginning to look at some very similar situations and as that Enron situation was all about. And get behind closed doors.

Get behind closed doors, figure it out in a matter of 24 hours. They figured out the Treasury and others that Bear Stearns needed to be build out and we took care of that. The American public needs to get bailed out. The taxpayers and the consumers are on their backs and we sit and do nothing. Your agency is not addressing the issue. And for the first time in 9 years, we have begun to ask some questions. And the fact of the matter is we may not have all the right terminology, and be able to ask those questions but we better, we are going to ask them and we better get some answers and we better get some action very, very quickly. Mr. Jackson.

STATISTICAL ANALYSIS PERSONNEL

Mr. JACKSON. Thank you, Madam Chair, and I apologize for having to step out of the hearing. In the CFTC's division on enforcement, Mr. Chairman, how many personnel are designated to perform statistical analysis on possible collaboration, and other illegal speculative behavior in the energy sector?

Mr. LUKKEN. Well, our division of enforcement, I think professionals are roughly around 100 individuals. These are all litigators, so these are people who are bringing actions to court based on manipulation. They utilize, however, our chief economists' office for analytical use to ensure that when they are trying to prove manipulation that they have the Ph.D economists working on these issues, so they have access to the six or seven individuals that are doing the economic modeling for that type of activity.

Mr. JACKSON. Six or seven individuals are responsible for the entire energy sector in the country?

Mr. LUKKEN. No. Absolutely not. We have a whole division of market oversight and surveillance. Economists are looking at these markets daily, these are, all of our economists are looking at this, this is just—you referenced the enforcement division, the people who are litigating these matters. Once we find evidence of manipulation, we will go after that aggressively and we use economists to help prove that.

Mr. JACKSON. How much money is provided to the division on enforcement for these tasks?

Mr. LUKKEN. I don't know specifics of how much goes directly, but it is sizeable. These are our largest division and they get the largest chunk of our budget.

Mr. JACKSON. I am also concerned that the emergence of commodity index funds are making commodity purchases far easier for a wide range investors, including hedge funds, investment banks, pension funds and university endowments. Many will argue that the index funds are contributing to the rapid rise in commodity prices and possibly creating a bubble. Mr. Chairman do you believe that the increase in trading by pension funds are having a negative effect on the price of commodities.

Mr. LUKKEN. This is something we are trying to study and figure out. We had our energy markets advisory committee hearing and we invited several index pension funds to come and testify. Calpers came, for instance, and others, they pointed out, look, our average person at Calpers is making $42,000 a year, 46–year-old individual that is looking for better returns on their retirement. And so I think it is important to note that although there is concern about how much money is coming in, this is benefiting retirees as a result of this. But we have asked in late May, we are using our special call authorities to get additional information from swap dealers that bring this pension money into the markets, we are gathering that information that is coming in right now, and we are hopeful to get that information to Congress as quickly as possible so they can make informed decisions about its impact on the markets.

FUNDS' IMPACT ON COMMODITY PRICES

Mr. JACKSON. Do you believe the increased trading by the funds are having a negative impact on the price of commodities?

Mr. LUKKEN. Do you mean that it is driving down prices?

Mr. JACKSON. That is correct.

Mr. LUKKEN. We are not sure it is having any impact. In the futures markets, there are zero sum games, there are just as many longs as shorts, so for every participant that enters, there is somebody on the other side of that, and it is important to remember too that these never get to delivery the index funds. They are always selling before there is physical delivery of the product. So we have not seen, in looking at these products, people with commodities with high percentages of index trading such as live cattle, have had very weak prices over the last year. So some with no index trading have had high prices over the years. We have no direct correlations that index trading is impacting rises, but we are continuing to get this data from the swap dealers.

Mr. JACKSON. How about the possibility of increasing the price of commodities as a result of the index trading?

Mr. LUKKEN. Increasing or decreasing, we haven't seen evidence.

Mr. JACKSON. Thank you, Mr. Chairman.

Ms. DELAURO. Ms. Kaptur.

Ms. KAPTUR. Thank you, Madam Chair. Chairman Lukken, you used to work for a man I have great admiration for, Senator Lugar of Indiana, who long ago told America that our greatest strategic vulnerability was our dependence on imported petroleum. I happen to agree with him coming from adjoining Ohio. And I love to drive to South Bend and see that big smokestack up there, many years ago beginning to process ethanol. Everything he has written, everything he said is right and we are suffering from not listening to people like Senator Lugar and many people on this subcommittee.

I wanted to read something from the Globe and mail and put it in the record for this hearing, an article from June 26th of this year basically says the focus of world investment activity is rapidly shifting from the established markets of the West to the emerging financial markets and I underline financial markets, in the Gulf and Far East. And we are all caught in this. And the question is whether we can see our way forward clearly and help our country and our citizens fast enough. A woman from my church came up to me a couple weeks ago after services and said, you know, Marcy, our country really doesn't belong to us anymore. And let me ask you this for the record. Which company, to your knowledge, made the most profits last year, which company operating in our marketplace would you guess? Do you know?

Mr. LUKKEN. I don't know.

EXXON MOBIL

Ms. KAPTUR. The answer is Exxon Mobil. Do you know how much they made in profits last year?

Mr. LUKKEN. I don't.

Ms. KAPTUR. It was $40 billion, the largest profits of any corporation in our history. Do you happen to know the largest privately held corporation in the world?

Mr. LUKKEN. I don't.

Ms. KAPTUR. It is Saudi Aramco in Saudi Arabia. Do you happen to know the percent of oil that this country imports approximately? Do you know what percent of what we use we actually import?

Mr. LUKKEN. I don't know those exact figures.

Ms. KAPTUR. It is almost 70 percent now. We are totally dependent. Totally dependent, and those petrodollars that we spend here are being recycled in the very markets that this article talks about. And one of my concerns because you are involved in regulation, but powers moving away from this country in the financial markets, because we are now the victims, we are moving into an economy, we are in an economy in this country, where we no longer produce as much as we used to, in terms of manufacturing and agricultural, we import we have $1 trillion trade deficit this year, and we have become the victims of finance capitalism. I agree with a Republican on this, a man named Kevin Phillips wrote a great book called Borrowed Prosperity. We are living in this era. And what concerns me about the agency that you operate is that you are being drawn into deals with Dubai and London and God knows where else that are causing you to provide exemptions in your regulations.

And I want you to talk to us a little bit about that because the standards that we have used to historically to manage the economy of this country are being undermined because we are no longer carrying our own weight, and we are borrowing from the very instrumentalities that do not share our political point of view. And for me, this is a fight for freedom and for freedom's institutions.

Now, it is my understanding the CFTC exempted London and the Dubai exchanges from certain strict rules that you had historically used in your own regulation, and could you please outline for us a little bit about that because you know they had these words. Now we are going to harmonize our patents with Japan. That is crazy. We have the best patents system in the world under our Constitution. Now it sounds like we are harmonizing our regulatory process with the very places that we are literally in competition with and not on the good end of the teeter totter here for the moment, could you outline for us what kind of exemptions you have provided in your current regulation?

And I want to know what other places other than London and Dubai have you provided these exemptions? And finally, what other steps are you taking to so-called internationalize your regulatory structure? Could you talk to us a little about this, please.

Mr. LUKKEN. I think it is important to recognize that we don't permit the trading of these types of contracts on other foreign boards of trade. For example, Hong Kong recently listed a WTI contract with no approval or access granted by the CFTC. There is another exchange in Dubai that has no access from the CFTC, the Dubai commodity and gold exchange, and they are listing a WTI contract that is linked to our contract. So they are allowed to trade and U.S. participants can access those markets through phones or foreign affiliates of theirs. They can trade in those markets. What we have done as an agency is try to, in granting direct participation in those markets, gain our leverage to condition that direct access of our U.S. participants on this access.

And so what we have done since 1996 is we go in and we look at the regulatory structure of these foreign jurisdictions. We go through to make sure that they are comparable with our regulatory structure. We also look at the exchange itself and since, and any of these linked contracts we are not harmonizing down to them, they are coming up to us, that we are going to get the same information that we get from NYMEX on the London exchange and the Dubai exchange. Dubai, by the way, is not listing a contract yet. And we also require the exact same position limits as our markets on those markets as well and so those are the issues that we felt so strongly about that we required them to abide by our standards.

So I think it has been helpful to recognize the global marketplace. We are not trying to go down to the lowest common denominator here; we are trying to make sure that people raise up to the proper global standards. That is reinforced, by the way, by our membership in the International Organization of Securities Commissions with which sets global standards. And all these organizations, Dubai and London and others, are active members in there that are making sure they are abiding by high global standards and we try to encourage that.

Ms. KAPTUR. Madam Chair, I know that my time has expired. I did want to place one other statistic on the record. It was the year 1998 that the United States began to import over half of the petroleum it consumed. The teeter totter began to swing the other way. These are very important moments in history we should all be aware of because we have to get out of this hole together. Thank you.

Ms. DELAURO. Mr. Boyd.

Mr. BOYD. Thank you, Madam Chair. And I want to thank you also for holding this hearing. This has been an intriguing hearing, and obviously from the interest you can tell that it is one that we all should know more about. I think, Madam Chair, also, I want to thank you for holding it because if it helps us understand this very important part of our economy and about how commodity producers and commodity end users interact with each other and create some sort of stable market, an economy, then that is a good thing, and I think there is a lot of confusion like Tom Latham said amongst Members of Congress about how this indeed works: How a farmer in Ames, Iowa who is producing 100 acres of corn and a cattle grower somewhere in Nebraska that is going to buy that corn agree ahead of time on what the price would be and it gives them great certainty in the operation of their business.

And not only that it goes beyond that what the end producer of that cow is at the producer level or at the slaughter level. So it is a market that works. It is a market that I know that some sitting on this committee have used and understood and certainly there is a lot, there is some psychology in that market. Would you agree with that.

Mr. LUKKEN. Absolutely.

Mr. BOYD. There is a psychology. And I think one of the things that is disturbing, a couple of things disturb me about the hearing this morning, and one is there is consistent going back to this oil thing and about what drilling may or may not do. Now, if there is some action by Congress on drilling, there will be a short term psy-

chological effect on the oil market. But it won't last long. Once the hedgers figure out that, it is going to be 10 years before that has any effect and you know what may or may not be found there, it will have very little effect. So I don't want us to overstate that. I want to ask, because ultimately you would agree, Mr. Lukken, that the fundamentals of supply and demand are what sets the market?

Mr. LUKKEN. Yes.

INDEX TRADING

Mr. BOYD. Now, I want to ask you one question about your business and it hasn't come up much today, but in your testimony, you said that the Commission recently announced several energy initiatives, including index trading and a review of whether additional controls or classifications for those traders are needed. Have you completed that study, and if so, what did it show? If not, do you think index trading of these commodities is a problem that relates to what we have been discussing here today?

Mr. LUKKEN. Index traders have been a new—there has been a new influx of index traders in our markets, and these are pension funds and endowments that are looking for long-term sort of "buy and hold" strategy in the commodity markets. We certainly recognize that and that is where we are trying to get better information. Most of them don't come directly to the futures markets. I think there is confusion about that. Most of them go through intermediaries, what we call a swap dealer. And a swap dealer such as Goldman Sachs or Morgan Stanley sells Calpers a product and says we are going to give you exposure to commodities. And they do this with lots of clients. And at end of the day, they take all those clients positions, but they also work with airlines and railroads and others and they bring all of that net risk to the market in the futures markets.

Right now, swap dealers are flat the market, interestingly enough, there are just as many long swap positions as there are short swap positions, meaning there is as much pressure that the prices will go down as go up in the swaps markets. But we are looking at the step beyond that to what the index funds, to what the over-the-counter index funds are bringing to the marketplace. We are getting that information started this week. This is coming in. These are complex books. We are trying to unravel all these things and get a better understanding of it. But we hope to, as soon as practical, get recommendations to Congress on this so we can tell you what is going on.

Mr. BOYD. If I could, when that Calpers, for example, goes to that broker at Goldman Sachs and says he wants to be long in the market Goldman Sachs doesn't hold that risk. They go into the market and hedge that risk so actually you have a buyer on one end and a seller on the other so——

Mr. LUKKEN. Exactly. And that is why we treat them as hedgers. As you said, they are hedging their price risk. Now we are revisiting that. We are looking to see whether that still makes sense. This was done in 1991, a determination of the Commission at the urging of Congress to do this, but we are looking to see are they really a commercial participant like we think of a farmer or a grain elevator or United Airlines or something along those lines. So that

is something we are reviewing. But they certainly are exposed to price risk. And if we put limitations on that, we don't want to expose them to systemic risk as we saw with Bear Stearns. So there is a balance there making sure they have access to transparent markets.

Mrs. EMERSON. Allen, can you yield to me for a quick second?

Mr. BOYD. Certainly, I yield.

SWAPS

Mrs. EMERSON. Can you kind of explain when you talk about swaps, you are throwing out all these terms, I sort of understand what you mean by a swap, but perhaps it would be helpful to you know more fully explain how Lehman Brothers or whomever take all these different orders, if you will, and then does a swap with it and kind of explain.

Ms. DELAURO. Like the subprime market.

Mrs. EMERSON. Let's talk about if you can just, in first grade talk, like Ray asked, explain that. If you don't mind, Mr. Boyd.

Mr. LUKKEN. A swap is just a transaction, a contract, so two individuals or entities, institutions sitting down and writing a contract based on potential risks. So let's say I am Delta Airlines, and that I am going to be consuming fuel for the next year and I want to lock in a price and this is how much I need. And so I can go to individually tailor to Delta's needs, how much risk they want to off-load, how much potentially they can even be involved in the physical transaction of the commodity.

So you write these individually tailored contracts for these people. At the end of the day, they have a lot of these contracts, Goldman Sachs does, and they bring them all together and through their risk management, they find out, you know, we are subject to this amount of price risk in crude oil, for example. And so how do we offlay that price risk at the end of the day? Well, they do it by coming to the standardized futures markets. So swaps are individually negotiated contracts. Futures markets are contracts too, but they are standardized.

And so you are converting individuals, individualized product to a standardized product and offsetting this risk. And it is helpful because, you know, Bear Stearns, they weren't able to offset the credit default swaps in the futures markets and if they had access to a clearinghouse and a transparent market that may have been averted. But so that is we don't want to cut off access of these institutions to our markets in whatever we do here.

Mr. LATHAM. Is there a difference in margin, margin requirements?

Ms. DELAURO. Yes.

Mr. LATHAM. Between what a speculator would do on swaps to hedge those.

Mr. LUKKEN. Because we don't directly regulate swaps but they are also making sure that whatever, it is the same idea as making sure that on a 1-day price move that margin is able to cover those 1-day price moves. So they are similar, but I am not sure they are exactly the same.

Mr. BOYD. Madam Chair, if I could briefly follow up the example you use of Delta Airlines, for instance, they could go into the fu-

tures market themselves, they wouldn't have to go into the index fund because they get an exemption and can trade for whatever they might actually use, can't they?

Mr. LUKKEN. Absolutely.

Mr. BOYD. But the swaps related to the index funds trading, aren't they generally just a combination of several commodities that now just are used to hedge against inflation generally?

Mr. LUKKEN. They are broad——

Mr. BOYD. Not users.

Mr. LUKKEN. Right. They are not commercials. Swap traders are bringing both. They are bringing passive sort of these endowment funds, these index trading as you referred to them, but they are also bringing in lots of commercial business as well.

Mr. BOYD. Thank you, thank you, Mr. Chairman, and Madam Chair, for your time.

Ms. DELAURO. One of the things we are going to try to do is, we have got several votes. And we want to go into a second round and I am going to ask the other panel to come up. And Mr. Lukken, I want to have you stay so we have an opportunity to get some more questions in. But there is a point that I wanted to try to make here which is that in 2000, as I understand it, that the Intercontinental Exchange became one of the exemptions entities. And so that, in fact, is not regulated by you. I think it is important to note and for the record, that when Enron failed and took its private unregulated energy exchange that went to the grave, another rose to take its place, something called the Intercontinental Exchange. It was the brain child of Morgan Stanley, Goldman Sachs, British Petroleum, Deutsche Bank, Dean Witter, Royal Dutch Shell, S.G. Investment Bank and Total Fina. 2001, ICE purchased the international petroleum exchange in London, renamed it ICE futures, it now operates as an exempt commercial market under section 2(h)(3) of the Commodity Exchange Act. Now, I think it is important also to note that on your energy advisory board here, that both Goldman Sachs and Morgan Stanley sit as advisers to the CFTC.

It is my concern, I don't know if it is the concern of others, that they are primary or they really are major beneficiaries of what the activity is here in terms of their personal gain and their profit and the speculation.

Does that not provide, does that not indicate to you that there is some major conflict of interest here in terms of, I mean, when I listen to Morgan Stanley or Goldman Sachs say the price of oil is going to go up to $200 a barrel, well, they know something maybe that the rest of us don't know. I think that we have a very serious issue here in terms of conflict of interest which is one of the reasons why a number of us want to really bring back if you will, this exempt market under the regulation of the CFTC and speculation, yes.

But to be at the core of this unregulated market and be making substantial amounts of money, yes, you take risks but they are making substantial amounts of money, and we see the costs in oil and prices going up, that it would just appear to me that that is your job is to protect the public from that kind of conflict and to be investigating that, not 2 weeks ago, not in May, not in June, but for the last several years when we have been watching this in-

crease, and so I don't know if you want to comment. I am happy to have you comment.

Mr. LUKKEN. The advisory committee we set up, we set it up so that we got everybody's voices so we have the airline industry as part of that. We have consumer groups as part of it, we have——

Ms. DELAURO. You don't have consumer groups. You have industrial groups. I have the list of people that are on your advisory board.

Mr. LUKKEN. Petroleum marketers association, we have the Industrial End Users Association.

Ms. DELAURO. Talk to me about—well——

Mr. LUKKEN. So we try to——

Ms. DELAURO. Is the Consumer Federation on the board? And who represents consumers?

Mr. LUKKEN. Well, we have the people, that petroleum marketers are on your next panel, they are a part of our advisory committee and these are all held in open public meetings so we try to get as much as information as we can from——

Ms. DELAURO. Goldman Sachs, Morgan Stanley were founders of the Intercontinental Exchange, which is now an exempt entity out of the purview off the screen of regulation by the CFTC and there are differences of opinion as to how effective the FSA in London is with regard to their own oversight of these areas, lots of different opinions, they also overseeing Northern Rock and what happened in Britain when Northern Rock which finally got nationalized. So we have serious deficiencies. Yes, Mr. LaHood.

Mr. LAHOOD. Sir, can you just respond to her question about is there a conflict of interest for these people to be sitting on your advisory committee?

Mr. LUKKEN. No. We followed the Federal Advisory Committee Act to, by the letter of the law to get people who are involved in these markets. And Goldman Sachs is involved in these markets so——

Ms. DELAURO. You are not subject. You are not subject to the Federal conflict of interest requirements that is something that we have learned from CRS.

Mr. LUKKEN. We follow the Federal Advisory Committee Act to the letter of the law to make sure that we are getting the right people on our advisory committee and this was approved by a bipartisan commission, these people who are involved on this commission.

Mr. HINOJOSA. Have they advised you that there is no relationship between the increase in the price of gasoline and heating oil and the outrageous speculation engaged in this industry?

Mr. LUKKEN. We have a variety of opinions on that, including the petroleum marketers believes it is speculation, and so does the airline industry, so we have heard from both sides of that committee.

Ms. DELAURO. We have about 4 minutes to vote. I would like to go to vote and I ask the panel to come back and we will bring up the panel and including yourself, Mr. Lukken, if you can stay a while longer we appreciate that because I believe there are other people who have questions for you.

Thank you.

[Recess.]

Ms. DELAURO. Thank you all. I know some other members of the subcommittee are coming back, and I appreciate your waiting.

And again, Chairman, I appreciate you staying and being able to answer some more questions.

I am very pleased to introduce our second panel today.

And Mr. Tom Devine, who is a small business owner of a full service biofuel and heating fuel company in southwestern Connecticut, Devine Bros., Inc. He manages the day-to-day operations of the Heating Fuels Department. And he is also here today representing the Independent Connecticut Petroleum Association and 549 independent and locally-owned-and-operated motor fuels and heating fuels distributors in Connecticut as a board member of the New England Fuel Institute, a 60-year-old trade group and public policy advocate representing well over a thousand heating-related services companies in the northeastern United States.

Dr. Mark Cooper is the director of research of the Consumer Federation of America and president of Citizens Research, an independent consulting firm. At the Consumer Federation, Dr. Cooper is responsible for energy, telecommunications and economic policy analysis, and is a frequent guest lecturer. As a consultant, he has provided expert testimony in over 250 cases on behalf of People's Counsels, attorneys general, and citizen intervenors before State public utility commissions in over three dozen jurisdictions. Dr. Cooper holds a Ph.D. from Yale University and is a former Yale University and Fulbright fellow.

Michael Greenberger is director of the Center for Health and Homeland Security at the University of Maryland and is a professor at the School of Law. Professor Greenberger teaches courses focused on counterterrorism and emergency response as well as constitutional law and a seminar on futures options and derivatives at the law school. Professor Greenberger has served as the Justice Department's Principal Deputy Associate Attorney General and as counselor to the United States Attorney General. Prior to entering government service, he spent 20 years in private practice before becoming director of the Division of Trading and Markets at the Commodity Futures Trading Commission. In that capacity, he was responsible for supervising exchange-traded futures and derivatives.

Finally, Johnathan Short is a senior vice president and general counsel of the Intercontinental Exchange, Inc., or ICE, and in his role as general counsel, he is responsible for managing ICE's legal and regulatory affairs. As corporate secretary, he is responsible for issues of corporate governance. Prior to joining ICE, Mr. Short practiced in a corporate law group of McKenna, Long and Aldridge.

We welcome you back, Chairman Lukken, and thank you all very much.

We will start, Mr. Devine, with you.

As I mentioned at the earlier panel, your full testimony will be part of the record, so you may feel free to summarize in whatever way you would like.

Mr. DEVINE. Thank you.

OPENING STATEMENT

Thank you, Chairman DeLauro, for having me here today, and distinguished members of the committee, thank you for the invita-

tion to appear before you on the issue of excess speculation and inadequate oversight of the energy commodities market and its impact on independent, small business energy distributors and their customers.

Thank you for your introduction. I appreciate that.

A little bit about Devine Bros. Devine Bros. is a 90-year-old family-owned business, a heating oil retail business in southwestern Connecticut. We retail bioheat as well as heating oil. We service lower Fairfield County, a full-service conservation service department and the heating oil. We are the largest facility between Stamford, Connecticut, and Bridgeport, Connecticut. We are located on the Long Island Sound. That is where our terminal is.

I serve the family as corporate secretary of the company, and as you said, I manage the day-to-day operations of the heating oil department.

Friday, June 6th, we refer to as Black Friday in the heating oil industry. On June 6th, the price of heating oil nearly went up $0.30 a gallon. I am totally amazed that the Chairman of the CFTC could not believe that speculation was not involved in something like that. The cost of crude hit almost $140 a barrel. Heating oil at that point was roughly $4 a gallon for the homeowners; 99 million barrels of heating oil traded that day, half of the United States' consumption in a year.

I am no longer confident that the markets are doing the job that they were set up to do. I can no longer use them as a risk-management tool. And if I had not purchased oil a day before the run-up, I wouldn't be in a better position, as my competitor down the street. If I bought oil just the beginning of this week, I would have been about $0.30 out of the money compared to my competitor. In 2 days, the price of heating oil moved $0.30 a gallon. If I bought a million gallons, I would basically have been out of $300,000 in 2 days.

A company like Devine Bros. cannot consistently lose that kind of money. Now, one could argue that I can get involved in options and buy call options, but that would add another $0.50 a gallon to my consumer. My consumer can't afford that. My consumer can't afford to spend an extra $0.50 a gallon to heat their homes when they are already paying $4 a gallon now. It just does not work.

It is easier to believe that there is no speculation in the market, but I feel that it is there. It is very volatile right now. There has been an awful lot of statistics thrown out earlier, I am sure you are going to hear more.

What I would like to focus on, if I could, is some of the stories that I have from customers that I am dealing with. They are actually bearing the burden of these high oil prices. And the fact is they can't afford it.

I am trying to collect the money from last year, which was a very high year for individuals. Next year is going to be double what it was last year. I am afraid to speculate and say what I think the price of oil per gallon may be next year because I might read it in the papers tomorrow, and it might drive the price up to where I think it might be, and that is due to the speculation that I believe is in the market.

I have a customer that actually has two sons that are fighting in Iraq, and he, basically, he fought in Vietnam. He is about 70-years old, and he can't afford to buy his oil for next year. He has been a 20-year customer of mine. And I don't know what I am going to do with him. I have to borrow an awful lot of money to pay for the inventory to deliver to my customers, and I have to be much stricter than I have been in the past.

At my level, there is going to be very cold people this winter unless something is done about the train that is totally out of control. I hear that speculation is good for the market; it brings liquidity into the market. After sitting here and listening today, I do agree with that, but I am swimming in liquidity. I mean, we are drowning in liquidity. There is too much. I believe personally that we have to see the margins increased on noncommercial speculators. I think there is something to that, so I can deliver oil and trade with other commercials and see the supply and demand come back to this market.

I deliver oil to a senior center that houses about 180 senior citizens. There are about 180 rooms. I had a meeting with them yesterday. I told them what the price of oil was going to be. They do get money from HUD, but he does not know how he is going to afford to pay for my heating oil that I have to deliver to him. He just does not know how to do it.

I talked to him on Monday morning, and by Wednesday, I was able to tell him that the prices of oil are coming down. It came down $0.30. It was a beautiful thing to see, but the price was still so high he couldn't figure out what he was going to do.

My customers ask me if I am running out of product. They don't see gas lines at the gas station. I say, no, I am not running out of product; I can get product. But the high speculation makes me jittery about buying any product. I don't want to buy product and all the sudden have this thing dump and me hold a lot of high, expensive product, because then I won't be able to make what little margin I need get by as a company.

Today, in the Wall Street Journal, I read that there is a fellow by the name of Gregory Mocek that is leaving there, and I would just like to quote it if I may: "The sheer volume of trading in these markets increases the occurrence of illegal conduct." That is his quote. I don't know if there is any illegal conduct. But I do know that there is an awful lot of conduct, a tremendous amount of speculation, a tremendous amount of money in the market.

I have heard the question regarding hoarding. I don't believe there is any hoarding, and I am just an oil dealer. But I don't believe there is any hoarding, but I believe the amount money that is in the market is creating the same type of outcome that hoarding would cause. And unfortunately, it is on the backs of my customers that are not going to be able to afford oil this winter, and they are going to be basically freezing, as far as I can see.

In Connecticut, we are very unique. We have set up the Fuel Oil Conservation Board to make our customers as conservative as possible in using heating oil. It is amazing how an industry can work so hard to make their customers be more conservative. We are the forefront State I think in New England in terms of bioheat. We do believe in bioheat. It is a cleaner-burning product. It helps retain

the efficiency into the winter, which will help the consumer. But even though we have made steps, taken steps to reduce through the efforts of national oil heat research grants to reduce the amount of oil used in the average household from 1,100 to 700 gallons a year, the pricing of oil is still making it very difficult for these consumers to buy the product.

And that is why I believe that the trading system at this point is not working. I think it is broken, and I think the efforts that you are doing here I commend, and I think you ought, you should keep on the heels of the CFTC, because I think that you alluded to a good point, and that is, why wait until this year to do something? And I think that with your efforts and staying on the heels of the CFTC and making them do something with the type of passion that I have seen here today may perhaps do something in the future. And I commend that.

Thank you.

[The statement of Mr. Devine follows:]

Testimony of
Mr. Thomas E. Devine
Independent Connecticut Petroleum Association
and the New England Fuel Institute

Before the
United States House of Representatives
Committee on Appropriations
Subcommittee for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Washington, DC
July 10, 2008

Madam Chairperson DeLauro, and distinguished members of the committee, thank you for the invitation to testify before you today on the issue of excessive speculation and inadequate oversight of the energy commodities markets, and its impact on independent, small business energy distributors and their customers.

About Devine Bros., Inc.

I feel that as a full service biofuel and heating fuel dealer in southwestern Connecticut, I am well suited to addressing these issues and any questions you may have on the subject. My company, Devine Bros., Inc, serves the home heating needs of people who reside in lower Fairfield County. The company is a third generation, 90 year old business located in Norwalk, CT. Our fuel oil terminal is located on the Norwalk River; we house the largest fuel oil terminal between Stamford, CT and Bridgeport, CT along the Long Island Sound Coast Line. Devine Bros. employs some 50 full time employees for our retail heating fuel department and a ready-mix concrete, building supply departments. I serve the family company as Corporate Secretary of the company, and I manage the day-to-day operations of the heating fuels department. This includes

management of our oil price hedging operations, product pricing, accounts receivable, and customer relations.

About NEFI & ICPA

I testify before you today as a board member and Legislative Chair of the Independent Connecticut Petroleum Association[1]. Our association was formed in 1950 and represents 549 independent, locally owned and operated motor fuels and heating fuels distributors in Connecticut that serve 682,000 heating consumers.

I also testify on behalf of the New England Fuel Institute (NEFI)[2] as a board member and Chair of its Government Affairs Committee. NEFI is a 60-year-old trade group and public policy advocate representing well over 1,000 heating fuel dealers and related services companies in the Northeastern United States. NEFI member companies market heating oil, bioheat, propane, kerosene, biodiesel, jet fuel, off-road diesel and motor vehicle fuels.

"Black Friday" Proves Excessive Speculation No Longer A Myth

On Friday, June 6th, the day that my industry is now calling oil trading "Black Friday," crude oil hit an all-time record of $139.12. Heating oil and gasoline closed at new highs of $3.98 and $3.55, respectively. Trading that day was at unprecedented volumes as well as prices. 1.09 billion barrels of crude oil were traded that day, 53 times daily U.S. consumption. Also that day, 99 million barrels of heating oil were traded, *half of total U.S. consumption per year.* Madame Chairperson, we are no longer confident that the markets are doing their job of providing our

[1] Official website www.icpa.org
[2] Official website www.nefi.com.

industry and consumers with a benchmark for pricing product that is based on economic dynamics of supply and demand, and they no longer function as a risk management tool. They have become completely disconnected from reality. Is excessive speculation a reality? The events of June 6th have shattered all doubt. Today the price of crude oil is hitting closer to $145. 00, translating to roughly $5.00 a gallon to the homeowner, almost double what it was for them last year at this time.

The media has missed the essential fact of these market moves – the December 2008 natural gas contract has increased in price 86% between January and July – so oil isn't the only issue. Our natural gas prices are skyrocketing, our diesel and gasoline prices are rising, our heating oil prices are increasing and because New England is disproportionately reliant on natural gas in electricity generation – our electric rates are going to increase as well. There is no refuge for our customers. Especially for the low-income and the elderly, who are sometimes faced with the awful choice of buying groceries, paying for prescription clothes or paying their fuel or natural gas bills.

Devine Bros. will try to provide some refuge to our customers through a locked- or capped-price program. A locked price being a price based off the futures market, and basically an agreed upon price that does not fluctuate throughout the heating season. A Cap price being a program based off of future call options which would give my customers the price protection of a locked price as well as afford them the ability to receive a lower price should the market price drop below an agreed upon price between my company and my customer. The cost of this program to the customer has increased substantially from the beginning of the year. For me to offer this

program I must buy call or put options. These add an extra cost of $.50 per gallon the cost of heating oil, up from $.21 priced at the end of March, 2008. These programs are under the stress of this market and their existence for our customer is under great consideration at this time. Leaving no refuge to the customer.

Our customers are searching for an answer to what they see as a sudden and abrupt run-up in the price of energy, and consequently, the goods and services they rely on to go about their day-to-day lives. How do you explain the 17- month near tripling of Crude oil and sky-high prices for nearly all other commodities? American consumers see no apparent shortages. There are not lines at the gas station like those experienced during the oil crisis of the 1970s. My customers often ask, "Are you guys running out of product?" The answer is no. There is no supply shortage. There is no sudden up-side demand shock. Simply put, we and our customers are being forced to ride the speculative roller coaster in the futures markets. It is about time someone put some the breaks on this runaway train and brought the markets back to reality.

My fellow witnesses today will explain to you how much speculation is playing a role in the markets and whether or not traders are "gaming" or manipulating the system. I am no commodities trading expert, but as a small businesses heating fuel dealer, I am able offer you expertise on the effect that this speculative fervor has had on our company and our customers, as well as the industry I represent here today. Also what it could mean for home heating in the upcoming winter.

The Effect on Small Businesses Petroleum Marketers

Petroleum marketers, like other small businesses, are required to secure lines of credit with a bank and supplier in order to purchase the product their retail consumers' demand. In the current environment, the doubling in price of motor and heating fuels over the last 17 months has forced these marketers to request a two-fold in their credit lines – and many are being denied. All the while, cash flow is slow to come in from customer receivables, especially from low income heating oil customers that have exhausted their fuel assistance money and are feeling the overall pressure of a slowing economy.

The average 2.5 million gallon heating oil company in Connecticut that had to capitalize $1,150,000 for wholesale oil in 98/99 is looking at $10,125,000 in 08/09. That same company sells 20% of their annual volume in January [500,000 gals], and will need $2,025,000 in credit to purchase oil on 10 or 30 day terms and wait 30-45-60 days to be paid by consumers, or longer. Banks and Wholesalers are extremely concerned about extending credit due to the volatility and high pricing in the fuel oil market.

Small, family business like ours continue to hold out hope that government will act soon to mitigate the speculative bonanza in the futures markets, but they must also look to their public officials for a more immediate solution to the "credit crunch" they are currently experiencing. We need access to the credit required to purchase gasoline, heating oil and other essential fuels in order to meet the needs of our customers, and in the current environment we struggle to do so.

Public Policy Solutions

So what can Congress do to help solve the problem? Many policies currently being touted on both sides of the isle seek to address the unprecedented run-up in energy prices. But these proposed initiatives miss the mark because they assume that prices are tied to a shortage of supply and an increase in demand. They assume that by increasing supply or by moving to alternatives- thereby reducing demand- their proposals will have a real and tangible effect on the market and, consequently, consumer prices.

Proponents of alternative energy are using the current environment to justify a quick and progressive advance toward an array of "renewable" and "sustainable" energy sources. Our industry agrees that alternatives must be developed in order to reduce our dependence on foreign oil and provide cost-effective alternatives to fossil fuels. However, to do so without correcting the opaque nature of the futures market could subject these emerging energy sources to the same volatility and speculation that today afflicts conventional fossil fuels and other commodities.

Alternatively, others on Capitol Hill have called for a quick lifting of the ban on off-shore drilling and in other areas with bans on oil recovery, such as the Arctic National Wildlife Refuge. Our industry supports and endorses proposals to increase domestic production of oil through both conventional means such as drilling and unconventional means such as coal-to-liquids technology. However, increasing domestic supply of oil will have little or no impact on the speculative price of a barrel of oil because these markets have become dislocated from supply and demand economics. For example, OPEC has repeatedly submitted that its attempts to increase production have fallen on the deaf ears of the speculator, and have thus translated to little or no global price relief.

Congress must move quickly and assertively to address dysfunction within the markets by:

1. implementing across-the-board transparency and accountability requirements on all energy trading environments, all market participants and for all sizes of positions held by closing the so-called "London," "Dubai" and "Swap Trader" loopholes;
2. substantially reducing speculation limits and raising margin requirements for all energy commodities;
3. setting aggregate position limits based on positions held in all trading environments and mechanisms;
4. substantially reducing the role non-commercial energy complex investors play in buying paper contracts where these players cannot and do not ultimately accept delivery of the physical energy being traded on paper;
5. implementing tough new financial consequences and mandatory jail sentences for market manipulators;
6. pressuring the CFTC to aggressively enforce existing and future authorities; and
7. doubling CFTC funding in order to provide it with the personnel and resources it needs to effectively monitor the markets to insure the are stable, function and that all trading is subject to the rule of law.

The House of Representatives should also pass the "Small Business and Farm Energy Emergency Relief Act," which has cleared the Senate and is currently pending before the Small Business Committee. This legislation would offer small business loan guarantees to heating fuel crises including the one we now find ourselves. It is essential to insure that heating fuel dealers

have access to the credit they need to purchase the heating fuels so essential to the lives of millions of Americans.

Finally, we hope that Congress will take a look at the heating oil contract on the New York Mercantile Exchange, or NYMEX. When the contract was created by NYMEX in 1978, heating oil consumption was much greater than diesel consumption, and therefore was used as a principle proxy for diesel fuel and other distillates. Today, even though diesel fuel consumption volumes have well surpassed heating oil consumption volumes, diesel and jet fuel is still hedged off of the NYMEX heating oil contract. As a result, heating oil may be forced to ride the increasing domestic and foreign demand for diesel fuel. This would explain the spring and early summer spikes in heating oil prices that our industry is seeing, despite a bottoming out of domestic heating oil demand. Congress should work with heating oil industry leaders and experts to determine whether or not diesel fuel and heating oil contracts should be separate NYMEX offerings.

Thank you again, Madam Chairperson, for this opportunity to share my insight on this issue. I commend you and your colleagues in this committee for looking hard at this issue, and for championing public policy solutions that will help to insure transparent, accountable and stable commodities futures markets. I am open to any questions that you might have.

Ms. DELAURO. Thank you very much, Mr. Devine.

Dr. Cooper.

Mr. COOPER. Madam Chairman, members of the committee, I appreciate the opportunity to appear before you today.

Mr. Kingston, you asked for an alternative account. There is one in my testimony. And here is a brief alternative view of what is going on out there in detail.

Market fundamentals indicate both an upward trend in price and a huge speculative premium. They can both coexist. The supply-demand balance has been tight but steady for the last 6 years, as has OPEC's spare capacity. The global reserve-to-production ratio has been rising slightly not falling. The world refinery industry is adapting to the heavier crudes that the world is producing.

Market models based on fundamentals at the U.S. Energy Information Administration and the Japanese Ministry of Economy, Trade, and Industry show a premium of $40 to $60 a barrel above fundamental. Analysis of the cost of crude suggest a premium of a similar magnitude, as does a simple trend line from 2002 to 2006 extended to today.

And last and probably least, oil company executives and OPEC oil ministers say there is a premium of $40 to $60 a barrel that is not explained by fundamentals. Everybody knows that there is a speculative premium out there, and that premium of $40 to $60 indicates a burden on the U.S. economy of $285 billion since January 2006. That is a direct bite out of the household budget of $1,200.

If not fundamentals, then what might account for this premium? We believe excessive speculation epitomized by a sixfold increase in exchange trading in the past 4 years has created a vicious price spiral. We identify specific policy decisions—and you have heard a lot about 2006; that is when it went bad—we identify specific policy decisions that have invited new players, new money, and new practices into the market. And we demonstrate a close association between the growth of open positions and the skyrocketing of profit. So we have correlation. We have temporal sequence. We also provide the link, the explanatory link, between these two.

We observe, and it is a fact, that as price rises and volatility increases, it becomes more and more difficult and expensive to get people who have oil in the ground to part with it. That observation is supported by statistical and anecdotal evidence. This is not about hoarding oil in tankers and tanks. It is about holding oil in the ground until you get bribed with a high enough price to bring it up.

Now, why would anybody profit from a rising price? Yet there are people on both sides, we are told? Let's be clear, traders profit from the upward spiral of prices because traders and exchanges benefit from transaction fees that grow with volume and value. Moreover, as account values rise, excess margins and special miscellaneous accounts allow the traders to take their money out of the market or leverage more trading to keep the upward spiral going.

Moreover, as long as there is new money coming into the market, then the old money that was there first benefits by the rising price. And let's be clear, major trading houses can promote that spiral and the inflow by advising the money, the new money, what to do.

They go to the pension funds and stay hey, bring the money in here. And then, of course, they benefit when they predict an ever-increasing price spiral.

So we have all of the elements here of an alternative explanation that fits the facts an awful lot better than the baloney that you have heard from the other side.

Now opponents of prudential regulation invoke phrases like "when unexpectedly high demand strains existing production" or "after years of ignoring the rather obvious fact that oil is a finite resource." Oil tripled in price from 2002 to 2006, and ultimately, they give me psychology, with a statement like, and I am reading from a New York Times opinion piece: "Everyone in the oil market is attuned to every little twitch that has the potential to damp supply increase demand. That is why, for instance, when Libya announced that it might cut oil production, oil jumped by $5. Meanwhile, when Brazil discovered a huge new oil field the market shrugs. That is not speculation at work," they say, "that is psychology."

Well, even if it is just psychology, we suggest that Congress is not obliged to let the psychos run wild in a market as vital as oil. If the traders in this market have become irrationally attuned to every little twitch that might increase price but disregard facts that might lower price, it is hard to conclude that the market is functioning properly. Congress can and should act to restore prudential regulation which will quell excess speculation and calm irrational exuberance by sedating the cycles.

I say "restore" prudential regulation because, let's be clear, the financial instruments, trading practices, and loopholes that are the target of the current policy debate did not exist or were rarely just utilized a decade ago. Commodity markets performed just fine without any of these contrivances which has opened the door to excessive speculation and the stampede of the psychos.

Bad policy and lax oversight created the problem. Good policy and effective oversight can burst the bubble, returning these markets to their proper role in society.

I would ask you, Madam Chairwoman, to provide me with a list of every question that was posed to Chairman Lukken in the last session. I will provide you with an alternative set of answers that gives you a very different view of what is working and what is not working in these markets.

Thank you.

[The statement of Mr. Cooper follows:]

Consumer Federation of America
1620 I Street, N.W., Suite 200 * Washington, DC 20006

STATEMENT OF DR. MARK COOPER

DIRECTOR OF RESEARCH

on

EXCESSIVE SPECULATION IN ENERGY COMMODITIES

Before the

Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies,
Appropriations Committee
United States House of Representatives
Hearing on Review of Legislation Amending the Commodity Exchange Act

July 10, 2008

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE,

My name is Dr. Mark Cooper. I am Director of Research at the Consumer Federation of America. We greatly appreciate the opportunity to testify today on the immense burden that the speculative bubble in energy commodities is placing on American households.

The story has been told many times, but the lessons have still not been learned. The lack of effective prudential regulation of financial and commodity markets leads to excessive speculation, bubbles and bursts that disrupt the economy and cost consumers hundreds of billions of dollars. Too much money chasing too few goods in the commodity markets has contributed to the price spiral, amping up volume, increasing volatility and adding to risk. We must turn down the volume in commodity markets and sound prudential regulation is the key to restoring order.

THE FAILURE OF PRUDENTIAL REGULATION OF COMMODITY MARKETS HAS COST OIL CONSUMERS HUNDREDS OF BILLION OF DOLLARS

Two and a half years ago I prepared a report for the Attorneys General of Illinois, Iowa, Missouri and Wisconsin that described and explained the 2005-2006 price bubble in natural gas.[1] A few months later I prepared a similar analysis dealing with oil for the Attorney General of Wisconsin, which reached the conclusion that excessive speculation was pushing up the price of oil.[2] In the past two years the Senate Permanent Committee on Investigations has confirmed my findings,[3] as have numerous other reports.[4]

In the years since my reports first came out, as demonstrated in my comments today, the speculation in oil alone has cost the economy about $285 billion. If we add in similar effects on natural gas, then the total reaches half a trillion dollars. This places a huge burden and household budgets. Average annual household expenditures on gasoline have increased by $1200. For households in rural areas, the increase has been over $1500 per year.

With such huge stakes foe consumers, it is encouraging to see that Congress is actively seeking to **restore prudential regulation** to the commodity futures markets and disappointing to

see a group of Op-ed page economic columnists outraged by the fact that Congress understands that some markets can fail sometimes and that prudential regulation can do some good[5] I emphasize **restore prudential regulation** because one thing the Op-ed economists never acknowledge is that the financial instruments, trading practices, and loopholes that are the target of the current policy debate did not exist or were rarely utilized just a decade ago. Commodity futures markets performed their important functions of smoothing the operation of physical markets for three quarters of a century without the contrivances that have opened the door to excessive speculation in the past decade. Bad policy and lax oversight created the conditions for the speculative bubble; good policy and effective oversight can burst the bubble, restoring these markets to their proper role in society.

Because I have written the technical side of the analysis and presented it to Congress several times in recent weeks,[6] I submit those for the record, but I want to use my testimony today to respond to the arguments made by the Op-ed economists. They are big names, in big newspapers that get a lot of notice and the surge of columns around the time of Congressional hearings is certain to get your attention. I frequently agree with them, but they are dead wrong on this issue.

MULTIPLE CAUSES OF RISING PRICES:
EXCESSIVE SPECULATION PLAYS AN IMPORTANT ROLE

The Op-ed economists are simply unwilling to accept the proposition that financial market can become dysfunctional or overshoot. They insist that whatever price the market puts on a barrel of oil must be right, except, of course, for the price last year, which was half of today's price. In that case, last year's price must have been wrong because it must have been too low. In the world of Op-ed economics it would appear that markets can only err on the low side.

The analysis of the current oil market must start from the recognition that oil prices have been rising for quite some time, as Exhibit 1 shows. The price increases between 2002 and 2005 reflected a tight market situation that produced the sharpest sustained increase in prices since the Arab oil embargo. Between 2002 and 2005 prices tripling from just over $17/bbl to just over

$52/bb, or about $0.73 per month. The 2005 price of just over $50 per barrel is right in the middle of the range where the oil industry executives have told Congress that the economic cost of delivering a barrel of oil is today.[7] In the two and a half years after January 2005, however, prices have been increasing over four times as fast, over $3.00 a month, rising to about $145/bbl in recent weeks. If the 2002-2005 trend had continued, the price of oil today would be about $65/bbl (see Exhibit 2).

Thus, we are not saying that markets are not tight or that prices should not have increased, but we are suggesting that the explosion of prices on top of an already rapid price increase was excessive. Speculation would not be having the effect it is if fundamentals were not so tight, but there is no doubt that speculation is making matters much worse. With the real marginal economic cost of a barrel of oil is in the range of $35 to $60 per barrel, adding a cartel rent for OPEC which is targeting $70 to $80 per barrel,[8] and even a geopolitical risk premium, we conclude that the current price at about $140 per barrel includes a large speculative premium. We think a speculative premium of $40 to $50 per barrel is excessive.

The effects of speculation are evident in much more sophisticated models than the simple trend line analysis in Exhibit 2. A recent paper from the Japanese Ministry of Economy Trade and Industry (METI) has echoed my conclusion and the conclusion of the Senate Permanent Subcommittee on Investigations.[9] We reach a similar conclusion when we compare the output of the results of the Energy Information Administration's *National Energy Modeling System*, which is a market fundamentals model used to produce the price projections in the *Annual Energy Outlook*,[10] to actual prices. As Exhibit 3 shows, the model did just fine predicting the price of crude one year in advance for 1995 to 2002. It then began to deviate on the low side. The magnitude of the underestimation for this year is just about $50 per barrel. This is another good indicator of a speculative premium.

Thus, a multi-causal explanation of rising oil prices is necessary, one that combines rising economic costs, rising cartel rents, **and** speculation, but the Op-ed economists seem unable to accept such an explanation. In a multi-causal world, Congress must pick it spots for action. There is not a lot congress can do to influence the rising economic cost of finding oil and OPEC's ability to collect cartel rents is difficult to challenge in the near term, but there is something Congress can do about excessive speculation. Even if you believe that the social, national security and environmental costs of oil consumption (the externalities) demand aggressive policies to end our national addiction to oil,[11] allowing cartels and speculators to rip the public off is not the way to solve the problem. Maybe we need to get to $145/bbl oil by 2020, but accelerating that price increase to 2008, with extremely low elasticities of supply and demand, just punishes consumers and the economy, while it enriches members of the oil cartel and speculators, who do not put the money to work solving the problem.

THE RECENT EXPLOSION OF OIL PRICES:
FUNDAMENTALS LEAVE A GREAT DEAL UNEXPLAINED

The claim that the problem is solely due to physical market fundamentals just does not fit the facts. What the Op-ed economists want you to do is get out an electron microscope and focus on minute changes in supply and demand that are barely perceptible and not closely correlated with price changes, arguing that in a jittery market these minuscule changes trigger huge price swings. At the same time they ask you to ignore the most obvious changes in trading patterns that are visible to the naked eye and highly correlated with changes in price.

As Exhibits 5 and 6 show, both short term and long term fundamentals had been essentially constant over the past six years. The short term measure most frequently cited is spare OPEC capacity (see Exhibit 5). While it has fluctuated, it shows no significant downward trend. In fact, over this period, the correlation between excess capacity and price is positive, not negative; which is, of course backwards.

Similarly, the best long-term measure of capacity – the reserve to consumption ratio – is also increasing slightly while prices are increasing (see Exhibit 6). Again, upon close examination we find that the correlation is slightly positive, which is contrary to the claim and expectations. These oil market numbers do not include a doubling of biofuel production, representing a growth of about 1 million barrels per day, equal to about half of the OPEC excess capacity.

If fundamentals did not change and are unlikely candidates as the cause of the explosion in prices, we have to find something that did change. A broad range of analysts and physical traders now point to the explosion of trading as the cause (see Exhibit 7).[12] There is no doubt that there has been a huge influx of money into these markets and a dramatic increase in the number of open positions. The volume of trading has increased four-fold in the past six years, while the value of trading has increased over twelve times and the price has risen a well.

This is just correlation. But the correlation between our causal factors and reality is a lot stronger than the correlation between the Op-Ed economists' causal factors and reality. At least it is in the correct direction; our account is more plausible.

CLOSE EXAMINATION OF CROSS-COMMODITY COMPARISONS STRENGTHEN THE CASE FOR A SPECULATIVE BUBBLE IN OIL

Although simple correlation of prices and the market fundamentals do not support their account, the Op-ed economists do rely on other simple correlations to try to make their point. One of the favorites is the rhetorical device of finding commodities that are not traded on exchanges but experience price increases.

> You see iron ore isn't traded on a global exchange; its price is set in direct deals between producers and consumers. So there's no easy way to speculate on ore prices. Yet the price of iron ore, like that of oil, has surged over the past year. In particular, the price Chinese steel makers pay to Australian mines has jumped 96 percent [13]
>
> Granted, raw materials prices have exploded across the board. From 2002 to 2007, oil prices rose 177 percent, corn 70 percent, copper 360 percent and aluminum 95 percent... Did speculators really cause *all* of those increases? If so, why did some prices go up more than

> others? And what about steel? It rose 117 percent – and has increased further in 2008 – even though it isn't traded on commodities futures markets.
>
> Recently, the giant mining company Rio Tinto disclosed an average 85 percent price increase in iron ore for its Chinese customers. That affirmed that physical supply and demand — not financial shenanigans – is setting prices: Iron ore isn't traded on futures markets.[14]

What these comparisons teach us is unclear for a number of reasons.

First as noted above, we do not claim that there are no physical market fundamentals that are pushing up prices, rather that speculation is magnifying the problem. For most of the comparisons, crude increased a great deal more than the other commodities. Moreover, not only has oil increased most, but the volume of trading of oil increased most as well, particularly in the past couple of years as new pension fund and index fund moneys have flowed in (see Exhibit 8). Again the correlation analysis supports our explanation.

Second, there is a logical policy contradiction created by invoking a comparison between commodities that are traded on exchanges and those that are traded bilaterally. If bilateral physical markets work to transmit price signals, then damping down trading in exchanges won't do much harm. Traders can do bilateral deals for physical crude. In fact, for most of the history of energy commodities, there were no exchanges or exchanges played a small role. Bilateral markets were the rule and they worked just fine.

Third, the empirical claim is dubious. The Op-ed economists point to a few recent deals made in iron and steel, but the price trend in the U.S. for oil and related products is radically different than that for iron and steel (see Exhibit 9). Comparing the producer price index for crude oil and the primary products derived form it (gasoline and diesel) to iron and steel and metals, supports out explanation, not theirs. The pricing patter is similar to the patterns we have seen throughout the empirical analysis.

Things were fairly stable across commodities in the 1998 to 2002 period, and then the oils began to lift off, exploding in the past year. Iron, steel and metals rose modestly and then ticked up

in the past couple of months. The difference is a good candidate for a speculative bubble. In the five and a half years from January 2002-to May 2007 oil prices increased by about 250 percent, while iron and steel prices had increased 100 percent, underscoring the much larger increase in crude prices. Over the past year, as measured by the producer price index, the surge in crude prices has been 100 percent, compared to the surge in iron prices of 20 percent. Whether and how the recent Chinese deals will be transmitted through to the market remains to be seen (some of it may have been in reaction to the earth quake which suggests an insufficient use of iron to reinforce concrete in construction).

These comparisons do not disprove the existence of a speculative bubble; they make a good case for the usefulness of bilateral trading. Of course, the Op-ed economists will argue that iron was too low because it had not kept up with oil.

THE LINK BETWEEN TRADING AND RISING PRICES

Our explanation does not stop with correlation, however. We go a couple steps further in to turn correlation into a proper causal explanation. First, the patterns of price increases we have observed above are coincident with changes in commodity market policy and trading behavior (see Exhibits 10 and 11). We identify specific policy changes that led to changes in behavior that triggered increases in both prices and volatility. This close temporal coincidence strengthens the causal claim.

Second, we identify the conceptual mechanisms through which speculation translates into higher commodity prices.[15] As prices and volatility rise in a market, it gets harder and harder to convince people who have the physical commodity in the ground to part with it. They have to be bribed with higher prices to lift the oil not only because they can expect a higher price in the future, but also because they demand a higher risk premium to insure against the chance that they are selling

at the bottom of volatile price swings. This basic fact has been clear in the academic literature for quite some time[16] and it is finally penetrating to the popular press.

> Another financial factor behind the price rise that hasn't been talked about much on Capitol Hill or elsewhere is reduced hedging by oil companies on futures markets, says Larry Goldstein, a longtime energy analyst. In the past, crude producers would offer buyers a portion of their energy output in future years in order to protect themselves if prices pulled back. But energy companies got burned as prices kept rising during the past two years and have since cut back on selling untapped production – forcing prices for energy futures even higher. [17]

Some of the Op-Ed economists do not get this basic fact, arguing that"Investors who buy paper oil do not alter the demand for physical oil."[18] Others admit that it can happen, although they doubt that it is happening now –

> "Under some circumstances, speculation in the oil futures market can indirectly raise prices, encouraging producers and other players to hoard oil rather than making it available for use.
>
> Whether that's happening now is a subject of highly technical dispute. Suffices it to say that some economists, myself included, make much of the fact that the usual telltale signs of a speculative price boom are missing."[19]
>
> In theory, high futures prices might reduce physical supplies by inspiring hoarding. But that's not happening. Inventories are modest.[20]

The Op-ed economists insist that there has to be evidence of hoarding, narrowly defined, to make a colorable claim of manipulation and they point to the failure to build stock as evidence that there is no hoarding. Excessive speculation is not about manipulation, but structural incentives to hold out (not withhold) for a higher price before producers will bring supplies to market. In this context the evidence would not be the obvious build up of stocks above the ground, but the build of raw materials in the ground, since suppliers are willing to wait to deliver and insist on a higher price.

There is more than anecdotal evidence to support this alternative view. The Energy Information Administration reports that proved reserves increased by 27.5 percent between 2002 and 2007. Production increased by only12.5 percent. As a result, the reserve to production ratio increased by 14. 7 percent. This includes Canadian oil sands reserves starting in 2003. If we exclude that from the total, production growth equaled reserve growth. However, the effect of rising prices

is to make more resources economic, so there is no reason to exclude these resources. The Op-ed economists cannot claim we need high prices to stimulate the search for alternatives, and then exclude the very reserves that are rendered economic by higher prices. Moreover, even without the oil sands, the reserve to production ratio is 36 years and the question becomes why a seven-fold increase in price did not lead to an acceleration of production and a decline in the reserve to production ratio. The answer is the incentive to keep crude in the ground. The OPEC cartel engages in explicit supply management,[21] while the oil companies call it capital discipline.[22]

Recognizing the difference between manipulation and excessive speculation is critical. The central issue is not manipulation, like the Hunt's in silver, or Enron in electricity, or Amaranth in natural gas, although there may be some of that in the present market. The central issue is a broader structural problem of excessive speculation. Dismissing the possibility of manipulation is a rhetorical point that proves little. Even here we get conflicting accounts of how futures market manipulation might work. On the one hand we are told that manipulation of electricity markets was possible because it cannot be stored,[23] on the other hand we are told that manipulation of oil markets is impossible because it is difficult and expensive to store.[24] The right answer is that the difficulty of transportation and storage increases the ability to push the price up, just as it makes manipulation more feasible.

THE INCENTIVE TO PUSH PRICES UP

The above discussion explains <u>how</u> excessive speculation raises the price of the physical commodity. In order to have a complete explanation, we must also offer a theory of <u>why</u> speculators push them up, how the profit by driving prices up. The Op-ed economists are fond of pointing out that if every commodity transaction matches a buyer and a seller, then winners cancel out the losers no matter how high the price (ignoring the fact that the public is the loser when it pays the higher price).

Traders can profit from a rising price in a variety of ways. As long as there is more new money coming in that is willing to bid the price up, the old money in the market benefits by staying long. Given the entry of a series of new pots of money – first banks, then hedge funds, then pension funds, then index funds – this upward spiral is sustainable and profitable.

It is easier to ensure the inflow of funds when you are "advising" the new money what to do and the upward spiral of prices when you are hyping the market with reports about how high the prices will go.[25] Traders can engage in wash trades to push the price up.

As account values rise, excess margins and special miscellaneous accounts allow the trader to take money out or leverage more trading, to keep the upward spiral going.

Traders and exchanges benefit from transaction fees that grow with value.

The fact that longs must equal the shorts glosses over the different interests of different kinds of traders. Speculators can be net long (and therefore benefit from constantly rolling over contracts at higher prices) in markets that the regulator cannot see (over the counter) or through affiliates in regulated markets that are not well tracked.

Although we do not approach the issue from the point of manipulation, the historical accounts of hundred of corners and squeezes and the dozens of fines in energy markets in recent years do attest to the motive and opportunity that exists for traders to attempt to push the market up to profit.

SPECULATION IS THE SURPRISE, NOT FUNDAMENTALS

Unable to deal with inconvenient facts, the Op-ed economists resort to surprises and emotions to fill the gap in the analysis.

"When unexpectedly high demand strains existing production, prices rise sharply as buyers scramble for scarce supplies."[26] "After years of ignoring the rather obvious fact that oil is a finite resource, the world has suddenly become acutely aware of that reality.[27] Well functioning market are

not supposed to be surprised. Indeed, in our account, far from ignoring the facts, the markets were dealing with the facts in the price run up from $17 to $50 in 2005. The trend line goes to $65 in 2008. The surprise is not the tight market, it is the speculative bubble.

Two recent pieces of analysis presented to the Energy and Commerce Committee by energy economists provide data that ties our account together. In Exhibits 10 and 11 we identified periods of trading by policy changes that affected trading behavior, primarily by attracting different kinds of players and trading strategies into the market. The upper part of Exhibit 12 shows a categorization of the periods that parallels ours which sees three broad structures – traditional, fundamentals (demand and supply) and financial. The lower part of Exhibit 12 shows the correlation between open market positions and price. We have argued that the fundamentals period began in 2002 and data in the exhibit supports that view. The basic point is that a speculative bubble has been added to the underlying price increase driven by fundamentals.

Exhibit 13 shows the finding cost curve and uses that cost curve to predict crude prices. The rise from about $20 in 2002 to about $70 in 2008 is consistent with our earlier trend line analysis and the EIA market fundamentals model. Thus, price tracked fundamental closely until 2006, when the speculative bubble began to inflate.

INCONVENIENT FACTS AND NONECONOMIC EXPLANATIONS

In the final analysis, even the electron microscope cannot find changes in fundamentals that account for the explosion of prices in recent months, so the Op-ed economists are forced to abandon economic explanations and embrace psychology.

> Everyone in the oil market is attuned to every little twitch that has the potential to damp supply or increase demand. That's why, for instance, when Libya announced on Thursday that it might cut oil production, oil jumped more than $5. Meanwhile, when Brazil discovers a huge new oil field, the market shrugs. That is not speculation at work – its market psychology. There's a big difference. If there is a bubble, that's what is causing it.[28]

In the end, if it is just psychology, we would urge policy makers to ask themselves whether they are obligated to let the psychos run wild in a market as vital as oil. We submit that you are not. If the traders in this market have become irrationally attuned to "every little twitch" that might increase prices, but disregard facts that might lower prices, it is hard to conclude that the market is functioning properly. The psychos need a little sedation to restore balance to their perspective. Prudential regulation has the benefit of both preventing excessive speculation and sedating the psychos, not to mention allowing the physical traders to reenter the market and use its price discovery and risk management functions.

REGULATORY REFORM IS THE WAY TO SOLVE THE PROBLEM

We urge you not to let the smoke and mirrors of the Op-ed economists dissuade you from your central mission to protect the public form abuse. The Congress is absolutely correct to conclude that it must address the problem of excessive speculation and correct in concluding that the CFTC cannot be trusted to effectively address the problem. With the commodities markets overwhelmed by speculation and the Congress empowering other agencies to do the job that the CFTC has failed to do, the CFTC has changed its tune, belatedly admitting that it did not have sufficient information to perform its primary function of preventing excessive speculation and recognizing that foreign boards of trade do not exercise effective regulation of trading. Begging foreign exchanges for data and foreign regulators to act responsibly is not only embarrassing; it is absurd when the CFTC has not put its own house in order. The CFTC's proposals are too little too late.

There are five areas in which reform is necessary, with a variety of policy making institutions needing to take action. We recognize that this is a tall order, but a half a trillion dollars sucked out of the economy and the pocketbooks of American households by the speculative bubble of recent years demands you take action now.

Chase out the bad guys

- **All traders must register and be certified (for honesty and competence, like bankers and brokers).**
- **All trading must be reported across all transactions**

Eliminate the funny money

- **Raise margin requirements**
- **Increase capital reserve requirements**

Reduce the ability to push prices up

- **Lower position limits and tie limits and margin policies to needs of physical traders**
- **Lengthen settlement windows**
- **Ban conflicts of interest (analyst's reports that enrich analyst's portfolios)**

Restore the proper functioning of commodity markets and their regulators

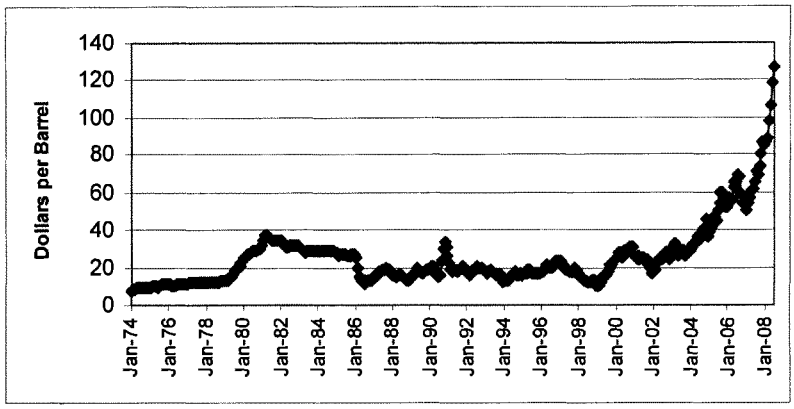
- **Enforce meaningful speculative limits**
- **Do honest analysis (classify traders correctly)**
- **Close the loopholes (foreign boards of Trade exemptions, the Enron and swaps)**
- **Create minimum criminal penalties for violation of commodity laws**

Redirect investment to productive long-term uses

- **Put a tax on short-term capital gains**
- **Move pension funds out of speculation**
- **Ban institutional index funds**

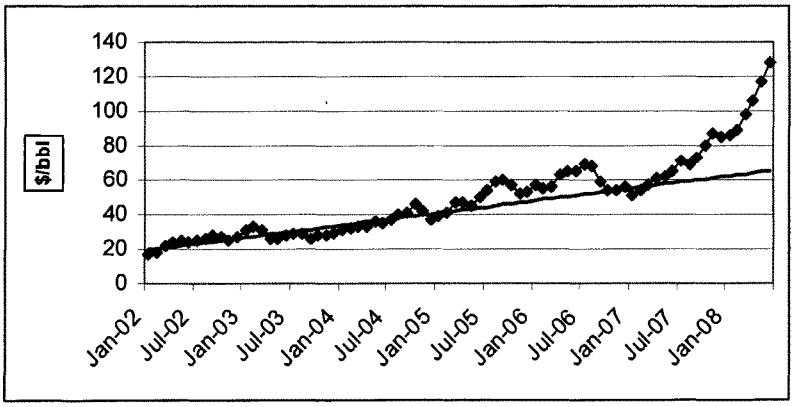
EXHIBITS

EXHIBIT 1:
LONG TERM TREND OF CRUDE OIL PRICES



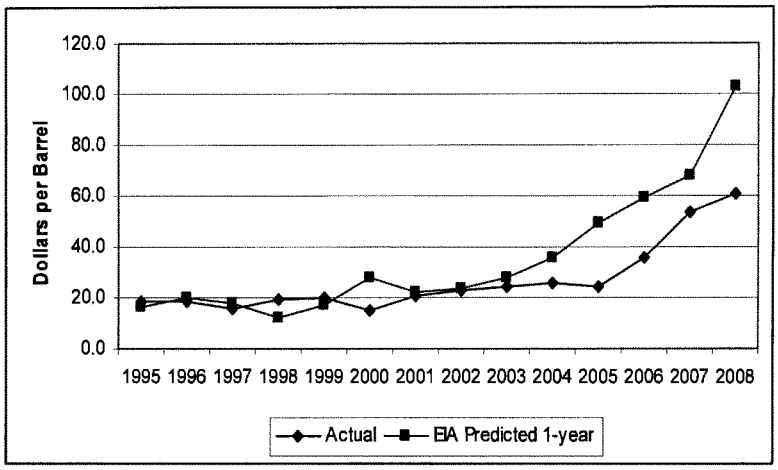
Source: Energy Information Administration, data base, *Refiner Acquisition Cost of Crude.*

EXHIBIT 2:
CRUDE PRICES COMPARED TO TREND LINE (1/2002-1/2005)



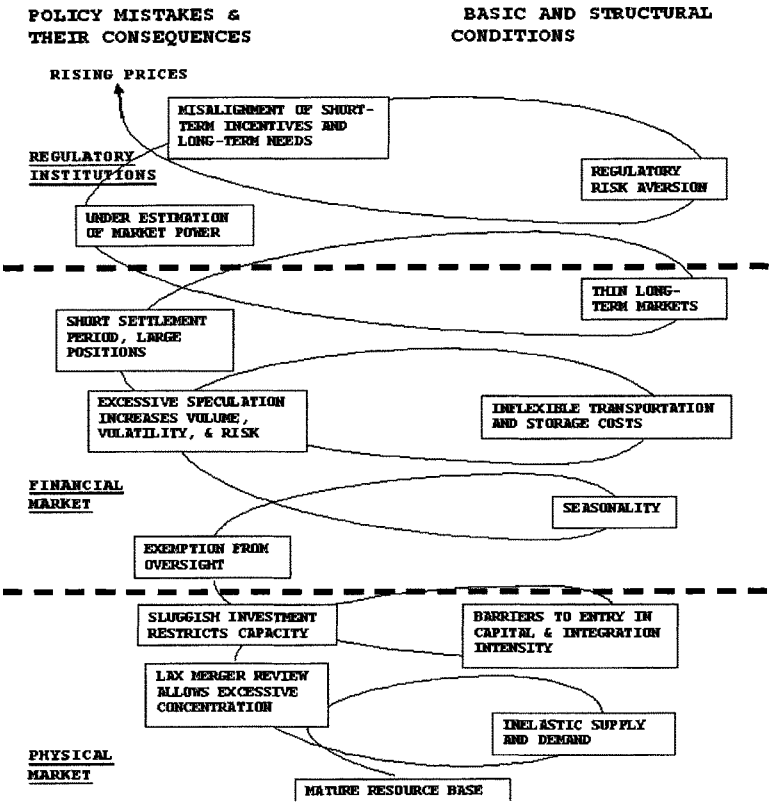
Source: Energy Information Administration, data base, *Refiner Acquisition Cost of Crude.*

EXHIBIT 3:
EIA CRUDE OIL PRICE PREDICTIONS (1-YEAR FORWARD) COMPARED TO ACTUAL PRICES



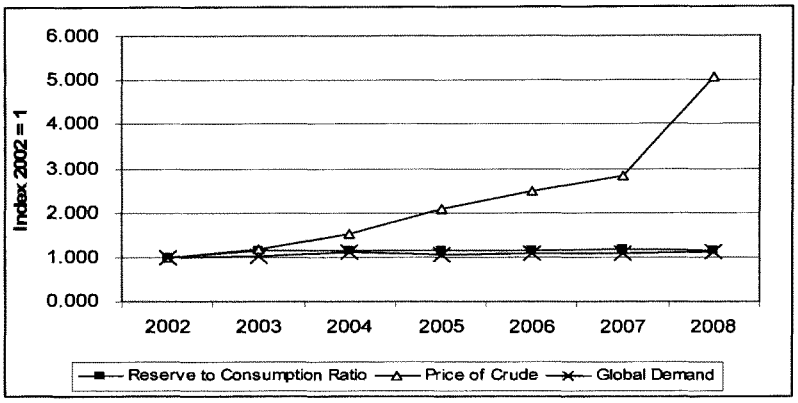
Source: Energy Information Administration, *Annual Energy Outlook: Retrospective Review, Evaluation of Projections in Past Editions (1983-2006), Annual Energy Outlook, 2006, 2007, 2008. Landed Cost of Crude,* is used for actual cost.

EXHIBIT 4:
PHYSICAL, FINANCIAL AND REGULATORY FACTORS IN THE ENERGY PRICE SPIRAL



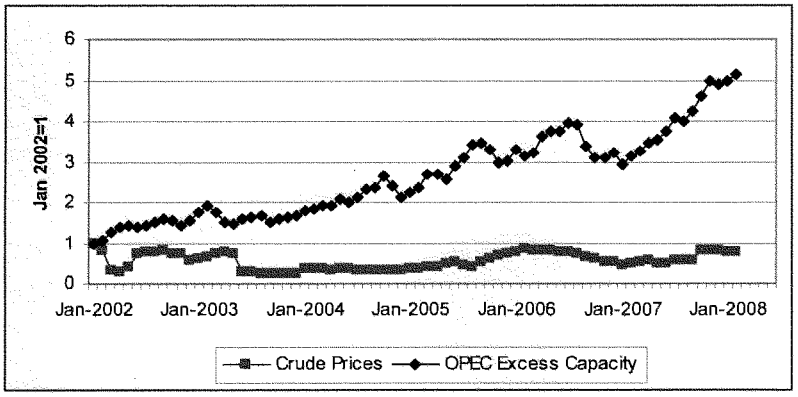
Source: Mark Cooper, "The Failure of Federal Authorities to Protect American Energy Consumers from Market Power and Other Abusive Practices," *Loyola Consumer Law Review,* 19:4 (2007), p. 318.

EXHIBIT 5:
LONG-TERM FUNDAMENTALS:
GLOBAL DEMAND AND RESERVE TO CONSUMPTION RATIO, COMPARED TO PRICE OF CRUDE



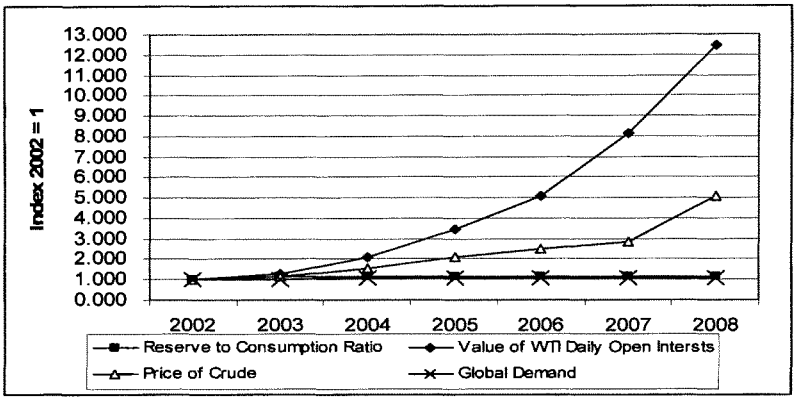
Source: Energy Information Administration, data base, *Refiner Acquisition Cost of Crude, International: World Oil Balance, Short Term Energy Outlook – OPEC Oil Production Capacity.*

EXHIBIT 6:
OPEC EXCESS CAPACITY COMPARED TO THE PRICE OF CRUDE



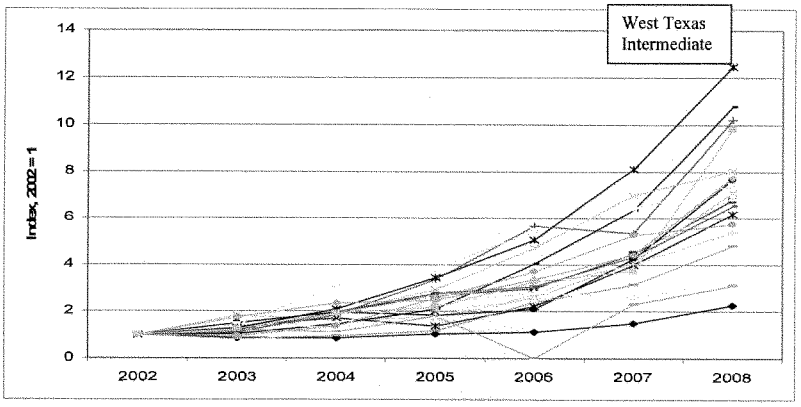
Source: Energy Information Administration, data base, *Refiner Acquisition Cost of Crude, International: World Oil Balance, Short Term Energy Outlook – OPEC Oil Production Capacity.*
EXHIBIT 7:
EXHIBIT 7:

AVERAGE DAILY VALUE OF OPEN POSITIONS ON WEST TEXAS INTERMEDIATE, CRUDE PRICES, LONG-TERM FUNDAMENTAL (RESERVES AND DEMAND)



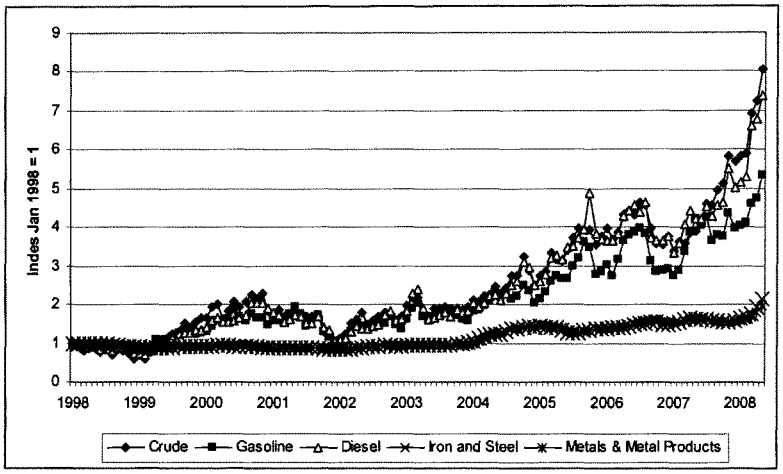
Source: EIA, Refiner Acquisition Cost of Crude, International: World Oil Balance, Short Term Energy Outlook – OPEC Oil Production Capacity. Testimony of Michael Masters, Managing Member/Portfolio Manager, Masters Capital Management, LLC, Committee on Homeland Security and Governmental Affairs, United States Senate, May 20, 2008, Note 16 for WTI Open positions.

EXHIBIT 8:
AVERAGE DAILY DOLLAR VALUE OF OPEN INTEREST: 20 INDEX COMMODITIES



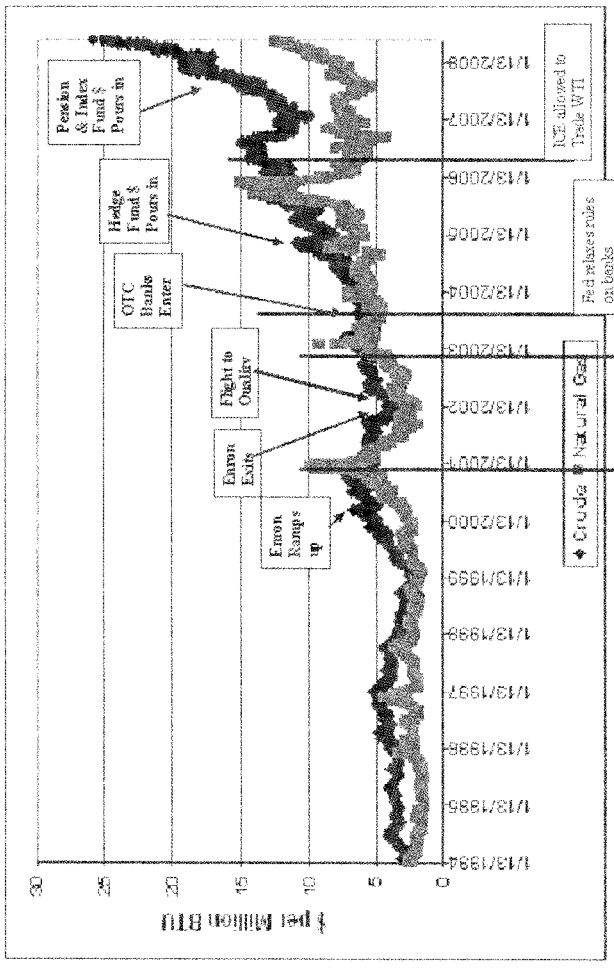
Testimony of Michael Masters, Managing Member/Portfolio Manager, Masters Capital Management, LLC, Committee on Homeland Security and Governmental Affairs, United States Senate, May 20, 2008, Note 16.

EXHIBIT 9:
PRODUCER PRICE INDICES FOR CRUDE, GASOLINE, DIESEL, IRON, STEEL AND METALS



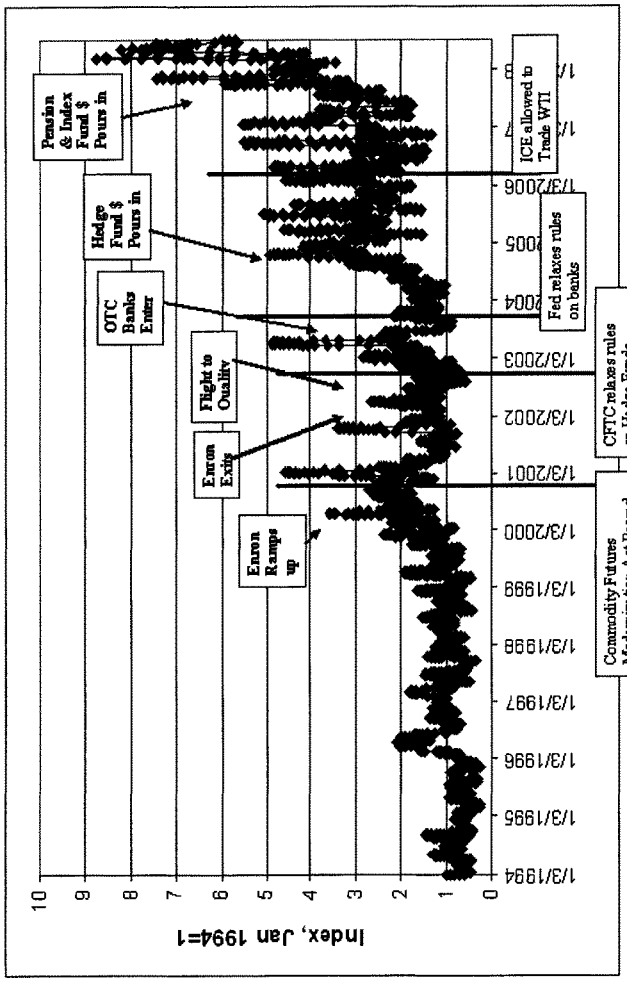
Source: Bureau of Labor Statistics, Producer Price Index.

EXHIBIT 10:
ENERGY SPOT PRICES, DEREGULATION AND CHANGES IN TRADING ACTIVITY



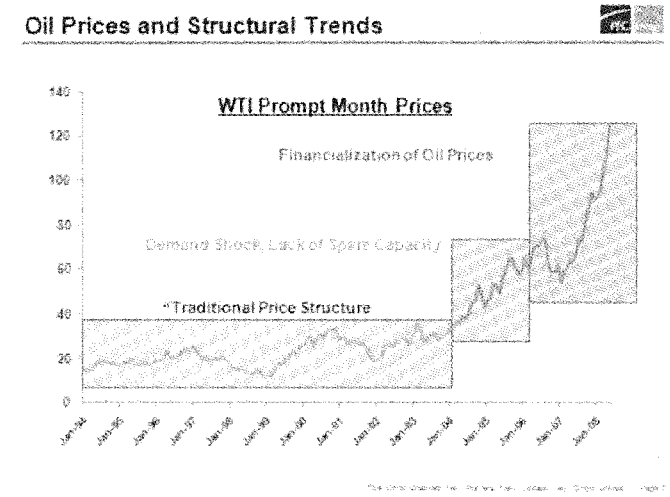
Source: Energy Information Administration, Database and Mark Cooper, *The Role of Supply, Demand and Financial Commodity Markets in the Natural Gas Price Spiral*, p. 8.

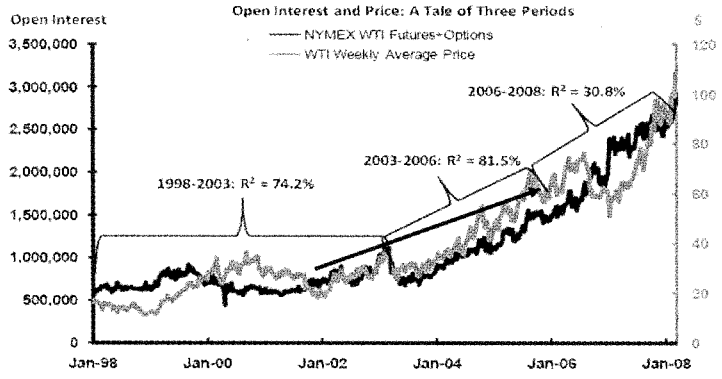
EXHIBIT 11:
SPOT PRICE VOLATILITY DEREGULATION AND CHANGES IN TRADING ACTIVITY
(30-DAY MOVING AVERAGE OF THE STANDARD DEVIATION OF THE DAILY SPOT PRICE)



Source: Energy Information Administration, Database and Mark Cooper, *The Role of Supply, Demand and Financial Commodity Markets in the Natural Gas Price Spiral*, p. 8.

Exhibit 12:



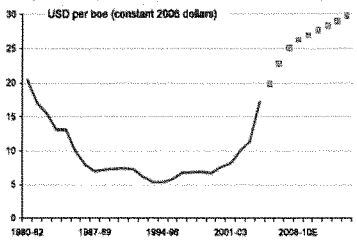


Source: "Testimony of Roger Diwan Regarding Energy Speculation: Is greater Regulation Necessary to Stop Price Manipulation," Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2008, pp. 2, 8

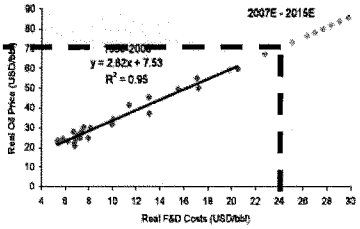
Exhibit 13:

What Does It Cost to Find a Barrel?

Worldwide Finding Costs (USD/bbl)



Oil Prices & Finding Costs Are Related



Source: DOE/EIA, Author

Outlook

- We estimate that finding and development costs have risen 20% per annum in real terms over the 2000 to 2006 period, and slower rates after that. This implies that F&D costs are likely to hit USD25/bbl in 2009 and possibly USD30/bbl in 2015.
- F&D costs have tended to be closely related to the oil price. Since 1980 we find that the oil price has tended to equal to 2.6x F&D costs plus USD7.5. This multiplier take into account taxes and gross margin.
- To get oil to USD200/bbl on a cost basis seems like a stretch- F&D costs of USD40/bbl and a multiplier of 5x, however USD80/bbl in the 2012-13 timeframe is very consistent with this data and USD100/bbl oil is possible.

Testimony of Adam Sieminski, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2008, p. 7.

ENDNOTES

[1] Mark Cooper, *The Role of Supply, Demand and Financial Commodity Markets in the Natural Gas Price Spiral, A Report Prepared for the Midwest Attorney General Natural Gas Working Group (Illinois, Iowa, Missouri, and Wisconsin* (March, 2006)

[2] Mark Cooper, *The Role of Supply, Demand, Industry Behavior and Financial Market in the Gasoline Price Spiral* (for the Wisconsin Attorney General, August, 2006).

[3] Senate Permanent Subcommittee on Investigations, Committee on Homeland Security, *The Role of Market Speculation in Rising Oil and Gas Prices: A Need to Put the Cop Back on the Beat* (June 27, 2006); *Excessive Speculation in the natural Gas Market*(June 25 and July 9, 2007).

[4] Akira Yanagisawa, *Decomposition Analysis of the Soaring Crude Oil Prices: Analyzing the Effects of Fundamentals and Premium* (Institute of Energy Economics, March 2008; Robert J. Shapiro and Nam D. Pham, *An Analysis of Spot and Futures Prices for Natural Gas: The Roles of Economic Fundamental, Market.*

[5] Paul Krugman, "Fuel on the Hill," *New York Times,* June 27, 2008; Joe Nocera, "Easy Target, But Not the Right One," *New York Times,* June 28, 2008, p. B8; Sebastian Mallaby, "Nixonian Fallacy," *Washington Post,* June 30, 2008; Robert J. Samuelson, "Who's Behind High Prices," *Washington Post,* July 1, 2008.

[6] Mark Cooper, "Testimony on Oversight of Energy Markets and Oil Futures," before the Joint Hearing of the Senate Appropriations Subcommittee on Financial Services and General Government and the Committee on Agriculture, Nutrition and Forestry, United States Senate, Jun 17, 2008; Testimony on Energy Market Manipulation and Federal Enforcement Regimes," before the Committee on Commerce, Science and Transportation, United States Senate, June 3. 2008; see also "The Failure of Federal Authorities to Protect American Energy Consumers from Market Power and Other Abusive Practices," Loyola Consumer Law Review, 19:4 (2007).

[7] J. Stephen Simon, Senior Vice President ExxonMobil, Select Committee on Energy Independence and Global Warming, put the cost at $50-$55. John Hofmeister, President of Shell Oil Co. put the cost at $35-$60 per barrel. John Lowe, Executive Vice President of ConnocoPhillip, put the figure at $90 per barrel, which appears to include OPEC cartel rents. Adam Siemiski's Testimony Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2008, p. 7, suggests a cost of $70, at the margin.

[8] We do not condone OPEC's illegal management of supplies to create cartel rents and support policies to counteract that rent collection.

[9] Akira Yanagisawa, *Decomposition Analysis of the Soaring Crude Oil Prices: Analyzing the Effects of Fundamentals and Premium* (Institute of Energy Economics, March 2008), p. 5, "According to the METI paper, during the second half of 2007, when the physical price of West Texas Intermediate crude averaged $US90 a barrel, market speculation, geopolitical risk and currency factors were responsible for $US30-$US40 of the price." The average WTI "fundamental price," consistent with the underlying supply/demand situation, was around $US60/barrel during the December half-year, according to the paper, citing research for the Institute of Energy Economics in Japan

[10] EIA, *NEMS International Energy Module (IEM): Model Documentation Report,* p. 2, "To summarize the model searches for a world price of oil compatible with supply-demand equilibrium in each region. Non-OPEC world demand and supply are determined by a set of price-quantity relationships, and in equilibrium the difference between world demand and non-OPEC world supply equals OPEC production. OPEC production is determined by an exogenously specified output path. Output of a price run includes forecast of the world oil price, OPEC production, world petroleum production and consumption, net imports by regions OPEC revenue, and spare OPEC capacity."

[11] Krugman, p. A19, "Regulating futures markets more tightly isn't a bad idea, but it won't bring back the days of cheap oil. Nothing will. Oil prices will fluctuate in the coming years – I wouldn't be surprised if they slip for a while as consumers drive less, switch to more fuel efficient cars and so on – but the long-term trend is surely up. Most of the adjustments to high oil prices will take place through private initiative, but the government can help the private sector in a variety of ways, such as helping develop alternative technologies and new methods of conservation and expanding the availability of public transit.

[12] Yanagisawa, Siemiski, "Testimony of Roger Diwan Regarding Energy Speculation: Is greater Regulation Necessary to Stop Price Manipulation," Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2008; Testimony of Michael Masters, Managing Member/Portfolio Manager, Masters Capital Management, LLC, Committee on Homeland Security and Governmental Affairs, United States Senate, May 20, 2008; "Testimony of Fadel Gheit," Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2008; Thomas Evans, Citi Futures Perspectives, July 3, 2008; Lehman Brothers, *Oil Cot-com,* May 29, 2008.

[13] Krugman, p. A19

[14] Samuelson, p. A1.

[15] See Cooper, Natural Gas, Chapter IV.

[16] Hans R. Dutt and Lawrence E. Harris, "Position Limits for Cash-Settled Derivative Contracts, *The Journal of Futures Markets,"* 25 (2005), p. 497, "Even when thee settlement of cash-settled contracts are not purposefully manipulated, the settlement mechanisms may increase underlying volatility when hedgers unwind their hedges if hey have no incentive to control their trading costs. This generally is the case when hedgers trade out of their positions at the same price that determine the final cash settlement price." Robert J. Pyndyck, "The Dynamics of Commodity Sport and Futures Markets: A Primer," *The Energy Journal,* 22(2001), p. 12, emphasis in original, "Increased volatility increases the value of producers' *operating options,* options to produce now (as an "exercise price" equal to the marginal production cost and with a "pay-off" equal to the spot prices), rather than waiting for possible increases or decreases in rice. These options add an opportunity cost to current production: namely the cost of exercising the option rather than preserving them. This increase in volatility increases the opportunity cost of current production." Although Stephen Craig Pirrong, *The Economics, Law and Public Policy of Market Power Manipulation* (Boston, Kluwer, 1996), focuses on market manipulation, the conditions that facilitate manipulation also facilitate excessive speculation, particularly with the influx of new money, "[B]y demanding excessive deliveries a long induces distortion in the spatial and temporal distribution of consumption, transportation and storage. Shorts must pay current owners of the commodity increasingly higher prices in order to compensate current owners of the commodity for the surplus foregone. 9pp. 24-25). "[A} trader who does not possess any informational advantage is able to acquire market power as long as the flow of orders from other traders to the futures market is sufficiently volatile and large relative to the size of deliverable supply… Put another way, the existence of "nose traders" makes fraud possible." (p. 12)

[17] Nelson C. Schwartz, "Asleep as the Spigot," *New York Times,* July 6, 2008, Business Section, p. 7.

[18] Mallaby, p. A11

[19] Krugman, p. A19.

[20] Samuelson, p. A11.

[21] EIA, *Annual Oil Market Chronology,* provides a chronology of OPEC's supply management policies.

[22] Cooper, Oil, chapter II. The current controversy over tens of thousands of idle leases, while oil companies "hold out" for more attractive leases, even though high prices make them all worth working, highlights an important issue. The claim that a lack of drilling resources makes it impossible to exploit the leases only proves the point that the current prices are excessive on the supply side. If we face a vertical supply curve in a classic economic welfare analysis, then price increases result in pure wealth transfers from consumers to producers and do not contribution to efficiency. Consumers did respond to the price increases in 2002-2006, as demonstrated by a CBO study (Congressional Budget Office, *Effects of Gasoline Prices on Driving Behavior and Vehicle Markets,* January 2008), but the elasticity is quite low on the demand side as well. A near vertical demand curve means that price increases result in huge wealth transfer from consumers to producers and small efficiency gains.

[23] Nocera, B8, "But remember, Enron was manipulating electricity prices, no oil, which was possible mainly because electricity cannot be stored." By getting power plants to shut down for hours at a time, Enron was able to create artificial shortages and jack up the price.

[24] Mallaby, p. A11. Every paper claim they buy is a paper claim they will later sell because they have no intention of converting their paper into real oil stocks. Oil is too expensive and cumbersome to store. A speculator is not going to show up in Cushing, Okla., when his futures contract matures and drive away with a tanker truck full of oil

[25] Goldman Sachs, *Global Energy: Oil, $100 Oil Reality, part 2: Has the Super-Spike End Game Begun?,* May 5, 2008; Morgan Stanley, *Commodity Shipping: Current Crude Oil Shipping Patterns Suggest $150/bbl WTI by July 4th,* June 5, 2008.

[26] Robert J. Samuelson, p. A11.

[27] Nocera, p. B8.

[28] Nocera, p. B8.

Ms. DELAURO. Professor Greenberger.

Mr. GREENBERGER. Thank you, Madam Chairwoman, and I also want to thank you for the leadership you have taken on this issue, not only in seeing what the resources are of the CFTC but also in the substantive side of these issues. Your bill, 6341, which I think you have introduced with Congressman Van Hollen, I think is a very, very good piece of legislation, which I support.

And I also know that you were very involved in getting H.R. 6377 passed in the House on June 26th. It was introduced in the morning and passed that night by a vote of 402 to 19. And I hope the Senate takes the same bipartisan approach.

The reason I think that bill is important is because what it essentially does is having Congress declare an emergency in these markets. And it asks for the CFTC, who could have declared their own emergency under their statute, to do an investigation across the markets and answer the questions that have been posed.

I am in support of what Dr. Cooper says, that I do believe there is a speculative premium. I don't discount for a second that we have a supply-demand problem, and everybody has a solution for supply-demand, but I think the United States' energy-consuming public, including some of our most important industries, are paying a speculative tax that has nothing to do with supply-demand. And I think, within a matter of weeks, we are going to see some very serious dysfunctions—I would look to the airlines first—if we don't provide relief in this regard.

The reason I say H.R. 6377 in its immediate effect and the kind of legislation that you have supported in a long-term effect is important is, I would say let's forget about trying to answer in the dark whether this is supply-demand or speculation. Let's get the information. Let's do a thorough investigation of these markets. If that thorough investigation shows that those of us who think speculation is at the heart of this shows we are wrong, God bless. But it is not healthy for a lot of people, and I would imagine a lot of your constituents, to walk around believing that this is a speculators problem if it is not.

So I think whichever side of this argument you are on, you should be in favor of transparency. Now we don't have transparency because of the Enron loophole and the so-called London loophole, which I would be happy to talk about at greater length, we switch, from December 20th, 2000, to December 21st, 2000, we allowed these energy futures contracts to be traded off-exchange, over-the-counter markets that don't have the same transparency that our regulated exchanges have.

Now it is true that Mr. Lukken since May 29th has been trying to get more information from one of these exchanges, but we don't have the kind of information and the tools to get it, and the kind of oversight to be sure about what we are dealing with here and to answer the fundamental questions. We are in the middle of a terrible economic emergency here, and I think we are only halfway down the slope. And I think when we get to the bottom of it, there is going to be some very serious consequences.

I would also say that your attention that you are paying to the CFTC, I believe, is important because it is not just energy futures. We have got agriculture futures problems, too, which fall on the

same line, and I can talk about that. But even more important, the subprime meltdown goes, in my view, to, is premised on an instrument, credit default swaps, which were deregulated by the December 20th, 2000, legislation. Swaps were excluded from State and Federal oversight. And I can elaborate on that, but the New York Insurance Superintendent who is trying to hold up an insurance company that has insured the banks against their losses took the position, why are these credit default swaps? These are nothing more than insurance contracts. And had they been insurance contracts, Bear Stearns would have had to have a adequate capital reserve to pay them, but they didn't because they thought housing prices would always go up, and they would never be called on their bets. We are now holding those instruments as United States taxpayers.

So the CFTC is a very, very important agency. I was there for 2 years. I have watched it. As far as I am concerned, if you wanted to pick out one financial regulator who has more to say about where our economy is today, it is the CFTC. When you are talking about deregulated energy futures, poorly managed—and I can explain that; I don't fully blame the CFTC for that—but the ag markets are not supposed to be deregulated and yet there are deregulated products out there, and the credit default swaps.

If we had not passed the Commodity Futures Modernization Act, I think Bear Stearns would still be here today. In fact, I think Enron would still be here today. So I congratulate you for focusing attention on this important agency. And I think this is going to be, wherever we end up legislatively, the silver cloud I see here is that we are beginning to understand as an American constituency what the futures market is and how vitally important it is to the United States economy.

Thank you.

[The statement of Mr. Greenberger follows:]

Testimony of

Michael Greenberger
Law School Professor
University of Maryland School of Law
500 West Baltimore Street
Baltimore, MD 21201

Before the House Appropriations Subcommittee on Agriculture, Rural Development. Food and Drug Administration, and Related Agencies

Regarding

Commodity Futures Trading Commission

Thursday & Friday, July 10, 2008
11:00 a.m.
2362-A Rayburn House Office Building

Introduction

My name is Michael Greenberger.

I want to thank the Subcommittee for inviting me to testify on the important issue that is the subject of today's hearings.

After 25 years in private legal practice, I served as the Director of the Division of Trading and Markets ("T&M") at the Commodity Futures Trading Commission ("CFTC") from September 1997 to September 1999. In that capacity, I supervised approximately 135 CFTC personnel in CFTC offices in DC, New York, Chicago, and Minneapolis, including lawyers and accountants who were engaged in overseeing the Nation's futures exchanges. During my tenure at the CFTC, I worked extensively on, *inter alia*, regulatory issues concerning exchange traded energy derivatives, the legal status of over-the-counter ("OTC") energy derivatives, and the CFTC authorization of trading of foreign exchange derivative products on computer terminals in the United States.

While at the CFTC, I also served on the Steering Committee of the President's Working Group on Financial Markets ("PWG"). In that capacity, I drafted, or oversaw the drafting of, portions of the April 1999 PWG Report entitled "Hedge Funds, Leverage, and the Lessons of Long-Term Capital Management," which recommended to Congress regulatory actions to be taken in the wake of the near collapse of the Long Term Capital Management (LTCM) hedge fund, including Appendix C to that report which outlined the CFTC's role in responding to that near collapse. As a member of the International Organization of Securities Commissions' ("IOSCO") Hedge Fund Task Force, I also participated in the drafting of the November 1999 report of IOSCO's Technical Committee relating to the LTCM episode: "Hedge Funds and Other Highly Leveraged Institutions."

After a two year stint between 1999 and 2001 as the Principal Deputy Associate Attorney General in the U.S. Department of Justice, I began service as a Professor at the University of Maryland School of Law. At the law school, I have, *inter alia*, focused my attention on futures and OTC derivatives trading, including academic writing and speaking on these subjects. I currently teach a course that I designed entitled "Futures, Options, and Derivatives."

The question of the role of the Commodity Futures Trading Commission's regulatory efforts pertaining to excessive speculation within U.S. energy futures markets in general, and futures based on U.S. delivered crude oil contracts specifically, has been the subject of many hearings. I have previously testified at six of those hearings, the most recent held on June 24, 2008 before the United States Senate Committee on Homeland Security & Government Affairs. To put the issue of this Subcommittee's hearing in context, I summarize and update the points I made at that hearing immediately below.

Summary and Update of Prior Testimony

One of the fundamental purposes of futures contracts is to provide price discovery in the "cash" or "spot" markets.[1] Those selling or buying commodities in the "spot" markets rely on futures prices

[1] The Economic Purpose of Futures Markets and How They Work, COMMODITY FUTURES TRADING COMMISSION, http://www.cftc.gov/educationcenter/economicpurpose.html (last visited July 8, 2008).

to judge amounts to charge or pay for the delivery of a commodity.[2] Since their creation in the agricultural context decades ago, it has been widely understood that, unless properly regulated, futures markets are easily subject to distorting the economic fundamentals of price discovery (*i.e.*, cause the paying of unnecessarily higher or lower prices) through excessive speculation, fraud, or manipulation.[3]

As the 1935 Report of this Committee stated: "The fundamental purpose of the measure [i.e., what was to become the Commodity Exchange Act of 1936 ("CEA")] is to insure fair practice and honest dealing on the commodity exchanges and to provide a measure of control over those forms of speculative activity which too often demoralize the markets to the injury of producers and consumers and the exchanges themselves."[4]

Indeed, President Roosevelt, when introducing what became the CEA said: "[I]t should be our national policy to restrict, as far as possible, the use of these exchanges for purely speculative operations."[5] In this regard, this Committee then stated: "This bill authorizes the Commission . . . to fix limitations upon purely speculative trades . . ."[6]

The CEA has long been judged to effectively prevent excessive speculation and manipulation. Accordingly, prior to the passage of the Commodity Futures Modernization Act of 2000 ("CFMA"), "all futures activity [was] confined by law (and eventually to criminal activity) to [CFTC regulated] exchanges alone."[7] At the behest of Enron, the CFMA authorized the "stunning"[8] change to the CEA to allow the option of trading energy commodities on deregulated trading platforms, *i.e.*, exchanges exempt from CFTC contract market registration requirements, thereby rejecting the contrary 1999 advice of the President's Working Group on Financial Markets, which included the Secretary of the Treasury, the Chairman of the Federal Reserve Board, and the Chairmen of the SEC and CFTC. [9] This exemption from contract market regulation is called the "Enron Loophole."

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[2] *See* Platts Oil Pricing and Market-on-Close Methodology Explained, Platts (July 2007) at 3, *available at* http://www.platts.com/Resources/whitepapers/index.xml.

[3] *See, e.g.*, Jonathan Ira Levy, *Contemplating Delivery: Futures Trading and the Problem of Commodity Exchange in the United States, 1875-1905*, AMERICAN HISTORICAL REVIEW 307 (2006) ("'[T]he man who managed or sold or owned those immense wheat fields has not as much to say with the regard to the price of the wheat that some young fellow who stands howling around the Chicago wheat pit could actually sell in a day'"(quoting *Fictitious Dealings in Agricultural Products: House Comm. on Agric. Committee Hearing Reports* (1892)).

[4] Report No. 421, U.S. House of Representatives 74th Cong, Accompanying the Commodity Exchange Act, March 18, 1935.

[5] President Franklin D. Roosevelt, Message to Congress, February 9, 1934.

[6] Report No. 421, U.S. House of Representatives 74th Cong., Accompanying the Commodity Exchange Act, March 18, 1935.

[7] PHILIP MCBRIDE JOHNSON & THOMAS LEE HAZEN, DERIVATIVES REGULATION 28 (Cumm. Supp. 2008).

[8] *Id.* at § 1.17.

[9] *Id.* at 28; *see also* President's Working Group on Financial Markets, Over-the-Counter Derivatives Markets and the Commodity Exchange Act 16 (1999), *available at* http://www.ustreas.gov/press/releases/reports/otcact.pdf (last visited July 8, 2008) ("Due to the characteristics of markets for non-financial commodities with finite supplies, however, the Working Group is unanimously recommending that the exclusion [from regulation] not be extended to agreements involving such commodities.").

Two prominent and detailed bipartisan studies by the Permanent Subcommittee on Investigations' ("PSI")[10] staff concluded that large financial institutions and wealthy investors had needlessly driven up the price of energy commodities over what economic fundamentals dictate, adding, for example, what the PSI estimated to be @ $20-$25 per barrel to the price of a barrel of crude oil.[11] At the time of that estimate, the price of crude oil had reached a then record high of $77. The conclusion that excessive speculation has added a considerable premium to energy products has been corroborated by many experts on[12], and observers of, these markets.[13]

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[10] PERMANENT SUBCOMMITTEE ON INVESTIGATIONS OF THE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS, THE ROLE OF MARKET SPECULATION IN RISING OIL AND GAS PRICES: A NEED TO PUT THE COP BACK ON THE BEAT (June 27, 2006) [hereinafter June 2006 Report]; PERMANENT SUBCOMMITTEE ON INVESTIGATIONS OF THE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS, EXCESSIVE SPECULATION IN THE NATURAL GAS MARKET (June 25, 2007) [hereinafter June 2007 Report].

[11] June 2006 Report, *supra* note 10, at 2, 23.

[12] *See, e.g.*, Edmund Conway, *George Soros: Rocketing Oil Price is a Bubble*, DAILY TELEGRAPH (May 27, 2008), *available at* http://www.telegraph.co.uk/money/main.jhtml?xml=/money/2008/05/26/cnsoros126.xml (last visited July 8, 2008) (quoting Mr. George Soros as stating "Speculation . . . is increasingly affecting the price"); Written Testimony of Michael Masters, *Hearing Before the Committee on Homeland Security and Governmental Affairs, U.S. Senate* 2 (May 20, 2008), *available at* http://hsgac.senate.gov/public/_files/052008Masters.pdf (last visited July 8, 2008) (quoting Michael W. Masters as stating "Are Institutional Investors contributing to food and energy price inflation? And my unequivocal answer is YES"); Oral Testimony of Edward Krapels, Hearing Before the Committee on Energy and Commerce Subcommittee on Oversight and Investigations, U.S. House of Representatives, (June 23, 2008) (quoting Mr. Edward Krapels as stating "I think the amount of speculation is really substantial [within the crude oil market.]"); Oral Testimony of Roger Diwan, Hearing Before the Committee on Energy and Commerce Subcommittee on Oversight and Investigations, U.S. House of Representatives, (June 23, 2008) (quoting Mr. Roger Diwan, responding to Rep. Whitfield's question: So you're saying if we adopt these regulatory changes, we could almost cut the retail price of gas in half in a relatively short period of time? "I don't know how quickly it takes to get prices down, but it's clear that prices will reflect closer the marginal cost of producing oil."); Alejandro Lazo, Energy *Stocks Haven't Caught Up With Oil Prices*, WASH. POST (Mar. 23, 2008), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/03/21/AR2008032103825.html (last visited July 8, 2008) (quoting Mr. Fadel Gheit as stating "The largest speculators are the largest financial companies."); MICHELLE FOSS, UNITED STATES NATURAL GAS PRICES TO 2015, 34 (2007), *available at* http://www.oxfordenergy.org/pdfs/NG18.pdf (last visited July 8, 2008) (asserting "The role of speculation in oil markets has been widely debated but could add upwards of $20 to the price per barrel."); Tim Evans, Citi Futures Perspective: PM Energy News & Views, at 2 (July 3, 2008) (quoting "With the latest push to the upside, we see the crude oil market becoming even more completely divorced from any connection to fundamental factors and becoming even more obsessed with the simple question, How high can it go?"); Advantage Business Media, *Economist Blames Subsidies for Oil Price Hike*, CHEM.INFO (2008), *available at* http://www.chem.info/ShowPR.aspx?PUBCODE=075&ACCT=0000100&ISSUE=0609&ORIGRELTYPE=DM&RELTYPE=PR&PRODCODE=00000&PRODLETT=M&CommonCount=0 (last visited July 8, 2008) (quoting Dr. Michelle Foss as stating "We have an overpriced commodity, and this is going to be around for a while."); Kenneth N. Gilpin, *OPEC Agrees to Increase Output in July to Ease Oil Prices*, N.Y. TIMES (June 3, 2004) *available at* http://www.nytimes.com/2004/06/03/business/03CND-OIL.html?ex=1401681600&en=5dbd50c5b369795b&ei=5007&partner=USERLAND (last visited July 8, 2008) (quoting Mr. Kyle Cooper as stating "There is not a crude shortage, which is why OPEC was so reluctant to raise production."); Upstream, *Speculators 'not to blame' for Oil Prices*, UPSTREAMONLINE.COM, (April 4, 2008), available at http://www.upstreamonline.com/live/article151805.ece (last visited July 8, 2008) (quoting Mr. Sean Cota as stating "It has become apparent that excessive speculation on energy trading facilities is the fuel that is driving this runaway train in crude prices"); Mike Norman, *The Danger of Speculation*, FOXNEWS.COM (Aug. 19, 2005), *available at* http://www.foxnews.com/story/0,2933,166038,00.html (last visited July 8, 2008) (Mr. Norman stating "Oil prices are high because of speculation, pure and simple. That's not an assertion, that's a fact. Yet rather than attack the speculation and rid ourselves of the problem, we flail away at the symptoms.").

[13] INTERNATIONAL MONETARY FUND, REGIONAL ECONOMIC OUTLOOK: MIDDLE EAST AND CENTRAL ASIA 27-28 (2008) ("Producers and many analysts say it is speculative activity that is pushing up oil prices now. Producers in

The PSI staff and others have identified the Intercontinental Exchange ("ICE") of Atlanta, Georgia, as an unregulated trading facility upon which a considerable amount of exempt U.S. energy futures trading is done.[14] For purposes of facilitating exempt natural gas futures, ICE is deemed a U.S. "exempt commercial market" under the Enron Loophole.[15] For purposes of its facilitating U.S. WTI crude oil futures on U.S. trading terminals, the CFTC, by informal staff action, considers ICE, because of its wholly owned subsidiary, ICE Futures Europe, to be a U.K. entity not subject to direct CFTC regulation even though ICE maintains U.S. headquarters and U.S. trading infrastructure (*i.e.*, terminals and servers), facilitating, *inter alia*, @ 30% of trades in U.S. WTI futures trades.[16]

The Dubai Mercantile Exchange, in affiliation with NYMEX, a U.S. exchange, has also been granted permission to trade the U.S. delivered WTI contract on U.S. terminals, but is, by virtue of a CFTC no action letter, to be regulated directly by the Dubai Financial Service Authority ("DFSA").[17] NYMEX describes itself as "a founder and has ownership share in [DME] and provides clearing services for that exchange." [18]

NYMEX itself, the U.S. premier regulated energy futures contract market capturing the overwhelming share, *e.g.*, of the U.S. delivered WTI futures market, has announced that it has applied to the United Kingdom's Financial Services Authority to have a NYMEX London trading platform registered with the that British agency,[19] after which NYMEX will apply for the kind of foreign board of trade no action relief that has already been granted to ICE and DME. Providing NYMEX's London trading platform with this kind of no action relief might very well convert full U.S. regulation of the most important U.S. crude oil futures contracts to considerable U.K. oversight.[20] These staff informal action letters, effectuating the exemptions for "foreign" owned U.S. trading terminals, by their own terms make it clear that they may be instantly revoked by the CFTC.[21]

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particular argue that fundamentals would yield an oil price of about US $80 a barrel, with the rest being the result of speculative activity."); *see also* Neil King Jr., *Saudi Arabia's Leverage In Oil Market Is Sapped*, WALL STREET J. (June 16, 2008), *available at* http://online.wsj.com/article/SB121355902769475555.html?mod=googlenews_wsj (last visited July 8, 2008) (quoting Saudi Oil Minister Ali Naimi as saying skyrocketing oil prices were "unjustified by the fundamentals" of supply and demand).

[14] *See* June 2007 Report, *supra* note 10, at 27.

[15] *See id.*

[16] *See* Written Testimony of Professor Michael Greenberger, *Energy Market Manipulation and Federal Enforcement Regimes: Hearing before the S. Comm. on Commerce, Science, and Transportation*, 3 (2008), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1026&context=cong_test (last visited July 8, 2008).

[17] Dubai Mercantile Exchange Ltd., CFTC No-Action Letter, 2007 CFTC Ltr. LEXIS 6 (May 24, 2007).

[18] *See* Written Testimony of Jim Newsome, Hearing Before the Committee on Energy and Commerce Subcommittee on Oversight and Investigations, U.S. House of Representatives, at 6 (June 23, 2008) [hereinafter June 23, 2008 Testimony of Jim Newsome].

[19] *Id.*; Jeremy Grant, *Nymex's Long Road to the Electronic Age*, FINANCIAL TIMES (Feb. 17, 2006), at 39. ("Nymex has indicated that it might be forced to move its electronically traded WTI to London so that it can compete on a level playing field with ICE.").

[20] *See* June 23, 2008 Testimony of Jim Newsome, *supra* note 18.

[21] *See* Written Testimony of Professor Michael Greenberger, *Energy Speculation: Is Greater Regulation Necessary to Stop Price Manipulation?: Hearing Before the H. Subcomm. on Oversight and Investigations* 11-12 (2007) (providing a complete discussion of the no-action letter process including termination), *available at*

One final gap in the oversight of excessive speculation in the U.S. crude oil (and agricultural) markets has been illuminated by the testimony of Michael W. Masters, Managing Member of Masters Capital Management, LLC, at recent May 20 and June 24 hearings before the Senate Committee on Homeland Security and Government Affairs.[22] Mr. Masters demonstrated that large financial institutions, such as investment banks and hedge funds, which were "hedging" their off exchange futures transactions on energy and agricultural prices on U.S. regulated exchanges, were being treated by NYMEX, for example, and the CFTC as "commercial interests," rather than as the speculators they clearly are.[23] By lumping large financial institutions with traditional commercial oil dealers (or farmers)[24] even fully regulated U.S. exchanges are not applying traditional speculation limits to the transactions engaged in by these speculative interests.[25] Mr. Masters has demonstrated that a significant percentage of the trades in WTI futures, for example, were controlled by non-commercial interests.[26] These exemptions from speculation limits for large financial institutions hedging off-exchange "swaps" transactions emanate from a CFTC letter issued on October 8, 1991[27] and they have continued to present day.[28]

Again, while the principal focus to date has been on skyrocketing energy prices, Mr. Masters' testimony, aided by a widely discussed cover story in the March 31, 2008 issue of *Barron's*,[29] has made clear that the categorization of swaps dealers outside of speculative controls even on U.S. regulated contract markets has been a cause of great volatility in food prices, as well as in the energy markets.

Many parties are now urging this Congress to close the Enron, London/Dubai, and Swaps Dealers Loopholes. On June 18, 2008, the Food Conservation and Energy Act of 2008[30] (the "Farm Bill") was enacted into law by a Congressional override of President Bush's veto. Title XIII of the Farm Bill is the CFTC Reauthorization Act of 2008, which, in turn, includes a provision that was intended to close the Enron Loophole.[31] This provision, while a good start, did not return to the status quo prior to the passage of the Enron Loophole: i.e., it did not bring *all* energy futures contracts within the U.S. futures regulatory format. Rather, the Farm Bill amendment requires the

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http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1011&context=cong_test (last visited July 8, 2008).

[22] Masters, *supra* note 12.

[23] *Id.* at 7-8.

[24] Gene Epstein, *Commodities: Who's Behind The Boom?*, BARRON'S 32 (March 31, 2008) ("The speculators, now so bullish, are mainly the index funds. . . . By using the [swaps dealers] as a conduit, the index funds get an exemption from position limits that are normally imposed on any other speculator, including the $1 in every $10 of index-fund money that does not go through the swaps dealers.").

[25] Masters, *supra* note 12, at 7.

[26] *Id.* at 8, 11.

[27] J. Aron & Co., CFTC Interpretive Letter, 1991 CFTC Ltr. LEXIS 18 (Oct. 8, 1991).

[28] *See* Written Testimony of Michael Masters, Hearing Before Committee on Energy and Commerce Subcommittee on Oversight and Investigations, U.S. House of Representatives, at 5 (June 23, 2008) *available at* http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.062308.Masters-testimony.pdf (quoting "assets allocated to commodity index trading strategies have risen from $13 billion at the end of 2003 to $260 billion as of March 2008, and the prices of the 25 commodities that compose these indices have risen by an average of 183% in those five years!").

[29] *See* Epstein, *supra* note 24.

[30] Food Conservation and Energy Act of 2008, Pub. L. No. 110-246, § 13201; 122 Stat. 1651 (2008).

[31] *Id.*

CFTC "at its discretion" to prove on a contract-by-contract basis through administrative proceedings governed by the notice and comment provisions of the Administrative Procedure Act[32] that an *individual* energy contract should be regulated if the CFTC can prove that the contract "serve[s] a significant price discovery function" in order to detect and prevent excessive speculation and manipulation.[33] The Farm Bill Amendment affords the CFTC 15 months after enactment to implement that re-regulation process specified therein.[34]

The CFTC has publicly stated that it intends to apply the new legislation to only one of ICE's many[35] unregulated ICE energy futures contract, *i.e.*, only ICE's Henry Hub natural gas futures contract would be removed from the Enron Loophole protection and become fully regulated.[36] Thus, by this CFTC pronouncement, it now seems that no crude oil, gasoline, and heating oil futures contracts will be covered by the new legislation—not even the multi-billion agricultural/commodity index futures funds premised upon the prices of U.S. energy and agricultural commodities about which, *inter alia*, Michael Masters has testified are destabilizing the economic fundamentals of the agriculture and energy markets.

The CFTC has also made it clear that the Farm Bill amendment will not cover any *U.S.* futures contracts relating to the price of *U.S.* delivered commodities traded on the *U.S.* terminals of foreign exchanges operating pursuant to CFTC staff "no action" letters. As mentioned above, the Intercontinental Exchange ("ICE") of Atlanta, Georgia, for purposes of facilitating U.S. delivered WTI crude oil futures, is considered by the CFTC, through an informal staff no action letter, to be a U.K. entity not subject to direct CFTC regulation even though ICE maintains U.S. headquarters and trading infrastructure, facilitating, *inter alia*, @ 30% of trades in U.S. WTI futures of its wholly owned the London subsidiary on which the no action permission is based. Moreover, the Dubai Mercantile Exchange ("DME"), in affiliation with NYMEX, a U.S. exchange, has also been granted permission to trade the U.S. delivered WTI contract on U.S. terminals, but is, by virtue of a CFTC no action letter, directly regulated by the Dubai Financial Service Authority ("DFSA"). Again, even though the plain language of the Farm Bill does not exempt contract markets engaged in the U.S. trading of futures premised upon U.S. delivered commodities, the CFTC will not use the Farm Bill amendment to close the "London/Dubai" Loophole.

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[32] *See* RICHARD J. PRINCE, JR., ADMINISTRATIVE LAW TREATISE 424-25, 441-43 (4TH ED. 2002).
[33] Food Conservation and Energy Act of 2008, Pub. L. No. 110-246, § 13201; 122 Stat. 1651 (2008).
[34] *Id.* at § 13204.
[35] *See* Written Testimony of Jeffrey C. Sprecher, To Examine Trading Regulated Exchanges and Exempt Commercial Markets: Hearing of the Commodity Futures Trading Commission, (September 18, 2007), *available at* http://files.shareholder.com/downloads/ICE/325023768x0x132117/53a6f61e-b72b-47ca-8f8e-f8282c21c12b/CFTC%20Testimony%20091807.pdf (last visited July 8, 2008).
[36] *See* Written Testimony of Acting Chair Walter Lukken, *Energy Speculation: Is Greater Regulation Necessary to Stop Price Manipulation?: Hearing Before the H. Subcomm. on Oversight and Investigations*, 4 (Dec. 12, 2007) *available at* http://www.cftc.gov/stellent/groups/public/@newsroom/documents/speechandtestimony/opalukken-32.pdf (emphasis added) (last visited July 8, 2008).

Congress Should Insist Upon Full Market Transparency to Ensure That Excessive Speculation Is Not Overwhelming Crude Oil Futures Trading

As the Subcommittee knows, there is debate over whether the U.S. crude oil futures market is overrun by excessive speculation. As I have said, my own view is that those independent observers who understand those markets, by and large, concur that the markets have come unhinged from supply/demand fundamentals in a manner that makes them no longer useable by the physical hedgers who find prices to be "locked in" too volatile and distant from market fundamentals.[37]

I would argue, however, that even if Congress has doubts about whether excessive speculation or more serious malpractices are occurring in these markets and thereby unnecessarily driving up the price of crude oil, then those very doubts argue for legislation that makes these markets fully transparent. If all of these markets (e.g., OTC, foreign board of trade U.S. trading terminals for futures dependent on U.S. commodities, and swaps dealers) were required to execute trades on U.S. designated contract markets or designated transaction execution facilities, the real time and constant reporting to both the CFTC and to the market's own self regulatory observers, would make it indisputably clear whether the markets are functioning solely on economic fundamentals; or whether excessive speculation is placing an unnecessary financial burden on them and the American energy consuming public.

As it is, those who reject transparency are those who ask the U.S. energy consumer to accept on blind faith (and I would argue in the face of substantial and reliable data pointing in the opposite direction) that these markets are functioning smoothly.

A Prompt Return to the Time Tested Futures Regulatory Format Predating the Enron Loophole Will Create Much Needed Crude Oil Market Transparency

While this Subcommittee does not have jurisdictional responsibility for the law governing the CFTC's regulatory actions, I know that for purposes of CFTC appropriations, it is interested in the role that is being envisioned by Members of Congress for the CFTC in overseeing these important markets. In that spirit, and because the Chairwoman has a major substantive legislative proposal on this issue which is under serious consideration, I thought it might be helpful to discuss what form any new legislation must take to increase transparency in all U.S. traded energy futures. I have been urging that the following principles be embedded in new CFTC oversight of energy futures markets to reassure the American energy consuming public that the price of crude oil is tied to market fundamentals rather than excessive speculation.

Completely Close the Enron Loophole. While the Farm Bill amendment was a good start, the radically rising price of crude oil even in the last few weeks now augurs for returning all U.S. energy futures trading to the safe harbor of fully transparent U.S. regulated contract markets. A simple amendment to existing law would redefine an "exempt commodity" as a commodity that does not include an agricultural or "*energy* commodity," thereby bringing all energy futures, including energy swaps based on the price of energy commodities, within the CEA's regulated contract market trading requirement. An energy commodity should include traditional energy products, *inter alia*, crude oil, gasoline, diesel fuel, heating oil, propane,

[37] See the many opinions from those experts in note 12 *supra*.

electricity, and natural gas, as well as metals which have also seen a drastic run up in price. The result of this legislation would return U.S. energy futures trading to the same status as U.S. agricultural trading, which must be conducted on the U.S. registered contract market.

U. S. Based Energy Futures Contracts Traded on U.S. Terminals Should Be Traded on U.S. Regulated Exchanges. To address the concerns about the "London/Dubai" Loophole, any futures contract premised on the price of U.S. delivered energy futures and traded on U.S. trading terminals should be required to be traded on U. S. registered contract markets. This requirement would not affect the overwhelming number of foreign exchanges now trading within the U.S. who have continued to limit their trading to foreign futures contracts.

Grace Periods. Reasonable grace periods should be provided in this kind of legislation to accommodate conversion of energy futures trading not now under U.S. oversight. A grace period no longer than six months should accommodate this conversion.

Aggregated Speculation Limits for Non-Commercial Hedgers. Consideration should also be given to requiring the CFTC to establish uniform speculation limits for non-commercial futures transactions involving the U.S. trading of energy futures contracts premised upon the price of U.S. delivered energy commodities. This would require the CFTC to "fix limits on the aggregate number of positions which may be held by any person" for each month and in *all* markets under CFTC jurisdiction. Under the existing regulatory regime, speculation limits are only applied by each contract market, and "aggregate positions" are never imposed. These aggregated limits would prevent a trader from spreading speculation over a host of markets, thereby accumulating a disproportionately large share of an energy market while satisfying each exchange's separate limits. The aggregated limits should not be applied to "bona fide hedging transactions" involving the trading of energy futures contracts by those having a true commercial interest in buying or selling the underlying commodity.

Legislation meeting most or all of the above listed criteria include H.R. 6341, introduced by Congressman Van Hollen and this Subcommittee's Chairwoman, requiring all energy futures contracts executed in the U.S. to be traded on U.S. regulated contract markets, thereby building on the Farm Bill amendment's closure of the Enron Loophole by returning *all* energy futures trading, including the energy swaps market, to where it was immediately prior to that provision's passage, i.e., on regulated exchanges; and that legislation expressly requires the trading on U.S. terminals of futures contracts premised upon U.S. delivered energy commodities to be similarly subject to a U.S. regulated contract market. The latter provision would close the "London/Dubai" Loophole.

Congressman Stupak has introduced H.R. 6330, the 2008 Pump Act, which mirrors in function the Van Hollen/DeLauro legislation, but, in what I refer to as a "belt and suspenders" approach, specifically brings energy swaps transactions into the regulated futures environment; nullifies after a grace period all foreign board of trade no action letters; imposes CTFC imposed aggregated speculation limits on non-commercial interests for energy futures trading; requires speculation limits to be imposed on all traders except those who are hedging commercial interests related to the underlying commodity (thereby eliminating the hedge exemption from speculation limits for swaps dealers); and provides strict Congressional oversight of any exemptions provided to energy futures trading from the contract market requirements of the legislation.

Senator Nelson of Florida, with Senator Obama as a co-sponsor, has introduced S. 3134, which is similar to that portion of H.R. 6341 requiring all energy futures contracts to be traded on regulated exchanges.[38] Senators Cantwell and Snowe have introduced S. 3122, which mirrors that portion of H.R. 6341 directed to closing the London/Dubai Loophole by requiring all trading of futures based on U.S. delivered energy commodity on U.S. platforms to be governed fully and directly by U.S. futures law.[39] S. 3205, introduced by Senator Cantwell, is the Senate version of Congressman Stupak's H.R. 6330.

Also worthy of consideration are Senators Lieberman and Collins legislative options designed to undercut excessive speculation in these markets through direct and aggregated controls on non-commercial futures traders. One of their proposals would require the CFTC to establish firm and aggregated speculation position limits on all U.S. speculative futures trading no matter where the platform on which the trading is geographically located.[40]

There Are No Legal Restraints to Barring the "Foreign" Impact of Manipulation on U.S. Markets

I know that this Subcommittee wants to know for appropriation purposes the extent of the CFTC's role in overseeing U.S. trading of U.S. energy futures contracts by the so-called "foreign" boards of trade such as ICE and DME. In this regard, arguments have been advanced that there are legal impediments to the CFTC applying U.S. regulatory protections on Foreign Boards of Trade which bring their trading terminals to the U.S. If that argument were correct, it would be an impediment to much of the legislation cited above requiring the CFTC to do just that. These arguments are premised upon Section 4 (b) of the Commodity Exchange Act (CEA). Section 4 (b) provides in part:

> No rule or regulation may be adopted by the Commission under this subsection that (1) requires Commission approval of any contract, rule, regulation, or action of any foreign board of trade, exchange, or market, or clearinghouse for such board of trade, exchange, or market, or (2) governs in any way any rule or contract term or action of any foreign board of trade, exchange, or market, or clearinghouse for such board of trade, exchange, or market. [41]

However, this clause has been construed only to mean that the CFTC does not have jurisdiction over transactions conducted by *foreign* persons in a *foreign* country on a *foreign* board of trade.[42] *Kleinberg v. Bear Stearns*,[43] dealt with a situation where London traders were committing acts of fraud on a London exchange.[44] In that case, the Court held that the CFTC did not have enforcement jurisdiction, but explained, "It has been consistently held, at least

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[38] S. 3134, 110th Cong. (2008), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s3134is.txt.pdf (last visited July 8, 2008).
[39] Policing United States Oil Commodities Markets Act of 2008, S. 3122, 110th Cong. (2008), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s3122is.txt.pdf (last visited July 8, 2008).
[40] Discussion Draft to establish aggregate speculative position limits (2008), *available at* http://hsgac.senate.gov/public/_files/aggspeclimits.pdf (last visited July 8, 2008).
[41] 7 U.S.C. § 6(b) (2008).
[42] PHILIP MCBRIDE JOHNSON & THOMAS LEE HAZEN, DERIVATIVES REGULATION 988 (2004 ed.).
[43] 1985 WL 1625 (1985).
[44] *Id.* at 1.

implicitly, that CFTC may regulate and prosecute those who practice fraud in the United States in connection with commodities trading on foreign exchanges."[45]

To similar effect is the recent case of *Mak v. Wocom Commodities*,[46] concerning a Hong Kong resident placing futures trades with the defendant commodity brokers, both of which are Hong Kong corporations (Wocom).[47] The claims were denied because they were not sufficiently particularized.[48] However, the court stated that jurisdiction would have been extended if it had been clearly shown that there was "particularized harm to our domestic markets."[49] With ICE we currently have trading by U.S. customers in U.S. denominated currency on U.S. terminals in the foremost benchmark U.S. crude oil futures contracts with substantial evidence demonstrating "particularized harm to our domestic markets."

Indeed these cases are consistent with a fundamental tenet of federal financial enforcement jurisprudence that federal financial regulatory jurisdiction extends even to wholly foreign transactions when domestic financial markets suffer "from the effects of [an] improper foreign transaction[.]"[50] The leading commentators on U.S. derivatives regulation have, accordingly stated: "[E]ven without substantial activity in the United States, jurisdiction will exist when conduct abroad has a substantial affect upon U.S. markets and U.S. investors."[51]

Confirmation of this broad sweep of U.S. jurisdiction to address overseas malpractices significantly impacting U.S. markets is evidenced most clearly by the *Sumitomo* case.[52] In that case, the CFTC's enforcement division reached a settlement agreement with a Japanese corporation upon determining that the Japanese head copper trader of the Sumitomo Corporation manipulated the price of U.S. copper almost exclusively through trading done in London on the London Metals Exchange.[53] The CFTC imposed $150 million in fines and restitution.[54] Only a small portion of the trading was done in the U.S. and the London Metals Exchange contact with the U.S. was limited to a U.S. warehouse.[55] Despite these limited U.S. contacts, "the penalty [assessed was then] *the largest ever levied by a U.S. Government agency*," and it was widely recognized that the settlement indicated that "manipulation of any commodity traded in the [U.S.] could be the subject of a C.F.T.C. action, *even if no acts were committed in this country.*"[56]

Clearly, then, trading done on trading platforms within the U.S. can and should be subject to full CFTC regulatory authority. The fact that ICE is headquartered in Atlanta with its

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[45] *Id.* at 2 (internal citations omitted).
[46] 112 F.3d 287 (7th Cir. 1997).
[47] *Id.* at 288.
[48] *Id.* at 290-91.
[49] *Id.* at 291.
[50] Des Brisay v. Goldfield Corp., 549 F.2d 133, 135 (9th Cir. 1977) (citing Schoenbaum v. Firstbrook, 405 F.2d 200, 206 (2d Cir. 1968), *modified in other respects*, 405 F.2d 215 (in banc), *cert. denied*, 395 U.S. 906, 89 S. Ct. 1747, 23 L. Ed. 2d 219 (1969)).
[51] JOHNSON & HAZEN, *supra* note 42, at 984.
[52] In the Matter of Sumitomo Corporation, 1998 CFTC LEXIS 96 (1998).
[53] *Id.* at 2-3.
[54] *Id.* at 24-25.
[55] *Id.* at 11-14.
[56] Floyd Norris, *The Markets; A Record Penalty of Sumitomo, a Lesson on Market Volatility*, N.Y. TIMES (May 12, 1998), at D13 (emphasis added).

trade matching engines in Chicago and it controls through its U.S. terminals over 30% of the lead U.S.-delivered petroleum contract only makes the jurisdictional question that much easier. The same is true of the Dubai exchange that partners with U.S.-based NYMEX to trade WTI contracts on U.S. terminals; and of the prospect of NYMEX opening a London trading platform for its energy futures products, but escaping U.S. regulation for that trading through a staff no action letter treating NYMEX as if it were a U.K. entity.

Even more important, *Sumitomo* and its progeny are an answer to those many threats levied by large U.S. financial institutions that assert, if their trading on "foreign" trading terminals located in the U.S. is regulated, they will simply move that trading abroad. To be clear, any trading done in the U.S. on foreign exchanges is *a fortiori* covered by the applicable U.S. commodity laws.[57] So when the threat is made that the U.S. institutions will trade abroad, it means that it will be done completely outside of the sovereign U.S. However, the *Sumitomo* line of cases make clear that the CFTC, and for that matter, United States Department of Justice for purposes of related criminal prosecution,[58] can enforce violations of U.S. laws abroad if U.S. markets are significantly impacted by the wrongdoing in foreign countries. In short, speculators cannot escape the reach of U.S. civil and criminal law if they cause price distortions in U.S. commodity markets.

Moreover, as I have testified elsewhere, no exchange, wherever located, can develop liquidity in and maximize profits from trading U.S. delivered futures products without having a substantial U.S. presence.[59] This is evidenced by the 18 CFTC staff no action letters issued to foreign exchanges from all over the world allowing the placement of trading terminals in the U.S. [60] In short, the threat that trading in U.S. delivered commodities will be done exclusively abroad is idle when confronted by both economic and legal realities.

The Intercontinental Exchange Cannot Fairly Be Deemed British for Purposes of Trading U.S. Petroleum Futures in U.S. Dollars on U.S. Trading Terminals with U.S. Trading Engines

Of course, all of the above jurisdictional analysis assumes that ICE (and DME) are "foreign" boards of trade. While ICE has a London wholly owned subsidiary, that office is controlled by ICE's headquarters in Atlanta; ICE's trading engines are in Chicago; it is trading over 30% of the U.S. premier crude oil futures contract in U.S. denominated currency. ICE's

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[57] JOHNSON & HAZEN, *supra* note 42, at 984.

[58] *See* Press Release, Department of Justice, U.S. Charges 47 After Long-Term Undercover Investigation Involving Foreign Exchange Markets, (Nov. 19, 2003), *available at* http://www.fbi.gov/dojpressrel/pressrel03/wooden111903.htm (last visited July 8, 2008).

[59] Written Testimony of Professor Michael Greenberger, *Energy Market Manipulation and Federal Enforcement Regimes: Hearing Before the United States Senate Committee on Commerce, Science, and Transportation*, 12 (2008), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1026&context=cong_test (last visited July 8, 2008).

[60] U.S. Commodity Futures Trading Commission, Foreign Boards of Trade Receiving Staff No Action Letters Permitting Direct Access from the U.S., *available at* http://services.cftc.gov/sirt/sirt.aspx?Topic=ForeignTerminalRelief (last visited July 8, 2008).

non-petroleum products, i.e., natural gas futures contracts, are clearly traded within U.S. jurisdiction and are subject to re-regulation under U.S. law by virtue of the Farm Bill's "End the Enron Loophole" provision.[61] ICE also owns a fully regulated U.S. exchange: formerly the New York Board of Trade (NYBOT); now ICE Futures U.S. It defies all logic that such an exchange can be called "foreign" based on the name given to its wholly owned subsidiary (ICE Futures Europe) and maintaining a London office that could as easily be operated out within the U.S.

The same is also true of the Dubai Mercantile Exchange. Its principal partner is the New York Mercantile Exchange (NYMEX), a U.S. regulated exchange and a U.S. entity. The President of NYMEX sits on DME's board. DME has authority to trade the U.S. delivered WTI contract on trading terminals in the U.S. Under these circumstances, DME is clearly a U.S. exchange

The illogic of the FBOT staff no action process is highlighted by NYMEX, a U.S. regulated exchange headquartered in the U.S., establishing a London futures trading platform under the United Kingdom's regulatory regime and then applying for an FBOT staff no action letter to allow trading within the U.S. on its NYMEX London platform. NYMEX will then have converted itself from a U.S. entity into a British entity for purposes of U.S. trades on the platform with the principal regulation of those trades in the hands of the United Kingdom.

And, why should NYMEX not do this? It is following precisely the ICE template. However, the proposal defies all good sense, and, even worse, it will add darkness to the trading markets that affect the price of crude oil, gasoline, and heating oil within the U.S.

Under the ICE, DME and London/NYMEX scenarios, each of these exchanges are clearly U.S. exchanges and their trading terminals should be regulated as U.S. regulated contract markets. Moreover, as U.S. contract markets, they and the traders on those exchanges (no matter whether they trade in the U.S. or abroad) are fully subject to both CFTC civil jurisdiction and United States federal criminal statutes.[62] For example, in *Tamari v. Bache*[63] the Seventh Circuit held there was federal jurisdiction to enforce the Commodity Exchange Act, even though the trader and the trader's broker accused of fraud were both situated in Lebanon,[64] by stating: "that Congress intended to proscribe fraudulent conduct associated with any commodity future transactions executed on a domestic exchange, regardless of the location of the agents that facilitate the trading" and thus there was jurisdiction.[65]

The CFTC Has Consistently Viewed Foreign Exchanges Trading on U.S. Terminals Subject to Full U.S. Regulation

It has been shown immediately above, that as a legal matter there is no bar either within the CEA as now drafted nor within the case law that prevents the CFTC from gaining full

[61]Food Conservation and Energy Act of 2008, Pub. L. No. 110-246, § 13201; 122 Stat. 1651 (2008); Jessica Marron, *House and Senate Lawmakers Move to Close 'Enron Loophole' with Amendment to Farm Bill*, PLATTS GLOBAL POWER REPORT, (May 1, 2008) (stating that the "initial target of the [the Farm's Bill End the Enron Loophole Provision] is ICE's financially settled Henry Hub swap contract").

[62] JOHNSON & HAZEN, *supra* note 42, at 986 (citing In the Matter of Ralli Brothers Bankers, [1986-1987 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 23, 314 (1986)).

[63] 730 F.2d 1103 (7th Cir. 1984).

[64] *Id.* at 1104-05.

[65] *Id.* at 1108; JOHNSON & HAZEN, *supra* note 42, at 987.

regulatory control, over any futures trading done in the U.S Even if one were to assume that ICE, for example, is truly a foreign board of trade, Section 4 (b) only bars regulation of trading done by foreign citizens in foreign countries trading foreign commodities on foreign exchanges when such trading does not cause substantial dysfunctions to U.S. markets. Below it is shown that this well established law has governed the CFTC's FBOT staff no action process since its inception.

The staff no action process initiated in 1999 was not developed under a view that, pursuant to Section 4 (b), the CFTC could not regulate foreign exchanges who wished to put trading terminals in the U.S. To the contrary, the history is clear that those foreign exchanges themselves recognized that, in the absence of an exemption under Section 4 (c) of the CEA,[66] they would have to fully register as a U.S. contract market. As their plain language made clear when they were first issued in 1999, the FBOT no action letters originated from a rulemaking proceeding that, by its very terms, indicated that permission to put terminals in the U.S. derived from Section 4 (c)'s exemption from full regulation and not from Section 4 (b)'s absolute bar against foreign regulation.[67] It must be remembered that Section 4 (b) does not countenance exceptions to its general restriction. The no action letters include a myriad of regulatory conditions on the foreign boards of trade that are completely inconsistent with the absolute bar within Section 4 (b).[68]

If there were any doubt about the above analysis, it was belied by the actions of the CFTC on June 17, 2008 and July 8, 2008, when it added four new conditions to the existing ICE Futures Europe and Dubai Mercantile Exchange no action letters.[69] While these additional

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[66] Written Testimony of Professor Michael Greenberger, *Energy Speculation: Is Greater Regulation Necessary to Stop Price Manipulation?: Hearing Before the H. Subcomm. On Oversight and Investigations*, 14-15 (2007), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1011&context=cong_test (last visited July 8, 2008).

[67] *See, e.g.*, LIFFE Administration & Management, CFTC No-Action Letter, 1999 CFTC Ltr. LEXIS 38, 4-5 (July 23, 1999); Access to Automated Boards of Trade (proposed rules), 64 Fed. Reg. 14,159, 14,174 (Mar. 24, 1999). As the proposed rules explained,

> Section 4(c) of the Act provides the Commission with authority "by rule, regulation, or order" to exempt "any agreement, contract or transaction" from the requirements of Section 4(a) of the act if the Commission determines that the exemption would be consistent with the public interest, that the contracts would be entered into solely by appropriate persons and that the exemption would not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory duties under the Act. *Id.* (internal citations omitted).

[68] Among the conditions present in all of the no action letters are the following: the exchange will satisfy the appropriate designation in its home jurisdiction, the exchange must work to ensure fair markets that prohibit fraud and other abuses by providing adequate supervision, continued adherence to IOSCO Principles for Oversight of Screen-Based Trading Systems for Derivative Products, members and guaranteed customers will only receive direct access if a clearing member guarantees and assumes all financial liability, there are sufficient safeguards to prevent unauthorized access or trading, at the Commission's request recipients will provide market information including access to books and records, and will submit all contracts to be made available through the no-action process, the volume of said trades and a list of names and addresses of all those using these exchanges. *See, e.g.*, LIFFE Administration and Management, CFTC No-Action Letter, 1999 CFTC Ltr. LEXIS 38, 65-72 (July 23, 1999); IPE, CFTC No-Action Letter, 1999 CFTC Ltr. LEXIS 152, 58-66 (Nov. 12, 1999); Dubai Mercantile Exchange Ltd., CFTC No-Action Letter, 2007 CFTC Ltr. LEXIS 6, 87-96 (May 24, 2007).

[69] Amendment to No-Action Letter Issued to the International Petroleum Exchange of London (now ICE Futures Europe), CFTC No-Action Letter, (June 17, 2008), *available at* http://www.cftc.gov/stellent/groups/public/@lrlettergeneral/documents/letter/08-09.pdf (last visited July 8, 2008); Press Release, CFTC, CFTC Conditions Foreign Access on Adoption of Position Limits on London Crude Oil

conditions have only been applied to ICE and DME, Acting Chairman Lukken's related comments show that the CFTC has the authority to incorporate them in the now outstanding 14 other FBOT staff no action letters affecting every foreign board of trade with U.S. terminals, as well as any FBOT that seeks an exemption from U.S. direct regulation in the future.[70]

If Section 4 (b)'s absolute prohibition were applicable to FBOTs with U.S. terminals, as some have argued as a predicate to limiting legislative or administrative action in this area, how could the CFTC add these new conditions to the outstanding no action letters? Those new conditions, *inter alia*, require large trader reporting and the imposition of speculation limits.[71] The failure of the FBOTs to comply could result in the revocation of the no action letters, thereby requiring each FBOT to register as a fully regulated U.S. contract market.[72]

Those who would attempt to limit Congressional and regulatory controls on ICE, DME, and NYMEX/London have also relied upon a November 2006 policy statement issued by the CFTC on the FBOT no action letter process.[73] Much is made about the fact that Section 4 (b) is cited and quoted therein. Whatever the purpose of that 4 (b) reference, the assertion that 4 (b) presents an absolute bar is belied by the following within that policy statement:

> [i]n the absence of no-action relief, a board of trade, exchange or market that permits direct access by U.S. persons might be subject to Commission action for violation of, among other provisions, section 4(a) of the CEA, if it were not found to qualify for the exclusion from the DCM designation or DTEF registration requirement.[74]

In short, the failure to gain no action relief would mean that, in the absence of registration as a fully regulated contract market, the FBOT would have to remove its U.S. terminals according to the CFTC's own analysis. As the CFTC expressly stated in its June17, 2008 letter to ICE imposing the new conditions on its no action status, if ICE satisfies the four new conditions, the CFTC "will not recommend that the Commission institute enforcement action against [ICE] based upon [ICE's] failure to seek contract market designation or registration as a DTEF under Sections 5 and 5a of the Act."

Contract (June 17, 2008) *available at* http://www.cftc.gov/newsroom/generalpressreleases/2008/pr5511-08.html (last visited July 8, 2008).

[70] Press Release, CFTC, CFTC Conditions Foreign Access on Adoption of Position Limits on London Crude Oil Contract (June 17, 2008) *available at* http://www.cftc.gov/newsroom/generalpressreleases/2008/pr5511-08.html (last visited July 8, 2008). As Acting Chairman Lukken stated,

> These new conditions for foreign access will provide the CFTC with additional oversight tools to monitor linked contracts. This powerful combination of enhanced trading data and additional market controls will help the CFTC in its surveillance of regulated domestic exchanges, while preserving the important benefits of our international recognition program that has enabled proper global oversight during the last decade. This raises the bar for all future foreign access requests and will ensure uniform oversight of linked contracts. *Id.*

[71] Amendment to No-Action Letter Issued to the International Petroleum Exchange of London (now ICE Futures Europe), CFTC No-Action Letter, (June 17, 2008) *available at* http://www.cftc.gov/stellent/groups/public/@irlettergeneral/documents/letter/08-09.pdf (last visited July 8, 2008).

[72] *See supra* notes 68-70 and accompanying text.

[73] Boards of Trade Located Outside of the United States and No-Action Relief from the Requirement to Become a Designated Contract Market or Derivatives Transaction Execution Facility, 71 Fed. Reg. 64,443 (Nov. 2, 2006).

[74] *Id.* at 64,445 n.23.

Again, the action of the CFTC adding further conditions to the ICE no action letter, including large trader reporting and speculation limits, upon pain of an enforcement proceeding based on the failure to register as a U.S. regulated contract market, clearly demonstrates that the CFTC meant what it said in the above quoted reference from its 2006 policy statement, it has broad powers to require a "foreign" exchange to fully register in the U.S. or terminate its presence in this country.[75] Section 4 (b) provides no impediment to those powers.

Efforts Designed to Oversee and Improve the Foreign Regulation of U.S. Delivered Futures on U.S. Terminals May Not Effectively Close the "London/Dubai" Loophole

Congressman Etheridge[76] and Senators Durbin and Levin in the Senate have introduced legislation which ratchets up the existing CFTC oversight of foreign boards of trade energy futures trading on U.S. trading terminals ("FBOTs"). That legislation, while a major improvement over the present regulatory environment, still leaves primary and direct enforcement and oversight in the hands of the foreign regulator, *e.g.*, the U.K.'s Financial Services Authority in the case of ICE; or the Dubai Financial Services Authority in the case of the DME.

It is my understanding the this legislation deferring to the primacy of foreign regulators to oversee U.S. terminals operated by FBOTs derives from a concern that section 4 (b) of the Act bars U.S. regulation of even those FBOTs in the U.S.[77] As has been shown above,[78] section 4 (b), whatever it means, is an absolute bar to any U.S. regulation,[79] whereas H. 6334 does ratchet up U.S. regulation of the foreign exchange. Moreover, as shown above,[80] section 4 (b)'s bar only applies to foreign trades on foreign exchanges of foreign commodities not having a significant impact on U.S. markets. Therefore, policy concerns about section 4 (b) should not govern the regulation of FBOT terminals in the U.S., especially when those terminals trade U.S. delivered futures contracts; and even more so when the FBOTs institutional ties are so closely affiliated with the U.S. and U.S. institutions that the FBOT loses all claim to foreign status.

Again, legislation such as that proposed by Congressman Etheridge, is a major improvement of what had been the CFTC's oversight of FBOTs' U.S. terminals.

This kind of legislation affords the CFTC the authority to enforce the prohibitions of section 9 of the Act, concerning criminal penalties, including anti-manipulation prohibitions therein, and "to limit, reduce, or liquidate any position" on the FBOT in aid of preventing, *inter alia*, manipulation and excessive speculation enforcement.[81] Imposition of restrictions on the FBOT, however, must be preceded by consultation with the FBOTs foreign regulator.[82]

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[75] Amendment to No-Action Letter Issued to the International Petroleum Exchange of London (now ICE Futures Europe), CFTC No-Action Letter, (June 17, 2008) *available at* http://www.cftc.gov/stellent/groups/public/@lrlettergeneral/documents/letter/08-09.pdf (last visited July 8, 2008).
[76] H.R. 6334.
[77] *See supra* notes 41-42 and accompanying text.
[78] *See supra* notes 43-60 and accompanying text.
[79] *See supra* notes 43-60 and accompanying text.
[80] *See supra* note 42 and accompanying text.
[81] *See* S. 3130 § 7, 110th Cong. (2008), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s3130is.txt.pdf (last visited July 8, 2008).
[82] *See id.*

The CFTC "may apply such recordkeeping requirements [to the FBOT] as the Commission determines are necessary,"[83] and before the CFTC exempts an FBOT from full U.S. contract market regulatory requirements, it must ensure that the FBOT operating the U.S. terminals "appl[y] comparable principles" to those of the CFTC for "daily publication of trading information and position limits or accountability levels for speculators" and provides to the CFTC "the information that the [CFTC] determines necessary to publish a Commitment of Traders report" for U.S regulated contract markets.[84]

Legislation of the kind introduced by Congressman Etheridge also requires the CFTC to conduct a review of FBOT no action status for existing FBOTs between the first anniversary of the passage of S. 3130 and one and one half years thereafter to ensure FBOT compliance with the new statutory requirements imposed by this legislation.[85]

In any event, recent actions taken by the CFTC to increase regulation of ICE and DME may place the requirements of Congressman Etheridge's bill in a new context.

CFTC's New Regulatory Requirements for Foreign Boards of Trade with U.S. Terminals

For at least two years prior to May 20, 2008, the CFTC had repeatedly assured Congress and market participants that the dramatic rise in crude oil, natural gas, gasoline, and heating oil was caused exclusively by supply/demand market fundamentals.[86] The CFTC had based its conclusions on its "exhaustive" research of all relevant market data.[87]

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[83] *Id.*
[84] *Id.* at §6.
[85] *Id.* at §11.
[86] Walt Lukken, Acting Chairman, CFTC, Prepared Remarks: Compliance and Enforcement in Energy Markets--The CFTC Perspective (Jan. 18, 2008), *available at* http://www.cftc.gov/stellent/groups/public/@newsroom/documents/speechandtestimony/opalukken-34.pdf (last visited June 21, 2008) (quoting Mr. Walter Lukken "While speculators play a integral role in the futures markets, the report concludes that speculative buying, as a whole, does not appear to drive up price"); Tina Seeley, *Energy Market Not Manipulated, U.S. Regulator Says (Update1)*, BLOOMBERG.COM (May 7, 2008), *available at* http://www.bloomberg.com/apps/news?pid=20601072&sid=aX0iaEd9bOMU&refer=energy (last visited June 21, 2008) (quoting Mr. Walter Lukken, "We have not seen that speculators are a major factor in driving these prices"); Ian Talley & Stephen Power, *Regulator Faults Energy-Futures Proposal*, WALL ST. J. (May 8, 2008) (stating that Mr. Walter Lukken commented that his agency hadn't seen evidence indicating that speculators are "a major factor" in driving up oil prices); Oral Testimony of Walter L. Lukken, Commissioner, CFTC, *Before the Committee on Agriculture, U.S. House of Representatives*, (April 27, 2006) (quoting Mr. Walter Lukken "[B]ased on our surveillance efforts to date, we believe that crude oil and gasoline futures markets have been accurately reflecting the underlying fundamentals of these markets"); Sharon Brown-Hruska, Chairman, CFTC, Address before the International Monetary Fund: Futures Markets in the Energy Sector (Jun. 15, 2006), *available at* http://www.cftc.gov/newsroom/speechestestimony/opabrownhruska-46.html (last visited Jun. 21, 2008) (stating "To date, the staff' findings have shown that these large speculators as a group tend to inject liquidity into the markets rather than having an undue impact on price movements"); Sharon Brown-Hruska, Chairman, CFTC, Keynote Address at the Managed Funds Association Annual Forum (Jun. 25, 2005), *available at* http://www.cftc.gov/opa/speeches05/opabrownhruska34.htm (last visited June 21, 2008) (stating the CFTC's study of the role of managed funds in our markets, "[C]ontradicts with force the anecdotal observations and conventional wisdom regarding hedge funds and speculators, in general.").
[87] *See, e.g., supra* note 86 and accompanying text.

Indeed, as recently as May 20, 2008, before the full Senate Homeland Security and Government Affairs Committee, the CFTC's Mr. Harris, testified: "[A]ll the data modeling and analysis we have done to date indicates there is little economic evidence to demonstrate that prices are being systematically driven by speculators in these [agriculture and energy] markets.... [O]ur *comprehensive* analysis of the *actual* position data of these traders fails to support [the] contention" that there is excessive speculation or manipulation.[88] Rather, he said "prices are being driven by powerful economic fundamental forces and the laws of supply demand."[89]

In a rather dramatic about face, the CFTC suddenly announced on May 29, 2008 (or just nine days after Mr. Harris testimony) that that agency is in the midst of an investigation into the crude oil energy markets[90] and it will now begin to collect substantial amounts of new data to determine what is undergirding high oil prices.[91] This reversal in course is almost certainly the product of intense pressure placed on the CFTC by Congress to ensure that excessive speculative activity is not being conducted on the principal market over which the CFTC has declined primary responsibility, i.e., trading done on ICE and on ICE's U.S. terminals.[92]

As crude oil and gas prices continued to spike even after the CFTC's May 29, 2008, announcement, the pressure on the CFTC did not let up. Thus, by June 17, 2008, the CFTC once again increased its pressure on ICE.

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[88] Written Testimony of Jeffrey Harris, Chief Economist, CFTC, *Before the Senate Committee on Homeland Security and Governmental Affairs, United States Senate* 20 (2008), *available at* http://www.cftc.gov/stellent/groups/public/@newsroom/documents/speechandtestimony/oeajeffharristestimony052008.pdf (last visited June 21, 2008).

[89] *Id.*; *see, e.g.*, Richard Hill, *Lieberman Says He Will Consider Legislation to Address Commodity Prices*, 40 BUREAU OF NAT'L. AFF. 21 (May 26, 2008) (emphasis added), *available at* http://corplawcenter.bna.com/pic2/clb.nsf/id/BNAP-7EVTDG?OpenDocument (last visited June 21, 2008).

[90] CFTC Commissioner Bart Chilton has acknowledged that the public announcement within the May 29 release raises the specter that "some people [will] head for the paper shredder [.]" Tina Seeley, *CFTC Targets Shipping, Storage in Oil Investigation (Update2)*, BLOOMBERG.COM (May 30, 2008), *available at* http://www.bloomberg.com/apps/news?pid=20601087&sid=aGzRMmD_b9MA&refer=home (last visited June 21, 2008).

[91] Press Release, U.S. Commodity Futures Trading Commission, CFTC Announces Multiple Energy Market Initiatives (May 29, 2008), *available at* http://www.cftc.gov/newsroom/generalpressreleases/2008/pr5503-08.html (last visited June 21, 2008).

[92] *See* Letter from Twenty-Two Senators to Walter Lukken, Acting Chairman, CFTC (May 23, 2008), *available at* http://cantwell.senate.gov/news/record.cfm?id=298325 (last visited June 21, 2008) (insisting that CFTC require ICE to demonstrate why it should not be subject to the same regulation as other U.S.-based exchanges and warning, "[a]bsent expeditious Commission action, Congress may need to step in to protect consumers and ensure that all markets trading U.S. delivered energy futures are transparent and free of fraud, manipulation, and excessive speculation"); Letter from Senator Jeff Bingaman to Walter Lukken, Acting Chairman, CFTC (May 27, 2008), *available at* http://energy.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=0fdd0eb4-4b1d-49f0-a3a2-f89fd0e4b1d3&Month=5&Year=2008&Party=0 (last visited June 21, 2008) (expressing concern that that "the Commission's assertions to date -- discounting the potential role of speculation in driving up oil prices -- have been based on a glaringly incomplete data set" and demanding an explanation of many CFTC activities); *Energy Speculation: Is Greater Regulation Necessary to Stop Price Manipulation?: Hearing Before the House Subcomm. on Oversight & Investigations*, 110th Cong. (2007) (statement of Rep. Joe Barton, Member, House Subcomm. on Investigations) (informing Walter Lukken, Acting Chairman, CFTC, that Congressed had empowered FERC to provide additional regulation in some energy markets because they were displeased with the CFTC's efforts).

In a dramatic June 17, 2008 letter to ICE, the CFTC Director of Market Oversight referenced the fact that ICE had moved its trading platform from London "to the ICE Platform operated by [ICE] in Atlanta, Georgia," and that that U.S. platform was now trading three U.S. delivered energy futures products (WTI, heating oil, and gasoline) "each of which is cash-settled on the price of physically-settled contracts traded on NYMEX."[93] Most importantly, the June 17 letter to ICE then stated:

> A foreign board of trade listing for trading a contract which settles on the price of a contract traded on a CFTC-regulated exchange *raises very serious concerns* for the Commission. . . . In the absence of preventive measures at [ICE], this circumstance *could compromise the [CFTC's] ability to carry out its market surveillance responsibilities*, as well as the integrity of prices established on CFTC-regulated exchanges. . .[T]he division retains the authority to condition further, modify, suspend, terminate, or otherwise restrict the terms of the no-action relief provided herein, in its discretion.[94]

In order to address the CFTC's "very serious concerns" that it had "compromise[d] [its own] ability to carry out its market surveillance responsibilities, as well as the integrity of the prices established" thereon, the letter then outlined four new conditions that it imposed upon ICE: "position limits or position accountability levels (including related hedge exemption provisions) as adopted by" U.S. regulated contract markets; quarterly reports of any member exceeding those levels and limits; publication of daily trading information comparable to that required of U.S. contract markets; daily reporting of "large trader positions" as provided by U.S. regulated markets.[95]

ICE was given 120 days to come into compliance with the new CFTC conditions.[96] The CFTC acknowledged that the new ICE rules would have to be approved by the FSA.[97] The June 17 letter to ICE concludes by stating that only if ICE complies with the conditions outlined therein can ICE be assured that the CFTC will "not recommend that the Commission institute enforcement action against [ICE] or its members" based on ICE's failure to register as a U.S. regulated contract market.[98]

On June 17, 2008, the day that that letter to ICE was released, CFTC Acting Chairman Lukken is reported to have told the Senate oversight committee: "The CFTC will also require other foreign exchanges that seek such direct access to provide the CFTC with comparable large trader reports and to impose comparable position and accountability limits for any products linked with US regulated futures contracts[.]" [99] On July 7, 2008, an identical CFTC staff letter was written to the DME.

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[93] Amendment to No-Action Letter Issued to the International Petroleum Exchange of London (now ICE Futures Europe), CFTC No-Action Letter 2 (June 17, 2008), *available at* http://www.cftc.gov/stellent/groups/public/@lrlettergeneral/documents/letter/08-09.pdf (last visited June 20, 2008).
[94] *Id.*
[95] *Id.* at 3.
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] Nick Snow, *US CFTC Unveils New Foreign Market Data Pact*, OIL & GAS J., (June 18, 2008), *available at* http://www.mapsearch.com/news/display.html?id=332086 (last visited June 21, 2008).

It would seem that much of what the CFTC has done implements the data collection requirements included in Congressman Etheridge's bill. Indeed, the CFTC's threat of enforcement authority against ICE in its June 17, 2008 letter, while limited for these purposes to failing to register as a U.S. regulated contract market, would seem to make it clear that that agency could enforce all civil and criminal penalties asserted throughout the CEA against ICE and its members if appropriate, thereby possibly even exceeding the grant of section 9 enforcement powers afforded the CFTC with regard to FBOTs in S. 3130.

As will be shown below, however, the present skyrocketing cost of crude oil and its derivative products, as well as the resulting destabilization of the U.S. economy, would seem to counsel the use of the full force of the CFTC's powers to bring ICE and similar "foreign" exchanges with trading terminals in the U.S. trading futures premised on U.S. delivered energy commodities under complete, direct, and real time U.S. regulatory control.

Deference to Foreign Regulators over U.S. Energy Futures Trading Deprives U.S. Energy Markets and U.S. Energy Consumers of the Full Weight of CEA Protections

The question arises whether the U.S. should continue to regulate FBOT trading of U.S. energy futures on U.S. terminals principally through foreign regulators while requiring more aggressive CFTC oversight of that process. Or, should trading of U.S. delivered energy products on U.S. terminals be deemed a sufficient nexus to the U.S. and the well being of its economy to require direct U.S. supervision. If Congress settles for the status quo as evidenced by the CFTC's most recent actions if forsakes a wealth of traditional regulatory tools that the CFTC has to ensure that U.S. energy markets and prices are rooted in economic fundamentals.

The Lack of Emergency Authority to Intervene in Market Distortions.

The most substantial risk in following the CFTC policy of leaving ICE and other similarly situated "foreign" exchanges under the principal supervision of foreign regulators while those exchanges have U.S. terminals trading critically important U.S. delivered energy products is that the CFTC cannot exercise its broad emergency authority to intervene immediately when confronted with emergencies and dysfunctions on U.S. regulated contract markets.[100]

Described as the CEA's "most potent tool," section 8a (9) provides that "whenever [the CFTC] has *reason to believe* that an emergency exists," it may take such actions "including, but not limited to "the setting of temporary emergency margin levels on any futures contract [and] the fixing of limits that may apply to a market position."[101] An "emergency" is defined:

> "to mean, in addition to threatened or actual market manipulations and corners, any act the United states or a foreign government affecting a commodity or any other major market disturbance *which prevents the market from accurately reflecting the forces of supply demand for such commodity.*"[102]

It should be born in mind that these emergency powers afford the CFTC the *immediate* right to alter on a real time basis margin requirements and speculation and position limits to deal with

[100] JOHNSON & HAZEN, *supra* note 42, at 1218.
[101] 7 U.S.C. § 12a(9) (2008) (emphasis added).
[102] *Id.* (emphasis added).

crises as they arise "*which prevent[] the market from accurately reflecting the forces of supply demand[.]*" While section 8a (9) affords direct judicial review of orders after they are issued in a federal court of appeals, it does not by its terms require emergency orders to be preceded by notice and an opportunity to be heard, thereby ensuring speedy restoration of normal market processes.[103]

When one reads this broad power afforded to the CFTC, one could reasonably ask why it has not been used on days such as Friday, June 6, 2008 when the WTI crude oil futures prices rose nearly $11 per barrel in a single day.[104] That is best explained by the fact that the only real time market data in the hands of the CFTC on that day was from NYMEX—the fully regulated U.S. exchange with speculation limits in place; perhaps if the CFTC had meaningful and real time ICE data on that day, thereby seeing the entirety of the WTI crude oil market, it might have seen a need to intervene under its emergency authority to impose temporary position limits and margin requirements to cool down what was widely viewed as breathtaking volatility.

Of course, even when it receives the ICE data within 120 days of its June 17, 2008 requirements, the CFTC will still not have the authority under the governing CFTC no action letter to use its emergency intervention powers on ICE even though over 60% of ICE U.S. delivered WTI futures trading is done within our own country. Rather than exercising real time emergency authority, the CFTC will have to once again "negotiate" with the FSA to have that U.K. regulator intervene to deal with, *inter alia*, ICE WTI trade matching systems located in Chicago, Illinois.

Moreover, relying upon the FSA to intervene on a real time basis for a "major market disturbance" on a U.S. delivered energy futures contract traded on U.S. terminals is as problematic as a matter of policy as it is as a matter of logistics. Unlike the robust emergency authority given by Congress to the CFTC under section 8a (9), the FSA emergency powers have been implemented in a quite lackluster fashion. While its governing statute affords intervention power[105], FSA makes clear on its web site that the U.K. has translated any such authority when "major operational disruptions" are detected on ICE, to a "Tripartite Standing Committee" that would convene the "Cross Market Business Continuity Group" (CMBCG) to:

> "provide[] a forum for establishing senior-level practitioner views . . . . Its role is advisory: decisions will be for the relevant official or market authorities or for firms themselves either individually or collectively through the agency of the CMBCG. The CMBCG may also have a role in pooling information to help facilitate private sector decisions and workarounds to alleviate pressures on the system."[106]

This U.K. guidance for sharing "views" and for "pooling information" in an "advisory" capacity to "help facilitate private sector" decisions in London is what the U.S. industrial consumers of crude oil and the U.S. gas consuming public are left to fall back upon when WTI

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[103] JOHNSON & HAZEN, supra note 42, at 1221-22.

[104] *See* Simon Webb, *OPEC hike unlikely at emergency oil talks*, REUTERSUK, (June 20, 2008), *available at* http://uk.reuters.com/article/oilRpt/idUKL2058919720080620 (last visited July 8, 2008).

[105] § 313(A), Financial Services and Markets Act 2000).

[106] *Developments in financial sector crisis management*, FSA Homepage, *available at* http://www.fsa.gov.uk/Pages/About/Teams/Stability/crisis/index.shtml (last visited July 8, 2008).

crude oil soon skyrockets to $150 per barrel as has been predicted by Morgan Stanley, one of the founders of ICE.[107] The CFTC's June 17 imposition of new conditions on ICE do not convert the U.K.'s lackluster emergency responses into the vigorous emergency responses called for by U.S. law.

Indeed, any effort by Congress to insist upon "comparability" on emergency powers is futile. As the *Financial Times* has so aptly commented on June 20, 2008, the U.K.'s futures regulator "operates a . . . system of 'credible deterrence' of wrongdoing by *engaging in a dialogue with market participants*. Since the FSA's creation in 1997, it has brought *no* civil or criminal cases in energy markets."[108] In stark contrast, as Acting Chairman Lukken recently proudly reported to Congress: "[s]ince December 2002 to the present time, the [CFTC] has filed a total of 39 enforcement actions charging a total of 64 defendants with violations involving the energy markets," having referred "35 criminal actions concerning energy market misconduct" to the Department of Justice.[109]

The contrast between FSA and CFTC enforcement activity in the energy futures markets under their control is quite remarkable, especially since ICE is responsible for nearly 50% of all crude oil futures contracts traded worldwide and since the CFTC has not had access to meaningful ICE data.[110]

The American gas consuming public's trust in the FSA might also be shaken by the U.K.'s response to the June 17, 2008 CFTC announcement of the imposition of new transparency requirements on ICE's use of U.S. terminals used as a critical part of ICE's control of over 30 % of the U.S. delivered WTI contract. Mr. Stuart Fraser, head of policy at the City of London Corporation, is reported in the *Financial Times* to have called the CFTC June 17 letter "American imperialism," and adding for measure "if a bunch of [S]enators want to get rude about the FSA, that's fine, but don't interfere in *our* market."[111]

Of course, the UK is wrong to think trading on U.S. terminals of the U.S. WTI contract is "their" market. ICE is U.S. owned, operated in Atlanta with trading terminals and engines in the

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[107] Tim Paradis, *Stocks decline in jobs data, surge in oil prices*, ASSOCIATED PRESS (June 6, 2008), available at http://ap.google.com/article/ALeqM5gHs5OM3gFG_DytQQZFbWfgPT08MAD914K0H80 (last visited July 8, 2008). Goldman Sachs, also one of the founders of ICE, has predicted that the price per barrel of crude oil will surpass $200 by October of this year. Neil King Jr. and Spencer Swartz, *U.S. News: Some See Oil at $150 This Year --- Range of Factors May Sustain Surge; $4.50-a-Gallon Gas*, WALL ST. J. (May 7, 2008) at A3; Greenberger, *supra* note 21, at 7.

[108] Jeremy Grant, *ICE restrictions cold comfort for FSA*, FINANCIAL TIMES (June 20, 2008) (emphasis added), *available at* http://www.ft.com/cms/s/0/2ba33a0e-3e35-11dd-b16d-0000779fd2ac.html (last visited July 8, 2008).

[109] Written testimony of Acting Chairman Walter Lukken, *Hearing Before the Senate Appropriations Subcommittee on Financial Services and General Government And The Senate Committee on Agriculture, Nutrition and Forestry* 4 (2008), *available at* http://www.cftc.gov/stellent/groups/public/@newsroom/documents/speechandtestimony/opalukken-41.pdf (last visited July 8, 2008).

[110] Intercontinental Exchange, Inc., Annual Report Form (10-K) at 63 (Dec. 31, 2007) *available at* http://www.secinfo.com/dsVsf.tU7.htm (last visited July 8, 2008) (showing that ICE's total crude oil futures market share is 47.8%).

[111] Jeremy Grant, *Storm over push for regulatory reform on positions at ICE*, FINANCIAL TIMES (June 20, 2008) (emphasis added), *available at* http://www.ft.com/cms/s/0/a00c6a00-3e62-11dd-b16d-0000779fd2ac.html (last visited July 8, 2008).

U.S. and trading over 30% of U.S. delivered crude oil futures market in U.S. dollar denominated currency.

However, one could easily see how those officials in the U.K. might mistakenly view WTI trading on U.S. terminals as "their" market when the CFTC and ICE continue to refer to this self evidently "U.S." market as being conducted on a "foreign" exchange. If the CFTC were to flatly state the obvious (*i.e.*, ICE Futures Europe is wholly owned by a U.S. concern, having brought the corpus of the old British International Petroleum Exchange, for all intents and purposes, to the U.S.). the UK might grasp the reality of the situation, rather than the ICE perpetuated "London" myth.

Deferring to Foreign Regulators Undercuts the Self Regulatory and Surveillance Requirements of U.S. Law.

Next to the inability to exercise the extraordinary emergency powers afforded the CFTC to oversee its markets by deferring to the foreign regulators to supervise U.S. energy futures products on U.S. trading terminals, the most serious problem with further CFTC or Congressional deference to FSA is the foregoing of the substantial self regulation and surveillance provided by U.S. regulated contract markets to assist U.S. regulators in policing futures markets.

The "core principles" within the CEA that must be followed by an approved U.S. regulated contract market emphasize the importance having those markets serve as the first line of defense for the CFTC in detecting fraud, manipulation, excessive speculation, and other unlawful trading malpractices.[112] Without aggressive self-policing of the entirety of the regulated U.S. futures markets, the CFTC simply cannot do its job.

The seriousness with which U.S. regulated markets take their statutorily mandated self-policing and surveillance role is evidenced by NYMEX's "standards and safeguards" concerning trade and market surveillance. For example, NYMEX makes clear:

> Market surveillance is required under CFTC regulations. Each day, the compliance staff compiles a profile of participants, identifying members and their customers holding reportable positions. In addition, daily surveillance is performed to ensure that Exchange prices reflect cash market price movements, that the futures market converges with the cash market at contract expiration, and *that there are no price distortions and no market manipulation. . . .*[113]

As to trade surveillance, NYMEX provides:

> Compliance department analysts are trained to spot instances of misconduct, including "front running" or trading ahead of a customer; wash or accommodation trading

[112] 7 U.S.C. § 7(d)(2)-(6) (2008); (2) (compliance with rules); (3) (contracts not readily subject to manipulation); (4) (monitoring of trading); (5) (position limits); (6) (emergency authority); 7 U.S.C. § 7a(d)(2)-(3) (2008); (2) (compliance with rules); (3) (monitoring of trading).

[113] NYMEX, Enforcement of Exchange Rules, *available at* http://www.nymex.com/ss_main.aspx?pg=6 (last visited July 8, 2008) (emphasis added).

(transactions creating the appearance of trading activity, but which have no real economic effect); prohibited cross trading (trading directly or indirectly with a customer except under very limited circumstances, or matching two customer orders without offering them competitively); prearranged trading; and non-competitive trading.[114]

NYMEX reports that is has @ $6.5 million budget for oversight market surveillance with an enforcement staff of @ 40 personnel.

No detailed analysis of ICE's self-regulatory and surveillance system is required. Suffice it to say, that for all of ICE's worldwide markets which are accessible by the U.S. trading terminals, including the U.S. WTI contract, reports are that ICE employs no more than ten individuals on its surveillance staff, i.e., a staff that is one quarter the size of NYMEX. This staff monitors trading of a host of ICE contracts, including those contracts which control over 47% of the world crude oil futures.[115] Of course, for those energy futures trades ICE executes under the Enron Loophole (because those trades do not derive from the old-IPE), such as the critical Henry Hub U.S. delivered natural gas futures contract, ICE, as of now, has *no* self-regulation or surveillance system.

Moreover, leaving ICE's paltry surveillance resources to the side, the principal regulator to which the CFTC is deferring to oversee directly over 30% of U.S. delivered WTI contracts, the U.K.'s FSA, has only "two full time supervisors," monitoring all of the ICE contracts under their jurisdiction.[116] Again, this includes 47% of world's energy futures contracts.

In sum, even though the CFTC has ratcheted up ICE's regulatory obligations by adding large trader reporting and speculation limits to the WTI trading, it defers to the FSA for the remainder of the oversight of ICE. In effect, this deference to the U.K. for U.S. trading of the critically important WTI contracts surrenders emergency authority to intervene when there are market dysfunctions to impose temporary margin requirements and position limits; and it sacrifices the real "eyes and ears" policing these markets (i.e., the regulated exchanges themselves) by depending upon ICE's meager surveillance systems.

In a time of economic distress for American industry and the American consumer caused by skyrocketing energy prices, this country cannot afford to outsource authority to the UK to oversee trading on 30% of our own U.S. delivered crude oil futures contracts, much of which is consummated on U.S. based trading terminals and all of which is trade matched in Chicago, Illinois.

It bears repeating that during last summer's subprime mortgage crisis, Northern Rock PLC, one of the U.K.'s largest banks, was required to borrow billions of dollars from the U.K.'s central bank.[117] After news of the bailout was released to the public, thousands of customers wary of losing their savings stood in long lines for several days outside of Northern Rock's

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[114] *Id.*
[115] *See supra* note 109 and accompanying text.
[116] Grant, *supra* note 108.
[117] *See Rock Expects £30bn Loan this Year*, BBC NEWS (Nov. 7, 2007), *available at* http://news.bbc.co.uk/1/hi/business/7073556.stm (last visited July 8, 2008).

branches to withdraw deposits.[118] With Northern Rock on the brink of collapse, the FSA provided over $100 billion in loans to the bank and in February 2008, the British government finally was required to nationalize it.[119] In March 2008, FSA published an internal report stating that its regulation of Northern Rock "was not carried out to a standard that is acceptable," and highlighted its own failure to provide adequate supervision, oversight, and resources.[120] In addition to FSA's self-criticism, in April 2008, the European Union opened a formal investigation into FSA's restructuring of Northern Rock.[121]

This episode, maybe more than any other, reveals that Congress cannot afford to leave direct oversight of trading on U.S. terminals of the most important futures contract in determining the price of oil, gasoline, and heating oil. As demonstrated above,[122] Congress has the full authority to pass legislation placing those U.S. terminals under U.S. regulatory control.

Threats that the U.S. reassertion of regulatory control over trading within the U.S. will drive trading overseas are undercut by the reality of every major futures foreign exchange having set up shop in the U.S.; and by the well documented law described above that even a foreign trader in a foreign country who illegally disrupts U.S. markets is subject to the full force and effect of that law.

Finally, contrary to the assertion of the City of London Corporation, this is not a "British" market; it is a U.S. market principally being traded in the U.S. by a trading entity controlled by a U.S. corporation. The economic distress now being suffered by Americans over high energy products cannot be placed in the hands of foreign governments when those products are traded here and have such a huge impact on our economy.

Conclusion

As can be seen from the above depiction of the need for aggressive oversight by the CFTC's over the full range of U. S. energy futures markets, there is a substantial prospect that the regulatory responsibilities imposed upon it by Congress will grow dramatically. If the CFTC is asked by Congress to increase its enforcement powers in this respect and if the CFTC accepts this new responsibility in a responsible manner, this Subcommittee will have to consider seriously expanding that agency's resources in a corresponding fashion. However, those resources should not be increased until it is fully understood that the CFTC will aggressively undertake any new roles assigned to it. It would be a mistake to give that agency additional resources if there is either no new work for it to do; or if it does not engage itself meaningfully in any new authority given to it.

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[118] *See Crisis Deepens for Northern Rock*, REUTERS (Sep. 17, 2007), *available at* http://www.iht.com/articles/2007/09/17/asia/17northern.php (last visited July 8, 2008).

[119] *See* Stephen Castle, *EU to Investigate Northern Rock Nationalization in Britain*, INTERNATIONAL HERALD TRIBUNE (April 2, 2008), *available at* http://www.iht.com/articles/2008/04/02/business/rock.php (last visited July 8, 2008).

[120] *See British Regulator Admits Failings in Oversight of Northern Rock, Announces New Procedures*, ASSOCIATED PRESS (March 26), 2008, *available at* http://www1.wsvn.com/news/articles/world/MI81198/ (last visited July 8, 2008).

[121] *See* Castle, *supra* note 119.

[122] *See supra* notes 41-60 and accompanying text.

Ms. DELAURO. Mr. Short.

Mr. SHORT. Madam Chairwoman DeLauro, Ranking Member Kinston.

I am Johnathan Short, senior vice president and general counsel of Intercontinental Exchange, or ICE. I very much appreciate the opportunity to appear before you today to provide our views on the energy futures markets, regulation of energy futures trading, and the role of speculation in these markets.

ICE is and always has been a strong proponent of transparent and properly regulated markets. As a public company our business depends upon it. ICE operates four separate lines of business, an OTC exempt commercial market through its parent holding company, and three regulated futures exchanges through three independent subsidiaries. Each of these regulated futures exchanges was an existing marketplace prior to its acquisition by ICE, and each of them has a separate governance and regulatory infrastructure mandated by their regulator in order to maintain their regulatory status.

Focusing on ICE's energy markets, ICE's ECM market, or exempt commercial market, was introduced in 2000 as the anti-Enron. It was a mini-to-mini marketplace that provided transparent electronic trading. Enron was a mini-to-one marketplace where Enron was the market. You traded with Enron; Enron traded with someone else. Enron also controlled the physical assets, and if you look at the California energy crisis, that is how Enron manipulated the California energy market, by withholding physical assets.

This is very important and ironic because the founder of ICE, Jeff Sprecher, was a California power plant developer who actually saw California's deregulation and saw that it was ripe for manipulation and thought that the better way to do this was on a mini-to-mini transparent platform like ICE. And he went out. He bought a company to prove his point. And I would note with some pride today that ICE is the only transparent part of the OTC market, and we take absolutely no positions in our market and do not control any physical assets.

Turning to our futures business, energy products are traded through ICE Futures Europe, which is formerly known as the International Petroleum Exchange. It is a fully regulated exchange headquartered in London, and it is a leading futures exchange outside of the United States.

ICE Futures Europe trades the benchmark Brent crude futures contract, which forms part of the complex that prices two-thirds of the world's crude oil, along with a West Texas Intermediate or WTI crude oil futures contract that is a financially settled derivative of the NYMEX futures contract.

ICE Futures Europe is a recognized investment exchange, and it is overseen by the U.K. Financial Services Authority, which is the equivalent of the CFTC in the United Kingdom.

Much has been said in the preceding weeks about the role of speculation in the crude oil futures market and what role trading in ICE's markets may be playing in determining crude oil prices. Some have improperly characterized ICE's markets as dark markets and have suggested that closing supposedly regulatory loop-

holes is the key to dramatically decreasing oil prices. Unfortunately, much of what has been said in this regard is factually inaccurate and unsupported by economic evidence, and furthermore, it is inconsistent with the following basic facts.

First, ICE Futures is a fully regulated exchange and, importantly, has been providing trading information regarding its WTI contract to the CFTC since April 2006, shortly after the launch of our WTI contract. As recently as June of this year, the director of enforcement of the CFTC publicly stated that the CFTC has seen no evidence of manipulative activity in ICE Futures WTI markets.

Second, trading in ICE Futures WTI contract comprises only 15 percent of the broader WTI trading market compared to the 85 percent of trading that considers on the NYMEX and has been steadily declining since prices began to spike last year, suggesting that there is little evidence that a London loophole is the root cause of recent increases in crude oil prices.

In any event, to the extent that there is concern that a London loophole ever existed, I think everyone would have to concede that it has been closed by the recent actions of the CFTC in modifying ICE's no action letter to impose accountability and position limited.

Third, ICE over-the-counter or OTC markets comprise approximately zero percent, I want to emphasize, again, zero percent of the OTC market for oil products, which are still predominantly traded through so-called voice brokers. Furthermore, the so-called Enron loophole for electronic OTC markets has been closed through provisions of the farm bill.

To be clear, Congress is right to examine trends in oil prices and to leave no stone unturned here. Unfortunately, however, we believe that the culprit here is an economic one. With markets driven by strong global supply and demand fundamentals and macroeconomic issues, such as the devaluation of the United States dollar, this view is supported by a plethora of economists and energy market experts, whom I cited in my written testimony.

In considering the proper level of speculation in futures markets, it is important to understand that futures markets are inherently speculative. They are attempting to predict the future price here of a global commodity anywhere from 1 month to 8 years into the future. Importantly, in trading futures contracts, speculators are not taking any physical crude oil off the market. They are simply attempting to predict what the future price may be based upon the best information available at the time, thereby serving as a very important early warning system for consumers and businesses alike about what the future may actually hold.

One of my co-witnesses here mentioned Friday, June the 6th, and the run-up in oil prices on that date. I just would like to point out that three separate events occurred on that date that were very significant. One was the European Central Bank raised interest rates, thereby further depressing the U.S. dollar. Another event, there was a Nigerian platform outage on that date. The third event was an Israeli government official said that war with Iran was inevitable.

When you want to think about properly operating markets and whether prices should rise on that news, consider what would have happened if Israel had actually bombed Iran the next day and the

Straits of Hormuz had closed. People that hedged their price risk at $138 that day would have been very pleased having done so because the price of oil would have shot through the roof.

In closing, ICE believes that Congress should proceed carefully in this area. If, as we contend, markets are accurately reflecting fundamentals, legislation aimed a diminishing speculative activity in the market could have the opposite of its intended effect, potentially making markets more volatile, driving energy prices higher, and making the cost of hedging more expensive.

I thank you. I would be pleased to answer any questions.

[The statement of Mr. Short follows:]

Atlanta Calgary Chicago Houston London New York Singapore

WRITTEN TESTIMONY OF JOHNATHAN SHORT
SENIOR VICE PRESIDENT AND GENERAL COUNSEL
INTERCONTINENTALEXCHANGE, INC.
BEFORE THE HOUSE APPROPRIATIONS COMMITTEE
SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,
AND DRUG ADMINISTRATION, AND RELATED AGENCIES
UNITED STATES HOUSE OF REPRESENTATIVES

Madame Chairwoman Delauro, Ranking Member Kingston, I am Johnathan Short, Senior Vice President and General Counsel of the IntercontinentalExchange, Inc., or "ICE." I very much appreciate the opportunity to appear before you today to provide ICE's views on energy futures markets, proper regulation of energy futures trading, and the role that speculative trading plays in these markets.

Much has been spoken and written in the preceding weeks regarding the role of speculation in the crude oil futures markets, and in particular, the allegations that speculation in ICE's crude oil markets may be having an upward price impact on West Texas Intermediate (WTI) crude oil. People have improperly characterized ICE's markets as "dark markets", and have suggested that closing so-called "regulatory loopholes" is the key to decreasing the price of oil. Certain people have even gone so far as to predict the exact percentage by which the price of a barrel of oil, a global commodity consumed, produced and sold around the world, will drop if only their legislative "silver bullet" is adopted.[1] Unfortunately, most of what has been said in this

[1] Testimony of I. Michael Greenberger before the Senate Committee on Energy and Commerce, June 3, 2008 (stating that legislation could drop oil prices 25-50% overnight), *see*, http://www.c-spanarchives.org/library/index.php?main_page=product_video_info&products_id=205797-1

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re gard is either factually untrue or unsupported by economic evidence. As I will elaborate upon below, such statements are also inconsistent with these basic facts:

- ICE is not a "dark market" – trading in ICE WTI futures contracts takes place on ICE Futures Europe, a fully regulated futures exchange. Importantly, ICE Futures Europe ***has been providing information regarding trading in its WTI contract to the Commodity Futures Trading Commission since April, 2006*** to allow the CFTC to fully monitor the WTI market, and as recently as June, the Director of Enforcement of the CFTC publicly stated that the Division of Enforcement ***has seen no evidence of manipulative activity in ICE's markets***.

- Trading in ICE's WTI futures contract ***comprises only 15% of the WTI trading market*** compared to 85% of trading that occurs on the New York Mercantile Exchange (NYMEX). In fact, ICE's share of the WTI market has been steadily declining since prices began to increase in May 2007.

- In over-the-counter or OTC markets, the so-called ***"Enron Loophole" has been closed*** by provisions of the recent farm bill legislation that was passed with bipartisan support in Congress. In addition, the inconvenient truth is that trading on ***ICE's OTC oil markets comprises approximately 0% of trading in OTC oil products,*** most of which is still traded through so called "voice brokers", and therefore ICE's OTC markets cannot be a source of any speculative premium in crude oil prices.

Importantly, misstatements and mischaracterizations of this nature mask the true problem that confronts us today. Energy futures markets are sending very strong and powerful signals about what our ***energy future*** will hold. These signals are vitally important to allow consumers and producers alike to adapt their behavior and realign supply and demand fundamentals for the future, and we are concerned that misguided attempts to "regulate speculation out of the market" could lead to unintended consequences and actually make matters worse for Americans in the long run.

Background Regarding ICE's Markets

As background, ICE was established in 2000 as an electronic OTC marketplace for trading energy commodities and OTC swap contracts. ICE was established to bring transparency to OTC markets that were traded at that time through opaque OTC voice brokers or through the flawed "one-to-many" Enron Online trading model. In the Enron model, Enron served as both the marketplace for trading and the counterparty to every trade occurring in the market. In stark contrast, ICE sought to develop a neutral "many to many" marketplace, in which we, the operator, take no position in the market while enforcing strict best bid/best offer trading protocols. ICE's electronic OTC markets have provided cost savings and efficiencies to participants while delivering an unprecedented level of OTC market transparency to both the Commodity Futures Trading Commission (CFTC) and the Federal Energy Regulatory Commission (FERC).

Since 2000, ICE has significantly diversified its business through acquisition. In addition to its OTC marketplace, which operates under the Commodity Exchange Act (CEA) as an "exempt commercial market," or ECM, ICE operates three regulated futures markets through three separate subsidiaries, each with a separate governance and regulatory infrastructure. ICE Futures Europe, formerly known as the "International Petroleum Exchange," is a 27-year old energy futures exchange headquartered in London that operates as a Recognised Investment Exchange, or RIE, and is subject to the oversight of the United Kingdom Financial Services Authority. In 2007, ICE acquired ICE Futures US, formerly known as The Board of Trade of the City of New York, or

NYBOT, a 137-year old exchange trading futures contracts in soft commodities, currencies, and equity indices; ICE Futures US is a Designated Contract Market (DCM) regulated by the CFTC. Finally, in late 2007, ICE acquired ICE Futures Canada, formerly known as the Winnipeg Commodity Exchange, a 120-year old futures exchange headquartered in Winnipeg, Manitoba which specializes in agricultural futures; ICE Futures Canada is regulated by the Manitoba Securities Commission. Importantly, each of these markets is separately operated, with majority independent boards at the subsidiary level.

ICE's Energy Markets

Suggestions by parties that ICE's markets are "dark markets" or that trading occurs out of London to obtain a regulatory advantage are fundamentally misguided. ICE has always been a proponent of transparency in trading markets, and has worked with regulators in both the United States and the United Kingdom to insure that regulators have access to any information that they need to monitor trading markets.

ICE Futures Europe, the market upon which ICE's WTI futures contract is traded, is a fully regulated futures market, with comparable principles-based regulation to that of a U.S. designated contract market. ICE Futures Europe has detailed exchange rules to prohibit misconduct, with which members must comply, and has a robust market monitoring program. Importantly, since the launch of ICE Futures Europe's WTI crude oil contract in February, 2006, ICE Futures Europe has provided the CFTC with trading information that the CFTC has requested to permit the CFTC to monitor the broader

market for trading in WTI crude futures contracts. ***Today, ICE has a relatively small 15% share of total WTI futures and options open interest, while NYMEX retains the remaining 85%.*** It is important to note that as recently as June, the Director of Enforcement of the CFTC publicly stated that the Division of Enforcement ***has seen no evidence of manipulative activity in ICE Futures Europe's markets.***

Furthermore, on June 17, 2008, the CFTC announced an amendment of the conditions under which ICE Futures Europe is permitted to operate through direct screen-based access in the United States. In addition to formalizing expanded information sharing arrangements the ICE Futures Europe had voluntarily agreed to in May, 2008, the amended letter conditions direct screen access on ICE Futures Europe's adoption of equivalent U.S. position limits and accountability levels on the ICE WTI futures contract. In addition, ICE Futures Europe will provide information to the CFTC that will allow trading data on ICE Futures Europe's markets to be incorporated into the CFTC's Commitments of Traders report, its weekly report on the level of commercial and speculative activity in a given market.

Likewise, suggestions that ICE's OTC trading markets are somehow to blame for high oil prices are similarly misguided. ***ICE's OTC oil markets have virtually no trading volume, comprising approximately 0% of trading in OTC oil products***, most of which is still traded through so called "voice brokers". It is therefore difficult to see how a lack of regulation of trading in oil products in ICE's electronic OTC markets could be the cause of any speculative premium in the price of oil. Furthermore, and contrary to the

statements of some, the so-called ***"Enron Loophole" has been closed*** by provisions of the farm bill legislation that was passed with bipartisan support in Congress. This legislation applies to oil products traded on ECM markets, and to the extent any such product serves a significant price discovery function, such contract would be subjected to regulation that is comparable to the regulation applied to fully regulated domestic futures exchanges.

Futures Markets Are Inherently Speculative Markets

Speculators are essential to futures markets. Speculators provide liquidity to markets, offering to assume the risk that other market participants want to sell. Speculators also make the cost of hedging in a market cheaper by tightening the bid/offer spread, bringing valuable views to the marketplace from a variety of sources. The result is lower transaction costs, greater price transparency, and the accordant risk reduction. In addition, speculators typically operate on both sides of the market (long and short) and are price neutral, looking to make a profit whether the price of commodity is rising or falling.

In considering the role of speculators in futures markets, it is important to understand that unlike other types of markets, futures markets are inherently speculative markets – because they are attempting to discern what the ***future price of a commodity will be.*** In one sense, it could be argued that futures markets are 100% speculative in nature in that each market participant – whether a commercial entity with an exposure to the underlying commodity or a financial market participant out to make a profit – is

taking a view of ***what the future will be***. Since nobody can accurately predict the future, this should fundamentally shape the debate about speculative activity in futures markets.

In addition, unlike a physical or cash market, where somebody is buying a physical asset (a physical barrel of oil, a share of stock, even a house for investment purposes), nothing is being bought or "taken off the market" today when a futures contract is bought or sold in a market. With most futures contracts positions being traded out of prior to contract expiration, no physical assets are being hoarded through the purchase of futures contracts, and equal and opposite buying and selling signals are sent to the market over time.[2] It is in this manner that futures market prices (people's view of what the future price of a commodity will be) ultimately converge with the physical or cash market for the underlying commodity (what the spot price of oil at Cushing, Oklahoma may be during a given month), with the latter being driven by supply and demand fundamentals at a particular location at a particular time.

Market Fundamentals – What the Markets are Telling Us About the Future

Recently, in testimony before the Congress, it has been suggested by some that "speculators" are the primary or significant driver of the price of oil in today's market. Most people who have taken this position have offered scant economic evidence to support their contentions, and have taken positions that have conveniently ignored significant market fundamentals and other economic conditions that have existed in the markets during this time of increasing prices over the past year.

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[2] *See, e.g., Introduction to Futures and Options Markets,* Institute for Financial Markets (IFM) http://www.theifm.org/tutorial/contracts2.htm.

Importantly, views that speculators are the primary driver of today's oil prices appear to be diametrically opposed to the views of noted economists and market experts alike[3]. The rise in the price of oil over the past year has been driven by a number of factors. First and foremost are supply and demand fundamentals – oil is a global commodity, and we live in an age in which there has been almost insatiable demand from emerging markets such as China, India and the Middle East, combined with diminishing supply from existing sources. This has led to a market with very little in the way of a supply cushion, and which responds to supply interruption events – or the threat of such events -- very quickly.

The International Energy Agency, in its *Medium-Term Oil Market Report,* states that global oil product demand is expected to grow by 1.6% per year on average over the next five years, primarily driven by growth in developing countries. The report notes that demand growth remains heavily concentrated in developing countries, where total consumption will nearly reach parity with mature economies by 2015. Asia, the Middle East and South America will account for nearly 90% of global demand growth over the next five years. On the supply side of the equation, oilfields worldwide are declining in production, especially given the underinvestment in energy infrastructure that has been caused by prior price collapses. Just to hold world production steady, over 3.5 million

[3] *See, e.g.* Henry Paulson, Secretary of Treasury; Samuel Bodman, Secretary of Energy; Dr. Daniel Yergin, Cambridge Energy Research Associates; Dr. James J. Angel, Professor, Georgetown University; Dr. Jeffery Harris, Chief Economist, Commodity Futures Trading Commision; Dr. Simon Johnson, Chief Economist, International Monetary Fund; Philip K. Verleger, energy market expert; Dr. Paul Krugman, Professor, Princeton University and New York Times columnist; Warren Buffet, investor; T. Boone Pickens, investor; Robert J. Samuelson, economics columnist, Newsweek; U.S. Energy Information Administration, June 10th Petroleum Outlook; International Energy Agency, *Medium-Term Oil Market Report* (July 2008).

barrels per day of new production is needed.[4] However, this new production, if it is possible, will come at a steep price. Costs of new production today are double the cost of new production four years ago.[5]

Furthermore, many of the countries that supply oil to the U.S. are in unstable parts of the world, making production challenging at best. The Nigerian delta, home to Nigeria's oil production, is currently very unstable, with oil field workers subject to a "very high risk of kidnapping, robbery, and other armed attacks."[6] Many other oil producing countries, such as Venezuela or Equatorial Guinea, are openly hostile to the United States. The cost of future production from these countries is calculated into the price of oil traded in futures markets.

Macroeconomic factors are also greatly affecting the price of oil. The devaluation of the dollar in world currency markets cannot be underestimated. Oil is priced in dollars, and the value of the dollar has decreased significantly over the last several years against a variety of world currencies. This trend has been exacerbated by actions that have been taken by the Federal Reserve in cutting interest rates in an effort to stimulate the economy. In recent testimony before the Senate Committee on Homeland Security and Governmental Affairs, Dr. Benn Steil of the Counsel on Foreign Relations submitted testimony showing the price of oil in Euros – while the price increase was significant, it

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[4] International Energy Agency, *Medium-Term Oil Market Report,* July 2008. (https://www.oilmarketreport.org).
[5] Cambridge Energy Research Associates, Special Report *Capitol Cost Analysis Forum—Upstream Market Review*, May 2008.
[6] http://www.travel.state.gov/travel/cis_pa_tw/tw/tw_928.html

was not nearly as steep as the price of oil in dollars. Even more dramatic is the price of oil plotted against the price of gold, which showed little in the way of price inflation.[7]

Against this backdrop, buyers and sellers of futures contracts are taking views on what the ***future price*** of oil will be. As noted above, unless they are purchasing physical oil in the cash markets, speculators are not taking physical oil off of the market that would otherwise be consumed. This leads to the uncomfortable conclusion that futures markets are likely reflecting what we all know to be true – that as a country, we have an oil problem (we consume too much and we produce too little), and to date we have not convinced the market that we have either a supply or demand solution for that problem. While we dislike the high price signals currently being sent by futures markets, it must be understood that these signals lead to fundamental changes in behavior that bring markets back into balance. Congress should be cautious in attempting to regulate the level of speculation in efficiently operating markets, as steps in this regard could lead to unintended consequences such as greater price volatility, making matters worse for Americans in the long run.

Conclusion

ICE has always been and continues to be a strong proponent of open and competitive markets in energy commodities and other derivatives, and of appropriate regulatory oversight of those markets. As an operator of global futures and OTC markets, and as a publicly-held company, ICE understands the importance of ensuring the

[7] http://www.cfr.org/publication/16311/

utmost confidence in its markets. We further believe that legislative action should be guided by facts and reasoned study rather than the "hope" that legislation will fix what is fundamentally an economic problem.

Madame Chairwoman, thank you for the opportunity to share our views with you. I would be happy to answer any questions you may have.

Ms. DELAURO. Thank you, Mr. Short.

And thank all of you for your testimony.

ENRON LOOPHOLE

I am going to see if I can open with several folks here. What I want to do is look at the Enron loophole.

And Chairman Lukken, let me just start with you.

And Mr. Short, both you and Acting Chair Lukken believe that the loophole has been closed.

But to the Chair let me just say this, critics of the farm bill alleged that the act has not sufficiently closed the loophole because it requires the CFTC to make determination of which contracts on ECMs need to be regulated on a case-by-case basis. Therefore, what happens is the burden of proof winds upon being on the CFTC and not on the industry.

Under the farm bill, you have up to 6 months to issue a proposed rule to implement the new provision, another 3 months to issue a final rule, then up to 6 months to complete reviews of electronic trading facilities that may have contracts performing significant price discovery functions. The farm bill was enacted May 22nd this year. So we could be looking at 14 months until you really make your findings that would lead to an actual closure of the loophole.

This is a year and a half until we get to some sort of a conclusion. What are you doing to expedite this? When will your proposed rule be published in the Federal Register for public comment? What target date have you set for issuing the final rule?

I will repeat those because I want to get in another piece here. There appears to be public statements by CFTC that say that the language would apply only to ICE's natural gas contracts. And further, well, if you are going to work with the farm bill on a contract-by-contract basis, sounds to me like an overwhelming task you are dealing with here, and can you tell us about how many contracts that we are talking about?

And then with regard to the farm bill, it is my understanding that you made it clear that you will not cover any U.S. future contracts relating to the price of U.S.-delivered commodities traded on the U.S. terminals of foreign exchanges operating pursuant to your no-action letters.

So if you would just talk about the rule, when you plan to do that, and if you could just talk about the, you know, your comments with regard to what you will cover and not cover.

Mr. LUKKEN. Certainly, we are trying to beat congressional deadlines in this area. Congress did provide us 180 days to come out with a proposed rulemaking. We are working feverishly to try to expedite that. Hopefully it is much quicker than that. I wish I could give you a certain date, but these are the same people that are also looking at the swaps information that is coming in, trying to put the foreign boards of trade information that is coming in. This is all being handled by our Division of Market Oversight. So we are working to try to do this in a very expedited manner so that we don't have to wait the 14 months, as you outlined.

Ms. DELAURO. Five months? Six months? Eight months? Ten months?

Mr. LUKKEN. Again, this is congressional timetables, but we are trying to beat this so that we are able to do this much more quickly.

I think the contract that was of concern when this was developed was the look-alike natural gas market that is listed on ICE's exempt market in Atlanta. We are certain this is something that is going to be a part of this new regime. And so we are looking at ways to expedite those that we are certain that these contracts are going to be part of this new oversight regime.

But it is not limited only to natural gas. Any product that is traded on an exempt commercial market that is either linked or somehow a price-discovery market that develops, we will regulate in this manner. So it is neutral in regards to any type of exempt product.

Ms. DELAURO. Professor Greenberger, again, Mr. Lukken and you just heard Mr. Short testify that the farm bill closed the Enron loophole. You maintain that it is still open, and you have two main criticisms, as I understand it from your testimony of the bill, that it puts the onus on the CFTC to regulate and that the 15-month issue is of concern.

Why are you concerned about the CFTC using its discretion to identify appropriate contracts of ECMs?

Mr. GREENBERGER. Well, when the Enron loophole went into effect on December 21st, 2000, the rule was that all energy futures contracts had been to be traded on a regulated exchange. So I would have thought, if you were going to close the Enron loophole, that you would go back to where you were on December 20th, 2000, and say that all energy futures contracts are going to be traded on a regulated exchange.

That is not what happened. What happened is the close the Enron loophole on the farm bill says that the CFTC in its discretion can re-regulate an energy futures contract if it can show that it has a, quote, significant price discovery function.

So ICE, when it testified in front of the CFTC, said they have thousands of contracts. Now my understanding is, I have read two statements by Mr. Lukken, and I read what Mr. Sprecher said before Mr. Lukken said anything, and they said the Henry hub contract on their unregulated United States exchange should be subject to significant price discovery—should be significant price discovery and re-regulated. Well, natural gas has nothing to do with petroleum.

Now, Mr. Short says, oh, but there are zero petroleum contracts being traded under the Enron loophole. I would dispute that from a general thing, but there are lots of bilateral standardized contracts being negotiated on a daily basis. As we sit here, there are hedge funds in investment banks in New York using standardized agreements to trade energy futures. On December 20th, 2000, those would have been regulated. Today they are not.

So we went from a posture of all futures contracts; what did that mean? That means position limits. That means large-trader data reporting. That means they have to have their own self-regulatory organizations, which is very important because they police wrongdoing. That means the CFTC would have had clear emergency authority over them.

But now we are going through, and my reading of the legislation is they have 270 days to do their general rule and then 180 days to apply it. I came up with a 15–month period. If I am wrong about that, I certainly want to know about it. But anyway it is going to be a long time. That is September 2009. What is Mr. Devine's people going to do until September 2009? And then it won't affect heating oil.

Mr. SHORT. Could I——

Ms. DELAURO. Yes, you can.

I also want to get Dr. Cooper in here.

Go ahead, Mr. Short, go ahead.

Mr. SHORT. A couple of points. First, ICE is actually not even awaiting the final rules that are going to be promulgated by the CFTC on this issue. We are actively working on implementing the systems today so that when the rules come out, we won't be in a situation where we are waiting for 15 months. That is the first point.

The second point about the coverage of contracts traded on ICE, trading in the contracts that we expect to be significant price discovery contracts will cover about approximately 90 percent of our traded volumes. The other contracts that we are talking about are illiquid swap markets for which we compete with telephone voice brokers and other people in the bilateral markets that don't serve a significant price discovery function. They are not linked to a designated contract market, or the cash markets aren't basing their prices off of them.

I think that is a very important distinction that Professor Greenberger has overlooked. I would also point out that his suggestion that we go back do the status quo ante of, what happened before the CFMA, I think there were plenty of people trading these contracts pursuant to exemption letters before the CFMA. And I also think that the CFMA has brought very valuable market benefits. Exempt commercial markets are electronic. They are transparent. There is a digital record of every trade that occurs on them. The CFTC can call in that information and look at it any time they want. They get weekly transaction reports from us on trading information.

To suggest that the CFMA was a bad thing I think was wrong because it has led to some positive things like the introduction of clearing for OTC swaps, and that is one of the problems that Mr. Lukken alluded to previously about Bear Stearns. If there had been a market where there was a clearable credit default product, maybe Bear would not have gone down. These are all very positive attributes that I think Professor Greenberger is overlooking.

Mr. GREENBERGER. I would just like to respond, Madam Chairwoman.

First of all, which ICE are we talking about here? Are we talking with ICE United States? Are we talking about ICE Futures Europe? Are we talking about ICE Futures United States? When Mr. Short says, oh, "we," he is talking about the Atlanta headquarters and their natural gas contracts. What about the WTI contracts on ICE Futures Europe?

Mr. SHORT. Absolutely, let me address that.

Mr. GREENBERGER. Mr. Short, if you would let me finish, I will let you talk.

If you the let me finish, Madam Chairwoman.

ICE Futures Europe a wholly owned subsidiary of ICE, which is located in Atlanta. It is run by ICE. It has U.S. Trading terminals in the United States. Its trading engines are in the United States. It is trading 30 percent of our West Texas Intermediate contract. It took 30 percent away from the regulated exchange. It is trading them in U.S.-denominated dollars, and the close the Enron loophole does not address that.

Now, when Mr. Short says, oh, we are providing all of this information to the CFTC, I wonder is it ICE U.S., or is it ICE Futures Europe? ICE Futures Europe, because of Mr. Lukken's actions on June 17th, will now start providing. I don't know where the information was in 2006, if Mr. Lukken is asking for it on June 17th. But even more important, Mr. Lukken had to negotiate—that is the words I believe that were used—with the United Kingdom's Financial Services Authority to get this information about our trading terminals wholly owned by a United States subsidiary with trading engines in Chicago trading 30 percent of our West Texas Intermediate contract.

Now, is that a wholly transparent situation? Up until June 17th—and by the way, the FSA has not agreed that they will do this—that information was not coming to our customers. I think we have to be clear which of these ICE subsidiaries we are talking about.

Mr. SHORT. I would absolutely like to answer that factually, because Professor Greenberger is again mischaracterizing the facts. First, I was, in fact, referring to ICE's OTC markets when I just spoke, but there is a separate market, ICE Futures Europe, as I indicated in my testimony. It is a fully regulated U.K. Futures exchange, independent governance, mandated by the Financial Services Authority. That market does come into the United States for direct market access pursuant to the no-action regime, and we are providing additional information to the CFTC on an expanded basis pursuant to the modifications they made to the CFTC no-action letter.

But factually, there are mischaracterizations that are occurring here, and if you don't believe me, please look at the Senate Permanent Committee staff rebuttal on the factual inaccuracies that we have had in the——

Ms. DELAURO. I have—I have, I have, Mr. Short. I have read it carefully, and I also read Professor's Greenberger's response to each of those questions.

So I am going to ask my colleague, Mr. Kingston, I would just like to get Dr. Cooper here for a second. And then, Jack——

Mr. COOPER. Let me pick up on a different point.

I mean, they have debated this question—it is quite clear the CFTC did not have enough information for years and years, and in the last month, they discovered that the FSA is not properly regulating that market. They want them to have a speculative limit and accountability, which they did not have before. Let's be clear. So for years when they said, hey, they have equivalent regulation, they did not have it.

Let me make a different point. Enron was the darling of the traders because they were an asset-lite corporation. They loved the idea that you did not have to have any assets in order to play this humongous game. They had a book with three-quarters of a trillion dollars with nothing behind it.

Bear Stearns, it turns out, as Mr. Greenberger suggested, might have been an asset-too-lite corporation. They were selling insurance without the backing of the necessary capital reserve. So one of the things that we talk about is capital reserve requirements here and margin limits, which are sucking money into this market and sucking it out of the stock exchange.

Let's be clear. Money goes where it is easy, where it is not regulated, where it is not asked to do much. And that is what has happened in these commodity markets. It is too easy for money to get there, so they don't have to try and work hard to build real productive assets. It is all paper, and it is sucking the money out of the rest of the economy.

Ms. DELAURO. Quick question. Is it 15 percent or 30 percent of the WTI?

Mr. SHORT. It is approximately 15 percent when you consider options and their convertibility into futures. I don't think Mr. Greenberger's statistic took into account options that ultimately, on an as-converted basis, would determine the overall market share. It is approximately 15 percent.

Mr. GREENBERGER. I have cited the information. I have cited the 30 percent figure. Everybody is operating, and ask Dr. Newsome of NYMEX what the figure is. This business was taken away from his regulated exchange. He uses the figure 30 percent. They have 50 percent, 47.8 according to their last 10(k), of all the world's futures markets. And how many people do they have surveilling that? Ten people. How many does Dr. Newsome have surveilling that on his exchange? Forty people. He spends $6.5 million to surveil trading ahead of customers, wash trades.

The FSA, which regulates ICE Futures Europe, wholly owned by ICE, has never brought an energy futures enforcement action since it began being a regulator.

Mr. SHORT. Again, Mr. Greenberger is just wrong.

Mr. KINGSTON. You know, this is very interesting.

I will say I am—I join Mr. Short being disturbed about Mr. Greenberger's testimony. I mean, this is a bipartisan rebuttal of your testimony. Bipartisan. And it is very specific on statements that you made and very thorough saying why it is not true.

Mr. GREENBERGER. This is my response to it, and I will tell you Mr. Kingston——

Mr. KINGSTON. I have not seen it.

Mr. GREENBERGER. No, I know you have not, but I will tell you——

Mr. KINGSTON. I am not yielding quite yet to you, but I will yield to you.

Have they accepted that response.

Mr. GREENBERGER. Chairman Peterson of the Agriculture Committee asked me to give him a response today.

Now, let me tell you, Mr. Kingston, go look for that bipartisan thing on their Web site. It is not there. I understand what you are

saying. My, what I understand is, that there are feelings that maybe that should not have seen the light of day. It is not on their Web site, and I certainly didn't want to join in the thing. But I would encourage you to look at what I say.

Mr. KINGSTON. Let me say this. I will do that, and I would not say putting something on the Web site is the gold standard either. But this is not just a page or two; this is pretty thick.

Mr. GREENBERGER. Well, this is a pretty thick response.

SPECULATION IN PRICE OF OIL

Mr. KINGSTON. And you know, the thing I think we have kind of gotten away from in this hearing because there are so many technical things. You guys have built careers learning this stuff. What my question is, is clarity on are speculators driving up the price of oil?

And I wanted to say one thing, that I read an article in—well, it was on the Web, from CNN Money, and it said today the number of paper barrels of oil traded on the NYMEX is over three times the number of physical barrels consumed worldwide.

And I was wondering if Mr. Short, Mr. Lukken, or anybody wants to respond to that.

Mr. LUKKEN. In risk-management markets, anybody who handles one barrel of oil has risk potentially from the person that is bringing it out of the ground, to the person who is shipping it, the person who refines it, to the person who consumes it ultimately. All of those people, those four or five people have risk involved with the price of that one barrel of oil. So naturally you are going to have multiples of the physical market. And certainly these are financial markets. They are not consuming. They are not taking a single barrel of oil off the marketplace.

So lots of information comes into the market through speculators and other participants to make sure that we are trying to find the right price. But the natural tendencies of these markets are to be a larger factor than the underlying crude oil markets.

Mr. KINGSTON. Let me ask this question, because I want to tie it to Mr. Devine on the Black Friday situation, which you gave three reasons, Nigeria's platform and so forth, tie this into that, because it does seem to me that he is so vulnerable now. Why wasn't he so vulnerable 5 years ago?

Mr. SHORT. I think what you saw on so-called Black Friday was a properly operating market. I think you did see the market come back down after the market had digested the news. But importantly and in particular, if one of those events had played out, you would have had a situation where the price would have probably gone up in the market, and you know, the ability to hedge at that price on that day, not withstanding it was $12 higher than the prior day, was good.

I wanted to circle back on the issue of overall trading volumes. I think when you cite a statistic like, look the at overall trading volumes compared to the underlying barrels of oil consumed in the country, it does not get at the issue, because a lot of that trading volume is intraday, making markets tighter. It is making markets tighter for commercials to come into the market and hedge at the cheapest price. It is not directional driving the prices up.

You may have a bunch of speculators going between $136.10 a barrel and $136.12 a barrel, constantly shrinking that market and making it as tight and liquid as possible. So I would hope no one would take that statistic and say, ipso facto, there must be a directional correlation in the price of oil.

Mr. COOPER. There is a directionality there. Let's be clear. Every one of these transactions costs money. Because these guys don't trade this stuff for free. They get a vig. They want a percent of that. When they increase the risk, they want their risk covered. So let's be clear, all of those transactions are not free. They increase costs. Liquidity ain't free. It is very expensive.

And that ends up—that is where Morgan and Goldman Sachs make their money. They charge for all these transactions, and they get it as a percentage of the total price. And darn it, the higher the price, the more they make. That is a heck of a coincidence.

Mr. KINGSTON. Madam Chairman, I want to get back to the 5-minute rule, but we have some very spirited witnesses here. So I hate to—I think it would be nice to have Mr. Short respond to that, but I do want—if you could do it in 20 seconds.

Mr. SHORT. Just very quickly, ICE does not get paid on the value of the underlying asset. I want to make that clear. It gets a flat fee. So whether the value of the underlying goes up, down, it does not make any difference to us. I would say that there are a lot of speculators out there who are pure liquidity providers. They are trying to capture those price increments, and it is not always Goldman Sachs or Morgan Stanley. It is true; I mean, if you are working with an investment bank, it is true they are making a profit off of this. But they are providing a service for that profit.

Ms. DELAURO. Mr. Bishop.

Mr. BISHOP. Thank you, very much.

CONSOLIDATION OF THE SEC AND CFTC

I have enjoyed this very spirited discussion. And I would like, Mr. Cooper, all of the witnesses, with the exception of Mr. Lukken, who I have already asked a question regarding the consolidation of the SEC and the CFTC, I would like to address it to the other four witnesses to find out how you feel about it as well as the self-regulation question.

That is, Mr. Paulson's plan to combine the SEC, which regulates equities and debt markets, with the Commodities Future Trading Commission, which regulates trading commodities and financial futures, with the different regulatory approaches that they have, what would your position be on the mergers? I would like to ask each of the four panelists other than Mr. Lukken's position.

And I would also like to ask whether or not, as I asked Mr. Lukken earlier, the CFTC, whether that traditional delegation of its regulatory oversight has really worked? Or whether or not we should move to more direct regulatory and oversight control?

Mr. SHORT. I don't profess to be an expert on the Treasury blueprint. I mean, certainly you can make a pretty strong argument that you do see convergence in financial markets. I think the real problem here is that we have probably had an underfund CFTC strained for resources. And I would in particular be afraid of losing some of the CFTC's expertise in these very complex derivative mar-

kets, because I think one thing that has been shown today by the testimony before this committee is, this is a very kind of inside baseball type area. And I would be afraid, if they were subsumed within SEC, some of that expertise might be diluted.

Mr. BISHOP. So you agree with Mr. Lukken on that?

Mr. SHORT. I do.

Mr. BISHOP. Professor Greenberger.

Mr. GREENBERGER. I want to make clear that I have studied Secretary Paulson's recommendations, and his recommendation—I think I am right about this, Walt—is that the CFTC be merged into the SEC but the SEC follow the principles-based regulation of the CFTC. As far as I am concerned, that is pushing the SEC into the CFTC and not the other way around.

Now, this principles-based regulation comes out of the thesis of the way the Financial Services Authority in England operates. And in March 2007, there was a lot of push from Wall Street that the United States should regulate the way the Financial Services Authority regulates in London. Now that agency, and I have got it in my thing, they basically regulate by conversations. For example, in the energy markets, they have not brought since 1997 an enforcement action. Mr. Lukken proudly says that his agency has brought 39 and referred 35 to the Justice Department in that same period.

Wall Street would love to be regulated by the Financial Services Authority. Now the Financial Services Authority is in a big hole right now, and this is the reason why. They oversaw the need to nationalize the fifth largest bank in the United Kingdom, Northern Rock. The Financial Services Authority is the equivalent to the Treasury, the SEC and the CFTC. Northern Rock had billions of U.S., in equivalency, U.S. dollars poured into it to save it from its subprime crisis. And finally, they had to nationalize the bank.

The FSA has done a self-regulatory study and said, we dropped the ball. The European Union has started an investigation of the FSA. So when Mr. Short says, our ICE Futures Europe, our wholly owned subsidiary, which really isn't here but is in London, is, quote, fully regulated, they are fully regulated by the FSA. I think with those terminals in the United States trading 30 percent of our product, they should be fully regulated by the CFTC.

So I am not supportive of these recommendations because the bottom line is, it is to deregulate, not to have further regulation, in my book.

Mr. COOPER. Frankly, now is the moment to restore prudential regulation across a number of sectors. Neither of the agencies you talked about have done a very good job in the last few years. We have a mess here. Merging them will not solve the mess. It will simply make it harder to see what is going on.

That does not mean they shouldn't cooperate. Certainly in our analysis of the natural gas spiral that I did for four attorneys general in 2006, we concluded that the ability of certain entities to straddle all of these markets made it very difficult for regulators to know what was going on, so they should cooperate.

But, frankly, we think each of them should be individually strengthened, and absolutely we need a return to direct regulation. Because each of these little loopholes that have been mentioned

here, which were created in the 1990s and expanded dramatically in 2000, have now swollen to overwhelm these markets.

So the indirect regulation, the self-regulation, is where all the action is. That is where all the money goes. We have to squeeze that bubble back down and get back to solid, sound prudential regulation of these commodities.

Mr. BISHOP. Mr. Devine.

Mr. DEVINE. Thank you.

I, too, believe that we don't need too much regulation, but I do believe, and I do believe that the CFTC should be funded and have the authority for direct regulation. And I believe, unfortunately, it is at this point in time, after sitting here and following what is going on for quite a while now, I think it is up to you to put the pressure on the CFTC to exert their authorities. Because I fail to see that it is happening. I don't see that it is happening. But I do believe that they ought to be a stand-alone organization. I don't believe that there should be too much oversight of them.

Mr. BISHOP. You don't believe that there should be too much oversight of them?

Mr. DEVINE. Of the CFTC. I think the CFTC ought to exert the authorities that they have. But I do believe that you, Congress, need to look at them and say, you guys have got to step up.

Mr. BISHOP. So you don't think the merger is a good idea?

Mr. DEVINE. I do not. No.

Mr. BISHOP. Thank you.

My time is up.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you, Madam Chair.

OIL FUTURES

Mr. Lukken, I was interested in your earlier comment about the—in exerting your authority and the budget that we have approved for that, and the new additional responsibilities in the farm bill, of the $5 trillion, approximately $5 trillion, that flows through the exchange daily, what percent of that flow goes into the oil futures?

Mr. LUKKEN. I think, on a percentage-wise, our markets are 85 percent financial. I think roughly 10 percent—let me make sure I have this right. I think 85 percent are financial products. And roughly 7 percent are agricultural, and the remaining are energy. If that adds up. Is that about right, 8 or 9 percent energy? I think that is approximately about the right percentages.

Mr. FARR. Is 10 percent all energy, or is that—I mean how much of that is natural gas, electricity? Are they all lumped together?

Mr. LUKKEN. They are all lumped together. So I think crude oil is the largest of those contracts. Natural gas is probably second.

Mr. FARR. And if the mission is to protect the public from manipulation, do you also look into whether, for example, the oil companies are manipulating by keeping the oil in the ground?

Mr. LUKKEN. In May, we announced an ongoing enforcement investigation into crude oil products which includes us looking at physical storage, pipelines, and all the cash over-the-counter as well as the futures markets.

Mr. FARR. What about just sitting on the leases that they have, the Federal leases, offshore and onshore leases?

Mr. LUKKEN. We haven't limited ourselves in what we are looking at.

Mr. FARR. So you are looking at that, at whether—they have paid for these leases. They have 38,000 acres of leased land that they are not doing anything on.

Mr. LUKKEN. We are certainly looking at whether people are hoarding oil or keeping oil off the markets to intentionally manipulate the markets.

Mr. FARR. When will you know that?

Mr. LUKKEN. It is ongoing. We hope to have results as quickly as possible.

Mr. FARR. How about the impact of the things like the Arab oil embargo and other kinds of hoarding or withholding?

Mr. LUKKEN. I don't think we have the ability to go after government entities; the CFTC does not.

Mr. FARR. No, but you have the ability to discuss—maybe it isn't your responsibility, maybe it is the Energy Department, I don't know where it comes from—but the information about how much oil would be on the market if there wasn't this embargo.

Mr. LUKKEN. We certainly talk with DOE about what we are seeing and what they are seeing. They are part of this task force that is looking into the supplies of crude oil as well as other commodities. We are always in discussions about that. And the participants in our markets are trading futures contracts.

Mr. FARR. You are looking at refining capacity, oil line capacity, infrastructure capacity to see whether that is being fully utilized?

Mr. LUKKEN. We are looking to see if anybody is intentionally utilizing any movements of oil to manipulate prices.

Mr. FARR. We have this dentist mentality around there that everybody is talking about drill, drill, drill. And I wonder if in fact there is manipulation of oil not being drilled that could be, of refining capacity that is not being used that should be, of pipeline capacity that is not being utilized. We ought to get that information out before we just lose it.

Mr. LUKKEN. I think that is something that DOE closely follows but certainly something that we would be interested in as part of this investigation.

Mr. FARR. I am just curious as to how much time it is going to take to get that information. It is the mantra of some people here in Congress. I would like to refute that mantra with some good data. So?

Mr. LUKKEN. Certainly. We are working as fast as we can. These are complex cases. They require resources, and if we find something, we will bring it as quickly as we can.

Mr. FARR. Well we have another call.

Thank you.

Ms. DELAURO. I am going to try to see if we can get through a round here with the three of us before we have to go to vote. I think there will be four votes so what we will do, I am going to try to move quickly. I actually have three questions.

NO-ACTION LETTERS

One has to do with the no-action letters. I think they are rather odd. The letter on June 17th to ICE says: The no-action position taken herein is taken by the Division only and does not necessarily reflect the views of the Commission or any other unit or member of the Commission's staff.

That seems to be boilerplate language. But then when you take a look at what the director of enforcement for CFTC says about ICE in particular: A foreign board of trade listing for trading a contract which settles on the price of a contract traded on a CFTC-regulated exchange raises very serious concerns for the Commission. In the absence of certain preventive measures at the foreign boards of trade, these circumstances could compromise the Commission's ability to carry out its market surveillance responsibilities, as well as the integrity of the prices established on CFTC-regulated exchanges.

Aren't the commissioners of the CFTC nominated, confirmed and paid to make decisions like this? Why are these letters done on such an arm's length basis by staff? And why don't the commissioners vote to approve or disapprove requests for no-action letters?

Mr. LUKKEN. This is something that started in 1996, I think, prior to Michael coming down to the agency. But we have limitations in our law that says that any individual can trade—must trade a futures contract on a U.S.-designated exchange unless it is located outside the United States. We also have a provision in our act that says we cannot regulate foreign boards of trade. So the discussion has been whether we can develop some policy to ensure that we are not regulating foreign boards of trade but we are allowing access to those foreign boards of trade. And this is the process that developed, but it was processed fully with the Commission's input.

We held, in 1999, there was significant discussions about this issue. Eventually they adopted the no-action policy. In 2006, again, when ICE linked a contract to one of our regulated contracts, the Commission again held hearings and put out for Federal comment on the issue of what we should do in this area.

Ms. DELAURO. The process seems to be flawed.

Mr. LUKKEN. Well, certainly, we have limitations as a result of our law. But also all of these no-action letters that come through the agency come through the Commission; they are fully aware of it. They have the ability to object to these as they come through. We could stop any of these as they are coming through. But it has worked well to ensure that global markets are properly regulated, but the CFTC is getting the right information to protect its marketplace.

Ms. DELAURO. That it does not reflect the view of the Commission or any of the Commission's staff. I think it is a flawed process.

Dr. Greenberger, I will give you a second.

I want to ask a question of Dr. Cooper and maybe even Mr. Devine.

Mr. GREENBERGER. Yes, I am the villain of the peace who drafted the template for the no-action letters, and essentially, the Commis-

sion could not reach—the commissioners could not agree on what to do, and they said, you take care of it. And we did.

Now, that was supposed to be a temporary process in 1999 until the commissioners enacted a rule. There is no rule today. Mr. Lukken is right. In 2006, they held a 1-day meeting to decide, and they re-endorsed the process of the staff making these decisions.

Now one other point I just want to make quickly, because I know you are running, as you pointed out, in the no-action letter that Mr. Lukken's staff issued, on June 17th, they say, look, here are four new conditions, guys. If you don't meet them, we are going to bring enforcement action against you to register as a U.S. exchange. There is no doubt in that letter about the jurisdiction of the Commission that they can't deal with these people.

I briefed this in my testimony elaborately. They are—this isn't located outside the United States. They are in the United, States. Trading our West Texas Intermediate contract in U.S.-denominated dollars. When they enter the United States—and I dealt with these guys—they did not say, you can't regulate us. They said, please, grant us an exemption from regulation. We understand you can regulate us.

Now the bargain that was struck was that they were foreign exchanges, not wholly owned by a U.S. corporation, and that they would not trade U.S. contracts in competition with U.S. exchanges. That changed in 2006, and that is why I believe these letters should be terminated.

Ms. DELAURO. Dr. Cooper, let me ask you, you make some suggestions about what we should do. Your recommendations about how we ought to address these issues, can you just briefly kind of summarize those? I would love to get some sense——

Mr. COOPER. There are five categories of things, and you have heard them already. And this comes primarily from our analysis of natural gas. One, we have to close the Enron loophole definitively, effectively. The presumption should be regulation, and the exception should be self-regulation. So everyone has to report, register, report, be certified, and you have to prove to the Commission that you don't need to be, not vice versa. Change the burden of proof.

Second of all, we have to eliminate this funny money. The margin requirements, the capital requirements, have made it too easy to go there. Those are thing that the CFTC could actually effect that if it so desires by declaring an emergency and a problem of excess speculation.

We have to reduce the ability to push up prices. Position limits are too low. The settlement window on natural gas is too short. We have to ban these conflicts of interest, where Goldman Sachs tells their pension funds, buy this stuff, buy the index, and then issues the report that says the price is going up, and then goes back and says, see the price is going up. That is a conflict of interest.

We also, in a broader sense, have to restore the profitability of productive investment. We need to rebalance the attractiveness of making long-term investments in steel in the ground, assets, not asset-lite corporations, versus this flipping of paper which is basically sucking up our assets in this country.

Ms. DELAURO. A quick question to you, Mr. Devine.

CREDIT ACCESS

How might companies like you get credit access that you need to purchase the product for the coming winter should there be no market relief present? What are you going to do?

Mr. DEVINE. What am I going to do? Right now, we are actively engaging with our banks to make sure we have the proper amount of credit that we need. We are lucky enough to have assets that we could leverage to get that kind of money that we think we need at this point in time.

We are also working closely with our wholesalers to make sure that we have a kind of credit limit with them. However, they are becoming extremely tight as well. And that is becoming more difficult. In Connecticut, the Independent Connecticut Petroleum Association is working with the Small Business Administration to look into perhaps getting loans from them as well. There is no question about it that the fuel oil dealers in Connecticut are going to need a lot more money.

Ten years ago, I would need about maybe $2 million a year to capitalize what I needed. This year, I am looking at $10 million, perhaps $3 million in 1 month, probably January. For my company, that is pretty big, to wait sometimes 45 to 60 days for the money because my customers can't pay for it.

Ms. DELAURO. I am going to bring the hearing to a close. I do know that Mr. Kingston wanted to come back. I have to bring the formal hearing to a close.

Mr. Kingston, I believe, will be coming back, if you could for 5 or 10 minutes, I think there may be a question that he would like to ask, and I would like to afford him the opportunity to be able to do that.

Let me just conclude with this comment. I do something called office hours every week in some town or city in my district. I was in a place called Naugatuck, Connecticut, a working, blue-collar middle-class community. A woman came to see me and she said, Rosa, and as she started to talk tears welled up. And she said, I don't know what to do. Tell me what I should do. Do I starve? Do I freeze? Do I not take my prescription drug medications?

She said, I have worked hard all of my life. I raised two kids. I just can't make it.

I went in to purchase a product and the gentleman said to me, Rosa—he wasn't angry. He said, what I think what I have to do is shut down my second floor, bring my kids downstairs. We can all sleep in the same place. It would be crowded, but that is the only way that I am going to make it.

That is the reality. That is the reality. And we have to respond. We come to people who have the obligation and the jurisdiction to do something about what is happening out there. We look to experts for information from all perspectives to do this. This is a national crisis.

And I hate to go back to the analogy again, but Bear Stearns appeared to be a national crisis as it was. We went with all deliberate speed to sort it out, to fix it, and so whether people liked it or did not like it, and they did something to keep the financial markets from crashing.

Please, please, let's keep the American people from crashing and burning this winter. That is why we are holding this hearing. And we are going to continue to ask these questions. And we are going to continue to look at what the solutions are in order to turn this around. That is the reason why we came here. And it ought to be the reason why the governmental agencies responsible for doing this are doing their job as well.

Thank you all very, very much for your patience, for your candor.

I can yield to Mr. Kingston, so I will go to vote.

I do have to come back. Mr. Kingston cannot close the hearing. There are rules and regulations around this institution.

Mr. GREENBERGER. Get a no-action letter.

[Recess.]

Mr. KINGSTON [presiding]. Actually, I wanted to ask Mr. Greenberger a question, but Mr. Cooper, I will switch to you.

You had talked about the hoarding of oil is in the ground.

Mr. COOPER. Yes.

Mr. KINGSTON. What ground would you be referring to?

HOARDING

Mr. COOPER. Well, this is a global question, because they keep telling me about the global market. And so over the past decade, you have had a very, very vigorous effort by OPEC to manage supply. It is an illegal cartel that we have never challenged on legal grounds, but clearly, there is strategic underinvestment in production capacity in OPEC.

Mr. KINGSTON. Let me ask you this, because I was recently over there and talked to them, and they said you come over here and whine about oil, but you will not build refineries and you will not drill on your own land. And when you talk about hoarding oil, the U.S. Government may be leading the way with 85 percent of our offshore tied up and 65 percent of our land resources. And so, well——

Mr. COOPER. In the U.S., you do have this immense number of idle leases. And so those are leases that, you know, maybe they were not economic at $30 a barrel when they were let, but at $100 a barrel or $80 a barrel, they are awfully economic. So the question of—and the minute you let the leases for these other environmentally sensitive areas, you are going to hear all kinds of other complaints why they can't go there. They don't have the rigs. An industry that does not have the rigs is clearly telling you that the supply side is not responding to increases in price. The question here is, you have got these idle leases and——

Mr. KINGSTON. Let me say what the oil companies say about these idle leases. You know, they are saying—first of all, they have paid a lot of money for it. Then they pay a lot of money to research to see what you just said, how expensive is it to extract the oil from that particular piece of land. And then these leases do expire. So I don't know what the definition of "idle lease" is. I know what "idle" really means, but I think it has become a political term which we need flesh out and say what is idle?

Mr. COOPER. They have them, and they ain't working them. That is a pretty good definition.

Mr. KINGSTON. Well, but they are working them.

Mr. COOPER. Well, but there is a lot of them that they are not working.

Mr. KINGSTON. How do you know that? Because I got to tell you, I don't know that they aren't working them, but I know they tell me that they are working them.

Mr. COOPER. They are working some of them.

Mr. KINGSTON. Maybe Mr. Lukken's committee, in response to what he just told Mr. Farr, is the answer here. Are they working those leases or not? Do you know? Are we finding out? Is anybody finding out? We are throwing around a term, "idle lease."

Mr. LUKKEN. Right, but we are looking at illegal manipulation, so——

Mr. KINGSTON. A little bit out of your realm.

Mr. LUKKEN. This is out of our lane a bit, but if they are, for business purposes, either developing or not developing, those are legitimate business purposes and are not a part of our manipulation investigation.

Mr. COOPER. But they are a part of the strategic underinvestment in resources, which is clearly evident in OPEC.

Mr. KINGSTON. Let me tell you this, Dr. Cooper, as a Member of Congress, people say to me, well, I guess the oil companies are a big presence up there. I don't think they are. I think they are fat, dumb, and happy exactly in this situation. I don't have Exxon Mobile knocking on my door to drill in ANWR or offshore. I do have lots of people who are paying $4 a gallon at the pump who are saying do that.

ICE

Let me ask Mr. Greenberger a question. On the London market that you have raised some concern about ICE, what is the difference between the U.K. Regs and the CFTC regs? Are they better? Are they worse? Are they inferior?

Mr. GREENBERGER. Well, I am sure Mr. Short will disagree with me, but I think they are much inferior. I mean, I think that is the whole reason people are so upset that this big bank failed over there, and the European Union is saying, hey, guys—there is an article I cite in my testimony from Jeremy Grant in the Financial Times where he described their regulatory techniques, and it is really dialoguing with people who are not doing what they should be doing. And that might have been fine when London was a little city—when I say "city," the city is like Wall Street, and they all knew each another—but now it is a world market.

Mr. KINGSTON. Well, let me stop you right there. You know, we are in this global situation, and markets tend to follow countries with less regulatory environment for good reasons and perhaps for some reasons that aren't so good. But let's say that Congress, through some act, closed down ICE Atlanta. You know, just decided, because I think Congress can be very dangerous on things they don't understand. And if you watch the ridiculous debate we had on horse meat last year, you would know what I mean.

But Mr. Short, suppose that happened, if the regulatory burden became too much on you, what would you guys do?

Mr. SHORT. First of all, the reason we are sitting down at this table and working with Members of Congress and working with the

CFTC is, you know, we want access to the United States and we think that the U.K. is an equivalent regulator. I think——

Mr. KINGSTON. Well, I guess, here is what my question is: Wouldn't it be the case that if ICE did not move to London, somebody else would pick up your mantle and move to London or Dubai or Singapore or Shanghai?

Mr. SHORT. I think there is a real risk of having too heavy a hand here and driving business offshore. That is not ICE. I mean, we are here at the table doing everything we have been asked to do. But I think there are some risks.

And just to circle back on the issue of FSA regulation, it is different, but these telephone calls that Professor Greenberger talks about, they happen with a high degree of frequency. You have kind of the equivalent of handlers, unlike, you know, in the U.S. So while they may not be, I guess, as prescriptive or have brought as many enforcement actions, they are sitting there with you.

I can't sit here and say that the FSA was a model of regulatory sanctity in the bank failure, but I don't think our regulatory system is perfect either. And we have had plenty of black eyes that we would be called to account for.

Mr. KINGSTON. Go ahead.

Mr. GREENBERGER. Well, I was just going to say, I think your question about whether they will go abroad is a really, really good one, and it is a fundamental one. And I am pleased to hear ICE will not go abroad. And I don't want ICE to go abroad. I believe ICE should be more regulated, but I think they are a valuable contributor to these markets. There is some consolidation on these exchanges that people are not happy about.

But for whatever it is worth, and I have this in my testimony, look, I was sitting in the Division of Trading and Markets—Mr. Lukken was right. In 1996, Germany came before I got there and said, we want to bring our terminals in the United States, and we are not going to be trading U.S. products in competition, but we want to have our terminals in. And I think nobody thought, well, what difference does it make? We will get them in. We will get some assurances from them. Well, it jumped into the number-one world exchange just because they had terminals in the United States. I arrived on the scene, and I have foreign regulators down my hallway saying, hey, you let Germany in, let us in, too. By that time, the Commission says, oh, this is a really big deal, and we do a dance; should there be a rule? And they settled on the no-action letters.

Now, my reading of the Web site is there are 15 exchanges. I think I heard Walter say at one point there are 20. But they are all coming this way. This is where the liquidity is. This is where the markets are. After all, ICE could have said, we will set up shop up in London.

Mr. KINGSTON. But at the same time, your fear and my fear seems to be the same, that they really don't have, since they don't have the commodity; they are a paper exchange. They are mobile. They could move anywhere they want if we over-regulated.

Mr. COOPER. Let me jump in here, if you assert the jurisdiction over U.S.-designated commodities on U.S. soil, okay, and you intend to regulate and you say, we will regulate all of that stuff, they

will come and register. They will succumb, submit to our regulation. They need to be trading in legal tender; that is U.S. dollars.

Mr. KINGSTON. You are talking about any country?

Mr. COOPER. The exchanges will come, absolutely. Because they want to be able to trade in this product legally.

Now what are the traders going to do? And I get a little flamboyant here, because you heard about the phone call. If you are sitting in America and you place that phone call to a foreign exchange trading in a U.S.-designated commodity that has not registered, you broke the law. And let's enforce that law. And I believe most traders in America don't want to live in Bangladesh or Sing Sing. They will obey the law, and they will not trade illegally. And countries that have agreements with us, that is extradition agreements, will in fact say, we want an exchange, we will register.

So, therefore, this is about U.S. authority, U.S. jurisdiction, and clearly, our product is very attractive. So you can in fact make the world conform to your regulatory scheme, not reduce your standards to theirs.

Mr. KINGSTON. Okay.

Mr. Short.

Mr. SHORT. I just wanted to clarify something. ICE will not come to the United States to register as a designated contract market, and let me explain why. You can't have duplicative regulation. You need a lead regulator with a lead regulatory system. There can be regulatory equivalency. ICE is all about the dialogue that we have had with the CFTC about the need to have regulatory equivalency, but there has to be a read regulator.

It would be like somebody standing up and saying, the New York Stock Exchange has screens in the United Kingdom, and someone in Parliament standing up and saying, well, you have got to become a recognized investment exchange here. That is not the way global electronic trading will ultimately work. And there are some very real problems with regulatory overlap and regulatory burden that I don't think anybody here at this table is talking about.

I think the proper way through this thicket is to look for regulatory equivalency. And by all means, if you don't think there are important regulatory steps being taken, there should be regulatory dialogue, and perhaps the screen-based access letter should be modified. But the idea of coming and registering as a DCM is just a terrible idea, because you are going to have CME registering in China. NYMEX registering around the world.

Professor Greenberger is talking about the past, about the United States being the be all, end all. I am talking about the future. We won't be in that position for long if we do that.

Mr. KINGSTON. Well, it does worry me, as somebody who just came back from Dubai and saw the largest building in the world, and the e-mail that goes around and tells you that 15 percent of the cranes in the world are in Dubai. I think that is accurate. If anything, probably under. I wonder what is going on in the Middle East when you have an emir making the laws with no regulation, and I just think it could be wide open.

Mr. GREENBERGER. I was just going to say, Mr. Kingston, one of the things is also, you know, Dubai has gotten a no-action letter to have U.S. trading terminals and trade West Texas Intermediate

and the principal regulator—now, Mr. Lukken is tightening that up. I am going to concede that. He just sent a letter the other day. But the principal regulator will be the Dubai Financial Services Authority.

Now, I want to make it clear, I don't want to regulate every foreign exchange. I don't know whose figure is right, and I will take Walter's word. It is 20 foreign exchanges are here. Only two of them are trading U.S. West Texas Intermediate. Well, let me be clear. ICE Futures Europe is trading West Texas Intermediate. Dubai has permission to do so and says it will do so soon. My view is I don't want to—and I am a minority on this because some of the people who are supportive of my views would say, let's regulate everybody. I don't want to regulate Germany. They are not competing with us. They came in and are following the rules. It is a German exchange trading German product. But if you come in and put U.S. trading terminals in the United States and trade our West Texas Intermediate, they should register.

Now also, do they have to register and have dual regulators? Why can't they do what ICE has done and set up a U.S. subsidiary and have that subsidiary be regulated rather than the whole exchange?

Mr. SHORT. I will answer that question directly if I could. We have European and U.K. customers that feel very strongly about U.K. regulation, U.K. bankruptcy law, keeping capital in a U.K. clearinghouse. In the U.S., if we came, we would have to split out our energy commodities across different exchanges. They would be cleared in different clearinghouses, and these are real regulatory obstacles. Our customers may not follow us.

Now I think that would be a great result in some people's mind, but it is one, from an operational standpoint, is just not the right result if you can get there through regulatory equivalency.

Mr. KINGSTON. I yield back.

Mr. COOPER. Let the FSA recede to CFTC for U.S. commodities. If U.K. customers don't want to be regulated by U.S. regulators for U.S. commodities, let them trade Brent. They can trade Brent. We won't regulate Brent. We will regulate WTI traded in the U.S.

Mr. SHORT. I would just add one point there. The idea that WTI is a, quote, U.S. commodity is—it has a U.S. delivery point, but if you really scratch the surface and you look, it is just a grade of light sweet crude oil. And there are a laundry list of substitutes for that grade of crude oil, and we import most of it in this country.

Mr. COOPER. How much WTI is exported?

Mr. SHORT. I didn't say any WTI was exported.

Mr. COOPER. There is a physical reality here we ought to remember. WTI is drilled here, produced here, and consumed here.

Mr. SHORT. Check the NYMEX contract spec.

Mr. KINGSTON. So it is not?

Mr. SHORT. Substitutable grades under the NYMEX contract include Brent, Nigerian, Bonny, Forties. You are just factually wrong.

Mr. COOPER. How much is exported? I ask you—I will tell you. Zero.

Mr. SHORT. I don't think——

Mr. COOPER. It goes into American refineries.

Mr. SHORT. If you are talking about something——

Mr. COOPER. Well, there is a physical reality.

Mr. SHORT. If you are talking about West Texas, the actual stuff that comes out of the ground in Texas, I doubt much of any. But that really isn't the question. We are talking about markets that are priced on the margin, and we are importing most of this into our country. And I think we have got to face the fact that we have got an energy problem here, and that is being reflected in the markets. And this isn't any effort to lay blame at anyone's doorstep, but we have got a problem. And regulation is not going to solve that, I am afraid, in terms of bringing down the price of oil.

Mr. GREENBERGER. The other thing, Mr. Kingston, because your question is really, as you can see, a provocative one and a good one, but what we are arguing about here is the speculation, speaking of the speculation, that people will go abroad. I am sure your constituents are like everyone else's constituents; they are being hurt real hard.

Mr. KINGSTON. You know, one of the things that I don't get, why does the price of gas at the pump go up $0.08 in 1 day, and then it crawls back down. And you may see it yourself, Mr. Devine. But the spikes are always like that, and then it just kind of——

Mr. COOPER. It is a theory called rockets and feathers. A series of articles analyzing the oil price, and basically, it goes up like a rocket and comes down like a feather because there is market power there. And so you hold on to every penny you can for as long as you can. And it has been in the literature for 30, 40 years, and the last round said, yeah, it does look like rockets and feathers, and that is a result of market power.

Mr. KINGSTON. Madam Chairman.

Ms. DELAURO. This has been a great hearing.

As it turns out, I do have one more question, which has to do with Mr. Lukken. We did pass legislation on June 26th in the House, a remarkable margin, 402 to 19. By those numbers, it is a bipartisan piece of legislation. It directs the CFTC to use all of its authority, including its emergency powers, to curb excessive speculation in the energy markets.

SPECULATION IN THE ENERGY MARKETS

I wanted to get your view of the legislation, and would you use that emergency authority if you were to find such speculation?

And I guess the third piece is, because of your inability in terms of regulating these exempted entities, does this in any way compromise the legislation in terms of what you are, does this compromise your ability to carry out the legislation?

Mr. LUKKEN. Certainly, in my written testimony, what we have been doing over the last year is trying to look for evidence that speculation is driving these price. Whether that is looking into the swaps markets to seeing if the swap dealers are bringing excessive speculation that is driving prices; whether it is happening on exempt commercial markets as part of the farm bill; whether it is happening on foreign boards of trade, we are looking for that. So certainly we are using every existing authority that we have now.

Ms. DELAURO. So you would use the emergency authority if you found such speculation?

Mr. LUKKEN. Well, we have a broad range of emergency authority. And certainly, if we felt it was necessary—emergency authorities traditionally have been used in very distinct short-term situations. We have used it four times. Not really in the last 25 years have we used it. But it has typically been either an active manipulation of the markets, so we see somebody illegally manipulating the market, and we have to get them out of positions; or a huge disruption in supply, such as the Russian grain embargo. So we used it four times over the last 33 years.

Raising margins is one of the issues that I think has been discussed as part of getting speculators out of the markets. I think my personal concern is that there are speculators on both the short and long side of the market.

Ms. DELAURO. Yes or no? Would you use the emergency powers—we passed a piece of legislation in this body. The House did. The Senate may be doing that in the next couple of weeks, presuming it is the same piece of legislation. I don't know whether or not the President has any intention of signing such a piece of legislation. But we passed a piece of legislation that directs—it says it directs. It was not a Sense of the Congress. It was not a resolution. It was specifically saying, directing you to use it. If you were to find—I am just asking, and this is if, would you use the emergency authority if you did find the speculation? And this is an if.

Mr. LUKKEN. Certainly, if we find that excessive speculation is driving prices, we will use all authorities in order to stop that.

Ms. DELAURO. Okay. Thank you.

Mr. KINGSTON. I have another question.

Mr. Lukken, I really would like you to explore this idle versus active lease definition. You said to Mr. Farr that you are looking at everything. So the leasing question has to come under some of your subcommittee work or your committee on it. I think it would be very interesting for us to have a definition of idle versus active.

Mr. LUKKEN. I think, in reference to Congressman Farr, I was talking about our manipulation investigation, and we are looking at all aspects of how crude oil is transported, stored, looked at. So we haven't ruled out any way. If somebody is intentionally holding back oil from the markets, that is something we would be interested in. It is for legitimate business purposes, whether they don't think there is oil there or there is other reasons not to drill, that would not be something that we would be investigating.

Mr. KINGSTON. Well, I do not support windfall profit taxes and punitive measures on that. But I think what Ms. Kaptur said reflects the view of so many millions of people that Exxon Mobil had a $40 billion profit. And my question would be, is there anybody out there who is handling these leases to say, you are not drilling here? Because I can tell you, Ms. DeLauro don't agree probably on a lot of this energy issue, but I don't ever get lobbied by an oil company asking for more drilling area.

Do you?

I mean, so to me, they are fat, dumb, and happy in this current market. I have been a Member of Congress for 16 years, and I remember one time there was some lease issue off the Gulf that some oil company wanted to talk to me about, but I—to me, they like this market as is. And so you could be that thin line between the

consumer, you know, to make sure that you are not kind of looking at, well this is capitalism, and is not—you know, just steady hand at the wheel here.

Mr. Greenberger.

Mr. GREENBERGER. Just quickly, I would say that the FTC was also asked to look into these markets in the December legislation, so you should also be—your question is an excellent question. They are also looking, and they should be asked the same thing you are asking of Mr. Lukken.

Mr. KINGSTON. Well, let me ask you—do I have more time?

I want to close with Mr. Devine but only after asking the other four panelists a question. Candidate forum. You guys are all running for Congress.

Dr. Cooper, you are going to go first. We are going to ask you, are oil prices being driven up by speculators?

Mr. COOPER. $40 to $60 a barrel. That is $1 to $1.50. And think about it, if oil were $3 today, would we be having this hearing? We probably would not be. We had adjusted. So I believe there is a premium there. Everything I look at says there is a premium there. The fundamental models and whether it is excessive speculation or cycles, we can fix it.

Mr. KINGSTON. Hold on one second, I am going to add a sub question to this.

Why, Mr. Short, particularly for you and Mr. Lukken, why is this happening now? Say 5 years ago, Mr. Devine did not have this problem. Why suddenly is it happening now? Because I think Dr. Cooper is going to tell me it is because of the speculators using the loopholes and the trading volume; people have found out another way to make a buck. And so the supply and demand curve really isn't that out of whack; it is the speculation.

So I will start again with my friend Dr. Cooper who has probably a very unpassionate answer to this.

But would you——

Mr. COOPER. If you look at the curves, January 2006 was the key date when we began to make these changes to—and I have now learned about the swaps guys coming in and saying, now we want to be treated—it is the explosion of value, of dollars in those markets at that time. With ICE coming in, WTI came in at the same time. If you look the at curve——

Mr. KINGSTON. I saw your charts. I want to get Mr. Short to look at those.

Mr. COOPER. That is a causal and temporal relationship to which we put the theory around about how that trading pulls the price up.

Mr. KINGSTON. Okay.

Candidate Greenberg.

Mr. GREENBERGER. Oh, boy, would I love to do it?

Look, I have come to the view that I would like to be able to tell my constituents is that there is a debate going on now. I have one view. My personal view as a candidate is that there is speculation. But, by God, we have people looking into this market, and in 45 days, we are going to have answers. I will tell you then. And by God, if there is speculation, I will do everything I can to stop it.

But what you do not have is this kind of aggressive, full court investigation.

Now look, one thing I will say about the CFTC, they are being asked to do an awful lot. They are short staffed. Walter is making a lot of things. And I think they could say—and I know your committee is trying to give them more—look this is a lot to ask us to do.

But the acting chair has set up an interagency task force. I think the Bush administration, what I would say is, you know, 45 days, get us an answer. Get Greenberger to shut up. I want to show him it is supply-demand. And by God, if you do, I will go back to teaching counterterrorism law.

But that is what I really feel now. We need answers, and I just came from the House Ag Committee, and there is speculation, where is the money going? Here, there, and everywhere. And all I say is, give me an answer.

Mr. SHORT. I guess, first of all, I wouldn't run for anything. I couldn't do your jobs.

So I will note that I think markets largely work in an efficient manner, and we are talking about the future price of a very scarce commodity with a lot of different factors at play. I don't think this is a loophole question.

With all due respect to Dr. Cooper, if you look at the actual statistics of when we launched our WTI contract and actually started building our market share, the price of oil was going down. I want to emphasize that; it was going down. And we have been losing our market share as it is going up. So I don't think it is a loophole issue.

I think there are a lot of different fundamentals at work here, including the devaluation of the dollar. And look, people are jittery given the very tight, you know, supply-demand situation we find ourselves in today. I couldn't hazard a guess as to, you know, if there is any type of speculative premium built into it.

What I will say is that I am a believer in markets and that if, in any market, speculators can, you know, impact a price for a short period of time. But they can't do it for a long period of time out of balance with physical supply and demand fundamentals.

Mr. LUKKEN. Certainly supply and demand factors are significant in the price of crude oil and other commodities. But as a candidate, I would do exactly what you are doing, which is holding the agency accountable for doing its job. And we are trying to do as best we can, the employees at CFTC, with historically low staffing levels, to do everything we can to ensure that speculation is not occurring. We have not found evidence that it is, but we all understand that we have to keep looking under every rock possible to ensure that it is not happening. And we owe that to the American public.

So we are doing that through fixing the foreign boards of trade issue, exempt commercial markets in the farm bill, speeding up implementation of that. We are doing that with regards to swap dealers. I think we are trying to address that.

I agree that, as candidates, you are doing the right thing. I have been up here six times to talk to Members of Congress to try to educate and inform so that people can make educated decisions as policymakers.

Mr. KINGSTON. Mr. Devine, I don't want to make you the voter and you choose one of them. But what I would like you to answer, I mean, you have been sitting here. You are an intelligent businessman. You have been listening to all of this. You are on the front line of these fuel prices. You know, what did you think today? We have some really smart people here.

Mr. DEVINE. Yes, and I am actually very honored to be here.

I would get involved in speculation that if the margin rates were increased, the price of oil would probably be decreased. I think that, in answering Chairman DeLauro's question earlier a little bit more, regarding what oil companies need to do going forward, is cut back on employment, which we have done. And it is going to happen more, which means the unemployment rate is going to go up. I think that stop investing in growing markets, which we have done in bioheat unfortunately for this year. We put off a major piece of work that we were going to do to our terminals. That is all going to stop, which is going to slow the economy.

But I think that we have a huge challenge on our hands. I do think we need an energy policy, but I think that we have to find out if the speculators are moving this market. And I think they are. I think that the speculators—I think there is speculation in this market. I am not a professional. I am not a trader, but the markets are moving very, very volatilely, and they are very, very high which creates in my industry just-in-time inventory, which when we do get to a cold winter, unless that oil is there, it is going to be extremely hard to get. So not only will we have a difficult price to deal with, we are going to have a difficult time getting product, because my wholesalers right now are telling me, if you don't have a contract for July, don't bother coming and picking up oil because you are not going to get it because we are not going to invest in it now, because if it drops tomorrow by 30 or 40 cents and we are holding a million gallons, then we are out 400,000 bucks. That is the reality of it. That is a scary thing.

And it is energy. It is energy. Natural gas is up 86 percent since January. It is going to be a tough, tough winter.

Thank you very much.

Ms. DELAURO. [presiding]. Again, thank you all very, very much for being here.

And again, I can't pass up this one point, though. And I think Professor Greenberger said, get us some answers. And I appreciate—I think it has been important for Members of Congress to take this issue on, as tough and as complex as it is, to begin to learn some things about it.

I will speak for myself, we are, you know—I am not an economist, and I am not an academic here, but trying to get hold of this very, very serious issue. But we do have 45 days or less. Let's get some answers, whatever the outcome is going to be. So that we can move forward.

Again, thank you. This hearing is concluded. I appreciate it.

Testimony of the Honorable Nancy C. Pellett
Chairman and Chief Executive Officer
Farm Credit Administration
Before the Subcommittee on Agriculture,
Rural Development, Food and Drug Administration, and Related Agencies
U.S. House of Representatives Committee on Appropriations
March 26, 2008

Madam Chairman, Members of the Subcommittee, I am Nancy C. Pellett, Chairman and Chief Executive Officer of the Farm Credit Administration (FCA or Agency). On behalf of my colleagues on the FCA Board, Dallas Tonsager of South Dakota and Leland Strom of Illinois, and all the dedicated men and women of the Agency, I am pleased and honored to provide this testimony to the Subcommittee.

I would like to thank the Subcommittee staff for its assistance during the budget process, and before I discuss the role and responsibility of the Farm Credit Administration and our budget request, I would respectfully bring to the Subcommittee's attention that FCA's administrative expenses are paid for by the institutions that we regulate and examine. In other words, FCA does not receive a Federal appropriation but is funded through annual assessments of Farm Credit System (FCS or System) institutions and the Federal Agricultural Mortgage Corporation (Farmer Mac). Earlier this fiscal year, the Agency submitted a proposed total budget request of $49,640,147 for FY 2009. The Agency's proposed budget for FY 2009 includes funding from current and prior assessments of $49,000,000 on System institutions, including Farmer Mac. Almost all this amount (approximately 82 percent) goes for salaries, benefits, and related costs.

MISSION OF THE FARM CREDIT ADMINISTRATION

As directed by Congress, FCA's mission is to ensure a safe, sound, and dependable source of credit and related services for agriculture and rural America. The Agency accomplishes its mission in two important ways.

First, FCA ensures that the System and Farmer Mac remain safe and sound and comply with the applicable law and regulations. Specifically, our risk-based examinations and oversight strategies focus on an institution's financial condition and any material existing or potential risk, as well as on the ability of its board and management to direct its operations. Our oversight and examination strategies also evaluate each institution's efforts to serve all eligible borrowers, including young, beginning, and small farmers and ranchers.

Secondly, FCA approves corporate charter changes and researches, develops, and adopts regulations and policies that govern how System institutions conduct their business and interact with their customers. If a System institution violates a law or regulation or operates in an unsafe or unsound manner, we use our supervisory and enforcement authorities to ensure appropriate corrective action.

FISCAL YEAR 2007 ACCOMPLISHMENTS

In FY 2007 we continued our efforts to achieve our Agency's strategic goals through (1) effective risk identification and corrective action and (2) responsible regulation and public

policymaking. FCA has worked hard to maintain the System's safety and soundness. We also continually explore ways to reduce regulatory burden on the FCS and to ensure that all System institutions are able to provide agriculture and rural America with continuous access to credit and related services.

Examination Programs for FCS Banks and Associations

The Agency's highest priority is to maintain appropriate efficient and effective risk-based oversight and examination programs. Our examination programs and practices have worked well over the years and have contributed to the present overall safe and sound condition of the System, but we must continue to evolve and prepare for the increasingly complex nature of financing agriculture and rural America.

With the changes in the System and our human capital challenges within the Agency (i.e., pending retirements, normal attrition of staff, and the ever-increasing need for more sophisticated skills in the financial sector), we have undertaken a number of initiatives to enhance our skills and expertise in key examination functions. We have also realigned our organizational structure to make the best use of our resources. Our Office of Examination has completed its transition from a regionally-based field office structure to divisions of nationally-based examination teams. Office locations have been retained, but the examination programs are now managed nationally to better manage strategic risks faced by the FCS institutions.

On a national level, we actively monitor risks that may affect groups of System institutions or the entire System, including risks that may arise from the agricultural, financial, and economic environment in which the System institutions operate. Examiners use a risk-based examination and supervision program to differentiate the risks and develop individual oversight plans for each FCS institution. For example, the System has been a leader in lending to the ethanol industry from its infancy and continues to support this rapidly evolving sector. Our examiners watch the concentration risk in this and other areas to make certain lending is done in a safe and sound manner.

We set the scope and frequency of each examination based on the level of risk in the institution. Examiners base the scope of their oversight and examination activities on their assessment of an institution's internal controls environment and the ability of the institution's board and management to manage risks. Our regulations require FCS institutions to have prudent loan underwriting and loan administration processes, to maintain strong asset-liability management capabilities, and to establish high standards for governance and transparent shareholder disclosures. The frequency and depth of our examination activities may vary, but each institution is provided a summary of our activities and a report on its overall condition at least every 18 months as required by the Farm Credit Act. Most issues are resolved through corrective actions established in the Report of Examination or other communications. In extreme cases, FCA will use its enforcement powers to effect changes in the institution's policies and practices to correct unsafe or unsound conditions or violations of law or regulations.

As part of our ongoing efforts, we evaluate each institution's risk profile. The Financial Institution Rating System (FIRS) is the primary risk categorization and rating tool used by examiners to indicate the safety and soundness of an institution. FIRS ratings range from 1 (for a sound institution) to 5 (for an institution that is likely to fail). As of December 31, 2007, FIRS ratings as a whole continued to reflect the stable financial condition of the FCS: 83 institutions

were rated 1, 14 institutions were rated 2, and three institutions were rated 3. Importantly, there were no institutions rated 4 or 5. In addition, no FCS institutions are under enforcement action and no FCS institution is in receivership. The overall financial strength maintained by the System remains strong and does not pose material risk to investors in FCS debt, the Farm Credit System Insurance Corporation (FCSIC), or FCS institution stockholders.

During FY 2007, FCA also performed various examination and other services for the Small Business Administration, the U.S. Department of Agriculture, FCSIC, and the National Consumer Cooperative Bank. Each of these entities reimbursed FCA for its services.

Regulatory Activity

Congress has given the FCA Board statutory authority to establish policy and prescribe regulations necessary to ensure that FCS institutions comply with the law and operate in a safe and sound manner. The Agency's regulatory philosophy articulates our commitment to establishing a flexible regulatory environment that enables the System, consistent with statutory authority, to offer high-quality, reasonably priced credit to farmers and ranchers, their cooperatives, rural residents, and other entities on which farming operations depend. This focuses our efforts on developing balanced, well-reasoned, flexible, and legally sound regulations. We strive to ensure that the benefits of regulations outweigh the costs; to maintain the System's relevance in the marketplace and rural America; and to ensure that FCA's policy actions encourage member-borrowers to participate in the management, control, and ownership of their Government-sponsored enterprise (GSE) institutions. For FY 2007, the Agency's regulatory and policy projects included the following:

- **Young, Beginning and Small Farmers (YBS).** The Board acted to ensure that all System institutions assist YBS farmers to enter, grow, or remain in agricultural or aquaculture production. A revised Bookletter, issued in August, provides guidance to all FCS institutions on interpreting the phrase "sound and constructive credit" when applied to YBS farmers and ranchers and on extending credit to part-time YBS farmers who demonstrate a commitment to be full-time agricultural producers. The Bookletter further encourages System lenders to provide credit enhancements so that YBS farmers can qualify for financing, and it encourages System lenders to mitigate the risk of lending to YBS farmers by increasing coordination with other lending entities and sharing best practices.

- **Policy Guidance Provided on Rural Housing Lending.** FC S institutions are authorized to provide rural housing financing for single-family, owner-occupied, and moderately priced dwellings, but System institutions had reported difficulties in applying the regulatory definition of a "moderately priced" rural home. In response, the Agency issued an Informational Memorandum providing answers about the regulatory definition of moderately priced housing, what is necessary to identify moderately priced housing values, and what data are acceptable to establish those values.

- **Disclosure and Reporting Final Rule.** The Agency issued a final rule amending existing disclosure requirements for reports to System shareholders and investors. These amendments ensure that the System's disclosures and financial reporting keep pace with recent changes in industry practices, Securities and Exchange Commission regulations

implementing the Sarbanes-Oxley Act of 2002, and Public Company Accounting Oversight Board auditing standards.

- **Final and Proposed Rule Updating the Farmer Mac Risk-Based Capital (RBC) Stress Test.** We amended the RBC regulations in response to changing financial markets, new business practices, and the evolution of the loan portfolio at Farmer Mac, as well as continued development of industry best practices among leading financial institutions. The RBC is used to calculate Farmer Mac's regulatory minimum risk-based capital level. The rule is intended to improve the model's output by more accurately reflecting risk. In addition, we also proposed to further amend RBC regulations to update the recent additions to Farmer Mac's program operations, to address assumptions on the carrying costs of nonperforming loans, and recognize counterparty risks on nonprogram investments. The FCA Board is expected to act on this final rule in 2008.

- **Advance Notice of Proposed Rulemaking (ANPR) on Capital Adequacy.** We issued an ANPR to solicit public input on appropriate changes to FCA's capital adequacy requirements for the System in light of Basel II proposals by the other Federal banking agencies.

The Agency has also adopted an ambitious regulatory and policy agenda for FY 2008. The agenda includes the following goals:

- Finalizing a proposed rule to change the requirement for determining the eligibility of processing and marketing entities for System funding.

- Developing a proposed rule to describe how System partnerships and investments can increase the availability of funds to help stimulate economic growth and development in rural America. The System began using such partnerships and investments under a pilot program initiated during FY 2005.

- Continuing to review current regulatory requirements governing eligibility and scope of lending to determine if these requirements are reasonable in light of agriculture's changing landscape. Agency staff will identify issues and explore options for the Board's consideration.

Corporate Activities

The pace of System restructuring remained slow in FY 2007. Only one corporate application was submitted for FCA Board review and approval during FY 2007, compared with four applications the prior year. As of January 1, 2008, the System had 94 direct-lender associations and five banks for a total of 99 banks and associations. Seven service corporations and special-purpose entities brought the total number of FCS institutions to 106 entities. Through mergers, the number of FCS associations has declined slightly more than 45 percent since 2000, and the number of FCS banks has decreased almost 30 percent.

CONDITION OF THE FARM CREDIT SYSTEM

As noted previously, the System's overall condition and performance remained strong throughout 2007. The FCS is fundamentally sound in all material aspects, and it continues to be a financially strong, reliable source of affordable credit to agriculture and rural America. Capital levels continued to be strong, especially in consideration of the System's risk profile. Asset quality remained high, loan volume growth was strong, and the System earned $2.7 billion in 2007, a 13.8 percent increase from 2006.

Gross loans grew by 15.8 percent in 2007, compared with 16.2 percent the previous year. Nonperforming loans increased by $6 million to $621 million as of December 31, 2007. However, nonperforming loans represented just 2.35 percent of total capital by the end of 2007, down from 2.52 percent at the end of 2006. The System has earned more than $1 billion consistently each year since the early 1990s; as a result, capital remains strong and is made up largely of earned surplus, the most stable form of capital. A strong capital position will help the System remain a viable, dependable, and competitive lender to agriculture and rural America during any near-term downturns in the agricultural economy.

FEDERAL AGRICULTURAL MORTGAGE CORPORATION

FCA also has oversight, examination, and regulatory responsibility for the Federal Agricultural Mortgage Corporation, which is commonly known as Farmer Mac. Congress established Farmer Mac in 1988 to provide secondary market arrangements for agricultural mortgage and rural home loans. In this capacity, Farmer Mac creates and guarantees securities and other secondary market products that are backed by mortgages on farms and rural homes. Through a separate office required by statute (Office of Secondary Market Oversight), the Agency examines, regulates, and monitors Farmer Mac's disclosures, financial condition, and operations on an ongoing basis and provides periodic reports to Congress.

Like the Farm Credit System, Farmer Mac is a GSE devoted to agriculture and rural America. FCA and the financial markets recognize Farmer Mac as a separate GSE from the System's banks and associations. Farmer Mac is not subject to any intra-System agreements or to the joint and several liability of the FCS banks, nor does the Farm Credit System Insurance Fund back Farmer Mac's securities. However, by statute, in extreme circumstances Farmer Mac may issue obligations to the U.S. Treasury Department to fulfill the guarantee obligations of Farmer Mac Guaranteed Securities.

CONCLUSION

In conclusion, we at FCA remain vigilant in our efforts to ensure that the Farm Credit System and Farmer Mac remain financially strong and focused on serving agriculture and rural America. It is our intent to stay within the constraints of our FY 2009 budget as presented, and we continue our efforts to be good stewards of the resources entrusted to us in order to meet our responsibilities. While we are proud of our record and accomplishments, I assure you that the Agency will continue its commitment to excellence, effectiveness, and cost efficiency and will remain focused on our mission of ensuring a safe, sound, and dependable source of credit for agriculture and rural America. On behalf of my colleagues on the FCA Board and at the Agency, this concludes my statement and I thank you for the opportunity to share this information.

WITNESSES

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