THE NATIONAL PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN: IS THE UNITED STATES READY FOR AVIAN FLU?

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

NOVEMBER 4, 2005

Serial No. 109–94

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

24–820 PDF WASHINGTON : 2005

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CONTENTS

THE NATIONAL PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN: IS THE UNITED STATES READY FOR AVIAN FLU?

FRIDAY, NOVEMBER 4, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis, Shays, Burton, Ros-Lehtinen, Gutknecht, Souder, Cannon, Duncan, Miller, Marchant, Schmidt, Waxman, Lantos, Kanjorski, Sanders, Cummings, Kucinich, Clay, Watson, Lynch, Van Hollen, Ruppersberger, Higgins, and Norton.

Staff present: Melissa Wojciak, staff director; David Marin, deputy staff director/communications director; Jennifer Safavian, chief counsel for oversight and investigations; Howie Denis and Anne Marie Turner, counsels; Rob White, press secretary; Drew Crockett, deputy director of communications; Susie Schulte, professional staff member; Sarah D'Orsie, deputy clerk; Allyson Blandford, office manager; Andrew James, staff assistant; Phil Barnett, minority staff director/chief counsel; Kristin Amerling, minority general counsel; Sarah Despres and Robin Appleberry, minority counsels; Josh Sharfstein, minority health policy advisor; Earley Green, minority chief clerk; and Stacey Warady, minority staff assistant.

Chairman TOM DAVIS. The committee will come to order.

Good morning. Today, we are honored to have Secretary Michael O. Leavitt here to discuss what health experts describe as the largest public health threat facing our Nation, the threat of pandemic flu.

We don't know when, or where, the next pandemic will strike. We don't even know what strain of influenza will be the culprit, although much evidence points to avian flu. The virulent H5N1 strain has already caused 62 deaths in Vietnam and Cambodia, Thailand and Indonesia. Nor do we know if avian flu will turn out to be more like the swine flu, a pandemic that never materialized.

Regardless, we need to improve your readiness because we can be sure the next flu pandemic is a matter of when and not if. And when that time does come, the stakes will be enormous. The Spanish influenza outbreak of 1918–1919, for example, caused an estimated 40 to 50 million deaths worldwide. Experts have projected

that more than half a million Americans could die, and over 2 million could be hospitalized in the event of a U.S. pandemic flu outbreak.

How quickly could an influenza pandemic spread across the globe? As fast as you can fly from Hanoi to Washington, DC. We live in a flat world, a world not only connected by e-mail carried by fiber-optic cables, but by commerce and cargo transported by jumbo jets. Pandemic flu can move just as fast.

As Federal officials, it is our responsibility to make sure America is prepared—prepared to detect the strain of pandemic flu, prepared to communicate with our State and local partners, and prepared to work with industry to get vaccine production moving as quickly as possible.

Earlier this week, President Bush outlined the administration's national strategy for pandemic influenza. The three pillars of this strategy are preparedness and communication, surveillance and detection, and response and containment. The strategy allows the government to make immediate steps to ensure early warning against the possibility of a flu pandemic.

The President has requested more than $7 billion in emergency funding to begin immediately implementing this national strategy. This includes nearly $3 billion to accelerate the development of cell culture technology, to move vaccine production away from the lengthy and fragile process that depends on cultivating the vaccine in chicken eggs, $1.5 billion to stockpile the H5N1 vaccine currently in clinical trials at NIH, and $1 billion to stockpile antiviral drugs to treat first responders and our most vulnerable populations.

Additionally, the strategy requests $580 million for pandemic preparedness and about $100 million to help States complete and exercise their pandemic plans. The strategy also calls for improving our detection capabilities, train personnel, and additional planning at both Federal and local levels.

While finalizing the HHS pandemic influenza plan was important and necessary to provide more detailed guidance to State and local health officials, many concerns about preparedness still remain. I have already heard concerns from the Department of Health in my home State of Virginia about the limited amount of money for stockpiling the federally recommended amounts of the antiviral treatments and the need for additional support across the board for emergency preparedness.

I think all of us here today agree that our State and local health officials will be on the front lines of a pandemic response. It is our job to provide them with the adequate support and essential resources they need to effectively prepare for and respond to a pandemic.

Today's Washington Post applauds the administration for, "taking preparedness seriously." But the editorial also says, "the plan seems divorced from reality" and "is too vague to be reassuring." This morning we will search for reality-based details in the hope of reassuring all Americans that we are on the road to preparedness.

I look forward to a constructive dialog with Secretary Leavitt on this life-and-death issue. I think the National Strategy and HHS

Pandemic Influenza Plan will offer appropriate guidance and help better prepare our country for the unknowns of pandemic flu. However, as the Secretary has mentioned before, we need to remember that the plan is a living and breathing document subject to improvement as we develop better strategies and practices.

I would now recognize our distinguished ranking member who has been so active in the field of health, Mr. Waxman, for his opening statement.

[The prepared statement of Chairman Tom Davis follows:]

Chairman Tom Davis
Opening Statement
"The National Pandemic Influenza Preparedness and Response Plan:
Is the U.S. Ready for Avian Flu?"
November 4, 2005

Good morning. Today, we are honored to have Secretary Michael O. Leavitt here to discuss what health experts describe as the largest public health threat facing our nation: the threat of pandemic flu.

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Regardless, we need to improve our readiness – because we can be sure that the next flu pandemic is a matter of when, not if. And when that time does come, the stakes will be enormous. The Spanish Influenza outbreak of 1918-19, for example, caused an estimated 40-50 million deaths worldwide. Experts have projected that more than half a million Americans could die, and over two million could be hospitalized in the event of a U.S. pandemic flu outbreak.

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I look forward to a constructive dialogue with Secretary Leavitt on this life-and-death issue. I think the National Strategy and HHS Pandemic Influenza Plan will offer appropriate guidance and help better prepare our country for the unknowns of pandemic flu. However, as the Secretary has mentioned before, we need to remember that the Plan is a living and breathing document subject to improvement as we develop better strategies and practices.

Mr. WAXMAN. Thank you very much, Chairman Davis, for calling today's hearing on the serious public health threat of a potential global influenza pandemic. And under your leadership, this will be this committee's seventh hearing related to a flu pandemic.

As those who have followed our hearings know, I have been extraordinarily critical of the administration's failure to prepare for a pandemic. Recently, my staff put together an analysis of these delays and mistakes that have characterized the Federal effort over the last 5 years, and I ask for unanimous consent that this analysis be made part of the record.

Mr. SHAYS [presiding]. Without objection, so ordered.

[The information referred to follows:]

REP. HENRY A. WAXMAN
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
OCTOBER 14, 2005

Fact Sheet

The Administration's Preparation for Avian Flu

On October 4, 2005, President Bush spoke at length about the dangers of an influenza pandemic. He stated: "The people of the country ought to rest assured that we're doing everything we can."

In fact, the Administration's record has been characterized by neglect and poor management. An influenza pandemic, which experts fear could develop from a highly contagious avian flu circulating in Asia, could kill millions of people and cause widespread economic disruption. Yet over the last five years, the Administration has:

- **Ignored at least six major expert reports and statements related to an influenza pandemic.** Experts recommended major new investments in public health, incentives for vaccine manufacturers, and expanded federal purchase of vaccine to ensure access.

- **Proposed substantial cuts in funding for public health preparedness.** In fiscal year 2005, the President proposed cutting $105 million from state and local public health departments. In fiscal year 2006, the President proposed $130 million in cuts. The Administration's failure to purchase available quantities of the antiviral drug Tamiflu has left the United States waiting in line behind other nations.

- **Failed to finalize a national response plan for an influenza pandemic.** Since November 2000, the Government Accountability Office has issued six separate reports criticizing the Administration's failure to develop a national response plan. GAO repeatedly found that the persistent failure to complete a response plan significantly undermined our nation's readiness for a pandemic.

- **Failed to endorse or propose pandemic-flu legislation.** Several important legislative proposals related to an influenza pandemic have been proposed in the House and the Senate. The Administration and the Republican leadership in Congress have neither supported any of these proposals nor put forward their own legislation.

The few positive steps taken by the Administration over the last five years have been limited. They include modest investments in research for the next generation of influenza vaccines and the testing and purchasing of a modest number of doses of avian flu vaccine. As a result, the United States lags behind other developed nations in preparing for an influenza pandemic.

Ignoring Expert Recommendations

Over the last five years, a series of expert bodies have made recommendations that would have bolstered the nation's fragile vaccine supply and improved the nation's readiness for an outbreak of avian flu or other influenza pandemic. These recommendations have been routinely ignored by Administration officials. In fact, it was not until October 7, 2005, that President Bush met with vaccine manufacturers to ask what could be done to increase their capacity to provide influenza vaccine for a pandemic.[1]

November 2001: Institute of Medicine Statement on the Need for a National Vaccine Authority

In November 2001, the Council of the Institute of Medicine, which is the institution's governing body, issued an extraordinary statement urging the creation of a "National Vaccine Authority" to coordinate a high-level response to a growing crisis in the supply of important vaccines, including the flu vaccine.[2] At the time, the Council included Dr. Anthony Fauci, head of the National Institute on Allergy and Infectious Diseases at NIH, Dr. Gail Wilensky, who had led the Health Care Financing Administration under President George H.W. Bush, and Dr. Kenneth Shine, the head of the Institute of Medicine.

The Administration did not create a National Vaccine Authority, nor did they enhance the existing office that oversees vaccine policy.

October 2002: National Vaccine Advisory Committee Report on the Need for Incentives for Vaccine Manufacturers

In October 2002, the National Vaccine Advisory Committee of the Department of Health and Human Services released a major report on vaccine supply. The Committee recommended the creation of a "multi-disciplinary group to evaluate the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines."[3]

The Administration did not create this multi-disciplinary group to assess incentives for the vaccine supply.

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[1] *Bush, Executives Consider Strategies to Ramp Up Vaccine Production*, Washington Post (Oct. 8, 2005).

[2] The Council noted, "the availability of influenza vaccines has been delayed over the past several years and in 2000, one company stopped production." IOM, *Statement from the IOM Council on Vaccine Development* (Nov. 5, 2001).

[3] National Vaccine Advisory Committee, *Strengthening the Supply of Routinely Recommended Vaccines in the United States* (Jan. 2003).

March 2003: Institute of Medicine Report on the Need for Investment in Antiviral Stockpiles and Public Health Infrastructure
April 2003: GAO Report on Gaps in Public Health Preparedness

In March 2003, the Institute of Medicine made a series of urgent recommendations in a report entitled *Microbial Threats to Health.* To prepare for an influenza pandemic or other global outbreak of infectious disease, the Institute of Medicine called for, among other measures, major investments in significant stockpiles of antiviral drugs and public health infrastructure.[4] These recommendations were echoed in a report released by the General Accounting Office in April 2003. GAO found major gaps in public health and hospital preparedness at state and local levels.[5]

The Administration did not pursue significant stockpiles of antiviral drugs and failed to propose a significant new investment in public health preparedness.

August 2003: Institute of Medicine Report on the Need for Market Incentives for Vaccines

In August 2003, the Institute of Medicine identified inadequate reimbursement and gaps in insurance coverage of vaccination as key factors in reducing pharmaceutical company interest in vaccine production. The Institute found that "federal and state governments currently lack a coherent policy" to address this problem, creating "uncertainty among both producers and purchasers, which in turn reduces incentives for future vaccine development."[6]

The Administration did not develop any major new initiatives to guarantee an acceptable market for the influenza vaccine or other vaccines.

December 2004: National Vaccine Advisory Committee Report on the Need to Bolster Annual Influenza Vaccination

In December 2004, the National Vaccine Advisory Committee of HHS released a report entitled *Strengthening the Nation's Influenza Vaccination System.* The report focused on ways to improve influenza vaccination to save lives during annual flu seasons and "foster preparedness for an influenza pandemic." The Committee recommended a series of steps to reduce barriers to vaccination, including new initiatives to vaccinate patients in emergency departments and to expand vaccination programs for adults.[7]

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[4] Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, and Response* (Mar. 18, 2003) (online at http://www.iom.edu/report.asp?id=5381).

[5] General Accounting Office, *Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 2003).

[6] IOM, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003).

[7] Charles M. Holmes et al. *Strengthening the Nation's Influenza Vaccination System: A National Vaccine Advisory Committee Assessment*, American Journal of Preventive Medicine, 221-226 (Oct. 2005) (online at http://www.hhs.gov/nvpo/nvac/NationsInfluenzaVaxSysAJPMOct05.pdf).

The Administration did not implement the recommended initiatives, such as the initiative to vaccinate patients in emergency departments or expand vaccination programs for adults.

Cutting Funds for Public Health

Asked earlier this month about preparations for an influenza pandemic, HHS Secretary Michael Leavitt has stated "any suggestion the president hasn't been fully engaged on this pre-Katrina would be wrong."[8] Contrary to Secretary Leavitt's assertion, the budgets submitted by the White House to Congress have included major cuts in public health preparedness, undermining the nation's defenses against a flu pandemic.

Fiscal Year 2005 Budget

In February 2004, President Bush submitted a budget to Congress that proposed cutting $113 million from the Centers for Disease Control and Prevention in fiscal year 2005, including $105 million from state and local public health preparedness.[9]

At a February 2004 hearing of the Government Reform Committee, Dr. Robert B. Stroube, Virginia's State Health Commissioner, testified: "The Administration's proposed cuts could jeopardize our ability to respond to a terrorist event, outbreak of an infectious disease or other public health threats or emergencies .... Such a cut will jeopardize our ability to protect the public we serve."[10]

The President's budget for pandemic flu also drew bipartisan opposition. Republican Chair Tom Davis and Democratic Ranking Member Henry Waxman of the Government Reform Committee wrote in May 2004 that the budget "does not provide any increase in funding for pandemic flu preparedness at CDC and state and local health departments, despite the need for improved planning."[11]

In the final appropriations legislation, Congress restored the Administration's proposed cuts to state and local public health preparedness, but did not provide for any increase.

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[8] *The Race Against Avian Flu*, Newsweek (Oct. 17, 2005).

[9] CDC, *FY 2005 CDC Budget Request — Detail of Increases/*Decreases (Feb. 2, 2004).

[10] Dr. Robert B. Stroube, Testimony before the Committee on Government Reform (Feb.12, 2004).

[11] Letter from Chairman Tom Davis and Ranking Minority Member Henry A. Waxman to Appropriations Committee Chairman Ralph Regula and Ranking Minority Member David R. Obey (May 4, 2004).

Fiscal Year 2006 Budget

In February 2005, the President proposed cutting the budget of the Centers for Disease Control and Prevention by $531 million in fiscal year 2006, including $130 million in cuts for state and local public health preparedness.[12]

According to Patrick M. Libbey, the executive director of the National Association of City and County Health Officials, the budget proposal would severely impair public health preparedness. He stated: "Local health departments make sure that life-saving vaccines or equipment actually reach the victims .... It's outrageous that the proposed budget reduces funding for local health departments to fight bioterrorism and would force them to scale back their efforts."[13]

The House-passed version of the 2006 appropriations for HHS restored only $52 million of the $130 million in the Administration's proposed cuts. The appropriations legislation is still pending in the Senate.

Tamiflu Purchases

The failure to propose adequate budgets for public health preparedness has impacted the ability of the United States to purchase the key antiviral drug Tamiflu, which is the only drug believed to be effective against avian flu. The supply of Tamiflu currently held by HHS can treat just 2% of the U.S. population, compared to stockpiles in other nations that can treat 20% to 40% of the population. According to one recent report, "had the administration placed a large order just a few months ago, Roche, Tamiflu's maker, could have delivered much of the supply by next year."[14] Instead, the United States now has to wait at least two years to bolster its stockpile.

Delaying a Response Plan

In a series of reports since November 2000, the Government Accountability Office has called on the Department of Health and Human Services to finalize a national response plan to an influenza pandemic. As of October 12, 2005, such a plan had yet to be finalized.

November 2000 GAO Report

In November 2000, GAO reported that federal efforts to develop a pandemic influenza plan were being hindered because "key federal decisions have not been made." These decisions included determining "the proportion of vaccines and antiviral drugs to be purchased, distributed, and administered by the public and private sectors" and "priorities for which population groups

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[12] CDC, *FY2006 CDC Functional Table Reflecting New Budget Structure* (Feb. 11, 2005).

[13] National Association of City and County Health Officials, *Restore Bioterrorism Funds, Local Health Officials Appeal* (Mar. 31, 2005).

[14] *After Delay, U.S. Faces Line for Flu Drug*, New York Times (Oct. 7, 2005).

should receive vaccines and antiviral drugs first when supplies are limited." GAO found that the lack of a plan "could contribute to public confusion and weaken the effectiveness of the public health response" to an influenza pandemic. GAO recommends that "HHS...complete the national response plan."

May 2001 GAO Report

In May 2001, GAO reported on fundamental weaknesses in the U.S. vaccine supply system. GAO found that "HHS has not completed a national pandemic response plan that would, among other things, address how to deal with shortages of vaccine."[15]

April 2003 GAO Report

In April 2003, GAO found that the absence of a national response plan is impeding public health preparedness at the state and local levels. GAO stated: "In our 2000 report on the influenza pandemic, we recommended that HHS ... complete the national response plan. To date, only limited progress has been made."[16]

February 2004 GAO Report

In February 2004, GAO reiterated that "federal plans for the purchase, distribution, and administration of vaccines and drugs in response to an influenza pandemic still have not been finalized, complicating the efforts of states to develop their state plans and heightening concern about our nation's ability to respond effectively to an influenza pandemic."[17]

September 2004 GAO Report

In September 2004, GAO reviewed a HHS draft pandemic influenza plan, which had been released in August 2004, and found that it "leaves some important decisions about the purchase, distribution, and administration of vaccines unresolved." In addition, GAO found that "the draft plan does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic." The result, according to GAO, is that "states are left to make their own decisions, potentially compromising the timing and adequacy of a response to an influenza pandemic."[18]

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[15] GAO, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for high Risk People* (May 2001).

[16] GAO. *Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts have Improved Public Health Response Capacity, but Gaps Remain* (Apr. 2003).

[17] GAO, *Public health Preparedness: Response Capacity Improving, but Much Remains to be Accomplished* (Feb. 2004).

[18] GAO, *Federal Challenges in Responding to Influenza Pandemics* (Sept. 2004).

June 2005 GAO Report

In June 2005, GAO reviewed preparedness efforts for an influenza pandemic and found the absence of a final preparedness plan to be a key barrier to progress. The agency stated: "key questions about the federal role in purchasing and distributing vaccines during a pandemic remain, and clear guidance on potential priority groups is lacking in HHS's current draft of its pandemic preparedness plan." GAO again concluded that "until key federal decisions are made, public health officials at all levels may find it difficult to plan for an influenza pandemic, and the timeliness and adequacy of response efforts may be compromised."[19]

The Consequences of Delay

The pervasive delays in the preparation of the national response plan have had significant consequences. In September 2004, just one week prior to last year's shortage of flu vaccine, GAO testified that "there is no mechanism in place to ensure distribution of flu vaccine to high-risk individuals before others when the vaccine is in short supply."[20] As GAO anticipated, the Administration's response to the flu vaccine shortage was marred by confusion, long lines, and poor access to vaccine for many high-risk individuals.

Failing to Support Pandemic-Flu-Related Legislation

In addition to failing to implement expert recommendations, reducing public health budgets, and delaying the national response plan, the Administration has failed to support recent legislation to close gaps in the nation's preparedness for an influenza pandemic.

The Flu Protection Act

On February 15, 2005, Representative Rahm Emanuel and Senator Evan Bayh introduced the Flu Protection Act of 2005.[21] The bill would create an outreach and education campaign; encourage early orders of flu vaccine; and institute efforts to increase production of, and access to, flu vaccine. The Administration has not endorsed this legislation.

Attacking Viral Influenza Across Nations Act

On April 28, 2005, Representative Nita Lowey and Senator Barack Obama introduced the Attacking Viral Influenza Across Nations Act of 2005.[22] The legislation would amend the Public Health Service Act to increase planning, preparedness, training and coordination of state activities addressing pandemic flu. The bill would also require stockpiling of vaccines and

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[19] GAO, *Influenza Pandemic: Challenges in Preparedness and* Response (June 2005).

[20] GAO, Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks (Sept. 2004).

[21] S.375 and H.R.813.

[22] S.969 and H.R.3369.

antiviral medicines, and would it would direct the Secretary of Health and Human Services to take steps to address pandemic flu in other countries. The Administration has not endorsed this legislation.

Vaccine Access and Supply Act

On July 29, 2005, Representative Henry Waxman and Senator Edward Kennedy introduced the Vaccine Access and Supply Act.[23] The bill would guarantee the market for the influenza vaccine and promote a stable vaccine supply. It has been endorsed by the American Public Health Association, the Association of State and Territorial Health Officials, and the National Association of City and County Health Officials. But the Administration has not supported the legislation.

Other Measures

Over the last five years, the Administration has made some positive steps to address the threat of an influenza pandemic. For example, the Administration has made modest investments in research for the next generation of influenza vaccines, improved reimbursement for influenza vaccination in Medicare, provided funding to promote year-round production of eggs for vaccine development, and provided support for global surveillance of influenza. Recently, NIH has tested and HHS has contracted for a modest number of doses of avian flu vaccine.

These steps, however, are small compared to the gaping holes in our nation's preparedness. Recently, a report from the *Trust for America's Health* found that the United Kingdom and Canada are significantly ahead of the United States in preparing for an influenza pandemic. In part because of the lack of preparations, the report estimated that even a mid-level pandemic could kill over 500,000 Americans.[24]

[23] S.1527 and H.R.3502.

[24] Trust for America's Health, *A Killer Flu?* (June 2005).

Mr. WAXMAN. What we document is that the Department of Health and Human Services and the White House have ignored report after report and warning after warning.

Four years ago, the Institute of Medicine urged the administration to create a national vaccine authority to coordinate a high-level response to a growing crisis in vaccine supply. This was an extraordinary recommendation made by a group of experts that included Dr. Anthony Fauci of the National Institutes of Health. Yet today these crucial recommendations still have not been implemented.

Three years ago, the National Vaccine Advisory Committee to the Department of HHS recommended that the administration enhance incentives to spur vaccine development and support the vaccine market. Yet nothing was done.

The front lines of fighting a flu pandemic are our State and local health departments, but the President's budget proposals repeatedly try to cut their funding. The result is that we have fallen significantly behind in our efforts to protect against the bird flu or other global pandemics.

Our Nation—other nations have released comprehensive plans and purchased significant quantities of antiviral drugs. Because of our delays we are at the back of the line. At last, however, some progress is being made. On Tuesday, the President announced a significant new proposal for funding influenza vaccine development and procurement. Then, on Wednesday, the Department of Health and Human Services released a detailed plan to guide Federal, State and local preparations.

These are important steps. And even as I wish they had been taking taken sooner, I commend the President and Secretary Leavitt for acting now. And we will all be safer if the events of this week become a turning point.

There are parts of the President's strategy that make a lot of sense. He has proposed investing in the next generation of flu vaccines which can be produced quickly and safely. He has also released a plan that provides important guidance to State and local health departments and laboratories.

But unfortunately, there are also some significant problems. The administration has given a key role to the Department of Homeland Security and FEMA to protect the Nation from a localized outbreak of pandemic flu in the United States. But given the abysmal performance of the Department of Homeland Security and FEMA in responding to Hurricane Katrina, this is a huge misjudgment. Protecting the public from a pandemic is a health problem, and it should be given to the government's health experts.

Another serious problem is inadequate funding. The administration has produced a detailed plan that instructs local and State governments to perform literally hundreds of tasks to prepare for an influenza pandemic, yet the administration is asking Congress for only $100 million to fund these activities. And even this $100 million increase is a phony number. The White House has not retracted its $130 million cut to State and local health departments.

Moreover, the administration is also asking States and localities to spend $510 million of their own money to purchase antiviral medications. As one health department director put it, "There

seems to be a lack of connection between the strategy and recognition of what it takes to pull off these plans on the ground."

A third problem is the administration's plan to shield vaccine manufacturers from liability without providing any meaningful compensation for people who are injured by the vaccine. We have learned during the administration's failed efforts to vaccinate several million health care workers, fire fighters and other first responders that a liability shield will not work unless those who might be injured by a vaccine know they will receive compensation. Yet the administration is poised to make the same mistake all over again.

These are serious problems, but they can be fixed; and I look forward to discussing these issues with Secretary Leavitt today. I thank him for his appearance. I hope this oversight hearing produces real improvements in public health preparedness for the benefit of the American people.

[The prepared statement of Hon. Henry A. Waxman follows:]

Statement of Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform Hearing on
"The National Pandemic Influenza Preparedness and Response Plan:
Is the U.S. Ready for Avian Flu?"
November 4, 2005

Thank you, Chairman Davis, for calling today's hearing on the serious public health threat of a potential global influenza pandemic. Under your leadership, this will be the Committee's seventh hearing related to a flu pandemic.

As those who have followed our hearings know, I have been extraordinarily critical of the Administration's failure to prepare for a pandemic. Recently, my staff put together an analysis of the delays and mistakes that have characterized the federal effort over the last five years. I ask that this analysis be made part of the record.

What we document is that the Department of Health and Human Services and the White House have ignored report after report and warning after warning.

Four years ago, the Institute of Medicine urged the Administration to create a National Vaccine Authority to coordinate a high-level response to a growing crisis in vaccine supply. This was an extraordinary recommendation made by a group of experts that included

Dr. Anthony Fauci of the National Institutes of Health. Yet today, these crucial recommendations still have not been implemented.

Three years ago, the National Vaccine Advisory Committee to the Department of Health and Human Services recommended that the Administration enhance incentives to spur vaccine development and support the vaccine market. Yet nothing was done.

The front lines of fighting a flu pandemic are our state and local health departments. But the President's budget proposals repeatedly tried to cut their funding.

The result is that we have fallen significantly behind in our efforts to protect against the bird flu or other global pandemic. Other nations have released comprehensive plans and purchased significant quantities of antiviral drugs. Because of our delays, we are at the back of the line.

At last, however, some progress is being made. On Tuesday, the President announced a significant new proposal for funding flu vaccine development and procurement. Then on Wednesday, the Department of Health and Human Services released a detailed plan to guide federal, state, and local preparations.

These are important steps. And even as I wish they had been taken sooner, I commend the President and Secretary Leavitt for acting now. We will all be safer if the events of this week become a turning point.

There are parts of the President's strategy that make a lot of sense. He has proposed investing in the next generation of flu vaccines, which can be produced quickly and safely. He has also released a plan that provides important guidance to state and local health departments and laboratories.

But unfortunately, there are also some significant problems

The Administration has given a key role to Department of Homeland Security and FEMA to protect the nation from a localized outbreak of pandemic flu in the United States. But given the abysmal performance of the Department of Homeland Security and FEMA in responding to Hurricane Katrina, this is a huge misjudgment.

Protecting the public from a pandemic is a health problem, and it should be given to the government's health experts.

Another serious problem is inadequate funding. The Administration has produced a detailed plan that instructs local and state

governments to perform literally hundreds of tasks to prepare for an influenza pandemic. Yet the Administration is asking Congress for only $100 million to fund these activities.

And even this $100 million increase is a phony number. The White House has not retracted its $130 million cut to state and local health departments. Moreover, the Administration is also asking states and localities to spend $510 million of their own money to purchase antiviral medications.

As one health department director put it, "There seems to be a lack of connection between the strategy and recognition of what it takes to pull off these plans on the ground."

A third problem is the Administration's plan to shield vaccine manufacturers from liability without providing any meaningful compensation for people injured by the vaccine. We learned during the Administration's failed efforts to vaccinate several million health care workers, firefighters, and other first responders that liability shields will not work unless those who might be injured by a vaccine know they will receive compensation. Yet the Administration is poised to make the same mistake all over again.

These are serious problems, but they can be fixed. I look forward to discussing these issues with Secretary Leavitt today, and I thank him for his appearance. I hope this oversight hearing produces real improvements in public health preparedness for the benefit of the American people.

Chairman TOM DAVIS. Mr. Waxman, thank you.

All Members will be able to enter statements into the record. I know there are some who want to speak now. I would just add, the Secretary has limited time so to the extent we are speaking, we won't be able to get maybe through all the questions, but I don't want to deprive anyone of making an opening statement.

Mr. Gutknecht, I know you wanted to say something.

Mr. GUTKNECHT. Mr. Chairman, ever so briefly. And I want to thank you for this hearing and I want to thank the Secretary for coming up here today.

I really think that one of the issues that I hope we will discuss today is the issue of duplication of efforts. Because I know that there are efforts going on in labs in my district, for example, that I think are very interesting; and my concern is that, ultimately, the Federal Government may wind up duplicating an awful lot of the good work that is being done right now. And so I think this is a very important issue.

The public is deeply concerned, but I think they also want us to be accountable for the money we spend. And so as we have this hearing I hope that issue will at least get some consideration.

I would yield back.

Chairman TOM DAVIS. Mr. Lantos.

Mr. LANTOS. Thank you, Mr. Chairman.

I want to welcome this distinguished panel. And I would like to raise some specific issues which relate to the geographic pattern of our preparedness.

One of the very severe problems we had in responding to September 11th was that, following historic patterns, we provided funding and made preparations on a nationwide basis, disregarding the fact that some areas are dramatically more likely to be targets of terrorist attacks than others.

Now, Mr. Chairman, the San Francisco International Airport is at the heart of my congressional district. And it is self-evident that this flu epidemic, generating in Asia, is most likely to hit, initially, the three major points of entry on the Pacific coast—San Francisco International Airport, Los Angeles, and Seattle.

Last year, Mr. Chairman, 32 million passengers came through San Francisco International Airport. Over 3 million of these individuals came from Asia. A similar number landed in Los Angeles and a smaller number in Seattle.

Now, the 1918 flu epidemic, which was responsible for the death of over 50 million people, circled the globe several times in 18 months, which was an amazing feat given the fact that we were a generation away from commercial air travel. Just consider what kind of devastation such a virus could unleash, given the enormous presence of global air travel.

I know that deadly airborne illnesses are not novel for San Francisco International Airport. I remember going down to the airport to catch a flight and seeing passengers arriving from Asia with medical masks, in 2003 during the SARS outbreak.

What I would like to ask Secretary Leavitt and his distinguished panel to tell us is, what specific provisions do you have in mind? What specific plans do you have to deal with the most likely initial points of entry with respect to quarantine and a dozen other items?

And I very much hope that in planning for this potential pandemic we will not make the mistake we did after September 11th, of assuming that Laramie, WY, is as likely to be hit as New York or San Francisco.

This pandemic, if it comes, is most likely to come from Asia, it is most likely to come via San Francisco, Los Angeles or other ports of entry; and I would be most appreciative if you could deal with this issue.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you, Mr. Lantos.

Yes, Mr. Duncan.

Mr. DUNCAN. Very briefly, Mr. Chairman, I thank you for calling this hearing; and I think it is very important that we look into this entire bird flu situation. However, I do have concerns and questions about whether we are overreacting because of breathless, overdramatized news reports, repeated over and over again in our 24-hour news cycles.

Have we turned something into a pandemic before it is even an epidemic? In fact, almost every major disease known to man kills more people around the world every day than this bird flu has in the last several months.

Now, from what I read, we are about to spend billions on a vaccine or medicine that we are not even sure will work on this particular virus. We have already scared people around the world so much that they are hoarding Tamiflu medicine that may or may not even help with this particular flu.

I am not a medical doctor or a public health specialist I am not saying we should do nothing. All I am saying is that possibly we should look before we leap. In today's political climate, almost every threat is exaggerated, and then legislators have to try to do everything possible to prove that they are doing more than anyone else in case something does happen.

I led a congressional delegation to Asia last February when we went into the Hong Kong airport. They immediately checked the temperatures of everybody in our delegation. Are we checking all those who are coming from countries where, or areas where, the bird flu has appeared and/or should we?

Again, I will say that I am not saying we should do nothing. All I am saying is that we should not panic before the facts are justified. We need all those in authority to ask many questions and take reasonable common-sense and intelligent steps to sensibly deal with this situation.

Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Kucinich.

Mr. KUCINICH. Thank you, Mr. Chairman.

Is the United States ready for avian flu? I don't think that there is any question that the answer is a clear "no." The question is what are we doing about it?

The administration finally released its plan this week under tremendous public pressure. It got overwhelming reviews—excuse me, it got underwhelming reviews from experts because it is deficient on several fronts that will be collectively necessary for us to fight this disease.

It is especially weak on efforts to stockpile antivirals. Our best antiviral bet will be Roche's Tamiflu. It is well established that it will take Roche years to produce enough American stockpile needs and—to produce enough to satisfy American stockpile needs. We have enough for less than 1 percent of the population. We need at least enough for 25 percent of the population.

Even after promised increases in production capacity, Roche's supply is far less than our stockpile needs. The same goes for countries around the world, including those where the outbreak is likely to originate if the virus mutates to pass easily from human to human. And yet there are plenty of production facilities to solve the problem. In fact, over 100 companies have expressed interest in making the drug.

So what is the problem? The problem is that Roche has a monopoly on Tamiflu.

We are very familiar with what happens when a company has a monopoly on a product the world needs. They control supply. And that is exactly what Roche is doing by choking world supply. And what is happening by choking world supply is not the only consequence of Roche's monopoly. If we need a reminder about the perils of concentrating production in the hands of a few, we only need to look to last year.

Chiron was forced to scrap half of the U.S. flu vaccine supply when their manufacturing facility failed to meet safety standards. That was for the conventional flu. Imagine what would happen if we lost half of our Tamiflu supply in the middle of an avian flu outbreak? And yet, at the cost of a potentially far more devastating avian flu pandemic, we are about to repeat our mistake.

But there is a solution. The solution is compulsory licensing. HHS, Mr. Secretary, has the authority to issue a compulsory license to get rid of this dangerous shortage by allowing other companies to make Tamiflu. Roche would get compensation. That authority exists specifically to prevent the most predictable scenario, a pharmaceutical company holding a drug hostage when it is needed to protect public health in order to increase its profits. And I believe that is what we are seeing here.

Roche's revenues increased 17 percent last quarter. Tamiflu sales more than doubled to 215 million in 3 months. They expect to make only almost $1 billion from Tamiflu sales this year. Of course, they would want to hang on to this monopoly; their ultimate responsibility is to their shareholders, not to the public.

We have heard a lot of promises from Roche that they are willing to negotiate with other companies to sublicense production, but I have not heard anything about a firm agreement to do so. Roche can keep fees too high in order to make it unprofitable for an outside company to manufacture Tamiflu. They can stipulate—and have indicated their willingness to do so—that any Tamiflu made by a company other than Roche would not be available for sale in the United States. In other words, they can continue to restrict supply.

And to top it off, the administration boasts it wants throw $1 billion into buying antivirals. But the drugs aren't there. There is nothing to buy. And as it stands, there won't be anything to buy in the near future. We may not have that kind of time. But the ad-

ministration is still sitting on its hands while Roche's profits skyrocket and Tamiflu production does not.

This is a clear choice of profits over public health.

As you know, Mr. Secretary, last month nine of my colleagues and I sent you a letter requesting compulsory licensing. We have given Roche plenty of time to act appropriately, and they have failed to do so.

In order to protect public health, we must issue a compulsory license for Tamiflu immediately.

I thank the Chair.

Chairman TOM DAVIS. Mr. Souder.

Mr. SOUDER. Thank you. I am grateful to Chairman Tom Davis for holding this important hearing as part of a series of hearings with Secretary Leavitt on our country's preparedness and response plan for the pandemic influenza.

Earlier this week, the President announced a National Strategy for Pandemic Influenza and Health and Human Services published its Pandemic Influenza Plan. These developments are encouraging signs that the administration is taking seriously the potential devastation of a new pandemic.

As stated in the HHS Pandemic Influenza Plan, "Preparedness planning is imperative to lessen the impact of a pandemic." I couldn't agree more. We should not have to relearn again and again that being caught unprepared for a predictable disaster makes an otherwise manageable situation spiral out of control. So while I commend the Secretary of Health and Human Services for attempting to get ahead of a possible influenza pandemic, I remain skeptical of the agency's ability to identify and respond to danger signals indicating a genuine national problem.

This country is already struggling with a serious epidemic, methamphetamine abuse and trafficking. This epidemic is already in every State viscously destroying lives and tearing apart communities. This national epidemic, however, is one in which HHS, under Secretary Leavitt's leadership, stood as a barrier for formulating a national comprehensive strategy to address this problem.

As this destructive epidemic was spreading, Congress was constantly asking the administration for a national plan to address this epidemic. But it was the HHS Secretary who was dragging his feet. The so-called "policy" that was finally announced at an August press conference—not in Washington, DC, but in Tennessee—after years of devastation and countless lives, is insufficient and hardly deserves to be called a national plan to address the epidemic. It was embarrassing.

Mr. Secretary, I would like you to show this committee and the American people that we can have confidence in the ability of the Nation's health agency to do more than talk about an epidemic. This kind of lip service we have received in the midst of a meth epidemic had better give way to real, effective planning and treatment for an influenza pandemic, or the inevitable devastation could be the worst this country has ever experienced.

I would like to add, I was just given your response to my letter of August 19th. And I appreciate receiving the response. In the future, as someone who represents the same party and as chairman of the subcommittee, I would hope it wouldn't take the full commit-

tee chairman having you at a hearing to get a timely response to questions.

I yield back.

Chairman TOM DAVIS. Thank you.

Mr. Sanders.

Mr. SANDERS. Thank you very much, Mr. Chairman. And Secretary Leavitt, thanks very much for being with us.

Mr. Chairman, I think perhaps Mr. Duncan was right in suggesting that we may be overreacting. But I believe that the American people want us to be safe rather than sorry. I think they will forgive us if we end up doing things and spending money, and in the long run it may turn out not to be necessary. If, in fact, we are going forward vigorously to prevent what could be a horrible, horrible situation.

I think we all remember, or read, that in 1918 some 50 million people in this world died from an influenza epidemic. And I think it is beholden upon our country and governments throughout the world to do everything that we can in every way to protect the American people and people throughout the world.

I think Mr. Kucinich a moment ago raised some very important issues. And the issue is that our job as the Government of the United States of America is not to worry at this moment about the corporate profits of the Roche company, or any other drug company, but to make certain that we are doing all that we can to prepare for what could be a terrible pandemic.

I hope that in that context we can all agree that now is not the time to be tiptoeing around intellectual property rights or letting bald-faced profiteering inhibit our ability to prepare for a pandemic.

This, in fact, is a matter of life and death. And the American people will never forgive us if we are not prepared and if we allow corporate profiteering to take the place of serious government action.

I think most of us understand that one of the important tools that we now have at our disposal is getting caught up in that hemming and hawing about whether or not we go forward in terms of dealing with Roche.

Tamiflu, as we all know, is the brand name of an antiviral medicine that is what we have right now for minimizing the scope and severity of damage from a pandemic flu outbreak. While we all, no doubt, support vigorous pursuit of an avian flu vaccine, antivirals are what we have got today, right now. But we don't have anywhere near the amount that we need; and I hope that the Secretary will address that important issue.

All the speeches, all the reports are fine. Do we have the medicine that we need and will we have it? The Infectious Diseases Society of America and the World Health Organization say the United States should have enough courses to treat from 25 to 40 percent of the population—our population. Right now, the United States only has enough to cover 1 to 2 percent of the population.

So that is an issue I hope that you will address, sir, when you speak.

Roche is the only company with a license to manufacture and sell Tamiflu in the United States. They have limited production capacity and simply cannot make enough Tamiflu to meet the demand.

The World Health Organization says it will take 10 years for Roche to adequately supply world demand for Tamiflu stockpiles. We don't have 10 years. Unfortunately, Roche has also been dragging its feet about licensing other manufacturers to mass produce it.

So, Mr. Secretary, you come from an administration which, most of the American people know, bends over backward to protect large multinational corporations, whether it is drug companies or oil companies. Now is not the time to worry about the profits or campaign contributions. Now is the time to protect the American people. If Roche does not have the capability of producing the volume of Tamiflu that we need, clearly what has to happen is, other companies have to jump in.

I know that Senator Schumer in the Senate has raised that issue. I hope that you will be able to tell us today that in one way or another you are going to make certain that Roche, either through compulsory licensing or through a voluntary approach working with other production capabilities and other companies, will start producing the medicine that we need.

This is not the time for a company to be making excessive profits when the American people do not have the medicine they need to protect themselves, nor for the world as well. So we hope that you will be strong in dealing with Roche and saying that the health and well-being of the American people comes before their corporate profits.

Thank you very much.

Chairman TOM DAVIS. Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman.

It is nice seeing all of you again.

First of all, I want to commend the President for making the speech that he made on protecting ourselves and preparing for a possible epidemic or pandemic to be very bad not only for the United States, but for the entire world.

I want to talk about another subject that is very, very important. And you folks will be making recommendations as well as getting the job done and helping produce the vaccines that are necessary to protect the American people.

For about 4 or 5 years, when I was chairman of the committee, we had hearings on contaminants in vaccines. The one that really bothered me was the mercury in the vaccine thimerosal. Thimerosal was never tested by the Food and Drug Administration because it was produced before you guys had the ability to do that. And it's been used in vaccines for a long, long time, since the 1930's.

And when I was a boy growing up, if you had measles, they quarantined you. Now they give you vaccinations for that. And kids get as many as 30 vaccinations before they go to school. And adults are getting all kinds of shots. I am ready to go over to Pakistan and India, and all the people on my CODEL are going to get a whole series of shots, and almost all of them contain thimerosal, which has 50 percent ethyl mercury in it.

Now, the reason I bring this up is we have had an epidemic of autism in this country. We gone from 1 in 10,000 children that are autistic to 1 in 166, according to CDC. It is an epidemic. We have had an increase in Alzheimer's, another neurological disorder. And people that I had before my committee for years, scientists from

around the world, said that one of the causes was the mercury in the vaccines.

And the reason I bring this up is we are going to have to produce the vaccines that are necessary. You and the pharmaceutical industry are going to have to produce the vaccines. I want to give them protection against class-action lawsuits, but in exchange for that—and this President talked about that—tort reform. In exchange for that, it is extremely important that the Vaccine Injury Compensation Fund be more user-friendly, and we put more money into it if it is necessary, and that can be done by a small increase in the costs per shot.

And the second thing is get mercury out of all vaccines. It can be done if you go to single shot vials or use something else as a preservative. But the mercury, in the opinion of scientists around the world, is causing neurological problems, an increase in Alzheimer's, autism and other things.

Now, you have been very helpful in getting it out of most of the children's vaccines. It is still in three or four. Please, when they start talking about legislation to deal with this, do those three things: Get mercury out of the vaccines, make the compensation fund more user-friendly, and then we will do everything we can, No. 3, to give the pharmaceutical industry the class-action lawsuit protection that they want.

I want them to produce those vaccines. I want them to keep this country and the world the safest it has ever been as far as health is concerned, and I know you feel that way, too. But you can't leave these contaminants, especially mercury, which is a known neurotoxin, in these vaccines. Thank you very much.

Chairman TOM DAVIS. Ms. Norton.

Ms. NORTON. Mr. Chairman, I appreciate that you called this hearing. I want to welcome the Secretary and others from the Department. Mr. Chairman, in the street they would say, this hearing is right on time, following the President's announcement. I wish I could say that the government's response here is on time.

I will be looking for answers to a number of questions concerning pandemic flu, why countries in Europe are more prepared, so that we may have to get in line behind them and, in fact, may not be able to get it at all if Europe decides to redirect whatever medicines they have and not allow their suppliers to deal with those who are offshore, if we get enough of a pandemic. Why there are large cuts in State and local public health budgets, the very vehicles that we will need in the event of a pandemic?

But if I may say so, I think Mr. Duncan, my colleague across the aisle, raises a point that may be in the minds of the American people. If this had been an early reaction, if this had been earlier, it might have been seen as an attempt to get early hold of a pandemic. And now for many Americans it does seem like an overreaction when you consider that apparently we haven't done first things first.

I don't know how Americans are to have confidence in the Department to deal with pandemic flu when already, this early in the season, we are having distribution problems with the vaccine we already are supposed to have.

And I raise it only because I believe it would be legislative malpractice not to raise it when already early in the flu season here we are seeing pop up problems of distribution all over this region and across the country. Walgreen's says they are going to stop doing it altogether because they don't have enough supply after November 6th.

We sat through the flu crisis of last year. I was so relieved when, before I got my shot here, Mr. Secretary, I wanted to make sure that the priorities were on straight, because the Congress had its supply when others did not, and I was assured that everybody had a supply. And here we have seniors standing in line. CDC, of course, tosses it off as a distribution problem.

The fact is that these are the kinds of problems that we pay you to make sure we do not have. Part of it is, of course, that you are victims of our success, although it is not because of your advertising campaign. It is because we ran out last year, and now people have flu vaccine on their minds, and they rush in to get it. Well, that was foreseeable, sir. It was foreseeable that this company that we rely on so heavily for this ordinary, annual vaccine is still on its knees, still has huge problems that it is not correcting, and yet they are a major supplier.

There is a huge confidence problem with respect to our ability to deal with the annual flu, the ordinary illnesses that are ordinary illnesses that Americans know they will get. It seems to me you have to get ahold of that problem, not say, oh, it is the distribution, or, it really isn't us. You have to tell us how you are going to get ahold of that problem before you can expect us to have any confidence that you can reach to a problem, which most Americans can't possibly take seriously yet because so few people, as Mr. Duncan says, have died. I think that is exactly when you want to get ahold of it.

But my question to you is why should Americans focus on pandemics from Asia when they cannot get the ordinary flu vaccine in the District of Columbia, Maryland, and Virginia and across the United States of America?

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you.

Any other Members on our side wish to address? How many other speakers we got here? OK, we will go straight on down the road.

Mr. Clay.

Mr. CLAY. Thank you, Mr. Chairman and Ranking Member Waxman, for holding today's hearing.

Given that a flu pandemic today can cause over 500,000 deaths and 2 million hospitalizations in the United States alone, it is essential that our Nation be prepared to effectively respond to a flu pandemic.

While I applaud the Bush administration's efforts to prepare for the danger of a pandemic flu outbreak, I am concerned that the President's strategy underfunds State and local preparedness efforts. The President' plan requires States to spend $510 million to purchase antivirals. As we all know, many States' budgets are already strapped. And where does the President expect them to get $510 million to afford such a purchase? It is imperative that Con-

gress ensure our constituents that this is not another underfunded mandate that will later be funded on the backs of poor people.

I welcome Secretary Leavitt and thank him for graciously providing our committee with insight into the steps being taken to stockpile enough vaccine to protect Americans against the bird flu.

It is my hope that today's hearing will also address recent reports that have indicated a possible repeat of last year's flu vaccine shortage.

I yield back and ask that my written statement be included in the record.

Chairman TOM DAVIS. Without objection, gentleman's statement and any other—Mr. Van Hollen.

Mr. VAN HOLLEN. Thank you, Mr. Chairman, I want to thank you and Mr. Waxman for holding these hearings, and for those of you who have been following this committee, you know that this is not the first hearing we have had on this issue. We have had hearings on this issue well over a year ago. And I want to commend the chairman and Mr. Waxman in trying to get ahead of this issue.

Mr. Secretary, I welcome you and all the others here today and look forward to your testimony. And I appreciate the fact that the President has come up with a plan, and I think it has many good components. I share the view of some of my colleagues expressing some of what I think are the shortcomings with the plan.

My major concern with the plan has to do with the amount of resources dedicated to trying to nip the problem in the bud overseas, trying to help our international partners, especially in Asia, be better prepared to respond to this issue. When we talk about the war on terrorism, the Bush administration has made a big point of the fact that it is important to fight the battle overseas before it comes here. We have to disrupt the terrorist networks overseas before they have time to organize and launch attacks here on the shores of the United States. Well, I can't think of a better case where it is better to address a problem overseas at its source before it gets here than the issue of pandemic flu and avian flu. I think we would all agree that by the time you ever saw this flu exhibiting itself in people here in the United States, it would already have gotten very much out of control worldwide.

And so I think if you look at the plan that you have put forward, as I understand it, you have allocated about $251 million to helping some of our partners and friends overseas on this issue. That is a near 3½ percent of the overall $7-plus billion in this plan. And if you look at this issue as trying to control things before they get out of control and trying to identify ways to prevent the spread and nip things in the bud and at their source, it seems to me that that is not nearly enough to accomplish that purpose.

Clearly, we want to stockpile drugs here. We want to have the ability to fight the virus in its current form, the ability to be able to quickly ramp up so we can meet whatever form it may take in the future. It is important to have antiviral drugs, but those stockpilings all assume and plan for the worst case. It seems to me we should be devoting more resources to preventing the worst case in terms of prevention at its source, and so I hope during your testimony you will address this.

I know you traveled to Asia. You have looked at some of the farm techniques. There has been talk from the United Nations and World Health Organization about trying to develop something to put in the feed of chickens that might immunize them, and there are lots of ideas out there. It just seems to me that the plan that has being presented is very light on the amount of resources committed to what I think should be a very big focus of this, which is stopping this problem at its most likely source.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Mr. RUPPERSBERGER. I think I am the last one, and then we will be able to get to the testimony.

Mr. Chairman, thank you for the hearing. Mr. Waxman, thank you for your leadership.

I am not going to repeat a lot that was said. First thing that we need to learn from what happened in the past last year with our flu vaccine shortage, that if we can learn from our mistakes and move forward, we will be better off.

I think the President, the fact that he is paying attention to this issue, making it a priority and moving ahead with the plan is good, but we have to implement the plan right now. I think the fact that local government is going to really be involved is a good thing because as first responders, they are closest to the people, as long as they get the resources. And we have discussed that here today also.

My major concern, though, is the issue of how with respect to the plan, and what is the delivery system?

On the last time you were here, Mr. Secretary, I asked a question about the issue of needles and injection devices, and I have not received a small response.

And I want to address what Congressman Souder said: We, here, have an oversight. We are relying on you. We have hearings to raise issues and to hopefully hold you accountable. My office sent a letter on October 7th asking about this issue, and I haven't received a return letter either. I understand you are very busy and you are not going to return a lot of letters, but I would hope you deal with us because we need the information from you to represent our constituents; that you have somebody on your staff highlight the fact and get back to us on the information that we need, especially before a hearing.

Now, with respect to that, my main concern is that we might acquire through manufacture all the vaccines we need. Hopefully we will have a system that will be able to do that, but there are some issues about that also. But I am concerned about the issue of whether or not we have the devices in place for needles and injections and whether there is a plan dealing with that. And I would hope that you can answer that question.

I also believe the Federal Government needs a strategic vaccine reserve and production capability. This would be a plant that in times of emergency can be converted or switched on to meet vaccine needs. If the government cannot do this, we need to give business the incentive to have a facility that in times of need can push out large numbers of needed vaccines and needles. Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman and Ranking Member Waxman, for holding this hearing. I want to thank the Secretary and members of the panel for helping the committee with its work.

I associate myself with the remarks of my colleagues here on both sides of the aisle. I just have two areas that haven't necessarily been addressed yet. One is, you know, we heard from Secretary Chertoff about the issue of rail security, and he said basically that the States are going to have to handle that responsibility, which I was surprised at, because an interstate rail security system cannot be handled by individual States.

Then we heard from Mr. Michael Brown, who said that disaster relief such as Katrina, the Katrina situation, that also should be better handled by the States, even though that would have affected multiple States, and I don't think it could effectively be dealt with in that fashion. And I noticed in the President's plan which has recently come out, that federally we are going to handle 44 million courses of this vaccine, and then the other, the balance of it, which would be in the area of $500 million would be handled by individual States.

And I am just curious, with this trend of giving all this added responsibility to the States, especially a global pandemic, asking individual States, in individual cases and circumstances, to handle the responsibility of containing a global pandemic, I just—you know, it is just a pattern of conduct that we have seen from this administration of handing more and more responsibility to the States for problems that they are not equipped to deal with. So I am very concerned about that.

The second issue that has not been talked about, understandably, is an issue that has been brought up by the Association for the Prudent Use of Antibiotics. Now, I realize it is a different animal than what we are dealing with from this avian flu, but also they are concerned about the lack of incentives for drug companies to develop new antibiotics and the lack of investment in government incentives for those drug companies to do so. And I am hoping that at some point in your remarks you might be able to address that concern. It is a problem of a different nature, but it is quite similar to the growing problem that we have here with these new iterations of flu, influenza epidemics that we are concerned about at this hearing. So I look forward to your comments. Thank you.

Chairman TOM DAVIS. Yes, sir. The gentleman from Maryland.

Mr. CUMMINGS. Thank you very much, Mr. Chairman, and again I want to thank you and the ranking member for holding this hearing.

And I want to thank you, Mr. Secretary, and all of you, for being with us this morning.

In the wake of any catastrophe, our citizens expect assurance that our Government works hard to avert such a calamity and that it is well prepared to meet their essential needs. Regrettably, recent events have shaken the American people's faith in that certainty. The devastating flu vaccine shortage that typified last flu season coupled with the failed response to Hurricane Katrina demonstrated that there is much work to be done to improve our Nation's capacity to address an act of nature. If these lessons of our

past are to have any value, we must seriously question our Nation's pandemic influenza preparedness. Further, we must acknowledge that while we do not have control over nature, we do have control over the policy choices that determine our ability to lessen the impact of nature's mighty blows.

Simply put, planning and execution matter. It is estimated that a pandemic would result in the deaths of over 500,000 Americans, and, in fact, 25 percent of the world's population. The Baltimore Sun reported in an article entitled Fears of Flu Pandemic Spurring Preparations that the threat of an avian flu pandemic from Asia could cause 12,000 deaths in the State of Maryland early on, with the possibility of many more later.

One need not be an expert to comprehend the magnitude of such a loss of life and the disastrous impact a pandemic would have on our economy and our society. With this in mind, the time is long overdue for the government to move forward in the best interests of the Nation to ensure that a flu—a future flu pandemic is handled effectively.

Fulfilling this obligation demands a comprehensive plan, one that covers intergovernmental coordination, international surveillance, public health and veterinary infrastructure, and process for obtaining and distributing vaccines and antivirals.

The administration took a step in the right direction when it released a national strategy for pandemic influenza. The President wisely stated, "in the last century our country and the world have been hit by three influenza pandemics, and viruses from birds contributed to all of them." Yet the same administration waited until November 2005 to introduce a pandemic flu preparedness plan. Americans should ask whether a flu pandemic was foreseeable during this long delay. The short answer is yes. It is unfortunate that valuable time was wasted that should have been spent substantially preparing.

Although State and local health departments will function on the front lines of the flu pandemic, the administration proposed undermining State and local preparedness by cutting $130 million in Federal support of those efforts in fiscal year 2006. The President's strategy proposes that State and local health departments primarily would respond to a pandemic, but too many Americans' assurances that localities are up to the task will not outweigh the memory of thousands enduring long lines and lotteries, public confusion and the inequitable distribution of limited vaccines that typified last year's flu season. I fear these concerns may be well founded.

Finally, I am also concerned that this plan creates an untenable financial burden for some cash-strapped States and seeks to fund State and local preparedness on the cheap. Specifically, the recently released strategy calls for only over $100 million to update State pandemic plans, but also requires States to spend approximately $510 million to purchase antivirals. The Federal Government must spare no expense and exhaust every effort to ensure that no citizen is given less of an opportunity to survive a pandemic because they reside in a poor State.

Mr. Chairman, the American people are closely watching how its Government responds to this challenge, one that will no doubt test

the wisdom of our priorities and the firmness of our resolve to protect our citizens from threats, both seen and unseen. In the end, we will be judged not by the hearings that were held, nor by the proposals that were offered, but by how well we tangibly lessened human suffering and equipped our citizens with the ability to withstand the onslaught of a flu pandemic.

With that, I yield back and thank you.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Opening Statement

Representative Elijah E. Cummings, D-Maryland

Full Committee Hearing: "The National Pandemic Influenza Preparedness Response Plan: Is the U.S. Ready for Avian Flu?"

Committee on Government Reform
U.S. House of Representatives
109th Congress

November 4, 2005

Mr. Chairman,

Thank you for holding this critically important hearing to assess our nation's preparedness to respond to pandemic influenza.

In the wake of any catastrophe, our citizens expect assurance that their government fought hard to avert such a calamity and that it is well-prepared to meet their essential needs. Regrettably, recent events have shaken the American people's faith in that certainty. The devastating flu vaccine shortage that typified last flu season, coupled with the failed response to Hurricane Katrina, demonstrated that there is much work to be done to improve our nation's capacity to address an act of nature. If these lessons of our past are to have any value, we must *seriously* question our nation's pandemic influenza preparedness. Further, we must acknowledge that while we do not have control over nature, we do have control over the

policy choices that determine our ability to lessen the impact of nature's mighty blows. Simply put, planning and execution matter.

It is estimated that a pandemic would result in the deaths of over *500,000* Americans and infect *25%* of the world's population. The *Baltimore Sun* reported in an article entitled, *Fears of Flu Pandemic Spurring Preparations*, that "the threat of an avian flu pandemic from Asia...[could cause] 12,000 deaths in the state [of Maryland] early on, with the possibility of many more later." One need not be an expert to comprehend the magnitude of such a loss of life and the disastrous impact a pandemic would have on our economy and society.

With this in mind, the time is long overdue for the government to move forward in the best interest of the nation, to ensure that a future flu pandemic is handled effectively. Fulfilling this obligation demands a comprehensive plan: one that covers intergovernmental coordination, international surveillance, public health and veterinary infrastructure, and a process for obtaining and distributing vaccines and antivirals.

The Administration took a step in the right direction when it released the National Strategy for Pandemic Influenza. The

President wisely stated, "In the last century, our country and the world have been hit by three influenza pandemics, and viruses from birds contributed to all of them." Yet, this same Administration waited until November 2005 to introduce a pandemic flu preparedness plan. Americans should ask whether a flu pandemic was foreseeable during this long delay? The short answer is yes. It is unfortunate that valuable time was wasted that should have been spent substantially preparing.

Although state and local health departments will function on the front lines of a flu pandemic, the Administration proposed undermining state and local preparedness by cutting $130 million in federal support of those efforts in FY 2006. The President's strategy proposes that state and local health departments primarily would respond to a pandemic. For too many Americans, assurances that localities are up to the task will not outweigh the memory of thousands enduring long-lines and lotteries, public confusion, and the inequitable distribution of limited vaccines that typified last year's flu season. I fear these concerns may be well-founded.

I am also concerned that this plan creates an untenable financial burden for some cash-strapped states and seeks to fund state and local preparedness "on the cheap." Specifically, the

recently released strategy calls for only $100 million to update state pandemic plans, but also requires states to spend approximately $510 million to purchase antivirals. The federal government must spare no expense and exhaust every effort to ensure that no citizen is given less of an opportunity to survive a pandemic because they reside in a poor state.

Mr. Chairman, the American people are closely watching how its government responds to this challenge—one that will no doubt test the wisdom of our priorities and the firmness of our resolve to protect our citizens from threats both seen and unseen. In the end, we will be judged not by the hearings that were held nor by the proposals that were offered, but by how well we tangibly lessened human suffering and equipped our citizens with the ability to withstand the onslaught of a flu pandemic.

I look forward to today's witness and yield balance of my time.

Chairman TOM DAVIS. Thank you.

Mr. Secretary, thank you very much for your patience. We have a vote on now; there is only one vote. Mr. Shays has already voted and come back and prepared to keep the helm of this. But what I want to do right now is let Mr. Cannon introduce you formally to the committee. I have asked him to do that, being from your home State. Then we will swear you in. And I will ask you at that point if you want to take a break for 10 minutes and let Members come back, or if you want to continue with your statement with Mr. Shays presiding.

Chris, why don't you go ahead.

Mr. CANNON. Thank you, Mr. Chairman. I couldn't be more proud to introduce my Governor, almost exactly my age. I think I endorsed him before he ran for Governor the first time. He did a great job. He was a three-term Governor of Utah. Then to my consternation he took one of the toughest jobs you can possibly take in American Government, and that is to head up the EPA. He did an impossible job remarkably well. And he has now taken on the position of Secretary of HHS, which comes with more problems than EPA, I suspect, a much more difficult task, much more difficult budget to deal with, and the focus of some of our problems in America. And yet it also is one of the agencies that has the most opportunities, and I am actually thrilled that he is there because he has a great deal of history.

I was on an airplane recently with a mutual friend, Steve Prescott, who ran our Huntsman Cancer Center in Utah. He is one of the guys who designed some of the breakthroughs we have had in Utah, including a merger between the university hospital system and our largest hospital, private hospital, Intermountain Health Care, for the purpose of figuring out how we can better combat cancer. And Governor Leavitt then had worked with him to help set up a not-for-profit, which I think is going to be transformational in the way we do medicine in the very near future. He oversees, of course, the CDC, National Cancer Institute and the FDA. Mr. Souder's subcommittee had a hearing with three of those agencies represented. All three of them pointed out that the declining costs of DNA decoding and the declining cost of computerization is transformational to our medical system.

I cannot imagine anyone better able to manage that process than Secretary Leavitt, who has done some remarkable things, including establishing the goal of getting a data base of health care so that we can deal in a new context with the development of drugs or the treating of disease through massive computing and databasing statistics rather than the double-blind study.

So it is my great honor to introduce my Governor, now the Secretary of HHS, Mike Leavitt. Thank you.

[The prepared statement of Hon. Chris Cannon follows:]

The Honorable Chris Cannon
Opening Statement
Committee on Government Reform
November 4, 2005

Thank you, Chairman Davis, for this opportunity to offer my views on the "The National Pandemic Influenza Preparedness and Response Plan."

Let me begin by thanking The Honorable Michael O. Leavitt, Secretary, Department of Health and Human Services and former Governor of Utah for appearing before the Committee today. Your testimony and expertise on health issues is extremely valuable and will help shape the strategic undertaking that is necessary in protecting Americans from a national pandemic.

The most recognizable and currently discussed flu pandemic is the avian influenza, commonly referred to as bird flu. The Center for Disease Control (CDC) describes bird flu as an infection caused by avian influenza viruses that occurs naturally among birds but rarely affects humans.

Although the risk of a flu pandemic relating to the avian influenza is relatively low for the United States it is necessary to turn to history to realize the impact

that a strand of avian influenza can potentially have in relation to a national pandemic. Both the 1957-58 and 1968-69 pandemics were caused by viruses containing a combination of genes from a human influenza virus and an avian influenza virus. Additionally, the 1918-19 pandemic virus appears to have an avian origin. The 1957-58 Asian pandemic caused about 70,000 deaths in the United States and the 1968-1969 Hong Kong flu caused about 34,000 deaths in the United States.

It is important to take note of these historic numbers in order to properly implement a national preparedness plan. Currently, the avian flu hasn't spread to the United States but it has infected and killed more than 62 people in Vietnam, Cambodia, Thailand, and Indonesia.

This week, President Bush and Secretary Leavitt announced an ambitious plan to prepare for a national pandemic. Included in this plan is a $7.1 billion national strategy to safeguard against the danger of pandemic influenza, stockpiling of antivirals and vaccines, developing a public education and communication strategy, and creating a seamless network of Federal, state and local preparedness.

I applaud the efforts of the President and the Secretary but am still concerned regarding the national stockpile of flu vaccines. Earlier this year, the Committee held a hearing on the flu vaccine production and the inefficient procurement and distribution plan that the Government had in place. A national preparedness and response plan must guarantee citizens that there will not be a shortfall and essentially a repeat of the problems that we had in issuing a common cold flu vaccine.

I strongly support the efforts of this Committee to investigate and then demonstrate to the nation that the Government is properly prepared to handle such a national crisis as a flu pandemic.

Again, thank you for coming. I look forward to your testimony. With that, I yield back the balance of my time.

Mr. LEAVITT. Thank you.

Chairman TOM DAVIS. Mr. Secretary, we always swear everyone in before you testify, so just rise and raise your right hand, and your staff.

For the record, we have Dr. Bruce Gellin, Dr. Anthony Fauci, Dr. Julie Gerberding and Dr. William Raub here as well.

[Witnesses sworn.]

[Recess.]

Chairman TOM DAVIS. Mr. Secretary, thank you for your patience, and we will go ahead and proceed.

STATEMENT OF MICHAEL O. LEAVITT, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. BRUCE GELLIN, DIRECTOR, NATIONAL VACCINE PLANNING OFFICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. JULIE GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DR. WILLIAM RAUB, SCIENCE ADVISOR TO THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary LEAVITT. Thank you, Mr. Chairman. This is a topic of importance, I think, demonstrated by the number of members who have expressed interest, and I look forward to the period where we can interact directly.

Chairman TOM DAVIS. Let me note that your entire statement is in the record, so you don't have to——

Secretary LEAVITT. I would like to just summarize the statement that was submitted.

The bottom line is that pandemics happen. And 10 times in the last 300 years, 3 times in the last 100 years, we have had circumstances where literally, masses have been made ill and millions have been caused to die. Whenever there is a human to human transmission of a killer virus, it presents risk everywhere.

Currently, we're worried about the HFN1 virus. It is primarily an animal disease, but there is no certainty it will remain such. There are troubling signs. If the H5N1 virus is not the spark of a pandemic, there will ultimately be another. Pandemics happen, they have happened in the past, they will happen in the future.

Yesterday, the President laid out a broad national strategy, it calls on Congress to appropriate $7.1 billion. Today, I would like to just provide an overview of that plan and then go directly to questions.

I will lay the plan out in basically six parts. The first part is the international surveillance; this was mentioned in the opening statements. The importance of determining when the virus transitions to human to human, and where.

One can think of the world as a vast forest susceptible to fire. Whenever a forest fire starts it starts with a spark. If you were there when the spark happens, it can be—the damage can be limited quickly by simply putting it out. But if it's allowed to smolder,

or if it goes on for a period of time, it burns to the point that it cannot be contained.

The construct of international surveillance involves having laboratories throughout the world, having epidemic investigators who can be there when the spark happens, having rapid response teams, having American expertise on the ground in all of the theaters where it is most likely to occur. It also involves joint containment agreements with our friends around the world to be there jointly to bring our resources if it is possible to contain an outbreak.

The second portion of the plan I'll refer to is domestic surveillance, essentially having the same capability in the United States as we've spoken of around the world, knowing when it happens and how broadly it has gone beyond, or if it's gone beyond containment.

Again, it requires laboratories, it requires trained medical personnel. The plan calls for the development of a system known as BioSense, which is already under development because of our interest in bioterrorism, where we would have real-time data available both at the CDC, and also among local and State health departments, for the purpose of ascertaining when these things occur.

The third part of the plan that I will refer to, and what I believe to be the foundation of this plan, is vaccines. The good news is that we do have a vaccine that has produced a sufficient immune response to protect human beings, the bad new is we do not have the capacity as a Nation within our vaccine industry to manufacture a sufficient supply in timeframes that would protect the American people, that needs to change. The plan calls for us to make heavy investments in three basic areas. The first is the expanding of our traditional egg base production of vaccine; the second is the rapid development of cell-based technology; and the third is agivent technology so that we're able to use that with the maximum level of efficiency.

The plan calls for essentially two objectives to be met, the first is to have the capacity of manufacturing 300 million courses of an appropriate vaccine within a 6-month period of a strain being identified. The second objective is to have a stockpile of some 20 million doses—or rather courses of vaccine for the purpose of being able to provide early protection to first responders and so forth. We know that vaccine would not likely be perfect because it would be the last available vaccine, but it would at least give us some protection in those early periods.

The forth area is in anti-virals. The importance of anti-virals is evident, however, it should not be overstated. There are serious limits in what anti-virals can do; they do need to be part of a comprehensive plan. Those on the panel today, if Members are interested, I'm sure we will be able to detail those limits. We are proposing collective stockpiles of some 81 million courses. The plan calls for the Federal Government to pay for some 70 percent of those and to provide States with the option of being able to acquire more; it does not make mandatory their participation.

The fifth area is communication, informing the public with the best available information. I think it's been evident by the nature of the conversation today by members of the committee, some are worried about whether or not this is overreaction, others worry

that we may have responded too slowly. Our objective now, and I must say, I believe good leadership, is to speak in a way that informs but does not inflame, to inspire preparation, but not panic.

The last section—and I suspect we will have some conversation about this—is the importance of State and local participation. And Mr. Chairman, I would emphasize the unique nature of a pandemic as a disaster. We have gone through many disasters in this country just in the last several months. Katrina, for example, a terrible disaster, stretched over Louisiana, Mississippi and parts of Alabama. It was, however, constrained to those areas. It was—the emergency unfolded in a 2 or 3-day period. It has taken us, of course, longer, and will take us longer to respond and to recover, but nevertheless the damage was done in a very limited period of time. A pandemic, on the other hand, is different, it is not constrained to a geographic area. It likely would be unfolding in thousands of different locations across the country and across the world simultaneously.

It also is not constrained as to time. It won't happen in a week, it will happen in a year or more, and it will happen in waives, and it will require that there are individual decisions made in different communities across the country at different times and for different reasons. What is happening in a rural city in Kansas will be different than what is happening in a metropolitan area in Tennessee. And there will be as many iterations of the disaster as there are locations.

The budget is presented in two major accounts, the vaccines and anti-virals in one account, and the public health efforts between the various public health efforts, we're talking about nearly $600 million.

I would just like to conclude my talking about the dilemma that's been presented today that will someday people look back and say H5N1 did not become a pandemic, therefore we overreacted? Will they say at some point in time, well, they were crying wolf? We do not know whether H5N1 will be the spark that creates a pandemic, but we do that know pandemics happen, they've happened in the past, they will happen in the future. And this plan is not about H5N1 alone, it is about general pandemic preparedness. And when we have concluded or when we have implemented this plan, the United States of America will be a better and safer place. We will have cell-based technology, something that will ultimately save millions of lives, a revolution in the way we conduct the business of vaccines and the way we protect the public from disease.

We will have annual flu vaccine capacity that well exceeds what we have today. A great deal of conversation has gone on in the committee today about the on-going difficulties of the flu vaccine dilemmas in our annual flu; that is because we lack capacity. This can change that once and for all, it can take off the table the dilemma of annual flu and pandemic flu vaccines by resolving it with new capacity and new technology.

This plan will create better prepared State and local governments. It will also provide an international surveillance system for disease. And we'll have the piece of mind of knowing we are prepared.

Cell-based technology, annual flu capacity, better State and local government preparedness, an international network of surveillance,

piece of mind of knowing we're prepared, that's what this plan is about, and I feel confident in saying, when it is implemented, that America will be a safer and healthier place.

[The prepared statement of Secretary Leavitt follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

The HHS Pandemic Influenza Plan

Statement of

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Friday, November 4, 2005

Good morning Mr. Chairman, Representative Waxman, and Members of the Committee. I am honored to be here today to present the President's request for funds for the HHS Pandemic Influenza Plan, which is an integral component of the National Strategy for Pandemic Influenza, which the President announced earlier this week. In the event that an outbreak of pandemic flu hits our shores, it will surely have profound impacts on almost every sector of our society. Such an outbreak will require a coordinated response at all levels of government – Federal, State, and local – and it will require the participation of the private sector and each of us as individuals. HHS has been a leader in this effort. With this budget request and the release of the HHS Pandemic Influenza Plan, we are taking another major step forward to improve our preparedness and response capabilities.

The threat of an outbreak of pandemic influenza is real. An influenza virus strain with potential to cause a pandemic of human disease could emerge with little or no warning and in almost any part of the world, as occurred 3 times during the 20th century. Influenza viruses infect birds, pigs, and other animals, as well as humans. The ability of these viruses to cross the species barrier from time to time creates the possibility for the appearance of new viral strains that have the potential to be highly infectious, readily transmissible, and highly lethal. If a pandemic virus strain emerges, it is estimated that upwards of 30 percent of people exposed could become infected and the death rate will likely be considerably higher than that seen with seasonal influenza. Faced with such a threat, the United States and its international partners will need to respond quickly and efficiently to reduce the scope and magnitude of this serious health threat.

Today's threat is the H5N1 avian influenza strain, which is spreading widely and rapidly in domestic and migratory fowl in Asia and now in Eastern Europe. While the virus has not demonstrated the ability to spread efficiently from person to person, it has infected more than one hundred people in Asia and approximately 50 percent of these known cases have died. The virus is now endemic in many bird species and in several countries, so elimination is not feasible. The feared pandemic could become a reality if this virus mutates further, remains highly virulent, and acquires the capability to spread as efficiently from person to person as do the commonly circulating virus strains that produce seasonal influenza epidemics. But even if H5N1 does not lead to a pandemic, the likelihood of an influenza pandemic at some point remains high. This is why we need to prepare now in order to swiftly and efficiently respond to an outbreak. I have come here today to ask for your support for funding for the HHS Pandemic Influenza Plan, which is our portion of the National Strategy for Pandemic Influenza.

This week, we have taken important steps forward. On Wednesday, I released the HHS Pandemic Influenza Plan, which is a blueprint for pandemic influenza preparation and response. The HHS Plan provides guidance to national, State, and local policy makers and health departments. The goal is for all involved to achieve a state of readiness and quick response.

The HHS Plan includes an overview of the threat of pandemic influenza, a description of the relationship of this document to other Federal plans and an outline of key roles and

responsibilities during a pandemic. In addition, the HHS Plan specifies needs and opportunities to build robust preparedness for and response to pandemic influenza. The preparations made for a pandemic today will have lasting benefits for the future.

A pandemic outbreak will allow very little time to develop new capabilities or build surge capacity for response if these efforts are not already in place. Unfortunately, current capacity for domestic manufacture of influenza vaccine and antiviral drugs can meet only a small fraction of the need projected for a pandemic response. If we are to have the capabilities and capacities needed when a pandemic emerges, the investments to bring them about must be made now. That is why the President is requesting additional FY 2006 appropriations for HHS totaling $6.7 billion for the HHS Pandemic Influenza Plan. Our goals in seeking this funding are to be able to produce a course of pandemic influenza vaccine for every American within six months of an outbreak; provide enough antiviral drugs and other medical supplies to treat over 25 percent of the U.S. population; and ensure a domestic and international public health capacity to respond to a pandemic influenza outbreak.

First, we must establish the domestic vaccine production capacity our Nation will need to protect all Americans within six months of detection of a virus that begins to spread efficiently from human to human. In anticipation of an influenza pandemic, we must stockpile in advance sufficient quantities of pre-pandemic vaccine that is protective against circulating influenza virus strains with pandemic potential in order to be in a position to initiate vaccination of health care workers and front-line workers critical to

the pandemic response. These pre-pandemic vaccine stockpiles must be regularly reevaluated and potentially replenished as the pandemic virus threat mutates and changes, and as vaccine potency degrades over time. In addition, as the virus strains evolve and potentially escape protection by the existing vaccines, newer vaccines that better match the current pandemic strain will need to be produced and stockpiled. The Nation must also expand its stocks of antivirals, personal protective equipment (masks, gloves, etc.) and other supplies to help provide a potentially over-burdened healthcare system with the means to treat and care for those who become seriously ill in an influenza pandemic.

Second, we must enhance the disease surveillance systems both internationally and domestically and train the personnel needed to reliably detect an outbreak quickly and to accurately determine its lethality and transmissibility. This includes obtaining samples of the virus from infected humans and animals and having laboratory capacity, personnel, and supplies necessary to conduct rapid analysis. Surveillance is our early warning system, and faster detection will enable public health officials to make recommendations about containment protocols, such as limits on travel and the assembly of large groups of people. Faster detection and identification of emerging influenza virus strains facilitate the conversion by industry to mass production of pandemic influenza vaccines. Better State, Federal, and international diagnostic laboratory systems will also allow for increased surge capacity needed to support front-line medical personnel, and effectively guide the use of scarce drugs, vaccines, and other resources.

Improved surveillance systems, including near real-time collection of data from hospital emergency departments in major metropolitan areas through BioSense, will allow us to continuously track the spread of the virus and the morbidity/mortality it produces and to evaluate the effectiveness or our intervention strategies. This information will be critical to determining the best uses of limited supplies of pandemic influenza countermeasures. We will also track vaccines and immunizations to ensure that we maximize its equitable use as well as its effectiveness and safety.

Third, we must develop in advance domestic and international plans for broad public education efforts that are culturally appropriate and provide critical information in ways that acknowledge different levels of health literacy. These efforts before and during a pandemic will help guide individual actions to prevent and reduce infection and clarify the need for prioritization of scarce vaccines and antivirals and other materials. Our request also includes funding for States and local municipalities to develop and/or update their pandemic influenza response plans and to integrate them with Federal plans.

INFLUENZA VACCINE

The Administration has been aggressively working to be able to acquire, over a two-year period, enough H5N1 vaccine and antivirals to protect 20 million people should they become infected with the pandemic virus. On July 15, 2005, the Administration submitted an FY 2006 Budget Amendment totaling $150 million to implement our "20/20" plan. This strategy was designed to give us considerable experience with commercial-scale manufacturing of this new vaccine, and provide some pre-pandemic

vaccine to our stockpile. However, as we are only able to obtain pre-pandemic vaccine during the few months of the year when influenza vaccine manufacturers are not running at full capacity making the seasonal trivalent vaccine, we are severely limited in the quantity of vaccine that we can stockpile. In addition to this limitation, since the submission of this Budget Amendment, we received results of H5N1vaccine clinical trials funded by NIH. As part of this strategy, the NIH has funded clinical trials of H5N1 influenza vaccine—which provided good news and, at the same time, sobering news. The good news was that the vaccine we developed works – it provides a good immune response that augurs well for protecting people against the H5N1 virus. The sobering news was that to achieve the desired immune response, the vaccine needed to be six times as potent as the seasonal vaccine -- 90 micrograms of the hemagluttinin component instead of 15 micrograms -- and that two doses are needed for the protective immune response. This has further driven home a point of which we were all aware—that the nation's capacity to produce enough 90 microgram doses of pandemic vaccine was woefully inadequate. We need an aggressive strategy to achieve the needed domestic vaccine manufacturing capacity as quickly as possible, and to initiate similarly aggressive action to implement other immediate preparedness strategies beyond these critical vaccine needs. This budget request is just such a strategy, building on the July Budget Amendment and responding aggressively to the results of the NIH clinical trials and our growing concern that a pandemic could involve hundreds of communities across the United States and around the world.

Of this week's $6.7 billion funding request, approximately $4.7 billion would go toward investments in creating pandemic influenza vaccine production capacity and stockpiles that will ensure that enough vaccine will be available to every American in the event of a flu pandemic. To accomplish this, HHS will pursue a multi-faceted strategy to create, as soon as possible, domestic influenza vaccine manufacturing capacity aimed at producing 300 million courses (two doses of vaccine per person) within six months of the onset of an influenza pandemic. With this immediate investment, the increased production capacity and related stockpile expansion will be achieved in phases between 2008 and 2013.

The initial component of this strategy is to expand the number of licensed domestic egg-based influenza vaccine manufacturers from the single one that currently exists. This would give the U.S. the ability to develop a 20 million course (40 million doses) pre-pandemic vaccine stockpile by 2009 – without disrupting the production of annual seasonal influenza vaccine. In the event of a pandemic outbreak, or perhaps before, the vaccine stockpile would be used to immunize healthcare workers, front-line responders, vaccine manufacturing personnel, and others critical to the pandemic response. Once this capacity is developed, current egg-based production techniques could then provide about 60 million courses of vaccine within six months of an outbreak, or about 20 percent of our goal of 300 million courses within six months.

The ultimate surge capacity goal of 300 million courses of vaccine cannot be achieved from egg-based production alone. Our best hope for creating capacity in the U.S. for

rapidly ramping up vaccine production at any point in time is expansion and acceleration of our investment in cell-based influenza vaccines—and much of our planned investment goes toward this initiative. While promising, success of cell-based influenza vaccine production and licensure is still years off, and not a guarantee. Therefore, our vaccine capacity expansion strategy invests in both cell-based vaccines and the traditional, tried and true egg-based vaccines. Therefore, HHS, in collaboration with the vaccine industry and its academic partners, will invest in the advanced development of cell-based techniques for manufacturing pandemic influenza vaccines. By financing the establishment of new cell-based vaccine manufacturing facilities that could open in 2010, our plan will develop the surge capacity needed to provide for the remaining ~80 percent (approximately 240 million courses) of the population within six months of a pandemic outbreak.

The HHS Pandemic Influenza Plan also acknowledges that existing manufacturing facilities can be directed to this effort and finances the retrofitting of existing domestic manufacturing facilities that would enable them to convert to production of pandemic influenza vaccine production, in an emergency. HHS will establish contingency arrangements with vaccine manufacturers in conjunction with the Food and Drug Administration so that, at the onset of an influenza pandemic, they will be able to readily adapt their facilities either to produce influenza vaccines or to provide a critical function, such as fill and finish bulk vaccine produced by other manufacturers.

We will also work with industry and academia to support advanced development of dose-stretching technologies, such as the use of adjuvants and new vaccine delivery systems. These investments, if successful, will extend the pandemic influenza vaccine supply and allow more Americans to receive pandemic vaccines sooner. We will also invest in research that may have potential to lead to broad-spectrum vaccines to protect against multiple and emerging strains of influenza viruses. This would allow for stockpiling of vaccines that could be useful even as the virus strains evolve and change.

However, as we seek to build domestic manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business. As we recognize the desperate need to create and expand vaccine manufacturing capacity, we have to remove such deterrents to participation by those with the knowledge and experience to accomplish this. It is crucial that those engaged in this work be shielded from unwarranted tort suits. Accordingly, the Administration is proposing limited liability protections for vaccine manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct. We believe this proposal strikes an appropriate balance of removing the liability risks that dissuade companies from producing pandemic countermeasures, while still retaining appropriate access to court remedies.

ANTIVIRALS

We also recognize the importance of having available a sufficient supply of stockpiled antiviral drugs to treat and care for infected individuals. For this, we request an

investment of $1.4 billion. These funds would help us achieve the national goal of having available 81 million courses of antivirals, which would be sufficient to treat 25 percent of the U.S. population (75 million courses) and a reserve supply (6 million courses) that could be used to contain an initial U.S. outbreak. Funding would also be used to accelerate development of promising new antiviral drug candidates in collaboration with academia and industry, since none of the antivirals today are likely to work perfectly against pandemic influenza.

Of the 81 million courses, six million courses will be designated to contain the first isolated domestic outbreaks. Of the 75 million courses that will be used to treat those who are infected with the pandemic virus, HHS would fully fund the procurement of 44 million treatment courses to provide protection to the highest priority groups in the event of an influenza pandemic. We will also work with our State partners to encourage them to acquire antivirals for rapid use for their populations. To help support these States efforts, we would establish contractual arrangements with manufacturers of approved antivirals whereby States may purchase up to 31 million treatment courses and HHS would pay for approximately 25 percent of the costs of these drugs. This arrangement will also ensure a more coordinated inter-governmental approach in the acquisition of antiviral drugs and pre-deployment stockpiles of antivirals around the nation. A guaranteed acquisition of up to 81 million courses of antiviral drugs will enable manufacturers to make significant expansion in its U.S.-based manufacturing capacity—thereby positioning itself to meet future demands much more readily than currently is possible.

I have personally been meeting with leaders of relevant vaccine manufacturers to determine how they might participate in preparedness for and response to a pandemic. To facilitate the development of new antivirals, HHS will collaborate with industrial organizations to develop, obtain approval, and establish commercial production of new antivirals that would help protect the citizens of our Nation.

DISEASE SURVEILLANCE, PUBLIC HEALTH INFRASTRUCTURE, AND RISK COMMUNICATION

In addition to the production and stockpiling of vaccines and antivirals, enhancing domestic and international resources to expand surveillance, strengthening public health infrastructure, and effectively communicating with the public about risks of an influenza pandemic are important components of the HHS Pandemic Influenza Plan, for which we are requesting $555 million. A critical step in enhancing public health infrastructure and international collaboration will be to implement and refine surveillance and epidemiological response. These investments will help us detect, investigate, and respond to the onset of a potential influenza pandemic anywhere in the world without delay. Because influenza characteristically spreads beyond country boundaries, we have included in our request funding to be used internationally. These funds will follow the evolution of the virus in Asia, detect human cases, and help contain outbreaks, where feasible.

With an enhanced domestic and international early warning system, we will be better positioned to mount an immediate emergency response to characterize the outbreak; obtain viral samples for analysis and possible vaccine production; and we will have a greater chance to prevent, contain, and/or retard the spread of infection. The ability to continually analyze data to help predict the further course of the pandemic will help guide the choice and timing of interventions (drugs, vaccine, and public health measures) and will help assess the efficacy of these interventions.

Enhancing our public health infrastructure also includes expanding the science base at the Food and Drug Administration, thus allowing for expedited regulatory review of pharmaceutical industry initiatives to develop the necessary new vaccine technologies, as well as speeding the licensure of the facilities and vaccines produced within them.

Risk communication is another integral part of an effective public health response plan. We must have in place the capability to employ effective risk communication practices that will guide us in providing the American people with the accurate, timely and credible information they will need to protect themselves and help others during an influenza pandemic. To ensure that our communications efforts resonate with target audiences, we will solicit the public's active participation and involvement in our efforts to develop relevant, easy-to-understand information and materials regarding influenza in general, and pandemic influenza in particular. To help in this effort, we have established a website devoted exclusively to this topic, pandemicflu.gov.

Public participation and involvement may include engaging the public in discussions on State and local community preparedness; assisting communities in developing procedures for disseminating information and guidance for all segments of our diverse population; and developing targeted informational tool-kits for distribution to particular stakeholders such as educators, physicians, and employers.

STATE AND LOCAL PARTNERS

Pandemic planning needs to incorporate every department of the Federal government but must also go deeper than that. Every State and local government must have a pandemic plan. Unlike most disasters, a pandemic outbreak can happen in hundreds or thousands of places simultaneously. The Federal government will play an important role, but engaged state and local partners are necessary for our success. Over the coming days, I will be asking the governors, mayors and State and local health and preparedness officials to join me in a concern we all must share -- preparing for a pandemic should one happen. Everyone in society has a role.

For example, the Federal government can deliver stockpiles of medication and supplies to a city in the U.S. in a matter of hours – but it is distribution at the State and local level that defines victory. In a moment of crisis, if we are not able to deliver pills to people over wide areas in short time frames, lives will be lost. We need to create a seamless preparedness network where we are all working together for the benefit of the American people. Of the $555 million for surveillance and public health infrastructure, our Budget request includes $100 million specifically for State and local pandemic preparedness

efforts. And, as mentioned previously, we will provide incentives to States to purchase their own stocks of antivirals by allowing them to buy off of HHS-negotiated contracts and subsidizing about 25% of the cost.

The plan and budget request outlined above will greatly improve our short and long term preparedness posture. We are well-positioned to implement the plan and invest these new resources wisely and effectively only because of the substantial pandemic influenza activities already underway at HHS. Scientists at the National Institutes of Health and the Food and Drug Administration, working with industry, have developed a vaccine that produces an immune response sufficient to provide protection from the H5N1 virus. This bodes well for our ability to develop a vaccine against a pandemic virus that may evolve from the current H5N1 strain. In September, HHS awarded a $100 million contract to manufacture 3.3 million doses of H5N1 vaccine, which at two doses per person would be enough for 1.67 million people. In addition, just last week we announced the award of a $62.5 million contract to produce even more vaccine. We have also initiated contracts to secure an adequate supply of specialized eggs to initiate surge production at any time of year.

This is not a new undertaking. We are making progress, and with your help will continue to do so. We realize we are asking for significant funding at a time when the Administration and Congress are trying to control spending and reduce the deficit. But we have controls in place at the Department, and within the structure of the funding request to ensure that these funds are used wisely and responsibly. When American lives

are at stake, we must take action to protect them. We acknowledge that investing in this plan without perfect knowledge of the future is expensive, and not without risk. However, waiting until a pandemic begins before preparedness is undertaken would be so much more expensive in terms of American lives and economic impact. In our view, waiting is not an option.

I look forward to answering your questions, and more importantly, to working closely with you and all members of Congress as we move forward together to protect our citizens.

Chairman TOM DAVIS. Mr. Secretary, thank you very much. And I think this is the most proactive—did anyone else want to say anything? I think this is the most proactive that any administration has ever been on this in history.

And as we learned from Hurricane Katrina, sometimes an ounce of prevention is worth a pound of cure. Should a pandemic develop and we are not prepared, we're talking about a hole in our economy of perhaps trillions of dollars, people not being able to move out of the country from their cities, international tourism industry and everything else. Plus, what it would be to medical bills and hospitals and everything else.

Let me ask this; according to the pandemic plan, the Federal Government requires States to pay for a substantial portion of the anti-virals. If States are responsible for the purchase of anti-virals, will the Federal Government help ensure that all of the States receive a lower nationally negotiated price?

Secretary LEAVITT. Yes, Mr. Chairman, we will. And that's a significant benefit.

I want to emphasize that our belief is that a pandemic is unique to all natural disasters for reasons I enumerated in my opening statement. It is not possible, it is a certainty that if we have a pandemic condition, communities all over the country will be dealing with it, and they need to be able to deal with it in their own and unique ways. We have—public health is a local and a State responsibility for a reason, because they're able to respond to local conditions.

Now the plan that's been put forward does have the national government paying for essentially 70 percent of the anti-virals, but a very important part of the way we would split this up in terms of divisions of labor, you will note that $400 million of the $1.4 billion that we have proposed for anti-virals goes into research for new and better anti-virals.

Why? Because there is no certainty at all that Tamiflu will be effective against H5N1, let alone whatever virus might ultimately be the one that in fact creates the pandemic. Any sense that having Tamiflu is synonymous with preparation or preparedness is wrong? It is an important part of a comprehensive strategy, but it is not synonymous with preparedness.

And so tying one's plan so closely to one anti-viral that may or may not be effective would be a mistake. And we are working with the—we want to work with the States to make it certain they have it as part of their plan, but it does not, in essence, create an overdependence on that as their only remedy.

Chairman TOM DAVIS. I didn't realize Tamiflu may not be effective. In that case, how long will it take to develop another antiviral?

Secretary LEAVITT. I'll ask Dr. Fauci to talk about both of those subjects, the limited effectiveness potential——

Chairman TOM DAVIS. And if I could just, because we're limited on time, throw out with that that we've heard some talk about Roche having the rights to Tamiflu and having a limited production capacity and our ability to get that out; and now I'm hearing that may not be an answer anyway.

Of course, you would only use this until—the vaccine is the best defense, but you would need this in the short period. So you can talk about that.

Dr. FAUCI. Yes, Mr. Chairman. Thank you, Mr. Secretary.

Tamiflu, the data that we have on the effectiveness on Tamiflu relates very heavily on and almost exclusively on the use of it in seasonal flu. And it's clear that in the standard seasonal flu, if you give Tamiflu, you need to give it within the first 24 to 48 hours to get an effect, and its main effect is to shave off about a day and a half from the symptomatic period of a viral infection with influenza. For example, if you would have been sick for 6 days or 7 days, you're sick for 4½ or 5 days.

The ability of Tamiflu to have a major impact on the seriousness of the infection that you would predict or project with a pandemic flu is still very much unclear. We're pushing the agenda with Tamiflu for stockpiling because it right now currently is the best that we have, but all of us, myself and Dr. Gerberding and others, are clearly in in our caution that this is not something that is going to be essentially the show stopper for a pandemic flu.

With regard to your second question, we have a robust program, and part of the research component of the plan is to pursue other mechanisms of suppression of the virus, other viral targets in addition to the new amenities, which is the target for Tamiflu and Relenza, as well as one other, the M2 protein, which is the target of Amantadine and Rimantadine. So we are pursuing, both by screening existing products as well as by targeting anti-virals to get a better drug than Tamiflu.

Chairman TOM DAVIS. Thank you very much. My time is up, Mr. Waxman, 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman. Mr. Secretary, thank you, and all of your colleagues who have come with you today and appearing before us. And I appreciate that the administration is taking this matter seriously. We do not know if there is going to be a pandemic, but I think it's prudent for us to make plans.

All the plans in the world aren't going to help, though, if we don't have on the ground in State and local governments the ability to respond to any kind of epidemic because they're on the front lines of a crisis, and they've got to have adequate funding to implement the plans. So I want to pursue that issue with you.

The President's budget called for $130 million cut to the grants to the States for public health preparedness, that was part of the budget that we received much earlier in the year. The administration hasn't rescinded that call for the budget cut. I know that money is being directed elsewhere, but it means it's less money for the States to deal with any kind of public health emergency. Now we have this pandemic flu strategy, and that calls for $100 million to go to the States for planning activities, so it's $100—so now they got $30 million left, because if you can cut $130 million, you have $100 now added, but there is an obligation for the States to spend money for part of the costs of the anti-viral medications, the Tamiflu or whatever other anti-virals there might be, and that is a requirement, an unfunded requirement or obligation to spend $510 million for the purchase of the anti-virals.

So the States and the local governments look at your overall proposals, they're not very enthusiastic about that. They say they can't afford it. Governor Huckaby, Republican of Arkansas, said "They expect us to pay 75 cents on the dollar for flu medicine; that's going to be a tough pill to swallow."

New York City Public Health Commissioner submitted testimony this morning that the administration's budget plan, "would seriously undermine our preparedness capabilities," and Dr. Rex archer, president of the National Association of City and County Health Officials, and director of Health for Kansas City, MO, said "you can't take $130 million with the right hand, give us $100 million with the left hand, with strings attached by the way, and expect that is going to get us where we need to go." How do you respond? It seems to me there is going to be a real problem for these local governments.

Secretary LEAVITT. As you pointed out, the $130 million was moved from one account to another. Preparedness dollars for States have actually gone up considerably. We also have substantial grants that have been offered to the States over the course of a 3-year period of $5 billion that we're still working with the States to draw down that can be used for this.

But most of all, Mr. Waxman, I would like to reconcile the Tamiflu. We have a national goal of 81 million courses in collective stockpiles, the plan calls for 50 million of those courses to be purchased entirely by the Federal Government and for us to—and we will likely place those in stockpiles in the States. As Dr. Fauci indicated to you, if we don't get Tamiflu, or if Tamiflu is not placed into the hands of people who are sick within 24 to 48 hours, it does not do the good that it's intended for, or that it's manufactured for.

The point is, it's distribution that ultimately defines victory, so we intend to put those stockpiles very closely out into the States where they can be deployed. That is 70 percent of the total. If States choose to buy more, we're prepared to assist in that. We are helping them meet a responsibility that they have, paying for 70 percent of the Tamiflu that will be available.

Now, we are willing to talk about how we go about it, because we want the States to be involved in the planning of this. If it is just knowing that the national government somehow has a stockpile of Tamiflu, they're not going to be involved in the distribution, and that's where we want them to be.

Mr. WAXMAN. Well, Dr. Gerberding, as the head of the Center for Disease Control, you work very closely with the State agencies that have to be on the front lines. If they can't afford to come up with the money for their share of the anti-virals and they're complaining about it, they're saying they can't deal with it, how is this Federal, State, local relationship going to work if they're complaining that they can't do their job and the Federal Government is only paying part of the cost.

Dr. GERBERDING. The State and local health officials have a tough job, and they've been working hard over the last few years with the investments in preparedness that we've been making to try to dig out of a hole that's been very deep for many decades, as you know.

I think the conversation that I had with the leaders of the health agencies yesterday would indicate to me that they're aware that they have a responsibility and a role to play, they are aware that we can't be successful if every component of the public health system doesn't step in and do its part. And we just want to work together to figure out how we are going to make sure that we have equitable coverage with Tamiflu.

This is a pretty good deal for the States to get the Federal Government to buy the drug at a discount. Our planning is——

Mr. WAXMAN. Well, the States don't have really a choice in this matter. The national plan is for 25 percent of the population to be covered in the stock pool, that requires that the States must purchase, it's not an option. So we're having, in effect, an unfunded mandate.

Secretary LEAVITT. It is an option. If they choose to, we will help them pay for it. We are going to be putting up the 50 million doses distributed in ways that meet the needs of the plan. So if a State chose not to do it, they would still have Tamiflu in their State, it wouldn't be the extent to which some other States might want to have it. But they need to step up and help with this, too. We need to have everyone involved in this, not just the Federal Government.

Mr. WAXMAN. You've got to continue your conversations with them because they're complaining about it. Because my red light is on, if the chairman will indulge me for a minute.

Because you're here, Mr. Secretary, I know this is not the end of this whole issue, it is just the beginning and we're going to have further conversations, but I want to express to you that I've been disappointed in my ability to get information from the Department. And I have a stack of letters that I've sent to the Department, and I just don't get responses to them. I think if we're going to have the dialog and efforts to work together, I want to impress upon you that we're all busy, but you do have a lot of people working under you, you don't have to personally answer each letter. I will like to impress upon that you have heard from other Members who have had the similar complaint, even on the Republican side, it is important and I'd like to make sure that we get responses. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you, Mr. Waxman.

Mr. Shays.

Mr. SHAYS. Thank you. I'd also like to add to Mr. Waxman's point. As the administration asks for more power, I think they need more legislative oversight, and it would be helpful to have greater cooperation, not less cooperation from the administration.

And I also want to say as you're surrounded by four very competent professionals, and I have high regard for HHS, I have high regard for you, Mr. Secretary, and the people who work around you. There is a black mark, in my judgment, with how the FDA has handled plan B when the experts have said that this should be available to prevent pregnancies and still not have this resolved, and I hope that you will find a way to quickly resolve that issue.

I want to ask you if—first, I want to acknowledge I think this is a huge problem, and we probably should have been addressing it sooner rather than later, but thank goodness we're addressing it now. But now I'm going to sound like I'm contradicting myself be-

cause I'm interested to know from our experts why—this isn't 1918. And for instance, we don't have traps and dirty trenches, there were secondary infections. We have antibiotics, I guess developed in 1929, so that was one good thing that happened in 1929. Those are the things that come to mind to me that are different. Maybe your experts could tell us what some of the other things that are different.

Secretary LEAVITT. I will ask Dr. Gerberding to lead, and then call on others.

Dr. GERBERDING. Well, we live in a very small world today, it's actually much smaller than it was in 1918. If you remember SARS where one physician went to a hotel, stayed on the same floor of that hotel with a dozen people and overnight SARS went around the world.

Mr. SHAYS. So that would argue that it's even a potentially worse environment.

Dr. GERBERDING. The connectivity and the connection between people in remote areas of the world with our backyard is much greater today than it was in 1918, and that's what we're worried about.

Mr. SHAYS. Any other points, either that minimize or make it more of a problem?

Dr. FAUCI. One of the potential misconceptions that we hear is that now that we're living in the era of antibiotics, that most of what happened in 1918 was due to secondary infections. When you actually go back and examine carefully the records of what we know, how the course of illness occurred in many, not all, but many, many, and perhaps most of the patients, it was highly likely that it was not the antibiotic-sensitive bacteria, that if we had the antibiotics, then we would have had a major, major impact on 1918. It's more likely that the virulence of the virus that is inherent to the virus itself caused a significant amount of the morbidity and the mortality, and that is something that doesn't change very much from 1918 to now.

Mr. SHAYS. So you're raising a second point as to why it may be more serious, not less?

Dr. FAUCI. Yes. In fact, not necessarily more serious, where it counterbalances the argument that well, we have antibiotics now, we're OK.

Mr. SHAYS. Any other points?

Dr. GELLIN. I want to build on what Dr. Fauci said in that the predicament we're in now with a single class of anti-virals, the Neuraminidase inhibitors reflect the misuse of anti-microbials. We're all too familiar with the misuse of antibiotics, particularly in the agricultural industry. There is evidence that there has been misuse of the older class of anti-virals in that industry in Asia has led to their——

Mr. SHAYS. So therefore they won't be as effective?

Dr. GELLIN. Oh, no. There are two classes of anti-virals for flu, one of them is essentially off the table for the H5 virus, H5N1 virus, and likely because of the misuse of a similar molecule in animal feed in Asia.

Mr. SHAYS. I guess I wasn't making myself clear. In other words, they are useless.

Dr. GELLIN. One class might be useless, we are left with one.

Secretary LEAVITT. Mr. Shays, I would also mention one other item. In 1918, they had the biology in play where we had no human immunity, we essentially have the same circumstance today. We are now dealing with 1918 biology in a 21st century new cycle. SARS is a fascinating model to look at when you're looking at the cultural economic and political disruption that comes from a pandemic. There were 8,000 people who were infected with SARS, that is, in pandemic terms, small. It completely disrupted the Chinese economy. There were major airports all over the world that were essentially vacant.

Part of the difficulty of a pandemic is of course the health impacts, but the economic cultural impacts that it creates are also profound.

Mr. SHAYS. Let me just—since my red light will come on soon, just put in a word for the World Health Organization. I think it is underfunded, underutilized. I know we sent some of our best experts to participate, and that's terrific, but I really believe that World Health Organization should be playing a greater role, and the United States should be helping to encourage that. Thank you.

Chairman TOM DAVIS. Thank you.

Mr. Lantos, 5 minutes.

Mr. LANTOS. Thank you, Mr. Chairman.

I'd like to ask you or any of your colleagues, Mr. Secretary, to address a, the geographic issue which I raised in my opening comment, San Francisco, Los Angeles, Seattle probably will be the first impacted area given air travel from Asia.

Second, I'd like to ask you to give us, as detailed as you are capable, a report of the dealings with Roche. What are the generic companies that are planning to undertake production? What is the timetable? What are the arrangements? Because as several of us have indicated, we must see to it that getting the product to our potential patients is dramatically more important than historic corporation relationships between companies and their licensees.

And finally, I would be grateful if you could discuss what specific plans you have to see to it that the potentially most vulnerable are diagnosed and then are provided with medication on a priority basis; because this has not always been the case, as you well know.

Secretary LEAVITT. I will ask Dr. Gerberding to deal with the issue of locale.

Dr. GERBERDING. Mr. Lantos, I share your concern about our quarantine stations, and we recognize what an important point of entry the west coast is.

I visited the Los Angeles quarantine station at LAX on Sunday so I could get a firsthand look at what steps are in place. And I'm pleased to report to you that with the investments that Congress has been making over the last 2 years, we've been able to make some significant improvements there, as well as in San Francisco and Seattle. Overall, we are going from eight quarantine stations at airports in 2003, we will have 18 by the end of this year, and we will have 25 by the end of 2006.

At SFO, we have a medical officer now which we didn't always have, we have a senior inspector, and we are planning for the possibility of an airplane with someone with suspected pandemic

strain, how we would quarantine and isolate people until further evaluation could be conducted. So it's a very, very important part of our containment program. The Secretary has worked this through in our doctrine, and we will be happy to keep you up to date as we make additional improvements in our border security.

Mr. LANTOS. I appreciate that.

Secretary LEAVITT. With respect to Roche, we have had on-going, very direct conversations. They have given us assurance that we will have sufficient supplies to meet our objectives——

Mr. LANTOS. What are those assurances?

Secretary LEAVITT. They have made representations that we will be able to reach our 20 million first target by fourth quarter of 2006, and that they also made further representations that we could get to our 81 million goal by the summer of 2007. And I might add that——

Mr. LANTOS. When you say—excuse me for interrupting. When you say representations, Mr. Secretary, were these oral commitments? Is there anything in writing? Is there anything you are prepared to share with the Congress and the American people? Or were these just conversations with Roche?

Secretary LEAVITT. We have ongoing negotiations with them. We are systemically making orders as we have appropriations to do so. We have orders in that will take us well over 5 million courses.

As respects the intellectual property issue, they have given us their assurance that, and not just the United States, but the world, that intellectual property issues will not be the means of constricting the supply. Now I am not a chemist, Congressman, but I have worked hard to understand the process that is undertaken to manufacture Tamiflu. And it is clear to me that this is a highly complex process that involves as many as five different manufacturing processes, some of which involve quite dangerous explosive processes.

Now I don't believe it will be intellectual property disputes that in any way limit the capacity for manufacturing, it's going to be the logistics. And it's my view that it's going to be, anywhere in the world, more than a year before we have additional manufacturers, and maybe as many as 2 years. That is just my assessment, and the——

Mr. LANTOS. Mr. Secretary, no one questions your good intentions, but what is at stake is the lives of potentially vast numbers of American citizens. Is there anything beyond conversation that you have with Roche? Are there any documents, any documents that you are prepared to share with this committee?

Secretary LEAVITT. The documents are, in fact, limited to those that I have outlined——

Mr. LANTOS. If the Chair would indulge me for a moment, this is a rather important item.

Chairman TOM DAVIS. I'll give him an opportunity to answer it.

Secretary LEAVITT. It is important, and you were not in the room when I made another thing that is very important and I hope clear, and that is that, in any sense that Tamiflu is synonymous with preparedness is wrong——

Mr. LANTOS. We know that.

Secretary LEAVITT. And we have proposed a $400 million appropriation to advance the development and the manufacture of advanced and improved anti-virals. We believe that Tamiflu is an important part of a comprehensive plan, but it should not be viewed as synonymous with good preparation.

We are putting forward a strategy that includes vaccines, that includes anti-virals, that includes surveillance, that includes good communication, and State and local preparedness.

Now we intend that every State would have a stockpile of Tamiflu, and that it could be deployed in a way that would be consistent with their needs, because if we can't get Tamiflu or some other suitable anti-viral into the hands of a sick person, it has done them no good unless it's there within 24 to 48 hours. So part of this is distribution, not just having a stockpile.

Chairman TOM DAVIS. Mr. Secretary, I think, though, Mr. Lantos' question is, are there any documents that you could share with the committee that have transpired between yourselves and the drug company at issue?

Secretary LEAVITT. The documents that I'm aware of are those that would relate to the purchase or the intent to purchase the first 5 million doses that I've spoken of.

Mr. LANTOS. There are discussions between Roche and generic drug manufacturers; is that correct?

Secretary LEAVITT. That is correct.

Mr. LANTOS. What can you tell us about those negotiations, and can we see those document as they become available?

Secretary LEAVITT. I am not party to those conversations, nor do I believe that anyone at HHS is. However, we have instructed and agreed with Roche that the FDA will work directly with them to facilitate the licensing of those arrangements.

Mr. LANTOS. May I just raise one more issue, Mr. Chairman, it will take just a minute. Several of my colleagues properly dealt with the budgetary ramifications of all of this. Have you given any thought of requesting the President to have a White House conference of donors from the private sector? Exxon made $10 billion in one quarter on these inflated petroleum prices. It is high time that these multi-national corporations with windfall profits deal with the health problems of the American people. Given the fiscal policies of the administration—which I think have been abominable, we have to turn to the private sector. Are there any plans of having a White House conference of funding the resources necessary so we won't have to have a dialog as you did with Mr. Waxman as to what happens if the States can't afford it?

Secretary LEAVITT. Congressman, the President has made clear that he will be bringing State and local officials together to plan, and that——

Mr. LANTOS. I'm talking about the private sector.

Secretary LEAVITT. I know of no plans to do what you have suggested.

Mr. LANTOS. What would be your idea of it——

Chairman TOM DAVIS. Mr. Gutknecht is recognized for 5 minutes.

Mr. GUTKNECHT. Thank you, Mr. Chairman. Benjamin Franklin said "I know no lamp by which to see the future than that of the

past." Mr. Secretary, 4 years ago, this city, indeed this very building, was the subject of an anthrax attack. And I know that most of this transpired before your watch, but I have to ask a few questions and submit for the record some other questions.

I have a copy of a Newsweek article that was posted on November 2nd talking about what the Department is doing relative to acquiring anthrax vaccines, and it's pretty troubling. And apparently, it is not just troubling to Members of the House, I also have a letter and an article—that I'd like to submit, Mr. Chairman, for the record—from CQ.com, with a letter enclosed from Senator Grassley asking about how we're handling this anthrax vaccine contract, as well as a letter that I'd like to submit from a former colleague of the House, and now a Member of the Senate, Dr. Tom Coburn. And in that letter, he raises 11 very specific questions.

[The information referred to follows:]

Hon. Michael Leavitt
Secretary
Department of Health and Human Services
Room 615F, Hubert Humphrey Bldg.
200 Independence Ave., SW
Washington, D.C. 20201
Fax: (202) 690-7203

October 24, 2005

Dear Mr. Secretary,

It has come to my attention that the Department of Health and Human Services (HHS) has used funds appropriated to the Department of Homeland Security (DHS) in Fiscal Year 2003 to support Project BioShield in procuring an experimental anthrax vaccine for the Strategic National Stockpile (SNS) from a single supplier. What makes this more troubling is that the contractor for the experimental vaccine, Vaxgen Corporation, has yet to announce the results of its Phase II clinical trials, expected last May, and there is considerable uncertainty as to when Vaxgen will be able to deliver licensable product to the SNS.

Moreover, despite a lack of publicly available peer-reviewed information, I have learned that Vaxgen is making significant claims about the safety and efficacy of its product, in apparent violation of FDA regulations governing pre-licensure statements of providers of biologics.

For example, at a recent conference in Washington, D.C., Vaxgen distributed written material claiming its experimental anthrax vaccine is "safer" and requires "significantly fewer doses for protection" than the FDA-licensed vaccine, and that those receiving the experimental vaccine "will achieve the immune response in a far less time" than they would with the FDA-approved vaccine. Dr. Lance Gordon, Chief Executive Officer of Vaxgen, stated at that same conference that Vaxgen's experimental anthrax vaccine had been "proven effective" against inhalation anthrax. These statements have been made in spite of the fact that the experimental vaccine is years away from licensure, according to its contra ct with HHS. I do not understand how Vaxgen or any HHS contractor could make such claims without successfully completing the full battery of required clinical trials and tests.

As a physician, I take very seriously any appearance of action by the Federal government supportive of off-label or misleading claims about products under review by

the FDA. And as a United States Senator with responsibility for oversight of the nation's homeland security, I take very seriously any action by the Federal government that may jeopardize the supply of safe and effective vaccines or adversely affect the nation's ability to respond to a bio-terrorist attack.

Therefore, I request the courtesy of your response to several questions I have regarding Vaxgen's recombinant Protective Antigen (rPA) anthrax vaccine:

1) What is the basis of Vaxgen's comparative claim that the experimental rPA anthrax vaccine is "safer" than the FDA-licensed anthrax vaccine? Is that claim permissible under current FDA law and regulations?
2) What is the basis for Vaxgen's comparative claim that the experimental rPA vaccine requires significantly fewer doses for protection, and that people receiving it will achieve the immune response in less time than they would with the FDA-approved anthrax vaccine? Are those claims permissible under current FDA law and regulations?
3) Can HHS guarantee that Vaxgen will deliver the experimental rPA anthrax vaccine into the SNS in accordance with the delivery schedule? What are the consequences under the contract should Vaxgen fail to meet any of its delivery obligations? What is the contract schedule for delivery of the vaccine?
4) Vaxgen is stating publicly that HHS will purchase and pay for the experimental rPA anthrax vaccine in advance of having any meaningful data on the stability of the vaccine in syringes. Why would HHS have made such an agreement?
5) Vaxgen is stating publicly that as soon as it completes production of the experimental rPA anthrax vaccine, it is entitled to deliver the product to, and receive payment from, HHS. What has HHS done to ensure that the vaccine delivered by Vaxgen will be "licensable" as required under Project BioShield? Will HHS pay for the vaccine before it is "licensable?" What more is required in order for the vaccine to reach the stage of being "licensable"? What is the timeline for achieving that stage? Do HHS and Vaxgen agree on what is required and on the timeline for achieving "licensability?"
6) Vaxgen is stating publicly that it offered HHS the right to require that Vaxgen share its technology with other manufacturers in order to establish a second source of supply for the experimental rPA anthrax vaccine. Vaxgen claims that HHS asked Vaxgen to delete that portion of the proposal. Please explain why HHS requested that Vaxgen delete that portion of its proposal.
7) Vaxgen is stating publicly that HHS is permitting Vaxgen to claim that the label for its unlicensed rPA anthrax vaccine will have fewer required package warnings than the FDA licensed AVA vaccine. Has HHS authorized Vaxgen to make any such claim? If so, what is the basis for that authorization?
8) What steps has HHS taken beyond the purchase of antibiotics and five million doses of AVA vaccine to prepare the nation for another anthrax attack in the event that Vaxgen fails to deliver its experimental rPA anthrax vaccine on time?

9) When will peer-reviewed Phase I and Phase II data become publicly available regarding the experimental rPA anthrax vaccine?
10) Were the recently completed clinical trials and animal studies of the experimental rPA anthrax vaccine sufficient to establish conclusively its efficacy against inhalation anthrax in humans? If more data is required, what additional testing will be necessary and how long will it take?
11) Why were the Phase II clinical trials designed without a head-to-head comparison between the current FDA-licensed anthrax vaccine and the experimental rPA anthrax vaccine? Will all future animal and clinical studies of the experimental rPA anthrax vaccine include a head-to-head comparison with the FDA-licensed anthrax vaccine? If not, why not?

Finally, while I support your recent public statements regarding the fragility of the vaccine and the importance of taking steps to ensure that we have sufficient domestic capacity for critically needed vaccines, it appears that the action s of HHS with respect top the anthrax vaccine supply may result in driving out of the market one of only nine domestic manufacturers of FDA-licensed vaccines. Given how little we currently know about the Vaxgen product, and the recent experience of the flu vaccine shortage, this policy seems short-sighted.

I would greatly appreciate your reviewing this matter and providing me with a plan on how the Department intends to address the apparent gap in our preparedness against the deadly anthrax threat. I would also like to see an explanation for the current single-supplier procurement plan for the anthrax vaccine.

Sincerely,

Tom A. Coburn, M.D.
United States Senate

CQ.com

Grassley Seeks Review of 'Inconsistent' Testimony on Anthrax Vaccine

By CQ Staff
September 27, 2005

Senate Finance Committee Chairman Charles E. Grassley, R-Iowa, has asked Health and Human Services Secretary Michael O. Leavitt to detail the status of his agency's efforts to purchase anthrax vaccine.

In a Sept. 23 letter, Grassley also asked Leavitt about what Grassley termed was "inconsistent testimony" from Stewart Simonson, HHS Assistant Secretary for Public Health Emergency Preparedness, on how many doses are now included in the Strategic National Stockpile (SNS).

In his letter, Grassley notes that in a May 4 letter, Simonson stated that up to 1.5 million doses of AVA, the only anthrax vaccine currently licensed for use in the United States, "will be available by the end of June 2005 and the full five million doses delivered to the SNS by the fall of 2006."

According to the manufacturer of AVA, BioPort, 2.9 million doses of the vaccine have been delivered to the SNS, Grassley wrote. But on July 14, Simonson testified before the House Committee on Government reform that HHS has 5 million doses of the currently licensed anthrax vaccine in the stockpile.

"The Department appears to be counting its chickens before the eggs are hatched," Grassley wrote. He added that on July 12, Simonson testified before another House panel that 1 million doses were in the SNS.

"I am concerned about the information being provided to Congress and the public regarding the nation's stockpile of anthrax vaccine," Grassley wrote to Leavitt, seeking a response by Oct. 5.

In a separate news release, Grassley said the HHS Inspector General's office has responded to his Sept. 14 request for an investigation of St. Rita's Nursing Home in St. Bernard Parish in Louisiana where 34 patients died in the facility in the wake of Hurricane Katrina.

The IG responded that it is assisting the Louisiana Attorney General's Office under the theory that false claims were submitted to the Medicaid program for care that was not given at the nursing home.

And in a separate inquiry, Grassley is asking the Guidant Corporation, whose products include implantable defibrillators and pacemakers, for information about the way it has complied with agreements it made with the federal government so it could continue doing business with the government after one of its subsidiaries settled criminal and civil charges two years ago.

"Taxpayers spend a lot of money through the Medicare and Medicaid programs for medical devices, so I have a responsibility to make sure these products are safe and that the federal agency charged with reviewing their safety is doing its job," Grassley stated in a news release.

Friday, September 23, 2005

Grassley seeks straight answers from government about anthrax vaccine stockpile

WASHINGTON - Sen. Chuck Grassley is asking the Secretary of Health and Human Services to sort through the inconsistent testimony of a department official regarding the nation's stockpile of vaccines to combat an anthrax attack.

Grassley described the varied reports of Assistant Secretary Stewart Simonson about the number of doses in the Strategic National Stockpile in a letter sent today. The text follows here along with copies of Grassley's previous inquiries about the anthrax vaccine.

September 23, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201
Dear Secretary Leavitt:
By letter dated April 4, 2005, I asked the Department of Health and Human Services (Department) to advise me of the status of the Department's efforts to purchase doses of anthrax vaccine for the Strategic National Stockpile (SNS) until a recombinant protective antigen (rPA) vaccine becomes available. In Assistant Secretary Stewart Simonson's May 4, 2005, response to that letter, I was informed that "Up to 1.5 million doses of AVA will be available by the end of June 2005, and the full 5 million dose order delivered to the SNS by the fall of 2006."

According to the manufacturer of AVA, the only anthrax vaccine currently licensed for use in this country, 2.9 million doses of AVA have been delivered to the SNS to date. However, the Department appears to be counting its chickens before the eggs are hatched. On July 14, 2005, Assistant Secretary Simonson stated before the House Committee on Government Reform that "We have 5 million, as you noted, 5 million doses of the currently licensed anthrax vaccine in the stockpile."

Two days earlier, on July 12, 2005, Assistant Secretary Simonson stated in testimony before the House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Science, and Technology that, "Delivery of this product [AVA] to the Stockpile began soon after contract award and over one million doses of the licensed anthrax vaccine are now in the SNS."

I am concerned about the information being provided to Congress and the public regarding the nation's stockpile of anthrax vaccine. As you may recall several months ago I brought to the Department's attention the fact that it issued a public press release regarding a "stronger and more effective" anthrax vaccine. The only problem there was that the "stronger and more effective" vaccine did not exist. In light of these facts, I request that the Department describe any actions it will take to remedy the current situation. In addition, as Chairman of the Committee on Finance, I request that the Department provide the Committee with the actual number of doses of anthrax vaccine that have been delivered to the SNS as of September 23, 2005, and state when the Department anticipates receipt of any remaining doses of the 5 million total that were purchased for the SNS.

I would appreciate a response to my inquiries no later than October 5, 2005. Please do not hesitate to contact me if you have any concerns.

Sincerely,
Charles E. Grassley
Chairman

Remember Anthrax?
While the government goes into high alert over bird flu, an old plan to develop an anthrax vaccine remains unfinished.

WEB EXCLUSIVE
By Michael Isikoff and Mark Hosenball
Newsweek
Updated: 6:27 p.m. ET Nov. 2, 2005
Nov. 2, 2005 - Just as President George W. Bush is launching an ambitious plan to guard against an avian flu pandemic, an administration program to prepare for a potential anthrax attack is running into new and unexpected hurdles. VaxGen Inc., a California biotech firm that last year was awarded an $877.5 million contract to supply a newly invented, and so far unlicensed, anthrax vaccine, acknowledged this week that it won't begin to start deliveries to the federal government until the latter part of next yearsix months later than it originally intended.

The company blames regulatory questions and production issues. But the production delay, along with apparent accounting difficulties and unanswered questions about the safety and effectiveness of the company's product, is likely to attract new attention on Capitol Hill. For months, investigators on both sides of the aisle have expressed concerns that the administration may have invested too big a chunk of the nation's biodefenses in one obscure and relatively untested company.

The need to build up the country's anthrax defenses first gained urgency four years ago following the mysterious mailings of anthrax powder to congressional offices and news organizationsan attack that killed five people and has yet to be solved by the FBI. The case prompted officials of the Department of Health and Human Services to begin searching for a reliable supplier of large quantities of anthrax vaccine that could be stockpiled and then distributed to the public in the event of another attack. The government has already stockpiled antibiotics that can be used to treat millions of people in the event of anthrax exposure, according to an HHS spokesman. But an anthrax vaccine would be an important second line of defense. Vaccine can be given with antibiotics to potentially shorten the duration of post-exposure prophylaxis, the spokesman said.

But last year's decision by HHS to award the contract to the little-known VaxGen is being scrutinized by at least two congressional committees over issues such as VaxGens repeated delays in filing timely financial reports with the Securities and Exchange Commissiona problem that last year caused the firm to be "delisted" from Nasdaq. In addition, VaxGen was hit with lawsuits claiming the firm misinformed investors about an AIDS vaccine it was heavily promoting that later turned out to be ineffective. The

HHS spokesperson said, Delays in these aggressive and accelerated development programs are not unexpected or unprecedented, adding that the governments eventually successful efforts to create a smallpox vaccine also took longer than originally expected.

This weeks announcement from VaxGen, ironically, came the same day that President Bush unveiled a $7.1 billion program to step up preparations for protecting the U.S. population against a possible catastrophic bird flu pandemic. The president's plan, which involves stepping up research and stockpiling vaccines and antiviral drugs, was announced in the wake of criticism from Congress and the media that the administration responses to recent natural disasters, particularly Hurricane Katrina, were so inadequate that they raised questions about the extent to which the United States is prepared for either natural disasters or man-made catastrophes like terrorist attacks. The newly revealed delay in anthrax-vaccine deliveries is likely to spur further complaints among Democrats and other Bush critics that the administration is still not effectively managing emergency preparedness programs.

In a telephone interview this week with NEWSWEEK, Lance Gordon, VaxGen's chief executive officer, stoutly defended the company's performance, maintaining that the newly announced delays in financial reporting and vaccine delivery are attributable to developments that ultimately will produce benefits both for investors in his company and for taxpayers who are funding the governments purchase of his company's so-far unproven anthrax vaccine. Gordon said that one of the reasons the company decided to announce a delay in its plans for delivering the first of 75 million doses of anthrax vaccine was to ensure that new quality-control procedures are fully installed and tested before the company starts full-scale production.

In a press release issued earlier this week, VaxGen attributed the delay to evolving regulatory requirements and product enhancements. Gordon and another company spokesman acknowledged, however, that at present, VaxGens anthrax vaccine, which it is making using ultramodern recombinant DNA technology originally invented by the U.S. Army, has so far been tested only on rabbits, monkeys and healthy human volunteers. According to company officials, the animal tests indicate that the new vaccine is effective when combined with antibiotics in curing anthrax in rabbits and rhesus monkeys, while the tests on healthy people show that the vaccine produces anthrax antibodies in humans and does not make test subjects gravely ill with side effects.

But the company's product will have to pass more large-scale tests proving its safety and effectiveness on people before it is fully licensed by the Food and Drug Administration for use on humans, and company officials say they do not expect it to be fully licensed at least until 2007. However, according to Gordon, under emergency "bioshield" legislation approved by Congress in the wake of the 9/11 and postal anthrax attacks of 2001, the government can buy and stockpile all 75 million doses of VaxGen's anthrax vaccine before the product is fully licensed and tested. Company officials also say that in an emergencyan anthrax attack by terrorists for examplethe bioshield legislation allows the government to administer the not-fully-licensed vaccine to people who might be attack victims. But the product cannot otherwise be administered to members of the public until it is fully tested and licensed.

Publicly traded VaxGen also says that the company plans to file updated and current financial statements with the Securities and Exchange Commission by the second quarter of 2006. According to a press release issued by the company last year, Nasdaq delisted its stock after VaxGen failed to file two scheduled quarterly financial reports in 2004. The companys stock is currently traded via a penny-stock listings service known as the "pink sheets."

In this weeks press release, the company said that it currently was behind in filing its annual reports for 2003 and 2004, and quarterly reports for 2004 and 2005. Gordon said that VaxGen on three occasions had issued new projections for when its financial statements, which are being restated for 2001, 2002

and 2003, as well, would be brought up to date. In a conference call with securities analysts earlier this year, a company official said the reason the company fell behind in producing financial information is because VaxGen refused to cut corners with its accounting. Gordon told NEWSWEEK that on the recommendation of its auditors, the company initially decided it had to review financial statements for several years because of questions over whether it had "underreported" revenues it got from government contracts it received for researching and developing its vaccine. Later, when accountants had sorted out that issue, Gordon said, they found other questions about possible underreporting of the value of an investment VaxGen had made in a drug production facility in South Korea.

Even before the company announced the latest delays, VaxGens anthrax deal with the government was attracting critical attention on Capitol Hill. In a letter to HHS Secretary Mike Leavitt in January, Senate Finance Committee Chairman Chuck Grassley noted that VaxGens vaccine has not been proven in people. Grassleys letter asserted that the administrations decision to procure a vaccine from a single manufacturerVaxGenwas highly suspect. Last April, Grassley sent a second letter to Leavitt, questioning why, in a March 2004 press release, HHS had asserted that the new vaccine that VaxGen was developing had already been stronger and more effective than an older vaccine made by BioPort, a Michigan company that is VaxGens rival and competitor. Grassley noted that the HHS press releases assertion about the VaxGen drug appears to have no basis in fact.

HHS later informed Grassley that it had withdrawn the press release, according to an aide to Grassley. VaxGen officials said they had nothing to do with the issuing of the government press release. An HHS spokesman said, VaxGen met strict U.S. government requirements, particularly technical ones, to be considered for this contract. The U.S. government is aggressively managing this program and monitoring performance. We are in active discussion with the company and are reviewing their development plans and timelines in order to determine the appropriate path forward. We remain committed to the goal of meeting the U.S. government requirement for 75 million doses of the next-generation anthrax vaccine.

VaxGens government contracts totaling nearly $1 billion have been the subject of intermittent controversy over the last two years both because of the companys troubles with its financial statements and because of questions surrounding the government's handling of the contract. In addition to the $887 million anthrax contract, the firm received $100 million from the National Institutes of Health to research and develop the vaccine. (VaxGen wont actually receive any of the $887 million until it actually begins to deliver vaccine doses to the government.)

A New York Times report last December noted that in addition to its problems in producing financial statements, the company had faced lawsuits filed by investors who claimed VaxGen misinformed them about an AIDS vaccine that the company had heavily promoted but which later failed to work. At least one such lawsuit was dismissed and another was settled.

A Forbes article last June also noted that VaxGen CEO Gordon was a long time acquaintance with a former research official from the U.S. Army bioweapons research agency based at the Pentagon and Fort Detrick, Md., that gave VaxGen a license to make its anthrax vaccine using technology developed by the Army. The former Army scientist later became a top contracting official at HHS. Gordon said that while he served on the board of a nonprofit medical foundation with the former Army official, during the period VaxGen was negotiating its main contract with the government, he and the official never met unless government lawyers were present. Gordon added that although the delay in producing financial statements may make it difficult for investors to gauge the company's financial health, government auditors have carefully monitored the company on a monthly basis and are fully aware of its financial condition.

Government and industry experts have defended the basic notion of the government giving vaccine development and supply contracts to companies like VaxGen without extensive track records by arguing that major drug firms have shied away from vaccine research and production because it carries too many legal and financial risks. Administration critics suggest this policy of throwing money at the problem was a product of post-9/11 hysteria about terrorism in general and biological terrorism in particular. These critics say the Hurricane Katrina experience has now raised big questions about government spending on bioterrorism and a whole range of other emergency-management priorities that were rushed to the top of the national agenda after September 11, 2001.

Mr. GUTKNECHT. Now, Mr. Secretary, have you received that letter from Senator Coburn?

Secretary LEAVITT. I have personally not read the letter. I do not know if it's been received yet.

Mr. GUTKNECHT. Well, the reason I'm going to submit it here in committee is that I hope you will not only respond to him, but I hope you will respond to the questions from this committee, because I think it does raise serious questions about the ability of the Department to manage these large contracts.

Four years after the anthrax problem we had here in the Capitol building, we still can't really say that we're protected with adequate doses of anthrax vaccine. Now, I try to remind—and you're not the first one I have reminded this of, but we won World War II in 3½ years, OK, and it shouldn't take 4 or 5 years for us to ramp up production and to purchase of an adequate supply of anthrax vaccine. What is troubled that is raised in the Newsweek article is that a contract has been given to a company, an $877 million contract has been given to a company that has never passed—I think they've never gone to phase three trials with this particular vaccine. They have, and it's documented at least in the article, that they have serious financial problems and are not going to be able to meet their production quotas this year, and perhaps not even next year.

And I go back to my statement that if we're unable to manage an issue that has been around for 4 years, what gives us confidence that we're going to be able to manage the Avian Flu problem?

Secretary LEAVITT. Congressman, you're referencing the fact that we are moving to develop a better anthrax medication. I'd like to ask Dr. Fauci to give you an update on our progress, and to make clear that we do, in fact, or have, in fact, made substantial preparation for anthrax, we're just working to get better all the time. So Dr. Fauci.

Dr. FAUCI. Thank you, Mr. Secretary.

As you know, there are two anthrax vaccines, there is the AVA, the standard one that have been used with the military. An Institute of Medicine committee has made it very clear that in order to prepare the country for an anthrax attack, that we need to make attempts to go beyond the older technology and use a new recombinant technology, which is the recombinant protective antigen. We have a supply, a modest supply in the stockpile of the older AVA, and there is an order for an additional amount of the AVA. But simultaneous with that, in the procurement process of getting companies to bid for making the recombinant protective antigen, the comment that you made is correct, we did not, and at the time—and this is an issue with trying to incentivize the big companies to get involved, the fact that the company in question, Vasogen, had not produced a vaccine beyond a phase 3 trial, I think bespeaks the lack of incentive of bigger companies to get involved, so we had to go with companies that, in fact, don't have a track record like a Merck or a GlaxoSmithKline and others.

You're correct that the pace of the milestones of the contract of getting the material into the strategic national stockpile is, in fact, slower than the Department had hoped it would be. This is being monitored very carefully by the contract people, and we would be

happy to keep you abreast of how this goes. But we are aware of the fact that they're behind schedule, and nonetheless, we will continue to monitor them very closely.

Mr. GUTKNECHT. Well, Mr. Secretary, thank you for that answer, and it helps some, but I think ultimately the word that the American people are going to be using more and more about how we spend their money is accountability. And if we're going to give contracts to people and we expect them to live up to their end of that contract, there have to be some consequences when they don't. And the consequence seems to be, around this city, well, gee whiz, you didn't meet that goal, we'll give you more money, and I'm not sure that's going to cut it.

The other thing I will say, though, and perhaps the most important thing that's come up out of this hearing so far this morning, at least from my perspective, is to deflate the idea that Tamiflu is the silver bullet relative to the potential outbreak of an Avian Flu virus pandemic. I yield back the balance of my time.

Chairman TOM DAVIS. Thank you very much.

Mr. Kucinich.

Mr. KUCINICH. Thank you very much.

Mr. Secretary, you stated earlier the obvious, you're not a chemist, but you are the Secretary. At what point are you going to act on behalf of the American public and issue a compulsory license for Tamiflu?

Secretary LEAVITT. Congressman, I mentioned earlier that there were—we've put $400 million into our proposal for the development of new anti-viral drugs.

Mr. KUCINICH. Could you answer the question directly, Mr. Secretary? It was a simple question.

Secretary LEAVITT. I do not intend to, if that's a direct answer.

Mr. KUCINICH. Mr. Chairman, that's——

Chairman TOM DAVIS. That's his answer. Do you have another question?

Mr. KUCINICH. Are you invoking the fifth amendment?

Secretary LEAVITT. No. I don't think I can be any more plain——

Mr. KUCINICH. You just said you don't intend to—you don't intend to what? You don't intend to answer the question?

Chairman TOM DAVIS. He doesn't intend to invoke it, I think it's pretty clear.

Mr. KUCINICH. You don't intend to issue compulsory licenses?

Secretary LEAVITT. That is correct.

Mr. KUCINICH. Why not?

Secretary LEAVITT. Because it's my belief that if we want to have the last anti-viral or new product we will ever have in this country, we will begin to violate intellectual property and patent rights——

Mr. KUCINICH. So you believe that intellectual property and patent rights are more important than having a large supply of an anti-viral that could save lives?

Secretary LEAVITT. I do not believe that violating their patent would unleash a new stream of Tamiflu.

Mr. KUCINICH. There are, according to some statements, over 100 companies waiting to begin production of Tamiflu. And contrary to what you've said about the complex process, there are many people waiting to go forward with the production. Now for you to sit here

as Secretary of HHS, it's kind of shocking to see you here defending intellectual property rights when the American people could be facing the results of a pandemic.

I want to ask you a question here. Have you had cabinet meetings? Have there been cabinet meetings about this issue of anti-viral and the Avian Flu?

Secretary LEAVITT. Yes.

Mr. KUCINICH. And have you participated in those meetings?

Secretary LEAVITT. I have.

Mr. KUCINICH. And has the Secretary of Defense participated in those meetings?

Secretary LEAVITT. Yes.

Mr. KUCINICH. Are you aware that the Secretary of Defense is an investor in Gilead Sciences, the California biotech company that owns rights to Tamiflu?

Secretary LEAVITT. I'm aware from news accounts that he has clearly set aside any interest in purchases of Tamiflu.

Mr. KUCINICH. You spoke to this being a highly complex process. Have you talked to people at Gilead?

Secretary LEAVITT. Yes, I have.

Mr. KUCINICH. And have people at Gilead made you aware that there are over 100 companies waiting to provide production of Tamiflu?

Secretary LEAVITT. Congressman, that isn't the case.

Mr. KUCINICH. Well, what is the case? Have they made you aware that there are many companies waiting to manufacture Tamiflu?

Secretary LEAVITT. They have made clear to me that there are those that have expressed an interest in licensing the product. And Roche has made clear to me that they are prepared——

Mr. KUCINICH. How many?

Secretary LEAVITT. They have not given me a number.

Mr. KUCINICH. And you're the Secretary and you never asked for a number when we're looking at increasing the size of Tamiflu? That's incredible.

Secretary LEAVITT. Congressman, if I thought we had the capacity to unleash a needed anti-viral, or that in some fashion we would be withholding an important life-saving drug, we would take whatever action is necessary. However, I do not believe, nor do my advisors nor would I say would the FDA believe that would occur.

Mr. KUCINICH. That what would occur?

Secretary LEAVITT. It is the chemical process, it is the manufacturing process that is constraining the capacity for this to be developed. Roche has made is very clear that they're prepared to license anyone who wants to manufacture it, but they're going to have to go through a very detailed process——

Mr. KUCINICH. Several countries have asked Roche for the right to make the generic copies of Tamiflu. I have another question to ask you. Are you negotiating a price with Roche for Tamiflu or are they setting a price?

Secretary LEAVITT. We're negotiating, Congressman.

Mr. KUCINICH. And when you're negotiating, is it in the same way that the Veteran's Department negotiates with the drug com-

panies to get the lowest possible price; or are you negotiating it so they can make the most profit?

Secretary LEAVITT. We are negotiating a price that has been steadily downward. They've been responding——

Mr. KUCINICH. Are you going to make those documents available to this committee so we can make sure that the American taxpayers are not paying a premium for this drug?

Secretary LEAVITT. To the extent that's necessary.

Mr. KUCINICH. Mr. Chairman, I think it would be important to the committee to have that information because they already talked about a first billion dollars for an anti-viral, since Tamiflu is the most effective, it certainly appears to me that we ought to know what we're getting for our money.

I think that this committee, Mr. Chairman, has an obligation to stay on this issue of compulsory licensing. For this administration to be in a position of taking a stronger issue with support for intellectual property than they are for making a wide availability of Tamiflu is pretty shocking and ought to send a message to the people of this country where this administration's priorities lie.

Chairman TOM DAVIS. Thank you, Mr. Kucinich, I think that question is addressed to me, and I think the answer is pretty clear that if Tamiflu were the solution and we knew that was the solution, we could be out there doing all kinds of things, but we're not even sure that is going to be helpful in a pandemic, and there have to be other anti-virals that have to be developed. And who is going to spend the money developing an anti-viral if whatever money is spent in the research and development is just taken away from them and given to somebody else? I think that's the way the markets work, and I think that, from my perspective, that the Secretary is behaving responsibly. And having said that, obviously when the prices are negotiated, this committee has oversight responsibility, and we will be happy to work with the Secretary and everyone else to do that.

Mr. KUCINICH. Will the gentleman yield?

Chairman TOM DAVIS. If you have another constructive comment, I want to get——

Mr. KUCINICH. Well, I have a question. Are we saying that even if Roche refused to make more Tamiflu or provide licenses to other companies and thousands of Americans lives hang in the balance, that we would still——

Chairman TOM DAVIS. No. And that's not the case.

Secretary LEAVITT. Mr. Chairman, no one is making that suggestion.

Chairman TOM DAVIS. Of course not.

Secretary LEAVITT. This is a very complex chemical manufacturing process. And to simply say that there are hundreds out there that are, a, willing, and b, able to manufacture it is a misstatement of the truth and it is——

Mr. KUCINICH. Well, your drilling for oil is complex, too. We're seeing the American consumer getting hit two ways here.

Chairman TOM DAVIS. I think we are getting a little off.

Mr. KUCINICH. I yield back.

Chairman TOM DAVIS. Mr. Burton.

Mr. BURTON. While we're on a couple of other subjects here, I do—when we passed Medicare prescription drug bill, one of the things that I was concerned about was that we do negotiate prices, the VA does, with the pharmaceutical companies, and there was a prohibition against that in the Medicare prescription drug bill, and I think that is something that ought to be revisited. Obviously, we want the pharmaceutical industry to make a lot of money because we want them to be able to do the research and development that is necessary for new pharmaceutical products and drugs, but at the same time, we ought to do what we can to make sure that there is a negotiation process, like there are in other countries, as far as buying these pharmaceuticals.

If we did that and provided a protection against the possible counterfeiting of pharmaceuticals—and that can be done—I've got a bill I'm going to introduce to do that—then I think we could negotiate these prices down like they're doing in other places, and that would be very good.

I read an article in the Wall Street Journal the other day from some noted physicians and scientists, and it said that—and I think it verifies what the chairman just said, and that is, that if we come up with a vaccination against the avian flu, it might mutate into something else and the vaccine might not be capable of dealing with a mutation that takes place. So this is a revolving, revolving situation that we face. And Tamiflu, while it might help now, if we produce an awful lot of it, by the time we get to the point where we do have an epidemic, it might not be worth the production costs that we did. So this is something that has to be looked at on a continual basis, as I understand it; is that correct?

Secretary LEAVITT. Your point is correct. That's one of the worries that the scientists at this table would express on Tamiflu. We don't know what the virus will be that will spark a pandemic. It's possible Tamiflu would have a positive impact, it is also quite possible it would not. And if we have simply used our resources to provide a stockpile of Tamiflu, we would not have prepared ourselves adequately.

Mr. BURTON. And it is my understanding from—go ahead, Dr. Fauci.

Dr. FAUCI. Mr. Burton, you raise an incredibly important question that is at the crux of what we're doing. At the same time that we're stockpiling, to the best that we can, Tamiflu, we're investing in alternative anti-viral drugs in case we run out of options with the evolution of resistance. Or even if in its best form, Tamiflu might not be up to the task of stopping this because of what I had mentioned in an earlier question, that we have no guarantee that this is going to be highly effective.

With regard to the vaccine, you bring up an even more important point, and it's the two-pronged approach of vaccine in the Department's plan, and that is at the same time that we're actually building a stockpile of the vaccine that we have in hand at this time, we are building the capacity to be able to respond in a timely and expeditious manner if and when—and we hope it never happens—but if and when the vaccine—the virus changes enough that we may have to substitute in our vaccine the most recent updated ver-

sion of the virus that we're dealing with. So we're doing them at the same time.

Mr. BURTON. And in the event, as I understand it from our testimony and answering other questions, in the event that it looks like there is going to be a production problem as the epidemic or pandemic grows, you would be willing to do emergency licensing with other pharmaceutical companies, even generics, in order to get the production level up to where it should be as quickly as possible.

Secretary LEAVITT. We would do what we need to do to provide for preparation for a pandemic.

Mr. BURTON. But you're prepared to do that if you have to do it.

Secretary LEAVITT. We will do what we have to do to protect the American people.

Mr. BURTON. Well, I really would like to know. I mean, in the event, let's say that Roche or any pharmaceutical company that makes vaccines is not capable of production levels that will protect as many Americans and people as possible, you would do whatever it took——

Secretary LEAVITT. We will do whatever it takes to protect the American people.

Mr. BURTON. That's what I wanted to hear, that's what you wanted to hear.

And finally, let me just go back to something I said in my opening statement. It is extremely important, in my opinion, and I've talked to you about this before, that we get mercury out of vaccines, adult as well as children vaccines, and you can do that, and you know you can, it might cost a little bit more. And I want to give the pharmaceutical industry the protection it wants against class action lawsuits, I'm for tort reform.

But the only way that many of us in good conscience can do that, and I think you might run into a problem here, and we're going to be watching the legislation that goes through to deal with this, is that we have to make sure that the Vaccine Injury Compensation Fund is user friendly so that people who do have children that are damaged or adults that are damaged have access to that and they don't have to go through a 10 or 12-year process to get compensation for the damage that's been done.

So if we could get the mercury out of the vaccines and go to single shop vials as necessary, make sure the Vaccine Injury Compensation Fund is user friendly, then you're going to get, and the vaccine industry is going to get what they want, and that is, protection against class action lawsuits.

We tried to do that in the 1980's. I and others are willing to do that now, we just want to make sure that the people who are damaged do have a modicum of protection, and right now that doesn't appear to be the case. Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman.

Mr. Secretary, I have questions on this issue, but I think I should give you the opportunity to respond to the glitches we've seen in the distribution system, to indicate where they come from and to give any assurances that you can about the existing flu vaccine. I think the overreaction problem comes from the fact that if

people see this one and are not assured, then of course, they're not going to take very seriously what we're trying, and what you quite appropriately are trying to focus them on.

Can you just give us some word about the issues that have come up, besides the fact that we know large numbers of people are coming forward?

Secretary LEAVITT. I'll ask Dr. Gerberding to give you an update.

Ms. NORTON. I'm sorry?

Secretary LEAVITT. I will ask Dr. Gerberding from CDC to give you an update.

Dr. GERBERDING. Thank you. Where we are right now this year with the vaccine supply is that approximately 63 million doses of vaccine have already been distributed. We're expecting more than 80 million doses to be available this year, which is potentially more than we've ever delivered in any given year——

Ms. NORTON. I think I want to get on to my questions here. I simply want to know, because we know of the availability, I'm trying to find out about the distribution glitches, in particular, because otherwise I won't get to ask my other questions.

Dr. GERBERDING. The distribution is in the hands of the private sector, as is most of the vaccines.

Ms. NORTON. So there is nothing the CDC can do about it?

Dr. GERBERDING. It is not something that we have control over. That's been one of the challenges and why what the President is proposing is so helpful to us because we can really increase our seasonal flu vaccine supply——

Ms. NORTON. I'm very sorry to hear that. It has a direct effect upon people who will have any confidence on what you're doing on the pandemic. And I ask you to look into the matter of distribution and not simply throw your hands up and say I guess there's nothing we can do about that.

If you can't get it to us, and I repeat what—I wrote it down, Mr. Secretary, distribution defines victory. Well, let me tell you, thousands of people die in the United States every year despite the fact that we do have vaccine available, so if you can't get it to them, if you can't help us on that score, then I guess victory is not ours.

Secretary LEAVITT. Ms. Norton, at the break I made a call, because of your opening statement I wanted to make certain I had the facts. There are two components to distribution, one is the ability for the company to get it to the place where it's been ordered, the other is the need for them to order enough. Washington, DC, ordered only 33,000 doses or, rather, courses of the vaccine, and one of the reasons that they may be having a shortage is because they didn't order enough.

Ms. NORTON. So you're saying—and so the fact that Walgreens across the country says they're not going to do it anymore——

Secretary, LEAVITT. There are distribution challenges, but in some cases, communities also didn't order enough.

Ms. NORTON. I will check with our Department of Health, and I'm sure the Congressman will check with his, and I appreciate that answer.

We've had trials that help us the next time to do know what do. The trial in this case was the smallpox vaccine, this completely collapsed. The President made a big and important announcement.

Most experts believe that the reason was that, while the manufacturer got a liability shield, people, first responders, that's who we're trying to get to go first, didn't have any confidence that if, in fact, something happened, that there would be some kind of compensation for them.

Now you know, Mr. Secretary, this—we get parents to vaccinate children because of the Vaccine Injury Compensation Program for childhood vaccines. The President didn't even mention this, even though he's had one failure already. You would think that there would have been some mention of or acknowledgement of that failure and saying that they were going to take some steps to deal with it.

Let me ask you whether you believe, at least in principle, that first responders who might also be asked to take this vaccine first deserve to be—and in light of our experience—to be effective must be assured that there will be some kind of compensation in case some small number, I'm sure it will be small, are, in fact, injured from the vaccine.

Secretary LEAVITT. We do need to provide incentives for first responders to be inoculated. We will need them very much in a State of national emergency, whether it's smallpox or a pandemic.

Ms. NORTON. And you think the childhood vaccines compensation program is something of a model that we might follow here?

Secretary LEAVITT. I know that has been effective to a degree and it can be improved still. I expect as the discussion goes forward it will be discussed.

Ms. NORTON. Well, it will be on you, Mr. Chairman, if you put it out to first responders and you get the same response you got from smallpox, so be forewarned.

Final question. Dr. Fauci testified here about—gave us some real hope during the last crisis—about moving on from this egg-based manufacturing to state-of-the-art, or the art apparently isn't here, cell culture, and, one, do we even have—are we any closer even for our annual vaccine needs; and two, is there any hope that, moving forward, we can leave this slow way of dealing with manufacturing of these vaccines for the annual flus and the other pandemics.

Dr. FAUCI. Yes. Thank you, Ms. Norton. The process that is going on now, since the last time I have spoken to you there has been considerably more of a transition. Right now the current technology of the industry as a whole is egg-based. The future of the influenza vaccine production will be based on cell. We are making significant investments, as are the companies themselves on their own dime, to ultimately transition into cell-based. Depending on the company, some are well into doing the transition——

Ms. NORTON. Any waiting on the annual vaccines, on cell-based on how close are they——

Dr. FAUCI. The annual vaccine for the seasonal flu that we will be distributing to our citizens at least over the next couple of years will continue to be egg——

Ms. NORTON. How soon, Dr. Fauci, even on that?

Dr. FAUCI. The industry likely will not transition over to a full cell-based for at least 4 years or more. I want to just emphasize, Ms. Norton, that this advantage, the primary advantage of cell-based is what we call surge capacity, the ability to rapidly rev up

on more doses and to have the flexibility of changing in midstream on the numbers that you need. We appreciate that is the wave of the future, but the technology itself will not allow the industry as a whole to get there for the next few years. So this year's is certainly egg-based. And I can guarantee you that next year is going to be egg-based also.

Chairman TOM DAVIS. Thank you. Thank you for that explanation.

Mr. Cannon.

Mr. CANNON. Thank you, Mr. Chairman.

I chair the Subcommittee on Commercial and Administrative Law which is part of the Judiciary Committee, and we are going to have a hearing next week on a tort liability limitation for flu vaccination or manufacturers of flu vaccine. And that is Darrell Issa's bill. So I got a bit engaged in this.

And if I can followup on the question of the gentlelady from D.C. In some of our recent discussions, it sounds to me like industry has had huge failures, huge costs, and not much progress on cell-based vaccines. And I was just as recently as yesterday told that—by a major manufacturer—that this is at least 5 years off. And that is "at least." So you said not within 4 years, but that means in 5 years or beyond we are looking at it. So this is not imminent; isn't that the case?

Dr. FAUCI. That is the case. It is not imminent. I think the investment that is taking place within the budget associated with the plan that was just released, that could be accelerated somewhat. But it is talking about 4 years at least and probably 5.

Mr. CANNON. We had—I think this is the same science-based issue, but on line Newsweek this week has an Isikoff story so this is a very high-level story that they are pursuing. I take it from your response that you are familiar with that Dr. Fauci?

Dr. FAUCI. Uh-huh.

Mr. CANNON. It is talking about the anthrax vaccine and VaxGen that is producing that with like a $900 million $800-some-odd, almost $900 million in funding, and only one company bid on the project. And the other companies refused to bid because it was not feasible to do it in the timeframes that the RFP suggested, and so now we have a small company failing to perform in an area where we—this is not—not bird flu, but it is associated because we are talking about the same technology here where we have an experimental technology to deal with a disease that we have already been attacked with, it has already been a bioterrorist tool, attacked several times with, and yet we don't have a stockpile, even though my understanding is that we have a company that has an FDA-approved vaccine for anthrax.

Is that a fair statement of where we are?

Dr. FAUCI. Yes, it is a fair statement. A little bit of a different interpretation of it, because there is a history behind why a company is pursuing what you say is an experimental approach. Which is not necessarily experimental; it is a recombinant DNA technology that is used with other vaccines. The Institute of Medicine, after careful examination of the anthrax problem, recommended that the Federal Government move on to a more advanced modern-day approach to vaccination after anthrax, and that was the recom-

binant DNA technology, the RPA. The vaccine that you refer to that is already licensed is the AVA that has been used in our Armed Forces. We do have some of that in our stockpile, and we have actually recently put in a purchase for an additional amount of the older AVA vaccine. The recombinant protective antigen is by a company that you mentioned, VaxGen. It is one of the few companies that put in a bid for the simple reason that we have trouble incentivizing the large companies to even get involved in the vaccine production industry.

Mr. CANNON. And I think in part that is because of what Mr. Burton said about liability. We want to help solve some of these liability problems. But are we going to be in the business of paying Federal dollars to develop marginal technologies with companies—and by the way, I think it was in the article someone mentioned that these guys are being sued because they overstated what they could do with an AIDS vaccine that didn't work.

So what you really have here, at least to me, sounds like a marginal company that is willing to say, yeah, we will do that $877 million, whatever that number is.

We are at the table and then we get the problems because I believe, as I understand it, that the other companies were saying we can't do what you are tasking us to do. And so are we just spending Federal money to create, with a hope and a lot of dollars, a path to something that may be good in the long run but which we can get to reasonably?

Dr. FAUCI. I think it is important to put into context that the ultimate purchase of RPA or any other of the countermeasures that will go into the Strategic National Stockpile will be through a mechanism called BioShield which is money that does not go to the company except if they deliver the product. So, although we will be late, they will not get paid for a product that does not get delivered.

Mr. CANNON. But of the $800 or $900 million we are dealing here for VaxGen, how much of that are they getting in advance to cover their R&D and other expenses?

Dr. FAUCI. They will get according to what the milestone is. So they will get the money when they meet a milestone. So if their milestone is late, their money will be late. If they never reach the milestone, they will not get the money.

Mr. CANNON. I would just as soon see this not become a major issue, but let me jump on because I think there are other issues that are more important. In the hearing I chaired recently in Mr. Souder's subcommittee—I mentioned in this my introduction of the Governor, and now Mr. Secretary—that there is an absolute consensus that the decreasing cost of DNA decoding and decreasing cost of computing has transformed the industry.

And I know Secretary Leavitt has been deeply involved in these kinds of issues. But there are at least a couple, maybe three different new technologies out there which allow immediate decoding not in a half hour, much later in time, but immediate decoding of DNA, which should allow us to be much more proactive in identifying where we are having these outbreaks.

Is anybody looking at that kind of technology in the Department today, and does it hold promise?

Mr. LEAVITT. The answer is yes. There is one point that I think Dr. Raub could add to this question that might be helpful. Could he have a moment.

Chairman TOM DAVIS. Sure. Dr. Raub, please respond and then we will move to Mr. Van Hollen.

Mr. RAUB. You were citing the article, and I have not seen that particular one, but it is incorrect to say that the VaxGen was the only bidder. In fact, we had multiple bidders. We had a spirited competition. It's true, the large industries stayed on the sidelines for its own reasons. But we had strong proposals, a very thorough technical review, and VaxGen won that competition.

Mr. CANNON. I hope, Mr. Chairman, that the Secretary could address the issue of new technology and identifying the DNA strands that identify the flu so that we can get a—if that would—the question, I guess, would that provide a better tool for identifying and containing a pandemic? And is it something we are pursuing?

Secretary LEAVITT. I will ask Dr. Gerberding. She can give you what I think will be a more satisfying answer.

Dr. GERBERDING. I think what you're referring to is the use of DNA-based diagnostics. In other words, to detect not the whole virus or wait until we grow it up and culture it, but to probe for specific components of the virus. And that technology is well underway. Actually, some preliminary approaches to this, using chip technology, are in clinical study now.

Mr. CANNON. If the chairman would grant unanimous consent for 10 more seconds.

Mr. BURTON [presiding]. If Mr. Van Hollen doesn't mind.

Mr. CANNON. Let me just suggest that I've heard of a test on malaria at Johns Hopkins using a new device that has been radically successful. And it might be worth pursuing that from your point of view. And I would be happy to get you information if you would like.

Mr. BURTON. Mr. Van Hollen.

Mr. VAN HOLLEN. Thank you, Mr. Chairman. And, again, thank all of you for your testimony.

Mr. Secretary, I want to focus on some of the issues I raised in my opening comments regarding the fact that as I look at the plan, I don't think enough emphasis is being spent on that early warning/early intervention/prevention part it.

As I listened to the testimony of a lot of people from the World Health Organization, the FAO and others, they say a critical part of a plan to prevent an outbreak would be to try to find a way to stop or slow down the transmission of the disease through the carriers, avian flu, birds and others.

And my question No. 1 is, first, do you agree that that is an important part of the strategy? No. 2, what are your understandings of the cost and what it would take in terms of resources to address that strategy? And No. 3, what amount of money in this plan—I don't see any money especially for that particular part, transmission among the carriers—is in this plan, and how do we make up any gap in that funding?

Secretary LEAVITT. I spent 9 days in Southeast Asia with the head of the World Health Organization and the head of the animal health organizations and with the pandemic representative from

the U.N. We spent time in the five major countries where the most cases have manifest.

I had a chance to walk through wet markets and go to farms and to sit down and speak with people who had actually contracted avian flu, and I think I began to develop a pretty good sense of what the challenge is.

We are investing heavily already, and have been for some time, in an international surveillance—disease surveillance system. We have people on the ground. We have laboratories on the ground. We are doing what we can now to build laboratory capacity. Ultimately we are going to have a decision to make when there is an outbreak of a pandemic flu, whatever the designation.

Is the capacity to contain possible? If it is a small village in a remote area of Thailand or Cambodia and it hasn't gone beyond that village, and it is a strain that appears to have low efficiency and not much virulence, then it is quite possible that it would be a very good use of our resources to go in and to put that spark out while we can.

If it is in a metropolitan area and it has spread to a number of places, and it is already achieving person-to-person transmission in a highly efficient way, the use of limited resources in the United States may not be the best choice.

Mr. VAN HOLLEN. Mr. Secretary, if I could, because my time is short, if I could just—I understand the importance of trying to prevent the outbreak among—if it gets from human-to-human transmission and the importance of that.

What I was referring to was part of a strategy that I understand many of the health experts in the WHO are talking about, trying to slow the transmission among the carrier population now of birds. You know, they have slaughtered millions of birds and we need to keep doing that to the extent that the virus exhibits itself. But there has been some talk about methods, through farming methods, but also even through putting stuff in the feed of chickens that would sort of immunize them against the further spread. And since they are the carriers, I don't see anything in this plan with respect to that.

Do you think that we—do you think that WHO and FAO folks are right, that we should focus on that as part of our strategy? And what resources will that take?

Secretary LEAVITT. The plan that—the President's plan does, in fact, have funds that would go to the Department of Agriculture and others who will be participating in those efforts. However, we need to remember that we now have a situation with tens of hundreds of millions of wild birds who are carrying the virus from continent to continent. We are seeing that unfold in the news virtually every day.

I had a chance to see birds being culled and vaccinated and other processes and, frankly, they are imperfect. And they are inconsistent. And while I believe everything that you have said is, in principle, an important step, I did not come away from Southeast Asia with high optimism that is going to ultimately be the way in which we defeat this problem.

Mr. VAN HOLLEN. And don't get me wrong. I am not suggesting we shouldn't be putting a lot of emphasis on what we do if there

is an outbreak. That is an absolutely critical part of the plan. But given the cost in lives and dollars of what an outbreak would mean, it just seems to me we should do everything humanly possible to prevent that spread.

Let me just ask you about the ability of the HHS to respond generally to an outbreak, and your capacity to do that in the delivery system that has been raised, because as I understand in the National Response Plan, you were the lead agency with respect to overseeing the Federal response at the medical level and health level.

And we have seen some early efforts to respond to catastrophes. We saw that with Hurricane Katrina. And I think there is general agreement that the Federal response over all—I am not talking especially about the health area—but overall inadequate. And we had some early look at that with respect to the health response earlier with some of the hurricanes in Florida in 2004. And a report was commissioned by the Department from someone from the CNA Corp. I am not sure whether you're familiar with that report. But its findings were that the Department was not prepared. And looking at a case study in response to those Florida hurricanes in 2004, it found that despite the agency's role as a coordinator, HHS is not viewed as a leader of the health and medical operations in the field; often sends inexperienced junior staff members. And the report states that HHS had a, "poor working relationship with key medical personnel from the Department of Homeland Security."

No. 1, are you familiar with the report and its findings? And, if so, have any actions been taken within the Department in response to the recommendations and findings in that report?

Secretary LEAVITT. I am not familiar with the report, and I will tell you that is inconsistent with my own experience. We lack perfection, but I will suggest that during Katrina in particular the medical response—not just HHS, but from the medical community in general—was, I thought, quite remarkable.

Mr. VAN HOLLEN. Well, Mr. Secretary, I have a copy of the report here. And, Mr. Chairman, I think it might be worthwhile for your folks to at least brief some of the committee staff and other interested——

Chairman TOM DAVIS [presiding]. That would be helpful, thank you, Mr. Van Hollen.

Thank you very much. Mr. Kanjorski.

Mr. KANJORSKI. Thank you, Mr. Chairman. I don't know whether there is any truth to it. Of course I am watching some of the national news programs that indicate that most of the industrial nations of the world are ahead of us in the preparation for a pandemic. Is that a reasonable conclusion?

Secretary LEAVITT. I believe that is not the case, Congressman. I think, if you would, I have met with all of the health ministers from all the major countries many—several times on this issue. And we are following parallel tracks. And I would tell you with respect to the fact that we have a vaccine, we are leading in the development of the vaccine. We are now sharing our technology with other nations and working to collaborate with them. Others have made orders of Tamiflu, like we have, and they wait for their supply in the same way we do. I would say there is no nation on Earth

that is particularly well prepared right now. But we are better prepared today than we were yesterday, and we intend to be better prepared tomorrow than we are today.

Mr. KANJORSKI. Mr. Secretary, in listening to the President's program and some of the testimony even here today, it strikes me that we are trying to resolve this problem within an existing culture of our economy and how it operates. We are looking at whether or not it is advantageous for companies to invest in this. It is a decision-making process for profit.

If, in fact, we are talking about something that could kill 100, 200, 300 million people in the world and several millions in the United States, it seems to me one of the largest challenges in modern time that we will have faced, and it would necessitate breaking the limitations of our—of the normal way we do business. And it seems that everything I am hearing is that we are trying to make sure we incentivize people, the drug companies; and they are not listening, they are not making enough profit.

I think back to if we had decided to stay within that system to invent the atom bomb, we couldn't have done it in 3 or 4 years. It would have taken us 20 years. And this may be something that necessitates a Manhattan-type Project. And the thing that brothers me in listening to this cell culture development—and I am all for it; I think the faster you can put a vaccine out to respond to an emergency or a situation, the better off you are.

I have a hard time believing when I hear 5 years and everybody—well, unless, it is the technology might not be developed sufficiently to commercialize it in time? Or what is the problem? Why should it take 5 years to implement manufacturing capacity of this cell-culture alternative, unless it is experimental and we are still in the process of developing? Have we developed? If we have, why can't we implement it in a matter of a year or two?

Secretary LEAVITT. I am going to ask Dr. Fauci, who is deeply and personally involved in this, to respond to that.

Dr. FAUCI. Using cell culture-based techniques to develop vaccines is not new. It is successfully used in other vaccines. To adapt it to influenza has not been easy from a number of standpoints. The cell lines that have initially been involved at this point in time are not particularly good yielders of virus in the sense of the yield of growing the virus in the cell lines compared to the egg-based.

The other is that what you have is a situation where companies, if they—and that gets into the incentive. And I appreciate what you're saying, sir, about the idea when you have an emergent situation, you have to go beyond incentives. But we had to deal with companies who are very tried and true in their egg-based culture to begin with. To get them to switch over is not an easy thing.

Mr. KANJORSKI. And that is what I sense, that we are trying to do this with an economic system that deals with normality rather than abnormality. And it seems to me it is going to be hard to tell people that they have lost their children or their grandparents or their friends or themselves, because, gee, it just wasn't—just didn't fit the capital structure that the American economy is based on. And we couldn't entice some of these manufacturers that would love to make an aspirin and make a lot more money on that than a vaccine.

I am suggesting why haven't you come forth with setting up a government-sponsored enterprise we put up the manufacturing capacity, we pay for it, so we can move? So that everything is going concurrently, you're developing the strains, and how you pick up that efficiency could occur while we are building a manufacturing facility. But it seems to me we are lollygoggling around, if you will, and we are just saying, well, we probably have 5 years. And we hope we do. And some of the people I listen to say we may have 5 or 10 years.

But what if we had had only 2 years and what if we had had a Manhattan Project, we could have put the capacity in place, we could have been ready, and we could have done it even governmentally? Why are you all——

Dr. FAUCI. First of all, with respect, sir, I don't think you could have a one-to-one relationship to say that if we don't get cell-based cultures next year as opposed to this year, or 2 years from now as opposed to 3 years from now, that is going to be the whole story of whether we are successful or not. It is not that simple and straightforward.

Mr. KANJORSKI. If we don't have sufficient vaccines, not only for the American population but for the world population, if we think we have suffered in Iraq, when we try and say we are not going to give to the rest of the world because we don't have enough—I mean, this country has suffered enough dissatisfaction from the rest of the world. We have to start thinking globally. We have a responsibility. But here we are talking about capacity to manufacture; something that should be American. We should be No. 1. I can't understand why you don't come forward and say, look, if we can't convince some of these companies—some of which are—one of which, the major producer of this, is in my district. And, you know, if they need infusion of capital to expand, let's do what we do for the military, let's buy them the equipment.

Dr. FAUCI. If you look at the plan——

Mr. KANJORSKI. Doctor, what I am so worried about is everybody talking about this magnificent plan that has been structured to operate over 5 years. And I am saying we may not have 5 years.

What is the fastest period of time we could do it? What would it cost? And how efficient could we do it? And do we need the CDC or somebody to be the government-sponsored enterprise to get this done?

And it is not only a one-use thing. We are not only doing it against this flu. We know that we are going to have diseases like this in the future that we have to meet with a vaccine. Why not have the capacity within the government to do that?

Secretary LEAVITT. Mr. Chairman, I think Dr. Raub, again, would have an insightful response.

Chairman TOM DAVIS. And then we will move to Mr. Cummings as our last question. Thank you, Dr. Raub.

Mr. RAUB. Sir, in many ways you have summarized the budget proposal that accompanies the plan that we discussed with the two appropriations subcommittees yesterday. The President is proposing $4.7 billion worth for that kind of incentive to revitalize the vaccine industry for domestic production for the very reasons you're

saying: to try to give an acceleration such that the limiting factor will be the technology rather than the investment decisions.

We are proposing a substantial sharing of risk between the Federal Government and this industry as a way to transform that landscape.

Mr. KANJORSKI. And I appreciate that. But all I am suggesting is that it sounds to me as though it is the regular order of how we do things. And it doesn't quite have the emphasis that I think one of these days all of us are going to be up here asking why didn't we do this and why did we lose a million people when we didn't have to? And if the technology is there, if cell culture works, let's do it and do it as fast and as soon as we can, regardless of what the expense will be.

And I am not talking about throwing money away. I am talking about, look, we own munitions plants to develop certain munitions that aren't manufactured in this country. If we can do that for war, why can't we consider this a war on disease and spend a couple billion dollars to accomplish that?

Chairman TOM DAVIS. Thank you. Gentleman's time has expired. But thank you for your comments.

Mr. Cummings, 5 minutes.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I just want to go back to the opening statement of my good friend, Mr. Duncan, an hour or 2 ago. And he questioned whether or not this is—we are doing overkill. In other words, whether the problem is not as bad as the kind of cures that we are trying to come up with; in other words, the efforts that we are putting forth.

Do you all think that we are under or overestimating the problem, the significance of this problem?

Secretary LEAVITT. Congressman, it is my belief it is a very serious problem and it is one that could have such profound impact on our country and the world that we absolutely have to respond and be ready.

Now, I don't have any certainty that it is going to occur. But I do know that if we proceed forward on the plan that we have laid out, that at the conclusion we will have cell-based technology. We will have the capacity for annual flu vaccine manufacturing that we don't have. We will have better prepared State and local governments for whatever the medical emergency should be, whether it is a pandemic or bioterrorism event or a nuclear event.

And we will have a bio—a disease surveillance system internationally unlike what we have today. And we will have the peace of mind of knowing we are ready for it, because it will in fact happen. Pandemics occur, and they will occur in the future just as they have in the past.

Mr. CUMMINGS. One of the things I want to just go back to my friend, Mr. Van Hollen, and some issues that he raised with regard to the international situation, Mr. Secretary. You know, the Food and Agricultural Organization of the U.N. Director said—and I want to quote—he said, countries at risk in the international community need to act rapidly to control avian influenza at source, in animals. We cannot afford to wait to battle the disease in pharmacies and hospitals, but we need to get rid of the virus in affected farmers' backyards. Prevention will be cheaper than the cure.

And then we have the New York Times article entitled "Poverty and Superstition and the Drive to Block Bird Flu at the Source." And I quote them: "A Cambodian farmer stopped by the clinic late one morning to pick up medicine for a chronic cough. He said if any of his chickens fell sick, he would not tell anyone for fear the government might arrange for the rest to be slaughtered without compensation. If they were very sick—and this is the farmer talking—before they died, then I might throw them in the brush, he said. But if they were only a little sick, I would probably eat them."

To what extent, if any, are you working to address this troubling reality, that farmers in the epicenter of this struggle have an economic disincentive to report avian flu contamination among their animals?

Secretary LEAVITT. Congressman, I sat in the living room or the family area of a man who did exactly that, who depended on——

Mr. CUMMINGS. Where was that, Mr. Secretary?

Secretary LEAVITT. It was in Vietnam. He and his family had 300 chickens. They depended heavily on them both for protein and for their livelihood.

And when their village got H5N1, five of his chickens died, and the village committee concluded they needed to kill the chickens. He did. He had only lost five of them, and he decided he needed to eat the others or at least invite his family over. And a week later, he got a very serious cough and a fever and nausea, and within 2 hours he was debilitated and headed for death. I asked his wife about the experience. And she told me that it was obviously a terrible moment in their lives. And she was looking for ways that she could raise money to keep his treatment going, and they had sold the only thing they had, which was chickens.

Now, I know the cross-pressures that you're speaking of and they are deep and they are all over Southeast Asia. Vietnam alone has, I think, 43 million farmers. Several million of them have chickens. In China there are 13.5 billion chickens.

This is a problem that may have already gone beyond our capacity to contain among animals. I don't know that with certainty, but it is part of the equation that we have to factor in. It is primarily an animal disease right now.

And for that, we can be grateful. And we need to move aggressively to contribute to the efforts that you've alluded to.

I will tell you that the head of animal health for the U.N. and for the World Animal Health Organization was with me on that trip. And we spent a lot of time walking through markets and dealing with the Health Ministers and the Agriculture Ministers from those nations who are perplexed by this.

Is it possible for the United States to be involved in compensating farmers? We will be. We will be helping them in other countries in culling their chickens. We will be helping them vaccinate. But I did not leave there with any sense of certainty or optimism that we would, through those efforts, be able to prevent a pandemic should the virus mutate. We don't know anything about what is going on in Burma. We haven't got a clue about what is going on in North Korea. There are major sectors of the Earth in Africa where we don't have sufficient surveillance, nor do they.

This is a tough problem. And ultimately if it makes that transition, it will become a human problem. And that is why we are taking this so seriously, to answer your first question.

Mr. CUMMINGS. Just one last question, Mr. Chairman. You know, as you just described, just based upon what you just said, it seems as if this is a problem that we don't have a lot of control over. I mean, am I right? Just going back to Mr. Van Hollen's concern that it is better to try to address this outside the country than inside the country, just based upon what you just said, it seems like it is almost an impossible task. And correct me if I'm wrong to try to address those farmers, because they seem to be on the first line of problems.

Secretary LEAVITT. If this makes a transition from an animal/bird disease to a human, there will be a spark. And if we are there, we will have an opportunity to contain it. But if it happens in a way that happens in a place, a massive urban city where people live close together with their animals and it spreads like wildfire, we will not have the ability to contain it. And our doctrine calls for us to begin containing it every other way we can, which we will begin to do things we talked about earlier in this hearing. There will need to be at that point provisions taken to do everything we can to keep it off the shores of the United States. If it doesn't, we need a surveillance system that will help us determine when it begins to manifest itself here, and where.

That is what this plan is about. That is why this is such a serious, difficult complex problem. And we all hope it doesn't make that transition. But if it does, we need to be ready. And if H5N1 isn't the virus, there will be another, and we need to be ready then.

Mr. CUMMINGS. Thank you, Mr. Chairman, Mr. Secretary.

Chairman TOM DAVIS. I thank the members for their questions. Mr. Secretary, you did a great job. Thank you and your team and keep up the good work.

The hearing is adjourned.

[Whereupon, at 12:45 p.m., the committee was adjourned.]

[The prepared statements of Hon. Jon C. Porter and Hon. Jean Schmidt, and additional information submitted for the hearing record follows:]

STATEMENT FOR THE RECORD
CONGRESSMAN JON C. PORTER (R-NV-3)
"The National Pandemic Influenza Preparedness and Response Plan: Is the U.S. Ready for Avian Flu?"
NOVEMBER 4, 2005

Mr. Chairman, thank you for holding this hearing today. I would also like to thank the witnesses for taking the time to be here.

As a Representative from the greater Las Vegas Valley, I am deeply concerned about the potential implications a pandemic illness, such as avian influenza, can bring.

The difference between a pandemic now, versus pandemics that history has seen, relates to the amount of time it can now take in order to spread throughout the globe. The recent SARS crisis reminded people of this grim reality—a disease can now spread throughout the world in a matter of hours, forcing leaders throughout to develop plans to mitigate the potential spread of a deadly flu virus.

With over 40 million visitors coming through McCarran airport alone, Las Vegas has become a hub for both national and international travel. On any given day, much like many metropolitan areas, tens of thousands of people travel in and around Las Vegas as both locals and tourists, increasing the possibility of widespread infections. People go home, and then infect others within their local communities.

Mr. Chairman, I applaud you for holding this hearing today, as it is very important that we review our nation's readiness for potential pandemics. In light of the flu vaccine shortages of last year, I am glad that the Administration has chosen to be on the forefront of this fight. I am looking forward to learning more about the Administration's plans from Secretary Leavitt so that Congress can work with them in order to make the necessary improvements to facilitate greater preparedness.

Again, thank you, Chairman Davis, for holding this hearing. I look forward to the testimony from our witnesses.

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Government Reform Committee
Opening Statement by Representative Jean Schmidt
"The National Pandemic Influenza Preparedness and Response Plan: Is the US ready for Avian Flu?"
Friday November 4, 2005

Thank you Mr. Chairman, members of the Committee, I am happy to be here today with Secretary Leavitt, to discuss this very important and pressing issue.

The fear of H5N1 or the Avian flu, is real. To date, it has infected and killed 62 people in Vietnam, Cambodia, Thailand and Indonesia. This strain is dangerous because most humans lack immunity. Previous pandemics such as the 1918 flu pandemic have killed millions of people. Should we fear this? Yes, and let me tell you why.

My Aunt Rose was on of those people infected by the 1918 flu. The entire family was quarantined from their neighbors and while she survived, she had permanent consequences including poor eyesight and hearing loss.

We are vulnerable today for numerous reasons, most importantly, mobility and terrorism.

I applaud the President for understanding the seriousness of this potential pandemic, and look forward to hearing Secretary Leavitt's plan to be proactive in protection, acting now, before it is too late.

United States Government Accountability Office

GAO

Testimony
Before the Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EST
Friday, November 4, 2005

INFLUENZA PANDEMIC

Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage

Statement for the Record by Marcia Crosse
Director, Health Care

GAO-06-221T

November 4, 2005

GAO
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Highlights

Highlights of GAO-06-221T, a statement for the record for the Committee on Government Reform, House of Representatives

INFLUENZA PANDEMIC

Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage

Why GAO Did This Study

Concern has been rising about the nation's preparedness to respond to vaccine shortages that could occur in future annual influenza seasons or during an influenza pandemic—a global influenza outbreak. Although the timing or extent of a future influenza pandemic cannot be predicted, studies suggest that its effect in the United States could be severe, and shortages of vaccine could occur. For the 2004–05 annual influenza season, the nation lost about half its expected influenza vaccine supply when one of two major manufacturers announced in October 2004 that it would not release any vaccine. GAO examined federal, state, and local actions taken in response to the shortage, including lessons learned. The nation's experience during the unexpected 2004–05 vaccine shortfall offers insights into some of the challenges that government entities will face in a pandemic.

GAO was asked to provide a statement on lessons learned from the 2004–05 vaccine shortage and their relevance to planning and preparing for similar situations in the future, including an influenza pandemic. This statement is based on a GAO report, *Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation* (GAO-05-984), and on previous GAO reports and testimonies about influenza vaccine supply and pandemic preparedness.

www.gao.gov/cgi-bin/getrpt?GAO-06-221T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

A number of lessons emerged from federal, state, and local responses to the 2004–05 influenza vaccine shortage that carry implications for handling future vaccine shortages in either an annual influenza season or an influenza pandemic.

- First, limited contingency planning slows response. At the start of the 2004–05 influenza season, when the supply shortfall became apparent, the nation lacked a contingency plan specifically to address severe shortages. The absence of such a plan led to delays and uncertainties on the part of state and local public health entities on how best to ensure access to vaccine by individuals at high risk of severe influenza-related complications.

- Second, streamlined mechanisms to expedite vaccine availability are key to an effective response. During the 2004–05 shortage, for example, federal purchases of vaccine licensed for use in other countries but not the United States were not completed in time to meet peak demand. Some states' experience also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another.

- Third, effective response requires clear and consistent communication. Consistency among federal, state, and local communications is critical for averting confusion. State and local health officials also emphasized the value of updated information when responding to changing circumstances, using diverse media to reach diverse audiences, and educating providers and the public about prevention alternatives.

Over the past 5 years, GAO has urged the Department of Health and Human Services (HHS) to complete its plan to prepare for and respond to an influenza pandemic. GAO has reported on the importance of planning to address critical issues such as how vaccine will be purchased and distributed; how population groups will be given priority for vaccination; and how federal resources should be deployed before the nation faces a pandemic. On November 2, 2005, HHS released its pandemic influenza plan. GAO did not have the opportunity to review the plan before issuing this statement to determine the extent to which the plan addresses these critical issues.

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to provide information on our recent review of the 2004–05 influenza vaccine shortage, with lessons to consider as the nation improves its ability to respond to an influenza pandemic (a global influenza outbreak resulting from a major genetic change in the influenza virus).[1] Concern about the nation's preparedness to respond to an influenza pandemic has been growing for some time, in part because of the increase in the number of identified human cases of avian influenza in Asia.[2] Studies suggest that a pandemic's effects in the United States could be severe, and shortages of vaccine could occur. The nation's experience responding to the shortage of annual influenza vaccine for the 2004–05 influenza season—in which the nation faced an unexpected loss of nearly half its projected vaccine supply—offers insight into the some of the challenges that federal, state, and local entities will face if a pandemic occurs.

My statement includes findings from our recent report on last winter's influenza vaccine shortage and discusses lessons learned from that experience that could help prepare the nation to respond to future vaccine shortages in either an annual influenza season or an influenza pandemic.[3] My statement also draws from several GAO reports and testimonies on influenza vaccine supply, pandemic planning, and emergency preparedness for emerging infectious diseases that we have issued since October 2000.[4] This body of work includes interviews with officials in the Department of Health and Human Services (HHS), such as officials from

[1]An influenza pandemic is defined by the emergence of a novel influenza virus, to which much or all of the population is susceptible, that is readily transmitted person to person and causes outbreaks in multiple countries. Among the most notorious 20th-century outbreaks was the "Spanish influenza" of 1918, which is estimated to have killed 500,000 or more people in the United States and 40–50 million people worldwide.

[2]Since December 2003, 122 confirmed avian influenza cases in humans have been reported to the World Health Organization (WHO); these cases have occurred in four countries, and about half the victims died. See World Health Organization, "Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO," http://www.who.int/csr/disease/avian_influenza/country/cases_table_2005_11_01/en/index.html, downloaded Nov.1, 2005. Avian influenza has also been confirmed in birds in Europe.

[3]GAO, *Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation*, GAO-05-984 (Washington, D.C.: Sept. 30, 2005).

[4]See "Related GAO Products" at the end of this testimony.

the Centers for Disease Control and Prevention (CDC) and the National Vaccine Program Office. For the report on the 2004–05 influenza vaccine shortage, we conducted site visits at a sample of states and localities.[5] We also interviewed officials from public health departments and a major influenza vaccine manufacturer; national organizations, including the Association of State and Territorial Health Officials and the Association of Immunization Managers; organizations that conduct mass immunization clinics; and a large purchaser of influenza vaccine. We conducted all of our work in accordance with generally accepted government auditing standards.

In summary, a number of lessons emerged from federal, state, and local responses to the 2004–05 influenza vaccine shortage that carry implications for handling future vaccine shortages in either an annual influenza season or an influenza pandemic. First, limited contingency planning slows response. At the start of the 2004–05 influenza season, when the nation unexpectedly lost roughly half its projected influenza vaccine supply, the nation lacked a contingency plan specifically for a severe vaccine shortage. The absence of such a plan led to delays and uncertainties on the part of state and local public health entities on how best to ensure access to vaccine by individuals at high risk of severe influenza-related complications. Since 2000, we have encouraged the development of a plan to address critical issues that could arise in an influenza pandemic. Second, streamlined mechanisms to expedite vaccine availability are key to an effective response. During the 2004–05 shortage, for example, federal purchases of vaccine licensed for use in other countries but not the United States were not completed in time to meet peak demand. Some states' experience also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another. Third, effective response requires clear and consistent communication. Consistency among federal, state, and local communications is critical for averting confusion. State and local health officials also emphasized the value of updated information when responding to changing circumstances, using diverse media to reach diverse audiences, and educating providers and the public about prevention alternatives.

[5]The states were California, Florida, Maine, Minnesota, and Washington, and the localities were San Diego and San Francisco, California; Miami-Dade County, Florida; Portland, Maine; Stearns County, Minnesota; and Seattle–King County, Washington. We selected these states and localities on the basis of geography, population size, and state vaccination success rates.

Background

Influenza is more severe than some viral respiratory infections, such as the common cold. During an annual influenza season, most people who contract influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. People aged 65 years and older, people of any age with chronic medical conditions, children younger than 2 years, and pregnant women are generally more likely than others to develop severe complications from influenza. In an average year in the United States, more than 36,000 individuals die and more than 200,000 are hospitalized from influenza and related complications.

Pandemic influenza differs from annual influenza in several ways. According to the World Health Organization, pandemic influenza spreads to all parts of the world very quickly, usually in less than a year, and can sicken more than a quarter of the global population, including young, healthy individuals. Although health experts cannot predict with certainty which strain of influenza virus will be involved in the next pandemic, they warn that the avian influenza virus identified in the human cases in Asia, known as H5N1, could lead to a pandemic if it acquires the genetic ability, so far absent, to spread quickly from person to person.

Vaccination is the primary method for preventing influenza and its complications. Produced in a complex process that involves growing viruses in millions of fertilized chicken eggs, influenza vaccine is administered each year to protect against particular influenza strains expected to be prevalent that year. Experience has shown that vaccine production generally takes 6 or more months after a virus strain has been identified; vaccines for certain influenza strains have been difficult to mass-produce. After vaccination for the annual influenza season, it takes about 2 weeks for the body to produce the antibodies that protect against infection. According to CDC recommendations, the optimal time for annual vaccination is October through November. Because the annual influenza season typically does not peak until January or February, however, in most years vaccination in December or later can still be beneficial.

At present, two vaccine types are recommended for protection against influenza in the United States: an inactivated virus vaccine injected into muscle and a live virus vaccine administered as a nasal spray. The injectable vaccine—which represents the large majority of influenza vaccine administered in this country—can be used to immunize both healthy individuals and individuals at highest risk for severe complications, including those with chronic illness and those aged 65

years and older. The nasal spray vaccine, in contrast, is currently approved for use only among healthy individuals aged 5 to 49 years who are not pregnant. For the 2003–04 influenza season, two manufacturers—one with production facilities in the United States (sanofi pasteur[6]) and one with production facilities in the United Kingdom (Chiron)—produced about 83 million doses of injectable vaccine, which represented about 96 percent of the U.S. vaccine supply. A third U.S. manufacturer (MedImmune) produced the nasal spray vaccine.[7] For the 2004–05 influenza season, CDC and its Advisory Committee on Immunization Practices (ACIP) initially recommended vaccination for about 188 million people in designated priority groups, including roughly 85 million people at high risk for severe complications.[8] On October 5, 2004, however, Chiron announced that it could not provide its expected production of 46–48 million doses—about half the expected U.S. influenza vaccine supply.

Although vaccination is the primary strategy for protecting individuals who are at greatest risk of severe complications and death from influenza, antiviral drugs can also help to treat infection. If taken within 2 days of a person's becoming ill, these drugs can ease symptoms and reduce contagion. In the event of a pandemic, such drugs could lower the number of deaths until a pandemic influenza vaccine became available. Four antiviral drugs have been approved by the Food and Drug Administration (FDA) for treatment of influenza: amantadine, rimantadine, oseltamivir, and zanamivir.[9]

HHS has primary responsibility for coordinating the nation's response to public health emergencies. Within HHS, CDC is one of the agencies that

[6]The company spells its name without capital letters.

[7]Another injectable influenza vaccine for adults, produced by GlaxoSmithKline Biologicals, based in Belgium, was approved and licensed by FDA on August 31, 2005, for the U.S. market. The company expects to produce about 8 million doses for the 2005–06 influenza season.

[8]Not everyone in target populations receives a vaccination each year. For example, CDC reported that in 2003 an estimated 66 percent of people aged 65 years and older received an influenza vaccination. See Centers for Disease Control and Prevention, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 54, no. RR-8 (2004), 1–40.

[9]According to CDC, the H5N1 avian influenza virus is resistant to amantadine and rimantadine, commonly used for influenza; oseltamivir and zanamivir would probably work to treat influenza caused by the H5N1 virus, but additional studies are still needed to prove their effectiveness.

protect the nation's health and safety. CDC's activities include efforts to prevent and control diseases and to respond to public health emergencies. CDC and ACIP recommend which population groups should be targeted for vaccination each year and, when vaccine supply allows, recommend that any person who wishes to decrease his or her risk of influenza be vaccinated.[10] In addition, the National Vaccine Program Office is responsible for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities; the office also issued a draft national pandemic influenza preparedness plan in August 2004.[11]

Preparing for and responding to an influenza pandemic differ in several respects from preparing for and responding to an annual influenza season. For example, past influenza pandemics have affected healthy young adults who are not typically at high risk for severe influenza-related complications, so the groups given priority for early vaccination may differ from those given priority in an annual influenza season. In addition, according to CDC, a vaccine probably would not be available in the early stages of a pandemic. Shortages of vaccine would therefore be likely during a pandemic, potentially creating a situation more challenging than a shortage of vaccine for an annual influenza season.

Limited Contingency Planning Slows Response

One lesson learned from the 2004–05 season that is relevant to a future vaccine shortage in either an annual influenza season or a pandemic is the importance of planning before a shortage occurs. At the time the influenza vaccine shortage became apparent, the nation lacked a contingency plan specifically designed to respond to a severe vaccine shortage. The absence of such a plan led to delays and uncertainty on the part of many state and local entities on how best to ensure access to vaccine during the shortage by individuals at high risk of severe complications and others in priority groups. Faced with the unanticipated shortfall, CDC redefined the priority

[10]In addition, FDA plays a role in preparing for annual influenza seasons and a potential pandemic in approving and regulating use of vaccines and drugs, including antiviral medications. FDA also develops influenza reference strains and reagents and makes them available to manufacturers for vaccine development and evaluation.

[11]Department of Health and Human Services, National Vaccine Program Office, *Draft Pandemic Influenza Preparedness and Response Plan* (Washington, D.C.: August 2004).

groups it had recommended for vaccination[12] and asked sanofi pasteur, the remaining manufacturer of injectable vaccine, to suspend distribution until the agency completed its assessment of the shortage's extent and developed a plan to distribute the manufacturer's remaining vaccine to providers serving individuals in the priority groups. Developing and implementing this distribution plan took time and led to delays in response and some confusion at state and local levels.

Our work showed that several areas of planning are particularly important for enhancing preparedness before a similar situation occurs in the future, including defining the responsibilities of federal, state, and local officials; using emergency preparedness plans and emergency health directives; and facilitating the distribution and administration of vaccine.

- Clearly defining responsibilities of federal, state, and local officials can minimize confusion. During the 2004–05 vaccine shortage, even though CDC worked with states and localities to coordinate roles and responsibilities, problems occurred. For example, CDC worked with national professional associations to survey long-term-care providers throughout the country to determine if seniors had adequate access to vaccine. Maine and other states, however, also surveyed their long-term-care providers to make the same determination. This duplication of effort expended additional resources, burdened some long-term-care providers in the states, and created confusion.[13]

- Emergency preparedness plans help coordinate local response. State and local health officials in several locations we visited reported that using existing emergency plans or incident command centers (the organizational systems set up specifically to handle the response to emergency situations) helped coordinate effective local responses to the vaccine shortage. For example, public health officials from Seattle–King County said that using the county's incident command system played a vital role in coordinating an effective and timely local response and in communicating a clear message to the public and providers. In addition, according to

[12]These revised recommendations decreased the number of people in groups recommended for vaccination by about half, from about 188 million to about 98 million. See Centers for Disease Control and Prevention, "Interim Influenza Vaccination Recommendations, 2004–05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 39 (2004), 923–924.

[13]After the 2004–05 influenza season, CDC reviewed its response to the vaccine shortage and took a number of steps, including issuing interim guidelines in August 2005 to assist in responding to possible future shortages.

public health officials, emergency public health directives helped ensure access to vaccine by supporting providers in enforcing the CDC recommendations and in helping to prevent price gouging in certain states.

- Partnerships between the public and private sectors can facilitate distribution and administration of vaccine. In San Diego County, California, for example, local health officials worked with a coalition of partners in public health, private businesses, and nonprofit groups throughout the county. Other mechanisms facilitated administering the limited supply of influenza vaccine to those in high-risk or other priority groups. In Stearns County, Minnesota, for example, public health officials worked with private providers to implement a system of vaccination by appointment. Rather than standing in long lines for vaccination, individuals with appointments went to a clinic during a given time slot.

Although an influenza pandemic may differ in some ways from an annual influenza season, experience during the 2004–05 shortage illustrated the importance of having contingency plans in place ahead of time to prevent delays when timing is critical. Some health officials indicated that, as a result of the experience with the influenza vaccine shortage, they were revising state and local preparedness plans or modifying command center protocols to prepare for future emergencies. For example, experiences during the 2004–05 influenza season led Maine state officials to recognize the need to speed completion of their pandemic influenza preparedness plan.

Over the past 5 years, we have reported on the importance of planning to address critical issues such as how vaccine will be purchased and distributed; how population groups will be given priority for vaccination; and how federal resources should be deployed before the nation faces a pandemic. We have also urged HHS to complete its pandemic preparedness and response plan, which the department released in draft form in August 2004. This draft plan described options for vaccine purchase and distribution and provided planning guidance to state and local health departments. As we testified earlier, however, the draft plan lacked clear guidance on potential priority groups for vaccination in a pandemic, and key questions remained about the federal role in purchasing and distributing vaccine.[14] The experience in 2004–05 also highlighted the importance of finalizing such planning details. On

[14]See GAO, *Influenza Pandemic: Challenges in Preparedness and Response*, GAO-05-863T (Washington, D.C.: June 30, 2005).

November 2, 2005, HHS released its pandemic influenza plan. We did not, however, have an opportunity to review the plan before issuing this statement to determine whether the plan addresses these critical issues.

Streamlined Mechanisms for Expediting Vaccine Availability Are Key to Effective Response

A second lesson from the experience of the 2004–05 vaccine shortage that is relevant to future vaccine shortages in either an annual influenza season or a pandemic is the importance of streamlined mechanisms to make vaccine available in an expedited manner. For example, HHS began efforts to purchase foreign vaccine that was licensed for use in other countries but not the United States shortly after learning in October 2004 that Chiron would not supply any vaccine. The purchase, however, took several months to complete, and so vaccine was not available to meet the fall 2004 demand; by the end of the season, this vaccine had not been used. In addition, recipients of this foreign vaccine could have been required to sign a consent form and follow up with a health care worker after vaccination—steps that, according to health officials we interviewed in several states, would be too cumbersome to administer.

Some states' experience during the 2004–05 vaccine shortage also highlighted the importance of mechanisms to transfer available vaccine quickly and easily from one state to another; the lack of mechanisms to do so delayed redistribution to some states. During the 2004–05 shortage, some state health officials reported problems with their ability to purchase vaccine, both in paying for vaccine and in administering the transfer process. Minnesota, for example, tried to sell its available vaccine to other states seeking additional vaccine for their priority populations. According to federal and state health officials, however, certain states lacked the funding or flexibility under state law to purchase the vaccine when Minnesota offered it. As we have previously testified, establishing the funding sources, authority, or processes for quick public-sector purchases may be needed as part of pandemic preparedness.[15]

Recognizing the need for mechanisms to make vaccine available in a timely manner in the event of a pandemic, HHS has taken some action to address the fragility of the current influenza vaccine market. In its budget request for fiscal year 2006, CDC requested $30 million to enter into guaranteed-purchase contracts with vaccine manufacturers to help ensure vaccine supply. According to the agency, maintaining an abundant supply

[15]GAO-05-863T.

of annual influenza vaccine is critically important for improving the nation's preparedness for an influenza pandemic. HHS is also taking steps toward developing a supply of vaccine to protect against avian influenza strains that could be involved in a pandemic.[16]

Effective Response Requires Clear and Consistent Communication

Experience during the 2004–05 shortage also illustrated the critical role communication plays when demand for vaccine exceeds supply and information about future vaccine availability is uncertain, as could happen in a future annual influenza season or a pandemic. During the 2004–05 shortage, CDC communicated regularly through a variety of media as the situation evolved. State and local officials, however, identified several communication lessons for future seasons or if an influenza pandemic occurred:

- Consistency among federal, state, and local communications is critical for averting confusion. State health officials reported several cases where inconsistent messages created confusion. Health officials in California, for example, reported that local radio stations in the state were running two public service announcements simultaneously—one from CDC advising those aged 65 years and older to be vaccinated, and one from the state advising those aged 50 years and older to be vaccinated.

- Disseminating clear, updated information is especially important when responding to changing circumstances. Beginning in October 2004, CDC asked individuals who were not in a high-risk group or another priority group to forgo or defer vaccination; this message, however, did not include instructions to check back with their providers later in the season, when more vaccine had become available. According to CDC, an estimated 17.5 million individuals specifically deferred vaccination to save

[16]In addition, HHS has also taken steps to stockpile antiviral drugs, which could be beneficial in the event of a pandemic, before a vaccine specific for the responsible virus strain is available or during a period of limited vaccine supply. By December 2004, HHS had purchased and stockpiled enough of two antiviral medications (rimantadine and oseltamivir) to treat more than 7 million people, and the department recently announced intentions to buy enough antiviral drugs to treat 20 million people. Like vaccine, however, antiviral drugs take several months to produce from raw materials, and HHS's National Vaccine Program Office has reported that in a pandemic, the manufacturing capacity and supply of antiviral drugs are likely to be less than global demand.

vaccine for those in priority groups;[17] local health officials said that many did not return when vaccine became available.

- Using diverse media helps reach diverse audiences. During the 2004–05 influenza season, public health officials emphasized the value of a variety of communication methods—such as telephone hotlines, Web sites, and bilingual radio advertisements—to reach as many individuals as possible and to increase the effectiveness of local efforts to raise vaccination rates. In Seattle–King County, Washington, for example, health department officials reported that a telephone hotline was important because some seniors did not have Internet access. Public health officials in Miami-Dade County, Florida, said that bilingual radio advertisements promoting influenza vaccine for those in priority groups helped increase the effectiveness of local efforts to raise vaccination rates.

- Education can alert providers and the public to prevention alternatives. In the 2004–05 shortage, some of the nasal spray vaccine for healthy individuals went unused, in part because of fears that the vaccine was too new and untested or that the live virus in the nasal spray could be transmitted to others.[18] Further, public health officials we interviewed said that education about all available forms of prevention, including the use of antiviral medications and good hygiene practices, can help reduce the spread of influenza.

Concluding Observations

Experience during the 2004–05 influenza vaccine shortage highlights the need to prepare the nation for handling future shortages in either an annual influenza season or an influenza pandemic. In particular, that season's shortage emphasized the vital need for early planning, mechanisms to make vaccine available, and effective communication to ensure available vaccine is targeted to those who need it most. As our work over the past 5 years has noted, it is important for federal, state, and local governments to develop and communicate plans regarding critical issues—such as how vaccine will be purchased and distributed, which

[17]See Centers for Disease Control and Prevention, "Estimated Influenza Vaccination Coverage among Adults and Children—United States, September 1, 2004–January 31, 2005," *Morbidity and Mortality Weekly Report*, vol. 54, no. 12 (2005), 304–307.

[18]The nasal spray vaccine was recommended for individuals aged 5–49 years who were not pregnant, including some individuals, such as health care workers in this age group and household contacts of children younger than 6 months, in the priority groups defined by CDC.

population groups are likely to have priority for vaccination, and what communication strategies are most effective—before we face another shortage of annual influenza vaccine or, worse, an influenza pandemic.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov. Kim Yamane, Assistant Director; George Bogart; Ellen W. Chu; Nicholas Larson; Jennifer Major; and Terry Saiki made key contributions to this statement.

Related GAO Products

Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation. GAO-05-984. Washington, D.C.: September 30, 2005.

Influenza Pandemic: Challenges in Preparedness and Response. GAO-05-863T. Washington, D.C.: June 30, 2005.

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Flu Vaccine: Recent Supply Shortages Underscore Ongoing Challenges. GAO-05-177T. Washington, D.C.: November 18, 2004.

Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks. GAO-04-1100T. Washington, D.C.: September 28, 2004.

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Influenza Pandemic: Plan Needed for Federal and State Response. GAO-01-4. Washington, D.C.: October 27, 2000.

HHS Pandemic Influenza Plan

U.S. Department of Health and Human Services

November 2005

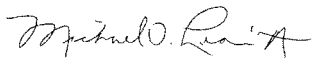
Statement by Health and Human Services Secretary Mike Leavitt:

One of the most important public health issues our Nation and the world faces is the threat of a global disease outbreak called a pandemic. No one in the world today is fully prepared for a pandemic -- but we are better prepared today than we were yesterday - and we will be better prepared tomorrow than we are today.

This *HHS Pandemic Influenza Plan* provides a blueprint from which to prepare for the challenges that lie ahead of us. Being prepared and responding effectively involves everyone: individuals, communities, businesses, States, Federal agencies, international countries and organizations. Here at home, we can use this *Plan* to create a seamless preparedness network where we are all working together for the benefit of the American people.

In the century past, we have experienced influenza pandemics three times: as recently as 1968 and 1957 and what has been called the Great Influenza in 1918, a pandemic that killed 40-50 million people worldwide. At some point in our nation's future another virus will emerge with the potential to create a global disease outbreak. History teaches us that everything we do today to prepare for that eventuality will have many lasting benefits for the future. We will realize important advances in healthcare, and we will be better prepared for other types of emergencies.

I am humbled by the enormity of the challenge that the global community confronts should there be a pandemic. Public cooperation and global partnerships will be essential tools in fighting back and creating a constant state of readiness. If together we take the steps necessary, we will be able to save the lives of millions of people in our country and all around the world.



Mike Leavitt
Health and Human Services Secretary

preface

Adequate planning for a pandemic requires the involvement of every level of our nation, and indeed, the world. The ubiquitous nature of an influenza pandemic compels federal, state and local governments, communities, corporations, families and individuals to learn about, prepare for, and collaborate in efforts to slow, respond to, mitigate, and recover from a potential pandemic. The development, refinement, and exercise of pandemic influenza plans by all stakeholders are critical components of preparedness.

This document, the **HHS Pandemic Influenza Plan**, serves as a blueprint for all HHS pandemic influenza preparedness planning and response activities. This plan updates the August 2004 draft HHS Pandemic Influenza Preparedness and Response Plan and features important additions and refinements. The Plan integrates changes made in the 2005 World Health Organization (WHO) classification of pandemic phases and expansion of international guidance and now is consistent with the National Response Plan (NRP) published in December 2004.

The **HHS Pandemic Influenza Plan** has three parts, the first two of which are contained in this document. Part 1, the **Strategic Plan** outlines federal plans and preparation for public health and medical support in the event of a pandemic. It identifies key roles of HHS and its agencies in a pandemic and provides planning assumptions for federal, state and local governments and public health operations plans. Part 2, **Public Health Guidance for State and Local Partners**, provides detailed guidance to state and local health departments in 11 key areas. Parts 1 and 2 will be regularly updated and refined. These documents will serve as tools for continued engagement with stakeholders, state and local partners.

Part 3, which is currently under development; will consist of **HHS Agencies' Operational Plans**. Each HHS component will prepare, maintain, update and exercise an operational plan that itemizes their specific roles and responsibilities in the event of a pandemic. These individual plans will also include detailed continuity of operations plans such as strategies for ensuring that critical everyday functions of each operating division are identified and maintained in the presence of the expected decreased staffing levels of a pandemic event. In addition to operations, these plans will elaborate on coordination, command and control, logistics, and planning, as well as financial and administration considerations.

Recognizing that an influenza pandemic has the capacity to cause disruptions across all levels of governments and in all communities, pandemic influenza preparedness is a shared responsibility. The following list includes some of the additional plans that will be required to mitigate the impact of a pandemic and to ensure continuity of essential services:

All plans should remain living documents. They should be updated periodically in the time before, during, and after a pandemic. All plans should be exercised to identify weaknesses and promote effective implementation.

International and Global Planning

Every nation should develop comprehensive strategies and contingency plans for a global pandemic. These plans should be coordinated regionally and at the global level. The opportunity to contain an initial outbreak can only be realized in the presence of a sophisticated global strategy.

National Strategy for Pandemic Influenza

The National Strategy provides a framework for future U.S. Government planning efforts. It acknowledges that the Nation must have a system of plans at all levels of government and in all sectors outside of government, that can be integrated to address the pandemic threat.

State and Local Pandemic Influenza Plans

These plans should detail how health departments and other agencies of state and local governments and tribal nations will prevent, mitigate, respond and recover from an influenza pandemic. They should be community specific where appropriate and should contemplate specific local and community needs.

Corporate, Infrastructure and Critical Service Provider Plans

School systems, hospitals, healthcare providers, community infrastructure providers and employers should develop plans that identify how they will respond in the event of an influenza pandemic.

All plans should remain living documents. They should be updated periodically in the time before, during, and after a pandemic. All plans should be exercised to identify weaknesses and promote effective implementation. Pandemic influenza response can be optimized by effectively engaging stakeholders during all phases of pandemic planning and response.

Although the timing, nature and severity of the next pandemic cannot be predicted with any certainty, preparedness planning is imperative to lessen the impact of a pandemic.

executive summary

An influenza pandemic has the potential to cause more death and illness than any other public health threat. If a pandemic influenza virus with similar virulence to the 1918 strain emerged today, in the absence of intervention, it is estimated that 1.9 million Americans could die and almost 10 million could be hospitalized over the course of the pandemic, which may evolve over a year or more. Although the timing, nature and severity of the next pandemic cannot be predicted with any certainty, preparedness planning is imperative to lessen the impact of a pandemic. The unique characteristics and events of a pandemic will strain local, state, and federal resources. It is unlikely that there will be sufficient personnel, equipment, and supplies to respond adequately to multiple areas of the country for a sustained period of time. Therefore, minimizing social and economic disruption will require a coordinated response. Governments, communities, and other public and private sector stakeholders will need to anticipate and prepare for a pandemic by defining roles and responsibilities and developing continuity of operations plans.

This document, the HHS Pandemic Influenza Plan, serves as a blueprint for all HHS pandemic influenza preparedness and response planning. Part 1, the **Strategic Plan**, describes a coordinated public health and medical care strategy to prepare for, and begin responding to, an influenza pandemic. Part 2, **Public Health Guidance for State and Local Partners** provides guidance on specific aspects of pandemic influenza planning and response for the development of state and local preparedness plans.

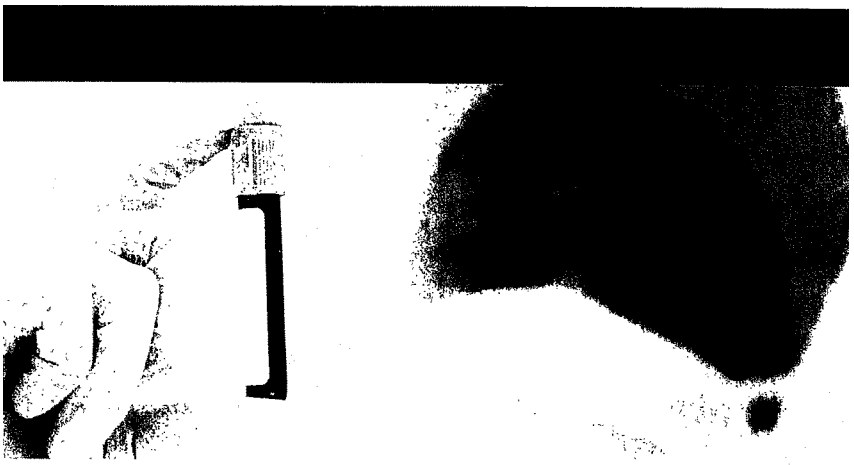
Part 1 – Strategic Plan

Part 1 describes the pandemic influenza threat and outlines planning assumptions and doctrine for the HHS pandemic influenza response. In addition, it identifies key pandemic response actions and the necessary capabilities for effective implementation. Finally, the **Strategic Plan** assigns lead roles and responsibilities for response actions to specific HHS agencies and offices.

The Pandemic Influenza Threat

A pandemic occurs when a novel influenza virus emerges that can infect and be efficiently transmitted among individuals because of a lack of pre-existing immunity in the population. The extent and severity of a pandemic depends on the specific characteristics of the virus.

Although a novel influenza virus could emerge from anywhere in the world at any time, scientists are particularly concerned about the avian influenza (H5N1) currently circulating in Asia and parts of Europe.



Outbreaks of influenza H5N1 have occurred among poultry in several countries in Asia since 1997. The H5N1 avian influenza virus is widespread in the region and has become endemic in migratory birds and several other animal species. As of October 2005, cases of human H5N1 infection have been reported in Thailand, Vietnam, Cambodia, and Indonesia. The reported death rate for these cases has been about 50 percent, although the true number of people who have been exposed to and infected by the H5N1 virus is unknown. While most of the reported cases seem to have occurred from direct contact with infected poultry or contaminated surfaces, the source of infection has not been documented in every instance. Of additional concern are the few instances where secondary transmission from person to person may have occurred. Given these events, we are currently in a Pandemic Alert Phase 3, defined by WHO as "human infections with a new subtype but no human-to-human spread or at most rare instances of spread to a close contact."[1]

Pandemic Planning Assumptions

As a result of the widespread emergence and spread of the H5N1 virus among birds, public health experts and government officials are escalating and intensifying their pandemic preparedness planning. Uncertainty about the magnitude of the next pandemic mandates planning for a severe pandemic such as occurred in 1918. Characteristics of an influenza pandemic that must be considered in strategic planning include:

The ability of the virus to spread rapidly worldwide;

The fact that people may be asymptomatic while infectious;

Simultaneous or near-simultaneous outbreaks in communities across the U.S., thereby limiting the ability of any jurisdiction to provide support and assistance to other areas;

Enormous demands on the healthcare system;

Delays and shortages in the availability of vaccines and antiviral drugs; and

Potential disruption of national and community infrastructures including transportation, commerce, utilities and public safety due to widespread illness and death among workers and their families and concern about on-going exposure to the virus.

[1] http://www.who.int/csr/resources/publications/influenza/whocdscsredc991.pdf

Doctrine for HHS Pandemic Influenza Planning and Response

The ongoing outbreaks of avian influenza in Asia and the progression from the interpandemic period (the period prior to human infections) to a pandemic alert (once human infections have occurred) have prompted HHS to enhance its preparedness planning and activities. In addition to the characteristics of a pandemic noted above, HHS' preparedness planning and response activities are guided by the following principles:

1. Preparedness will require coordination among federal, state and local government and partners in the private sector.
2. An informed and responsive public is essential to minimizing the health effects of a pandemic and the resulting consequences to society.
3. Domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population is critical, as is development of vaccine against each circulating influenza virus with pandemic potential and acquisition of sufficient quantities to help protect first responders and other critical personnel at the onset of a pandemic.
4. Quantities of antiviral drugs sufficient to treat 25% of the U.S. population should be stockpiled.
5. Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the United States.
6. When possible and appropriate, protective public health measures will be employed to attempt to reduce person-to-person viral transmission and prevent or delay influenza outbreaks.
7. At the onset of a pandemic, vaccine, which will initially be in short supply, will be procured by HHS and distributed to state and local health departments for immunization of pre-determined priority groups.
8. At the onset of a pandemic, antiviral drugs from public stockpiles will be distributed to health care providers for administration to pre-determined priority groups.

Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the United States.

Key Pandemic Response Elements and Capabilities for Effective Implementation

The nature of the HHS response will be guided by the epidemiologic features of the virus and the course of the pandemic. An influenza pandemic will place extraordinary and sustained demands not only on public health and health care providers, but also on providers of essential services across the United States and around the globe. Realizing that pandemic influenza preparedness is a process, not an isolated event, to most effectively implement key pandemic response actions, specific capabilities must be developed through preparedness activities implemented before the pandemic occurs. This plan outlines key actions for an effective pandemic response, involving surveillance, investigation, protective public health measures; vaccines and antiviral drug production; healthcare and emergency response; and communications and public outreach. In addition, the Strategic Plan sorts these actions by the WHO Pandemic phases. Recognizing that this potential public health catastrophe can occur at any time, HHS has aggressively embarked on preparing for a pandemic.

Surveillance, Investigation, Protective Public Health Measures

Aggressive surveillance measures ensure early detection and isolation of novel virus strains. Since a new virus could emerge anywhere in the world, surveillance activities must be conducted globally. To date, working with our international partners, HHS has greatly intensified its U.S. and global surveillance activities. In addition, HHS is developing comprehensive infection control strategies.

Once sustained human infection is documented, early in a pandemic, especially before a vaccine is available or during a period of limited supply, HHS may implement travel-related and community-based public health strategies in order to impede the spread of the virus and reduce the number of people infected. In particular, travel advisories and precautions, screening of persons arriving from affected areas, closing schools, restricting public gatherings, quarantine of exposed persons and isolation of infected persons may be implemented with the intent of slowing introduction and transmission of the virus. The use and continuation of these interventions will be determined by assessments of their effectiveness.

Vaccines and Antiviral Drugs

Vaccines and antiviral drugs have the potential to significantly reduce morbidity and mortality during a pandemic. In addition, vaccines and antiviral drugs may also limit viral spread. Although antiviral drugs can be stockpiled, a pandemic vaccine can only be made once the pandemic virus is identified. HHS is currently initiating vaccine development and clinical testing leading toward a vaccine that may provide complete or partial protection against potential pandemic viral strains and also increasing and diversifying antiviral medicines in the Strategic National Stockpile (SNS), a cache of medical and pharmaceutical supplies maintained by HHS. FDA is currently working with industry to facilitate the development, licensure/approval, production and availability of pandemic influenza countermeasures.

At the onset of a pandemic, HHS will accelerate its ongoing work with industry to facilitate the production and distribution of antiviral drugs and pandemic vaccines. HHS will continue to monitor antiviral drug and pandemic vaccine distribution effectiveness, and adverse events Since vaccine and antiviral drugs are likely to be in short supply at the onset of an influenza pandemic, identification of predefined groups in which these medications will be used will be discussed as part of federal planning activities. HHS will work with state and local governments to develop guidelines and operational plans for the distribution of available supplies of a pandemic vaccine and antiviral drugs.

Healthcare and Emergency Response

An effective healthcare and emergency response requires planning and coordination among all levels of government and providers of direct patient care and essential services. HHS is working with its state and local partners to increase health care surge capacity of medical equipment, materials and personnel.

During a pandemic, HHS will work with states and local governments, and the private sector to optimize healthcare and emergency response. Since a pandemic may unfold in an unpredictable way, HHS actions in a pandemic will be shaped by regular assessments and adjustments of its strategies.

Communications and Public Outreach

Dissemination of information to all Americans is a critical component of effective pandemic planning and response. HHS is currently developing communication and outreach materials and messages. In addition, HHS is developing strategies to address psychosocial concerns and procedures for implementation of communications plans for health care providers and the public.

During a pandemic, HHS will provide honest, accurate and timely information on the pandemic to the public. It will also monitor and evaluate its interventions and will communicate lessons learned to healthcare providers and public health agencies on the effectiveness of clinical and public health responses.

All state, local, and tribal governments must be prepared to detect the earliest cases of pandemic influenza infection and disease, to minimize illness and morbidity, and to decrease social disruption and economic loss.

Part 2 – Public Health Guidance to State and Local Partners

All state, local, and tribal governments must be prepared to detect the earliest cases of pandemic influenza infection and disease, to minimize illness and morbidity, and to decrease social disruption and economic loss. Specific guidance and recommendations for pandemic influenza preparedness for state, local and tribal governments are detailed in eleven supplements in Part 2.

Surveillance (Supplement 1) provides recommendations to state and local partners on surveillance for influenza viruses and disease to monitor the health impact of influenza throughout the pandemic phases.

Laboratory Diagnostics (Supplement 2) provides recommendations to state and local public health partners and other laboratories on the use of diagnostic tests to detect, characterize, and monitor novel subtypes of influenza, including avian influenza A (H5N1) and other viruses with pandemic potential.

Healthcare Planning (Supplement 3) provides healthcare partners with recommendations for developing plans to respond to an influenza pandemic with a focus on planning for pandemic influenza surveillance, decision-making structures for responding to a pandemic, hospital communications, education and training, patient triage, clinical evaluation and admission, facility access, occupational health, distribution of vaccines and antiviral drugs, surge capacity, and mortuary issues. Planning for the provision of care in non-hospital settings—including residential care facilities, physicians' offices, private home healthcare services, emergency medical services, federally qualified health centers, rural health clinics, and alternative care sites—is also addressed.

Infection Control (Supplement 4) provides guidance to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza including the selection and use of personal protective equipment; hand hygiene and safe work practices; cleaning and disinfection of environmental surfaces; handling of laboratory specimens; and post-mortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high-risk for severe influenza or its complications, and issues concerning occupational health.

Clinical Guidelines (Supplement 5) provides clinical procedures for the initial screening, assessment, and management of patients with suspected novel influenza during the Interpandemic and Pandemic Alert Periods and for patients with suspected pandemic influenza during the Pandemic Period.

Robust preparedness for the next pandemic requires coordination with state and local emergency responders.

HHS encourages all levels of government to use this plan and begin refining their own.

Vaccine Distribution and Use (Supplement 6) provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program, including vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, training, data collection on use, effectiveness, safety and the development of drug resistance.

Antiviral Drug Distribution and Use (Supplement 7) provides recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis throughout the pandemic phases, including issues such as procurement, distribution to pre-defined priority groups, legal preparedness, training and data collection.

Community Disease Control and Prevention (Supplement 8) provides recommendations to state and local partners on the use of disease containment strategies to prevent or decrease transmission during different pandemic phases.

Managing Travel-Related Risks of Disease (Supplement 9) provides recommendations to state and local partners on travel-related containment strategies that can be used during different phases of an influenza pandemic, including strategies that range from distribution of travel health alert notices, to isolation and quarantine of new arrivals, to restriction or cancellation of nonessential travel.

Public Health Communications (Supplement 10) outlines key influenza pandemic risk communications concepts including:

- When health risks are uncertain, as likely will be the case during an influenza pandemic, people need information about what is known and unknown, as well as interim guidance to formulate decisions to help protect their health and the health of others;
- An influenza pandemic will generate immediate, intense, and sustained demand for information from the public, healthcare providers, policy makers, and news media;
- Timely and transparent dissemination of clear, accurate, science-based, culturally competent information about pandemic influenza and the progress of the response can build public trust and confidence;
- Coordination of message development and release of information among federal, state, and local health officials is critical to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures;
- Information to public audiences should be technically correct and sufficiently complete to encourage support of policies and official actions.

Workforce Support: Psychosocial Considerations and Information Needs (Supplement 11) focuses on the institutionalization of psychosocial support services that will help workers manage emotional stress during the response to an influenza pandemic and resolve related personal, professional, and family issues.

Robust preparedness for the next pandemic also requires coordination with state and local emergency responders. HHS encourages all levels of government to use this plan and begin refining their own. To this end, HHS plans to engage all stakeholders in an ongoing dialogue to refine and better coordinate preparedness plans.

NATIONAL STRATEGY FOR

PANDEMIC INFLUENZA

HOMELAND SECURITY COUNCIL

NOVEMBER 2005

NATIONAL STRATEGY FOR PANDEMIC INFLUENZA

HOMELAND SECURITY COUNCIL

NOVEMBER 2005

THE WHITE HOUSE
WASHINGTON

My fellow Americans,

Once again, nature has presented us with a daunting challenge: the possibility of an influenza pandemic.

Most of us are accustomed to seasonal influenza, or "the flu," a viral infection that continues to be a significant public health challenge. From time to time, changes in the influenza virus result in a new strain to which people have never been exposed. These new strains have the potential to sweep the globe, causing millions of illnesses, in what is called a pandemic.

A new strain of influenza virus has been found in birds in Asia, and has shown that it can infect humans. If this virus undergoes further change, it could very well result in the next human pandemic.

We have an opportunity to prepare ourselves, our Nation, and our world to fight this potentially devastating outbreak of infectious disease.

The *National Strategy for Pandemic Influenza* presents our approach to address the threat of pandemic influenza, whether it results from the strain currently in birds in Asia or another influenza virus. It outlines how we intend to prepare, detect, and respond to a pandemic. It also outlines the important roles to be played not only by the Federal government, but also by State and local governments, private industry, our international partners, and most importantly individual citizens, including you and your families.

While your government will do much to prepare for a pandemic, individual action and individual responsibility are necessary for the success of any measures. Not only should you take action to protect yourself and your families, you should also take action to prevent the spread of influenza if you or anyone in your family becomes ill.

Together we will confront this emerging threat and together, as Americans, we will be prepared to protect our families, our communities, this great Nation, and our world.

GEORGE W. BUSH
THE WHITE HOUSE
November 1, 2005

NATIONAL STRATEGY FOR PANDEMIC INFLUENZA

TABLE OF CONTENTS

NATIONAL STRATEGY FOR PANDEMIC INFLUENZA

INTRODUCTION

Although remarkable advances have been made in science and medicine during the past century, we are constantly reminded that we live in a universe of microbes - viruses, bacteria, protozoa and fungi that are forever changing and adapting themselves to the human host and the defenses that humans create.

Influenza viruses are notable for their resilience and adaptability. While science has been able to develop highly effective vaccines and treatments for many infectious diseases that threaten public health, acquiring these tools is an ongoing challenge with the influenza virus. Changes in the genetic makeup of the virus require us to develop new vaccines on an annual basis and forecast which strains are likely to predominate.

As a result, and despite annual vaccinations, the U.S. faces a burden of influenza that results in approximately 36,000 deaths and more than 200,000 hospitalizations each year. In addition to this human toll, influenza is annually responsible for a total cost of over $10 billion in the U.S.

A pandemic, or worldwide outbreak of a new influenza virus, could dwarf this impact by overwhelming our health and medical capabilities, potentially resulting in hundreds of thousands of deaths, millions of hospitalizations, and hundreds of billions of dollars in direct and indirect costs. This *Strategy* will guide our preparedness and response activities to mitigate that impact.

THE PANDEMIC THREAT

Pandemics happen when a novel influenza virus emerges that infects and can be efficiently transmitted between humans. Animals are the most likely reservoir for these emerging viruses; avian viruses played a role in the last three influenza pandemics. Two of these pandemic-causing viruses remain in circulation and are responsible for the majority of influenza cases each year.

Pandemics have occurred intermittently over centuries. The last three pandemics, in 1918, 1957 and 1968, killed approximately 40 million, 2 million and 1 million people worldwide, respectively. Although the timing cannot be predicted, history and science suggest that we will face one or more pandemics in this century.

The current pandemic threat stems from an unprecedented outbreak of avian influenza in Asia and Europe, caused by the H5N1 strain of the Influenza A virus. To date, the virus has infected birds in 16 countries and has resulted in the deaths, through illness and culling, of approximately 200 million birds across Asia. While traditional control measures have been attempted, the virus is now endemic in Southeast Asia, present in long-range migratory birds, and unlikely to be eradicated soon.

A notable and worrisome feature of the H5N1 virus is its ability to infect a wide range of hosts, including birds and humans. As of the date of this document, the virus is known to have infected 121 people in four countries, resulting in 62 deaths over the past two years. Although the virus has not yet shown an ability to transmit efficiently between humans, as is seen with the annual influenza virus, there is concern that it will acquire this capability through genetic mutation or exchange of genetic material with a human influenza virus.

It is impossible to know whether the currently circulating H5N1 virus will cause a human pandemic. The widespread nature of H5N1 in birds and the likelihood of mutations over time raise our concerns that

the virus will become transmissible between humans, with potentially catastrophic consequences. If this does not happen with the current H5N1 strain, history suggests that a different influenza virus will emerge and result in the next pandemic.

THE *NATIONAL STRATEGY FOR PANDEMIC INFLUENZA*

Preparing for a pandemic requires the leveraging of all instruments of national power, and coordinated action by all segments of government and society. Influenza viruses do not respect the distinctions of race, sex, age, profession or nationality, and are not constrained by geographic boundaries. The next pandemic is likely to come in waves, each lasting months, and pass through communities of all size across the nation and world. While a pandemic will not damage power lines, banks or computer networks, it will ultimately threaten all critical infrastructure by removing essential personnel from the workplace for weeks or months.

This makes a pandemic a unique circumstance necessitating a strategy that extends well beyond health and medical boundaries, to include the sustainment of critical infrastructure, private-sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations. The uncertainties associated with influenza viruses require that our *Strategy* be versatile, to ensure that we are prepared for any virus with pandemic potential, as well as the annual burden of influenza that we know we will face.

The *National Strategy for Pandemic Influenza* guides our preparedness and response to an influenza pandemic, with the intent of (1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society.

The *Strategy* will provide a framework for future U.S. Government planning efforts that is consistent with *The National Security Strategy* and the *National Strategy for Homeland Security*. It recognizes that preparing for and responding to a pandemic cannot be viewed as a purely federal responsibility, and that the nation must have a system of plans at all levels of government and in all sectors outside of government that can be integrated to address the pandemic threat. It is guided by the following principles:

- The federal government will use all instruments of national power to address the pandemic threat.
- States and communities should have credible pandemic preparedness plans to respond to an outbreak within their jurisdictions.
- The private sector should play an integral role in preparedness before a pandemic begins, and should be part of the national response.
- Individual citizens should be prepared for an influenza pandemic, and be educated about individual responsibility to limit the spread of infection if they or their family members become ill.
- Global partnerships will be leveraged to address the pandemic threat.

PILLARS OF THE *NATIONAL STRATEGY*

Our *Strategy* addresses the full spectrum of events that link a farmyard overseas to a living room in America. While the circumstances that connect these environments are very different, our strategic principles remain relevant. The pillars of our *Strategy* are:

- **Preparedness and Communication**: Activities that should be undertaken before a pandemic to ensure preparedness, and the communication of roles and responsibilities to all levels of government, segments of society and individuals.
- **Surveillance and Detection**: Domestic and international systems that provide continuous "situational awareness," to ensure the earliest warning possible to protect the population.
- **Response and Containment**: Actions to limit the spread of the outbreak and to mitigate the health, social and economic impacts of a pandemic.

IMPLEMENTATION OF THE *NATIONAL STRATEGY*

This *Strategy* reflects the federal government's approach to the pandemic threat. While it provides strategic direction for the Departments and Agencies of the U.S. Government, it does not attempt to catalogue and assign all federal responsibilities. The implementation of this *Strategy* and specific responsibilities will be described separately.

PILLAR ONE: PREPAREDNESS AND COMMUNICATION

Preparedness is the underpinning of the entire spectrum of activities, including surveillance, detection, containment and response efforts. We will support pandemic planning efforts, and clearly communicate expectations to individuals, communities and governments, whether overseas or in the United States, recognizing that all share the responsibility to limit the spread of infection in order to protect populations beyond their borders.

Planning for a Pandemic

To enhance preparedness, we will:

- Develop federal implementation plans to support this *Strategy*, to include all components of the U.S. government and to address the full range of consequences of a pandemic, including human and animal health, security, transportation, economic, trade and infrastructure considerations.
- Work through multilateral health organizations such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), World Organization for Animal Health (OIE) and regional organizations such as the Asia-Pacific Economic Cooperation (APEC) forum, as well as through bilateral and multilateral contacts to:
    - Support the development and exercising of avian and pandemic response plans;
    - Expand in-country medical, veterinary and scientific capacity to respond to an outbreak; and
    - Educate populations at home and abroad about high-risk practices that increase the likelihood of virus transmission between species.
- Continue to work with states and localities to:
    - Establish and exercise pandemic response plans;
    - Develop medical and veterinary surge capacity plans; and
    - Integrate non-health sectors, including the private sector and critical infrastructure entities, in these planning efforts.
- Build upon existing domestic mechanisms to rapidly recruit and deploy large numbers of health, medical and veterinary providers within or across jurisdictions to match medical requirements with capabilities.

Communicating Expectations and Responsibilities

A critical element of pandemic planning is ensuring that people and entities not accustomed to responding to health crises understand the actions and priorities required to prepare for and respond to a pandemic. Those groups include political leadership at all levels of government, non-health components of government and members of the private sector. Essential planning also includes the coordination of efforts between human and animal health authorities. In order to accomplish this, we will:

- Work to ensure clear, effective and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative messages in a timely manner.
- Provide guidance to the private sector and critical infrastructure entities on

their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.

- Provide guidance to individuals on infection control behaviors they should adopt pre-pandemic, and the specific actions they will need to take during a severe influenza season or pandemic, such as self-isolation and protection of others if they themselves contract influenza.
- Provide guidance and support to poultry, swine and related industries on their role in responding to an outbreak of avian influenza, including ensuring the protection of animal workers and initiating or strengthening public education campaigns to minimize the risks of infection from animal products.

Producing and Stockpiling Vaccines, Antivirals and Medical Material

In combination with traditional public health measures, vaccines and antiviral drugs form the foundation of our infection control strategy. Vaccination is the most important element of this strategy, but we acknowledge that a two-pronged strategy incorporating both vaccines and antivirals is essential. To establish production capacity and stockpiles in support of our containment and response strategies, we will:

- Encourage nations to develop production capacity and stockpiles to support their response needs, to include pooling of efforts to create regional capacity.
- Encourage and subsidize the development of state-based antiviral stockpiles to support response activities.
- Ensure that our national stockpile and stockpiles based in states and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics and general supplies.
- Establish domestic production capacity and stockpiles of countermeasures to ensure:
    - Sufficient vaccine to vaccinate front-line personnel and at-risk populations, including military personnel;
    - Sufficient vaccine to vaccinate the entire U.S. population within six months of the emergence of a virus with pandemic potential; and
    - Antiviral treatment for those who contract a pandemic strain of influenza.
- Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.
- Address regulatory and other legal barriers to the expansion of our domestic vaccine production capacity.
- Expand the public health recommendations for domestic seasonal influenza vaccination and encourage the same practice internationally.
- Expand the domestic supply of avian influenza vaccine to control a domestic outbreak of avian influenza in bird populations.

Establishing Distribution Plans for Vaccines and Antivirals

It is essential that we prioritize the allocation of countermeasures (vaccines and antivirals) that are in limited supply and define effective distribution modalities during a pandemic. We will:

- Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.

- Prioritize countermeasure allocation before an outbreak, and update this prioritization immediately after the outbreak begins based on the at-risk populations, available supplies and the characteristics of the virus.

Advancing Scientific Knowledge and Accelerating Development

Research and development of vaccines, antivirals, adjuvants and diagnostics represents our best defense against a pandemic. To realize our goal of next-generation countermeasures against influenza, we must make significant and targeted investments in promising technologies. We will:

- Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities and the private sector.
- Work with our international partners to ensure that we are all leveraging the most advanced technological approaches available for vaccine production.
- Accelerate the development of cell culture technology for influenza vaccine production and establish a domestic production base to support vaccination demands.
- Use novel investment strategies to advance the development of next-generation influenza diagnostics and countermeasures, including new antivirals, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains and seasons of the influenza virus.

PILLAR TWO: SURVEILLANCE AND DETECTION

Early warning of a pandemic and our ability to closely track the spread of avian influenza outbreak is critical to being able to rapidly employ resources to contain the spread of the virus. An effective surveillance and detection system will save lives by allowing us to activate our response plans before the arrival of a pandemic virus to the U.S., activate additional surveillance systems and initiate vaccine production and administration.

Ensuring Rapid Reporting of Outbreaks

To support our need for "situational awareness," both domestically and internationally, we will:

- Work through the International Partnership on Avian and Pandemic Influenza, as well as through other political and diplomatic channels such as the United Nations and the Asia-Pacific Economic Cooperation forum, to ensure transparency, scientific cooperation and rapid reporting of avian and human influenza cases.
- Support the development of the proper scientific and epidemiologic expertise in affected regions to ensure early recognition of changes in the pattern of avian or human outbreaks.
- Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.
- Advance mechanisms for "real-time" clinical surveillance in domestic acute care settings such as emergency departments, intensive care units and laboratories to provide local, state and federal public health officials with continuous awareness of the profile of illness in communities, and leverage all federal medical capabilities, both domestic and international, in support of this objective.
- Develop and deploy rapid diagnostics with greater sensitivity and reproducibility to allow onsite diagnosis of pandemic strains of influenza at home and abroad, in animals and humans, to facilitate early warning, outbreak control and targeting of antiviral therapy.
- Expand our domestic livestock and wildlife surveillance activities to ensure early warning of the spread of an outbreak to our shores.

Using Surveillance to Limit Spread

Although influenza does not respect geographic or political borders, entry to and egress from affected areas represent opportunities to control or at the very least slow the spread of infection. In parallel to our containment measures, we will:

- Develop mechanisms to rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza, for the purposes of contact tracing and outbreak investigation.
- Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.
- Expand and enhance mechanisms for screening and monitoring animals that may harbor viruses with pandemic potential.
- Develop screening and monitoring mechanisms and agreements to appropriately control travel and shipping of potentially infected products to and from affected regions if necessary, and to protect unaffected populations.

PILLAR THREE: RESPONSE AND CONTAINMENT

We recognize that a virus with pandemic potential anywhere represents a risk to populations everywhere. Once health authorities have signaled sustained and efficient human-to-human spread of the virus has occurred, a cascade of response mechanisms will be initiated, from the site of the documented transmission to locations around the globe.

Containing Outbreaks

The most effective way to protect the American population is to contain an outbreak beyond the borders of the U.S. While we work to prevent a pandemic from reaching our shores, we recognize that slowing or limiting the spread of the outbreak is a more realistic outcome and can save many lives. In support of our containment strategy, we will:

- Work through the International Partnership to develop a coalition of strong partners to coordinate actions to limit the spread of a virus with pandemic potential beyond the location where it is first recognized in order to protect U.S. interests abroad.
- Where appropriate, offer and coordinate assistance from the United States and other members of the International Partnership.
- Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, state or nation.
- Where appropriate, use governmental authorities to limit non-essential movement of people, goods and services into and out of areas where an outbreak occurs.
- Provide guidance to all levels of government on the range of options for infection-control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.
- Emphasize the roles and responsibilities of the individual in preventing the spread of an outbreak, and the risk to others if infection-control practices are not followed.
- Provide guidance for states, localities and industry on best practices to prevent the spread of avian influenza in commercial, domestic and wild birds, and other animals.

Leveraging National Medical and Public Health Surge Capacity

Rather than generating a focal point of casualties, the medical burden of a pandemic is likely to be distributed in communities across the nation for an extended period of time. In order to save lives and limit suffering, we will:

- Implement state and local public health and medical surge plans, and leverage all federal medical facilities, personnel and response capabilities to support the national surge requirement.
- Activate plans to distribute medical countermeasures, including non-medical equipment and other material, from the Strategic National Stockpile and other distribution centers to federal, state and local authorities.
- Address barriers to the flow of public health, medical and veterinary personnel across state and local jurisdictions to meet local shortfalls in public health, medical and veterinary capacity.
- Determine the spectrum of public health, medical and veterinary surge

capacity activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.

Sustaining Infrastructure, Essential Services and the Economy

Movement of essential personnel, goods and services, and maintenance of critical infrastructure are necessary during an event that spans months in any given community. The private sector and critical infrastructure entities must respond in a manner that allows them to maintain the essential elements of their operations for a prolonged period of time, in order to prevent severe disruption of life in our communities. To ensure this, we will:

- Encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.
- Provide guidance to activate contingency plans to ensure that personnel are protected, that the delivery of essential goods and services is maintained, and that sectors remain functional despite significant and sustained worker absenteeism.
- Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.

Ensuring Effective Risk Communication

Effective risk communication is essential to inform the public and mitigate panic. We will:

- Ensure that timely, clear, coordinated messages are delivered to the American public from trained spokespersons at all levels of government and assist the governments of affected nations to do the same.
- Work with state and local governments to develop guidelines to assure the public of the safety of the food supply and mitigate the risk of exposure from wildlife.

ROLES AND RESPONSIBILITIES

Because of its unique nature, responsibility for preparedness and response to a pandemic extends across all levels of government and all segments of society. No single entity alone can prevent or mitigate the impact of a pandemic.

The Federal Government

While the Federal government plays a critical role in elements of preparedness and response to a pandemic, the success of these measures is predicated on actions taken at the individual level and in states and communities. Federal responsibilities include the following:

- Advancing international preparedness, surveillance, response and containment activities.
- Supporting the establishment of countermeasure stockpiles and production capacity by:
    - Facilitating the development of sufficient domestic production capacity for vaccines, antivirals, diagnostics and personal protective equipment to support domestic needs, and encouraging the development of production capacity around the world;
    - Advancing the science necessary to produce effective vaccines, therapeutics and diagnostics; and
    - Stockpiling and coordinating the distribution of necessary countermeasures, in concert with states and other entities.
- Ensuring that federal departments and agencies, including federal health care systems, have developed and exercised preparedness and response plans that take into account the potential impact of a pandemic on the federal workforce, and are configured to support state, local and private sector efforts as appropriate.
- Facilitating state and local planning through funding and guidance.
- Providing guidance to the private sector and public on preparedness and response planning, in conjunction with states and communities.

Lead departments have been identified for the medical response (Department of Health and Human Services), veterinary response (Department of Agriculture), international activities (Department of State) and the overall domestic incident management and Federal coordination (Department of Homeland Security). Each department is responsible for coordination of all efforts within its authorized mission, and departments are responsible for developing plans to implement this *Strategy*.

States and Localities

Our communities are on the front lines of a pandemic and will face many challenges in maintaining continuity of society in the face of widespread illness and increased demand on most essential government services. State and local responsibilities include the following:

- Ensuring that all reasonable measures are taken to limit the spread of an outbreak within and beyond the community's borders.
- Establishing comprehensive and credible preparedness and response plans that are exercised on a regular basis.
- Integrating non-health entities in the planning for a pandemic, including law enforcement, utilities, city services and political leadership.

- Establishing state and community-based stockpiles and distribution systems to support a comprehensive pandemic response.
- Identifying key spokespersons for the community, ensuring that they are educated in risk communication, and have coordinated crisis communications plans.
- Providing public education campaigns on pandemic influenza and public and private interventions.

The Private Sector and Critical Infrastructure Entities

The private sector represents an essential pillar of our society because of the essential goods and services that it provides. Moreover, it touches the majority of our population on a daily basis, through an employer-employee or vendor-customer relationship. For these reasons, it is essential that the U.S. private sector be engaged in all preparedness and response activities for a pandemic.

Critical infrastructure entities also must be engaged in planning for a pandemic because of our society's dependence upon their services. Both the private sector and critical infrastructure entities represent essential underpinnings for the functioning of American society. Responsibilities of the U.S. private sector and critical infrastructure entities include the following:

- Establishing an ethic of infection control in the workplace that is reinforced during the annual influenza season, to include, if possible, options for working offsite while ill, systems to reduce infection transmission, and worker education.
- Establishing contingency systems to maintain delivery of essential goods and services during times of significant and sustained worker absenteeism.
- Where possible, establishing mechanisms to allow workers to provide services from home if public health officials advise against non-essential travel outside the home.
- Establishing partnerships with other members of the sector to provide mutual support and maintenance of essential services during a pandemic.

Individuals and Families

The critical role of individuals and families in controlling a pandemic cannot be overstated. Modeling of the transmission of influenza vividly illustrates the impact of one individual's behavior on the spread of disease, by showing that an infection carried by one person can be transmitted to tens or hundreds of others. For this reason, individual action is perhaps the most important element of pandemic preparedness and response.

Education on pandemic preparedness for the population should begin before a pandemic, should be provided by all levels of government and the private sector, and should occur in the context of preventing the transmission of any infection, such as the annual influenza or the common cold. Responsibilities of the individual and families include:

- Taking precautions to prevent the spread of infection to others if an individual or a family member has symptoms of influenza.
- Being prepared to follow public health guidance that may include limitation of attendance at public gatherings and non-essential travel for several days or weeks.
- Keeping supplies of materials at home, as recommended by authorities, to support essential needs of the household for several days if necessary.

International Partners

We rely upon our international partnerships, with the United Nations, international organizations and private non-profit organizations, to amplify our efforts, and will engage them on a multilateral and bilateral basis. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza is a central component of our overall strategy. In many ways, the character and quality of the U.S. response and that of our international partners may play a determining role in the severity of a pandemic.

The International Partnership on Avian and Pandemic Influenza stands in support of multinational organizations. Members of the Partnership have agreed that the following 10 principles will guide their efforts:

1. International cooperation to protect the lives and health of our people;
2. Timely and sustained high-level global political leadership to combat avian and pandemic influenza;
3. Transparency in reporting of influenza cases in humans and in animals caused by virus strains that have pandemic potential, to increase understanding and preparedness and especially to ensure rapid and timely response to potential outbreaks;
4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible, by utilizing, where appropriate, existing networks and mechanisms;
5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains so that appropriate international and national resources can be brought to bear;
6. Prevent and contain an incipient epidemic through capacity building and in-country collaboration with international partners;
7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (including the WHO, Food and Agriculture Organization and World Organization for Animal Health);
8. Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans;
9. Increased coordination and harmonization of preparedness, prevention, response and containment activities among nations, complementing domestic and regional preparedness initiatives, and encouraging where appropriate the development of strategic regional initiatives; and
10. Actions based on the best available science.

Through the Partnership and other bilateral and multilateral initiatives, we will promote these principles and support the development of an international capacity to prepare, detect and respond to an influenza pandemic.

Written Testimony of

The Honorable Lowell Weicker, Jr.
President of the Board
Trust for America's Health

Submitted to

U.S. House of Representatives
Committee on Government Reform

November 4, 2005

Avian Influenza Preparedness

For further information:
Richard S. Hamburg
Director of Government Relations
Trust for America's Health
202-223-9876 (ph)
rhamburg@tfah.org

Mr. Chairman and members of the Committee, thank you for the opportunity to provide our views on *Avian Influenza Preparedness*. As 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, Trust for America's Health (TFAH) believes that pandemic influenza poses a major threat to the nation's health, security and economy. We also believe that the government's preparedness efforts must be commensurate with the threat. To that end, we commend the Administration for issuing a revised pandemic plan, a request for funds to implement it and the outline for a larger government wide pandemic response. While we may differ on some of the specifics outlined in the documents released earlier this week, the very fact that they were issued is a major step forward.

Pandemic Preparedness: Positive Developments

In general, we are pleased that the revised national pandemic flu preparedness plan reflects the professional judgment of leading health and scientific experts. We are encouraged that the Administration is developing a government-wide strategy for pandemic preparedness. Most importantly, we are pleased to see the funding request to support the plan, which is the real marker of how seriously the Administration is taking this threat to the nation's health. Although we have some differences on how the federal dollars should be spent, the Administration's budget request, coupled with recent appropriations actions by the U.S. Senate, should allow the nation to invest in the technology, medicines, state and local public health infrastructure improvements and surge capacity necessary to save lives and mitigate suffering.

With respect to vaccines, TFAH applauds the Administration's commitment to increasing U.S. vaccine production, including its support for improving vaccine production technology. Vaccines represent the most important potential protection against a new, severe flu strain. This proposal recognizes that a large investment must be made to revitalize and modernize the broken vaccine industry in this country. The goal of achieving a vaccine for every American is laudable and TFAH believes that the Administration's multi-pronged approach, which includes vaccine research and development, retrofitting domestic facilities for emergency production of vaccine, encouraging the creation of additional egg-based and cell-based vaccine production facilities, and developing a vaccine registry to monitor vaccine safety, distribution, and use during a pandemic, is both strategic and appropriate. This is a wise investment, both for pandemic preparedness and to improve our capacity to vaccinate more Americans against seasonal flu, which kills 36,000 people a year -- many of whom would not die if vaccinated.

However, issues around vaccine liability and compensation need to be addressed in tandem to avoid a repeat of the problems associated with the smallpox vaccination program. And very importantly, methods for distributing vaccine and inoculating 300 million Americans must become a priority for federal, state and local health officials. In order to do so, we need a detailed allocation and distribution plan that is tested in every community of the nation.

TFAH also commends the Administration for providing $212 million to purchase critical medical supplies and devises for the Strategic National Stockpile (i.e., ventilators, syringes, masks, intravenous antibiotics) for distribution to children and adults.

The Administration's plan and budget request reflect a move toward stockpiling enough antivirals to cover approximately 75 million people, enough to treat 25 percent of the U.S. population -- the amount the World Health Organization (WHO) suggests countries plan for. This indicates the U.S. will catch up with the level of antivirals that other countries have already ordered to protect their citizens, and begin to bolster the quantities in hand. Specifically, the budget request provides for the federal purchase of 44 million courses of antiviral drugs. This is a step in the right direction.

Remaining Concerns

However, TFAH is deeply concerned that the Administration expects the states to purchase the remaining 31 million antiviral courses with a 25 percent federal subsidy, which amounts to $170 million. Germs don't respect jurisdictional boundaries, and public health officials must have the flexibility to provide the medication where outbreaks are most severe.

Mr. Chairman, requiring each state to purchase antivirals separately does not make sense from a health or economic perspective. Reliance on states to pay for a substantial portion of the cost of purchasing enough antiviral medication to cover their population amounts to an unfunded mandate to the tune of $510 million. We hope that Congress will address this issue immediately by requiring the federal government to protect Americans by purchasing the full 75 million antiviral treatment courses.

Nevertheless, if states ultimately become responsible for the purchase of a share of the antivirals, measures should be taken to ensure that they are able to purchase the medication at a lower nationally-negotiated cost, rather than purchasing at a higher rate on a state-by-state basis. Pandemic influenza is a national threat. The level of protection Americans receive should not be determined by where they live and the current fiscal position of their states.

We are also concerned about the long time-frame associated with building this stockpile. The patent for the principal antiviral to be stockpiled, oseltamivir (Tamiflu) is held by Gilead Sciences; the drug is produced under an exclusive license by Roche. Given both domestic and worldwide needs, more production capacity is essential, especially in the absence of sufficient vaccine production capacity. We urge the Administration to work with both Gilead and Roche to determine what steps can be taken to increase production capacity by Roche or other potential producers.

Mr. Chairman, other significant gaps in pandemic readiness remain. The Administration's budget request does not adequately fund support for state and local health departments, surge capacity and risk communications.

State and local health departments will be at the forefront of the pandemic response. Yet, the Administration's proposal sets the additional federal investment in state and local preparedness at only $100 million, not nearly enough to allow them to prepare, especially

when states are being asked to spend a cumulative $510 million for antivirals. In contrast, the Senate provided $600 million for state and local pandemic preparedness in the FY 2006 Labor Health and Human Services appropriations amendment passed last week. TFAH supports the Senate mark, and in addition calls on the Congress to restore funding for general state and local public health preparedness, which may be cut this year by up to $130 million.

TFAH hopes that Congress will address the following additional weaknesses in the plan and budget request:

- Contingency planning and surge capacity are not adequately funded. Funding is needed for states, localities, and private sector health care organizations to fully prepare for a pandemic -- ranging from identifying surge capacity for health care facilities, to creating distribution systems for vaccine and antiviral delivery and continuity planning for critical businesses and public services. The estimated shortfall is $250 million.

- Improved availability of diagnostics and reagents is not funded in this request. These funds are critical for laboratories across the country if they are to identify the emergence of a pandemic strain in a particular locality. Congress should provide an additional $75 million to ensure rapid identification of a pandemic strain.

- Risk communication is inadequately funded at $43 million in thee Administration's request. The federal government must take the lead in supporting a national effort to assure that all sectors of society understand the implications of a pandemic. In order to communicate with the public, corporate America, and the health care community, the federal government must develop tailored and specific messages outlining risks and providing recommendations for each sector. TFAH estimates that it will take an investment of at least $150 million to effectively communicate with all sectors of American society and help reduce public panic.

Mr. Chairman, the Administration's national pandemic strategy document lacks the substance and level of detail needed to prepare for the impact a pandemic could have government-wide and on the economy, business operations, transportation, and other crucial areas of daily life. While we applaud the Department of Health and Human Services (DHHS) for releasing a revised and much more detailed Pandemic Influenza Preparedness plan, TFAH calls on the President to present an equally detailed government-wide pandemic plan. We hope this plan will reflect a similar level of specificity and will clearly articulate how *all* departments in the government are addressing the very large impact a pandemic would have on health, the economy, public safety, and civil society in general.

Finally, it is disturbing that the national strategy calls for the Department of Homeland Security to be in charge of the overall domestic incident management and federal coordination, essentially divorcing the expertise that will be needed to respond to a complicated health threat from the top chain of leadership. A pandemic flu response must

be driven by public health experts with support from emergency preparedness officials, not the other way around.

In summary, TFAH maintains that the failure to establish a cohesive, rapid, and transparent government-wide pandemic strategy could prove a major weakness against a virulent and efficient virus -- putting Americans needlessly at risk. While experts predict a pandemic flu may be "inevitable," subsequent death rates predicted to be in the millions are not.

The clock is ticking as the threat is growing. The Administration's strategy, plan, and budget request help move the country toward better preparedness. But, Congress must now act expeditiously to fill the remaining weaknesses and ensure that America is as prepared as possible to face this serious threat.

I thank you again for this opportunity to express TFAH's views on evaluating the U.S. readiness for the next flu pandemic.

1100 17TH STREET, NW, 2ND FLOOR
WASHINGTON, DC 20036
(202) 783-5550
(202) 783-1583 FAX
WWW.NACCHO.ORG

NATIONAL
ASSOCIATION OF
COUNTY & CITY
HEALTH OFFICIALS

Statement of the National Association of County & City Health Officials

Submitted for the Record

Hearing on "The National Pandemic Influenza Preparedness and Response Plan: Is the U.S. Ready for Avian Flu?"

House Committee on Government Reform

November 4, 2005

The National Association of County and City Health Officials (NACCHO) commends the Administration's comprehensive approach to pandemic influenza preparations. However, the nation's local health departments, who play key roles in protecting their communities, have great concern about the amount of proposed federal resources to help communities prepare and respond. The resources are disproportionately small, compared to the magnitude of the task ahead.

The plan of the Department of Health and Human Services (HHS) enumerates broad responsibilities for local and state governments in responding to an influenza pandemic. However, earlier this year, the Administration proposed a cut of $130 million in state and local public health preparedness funding. Although the Administration has proposed an additional $100 million in funding for both state and local pandemic influenza preparedness, this sum does not even offset the previous proposed cut in funding.

Local health departments have been working intensively to improve public health preparedness for several years. The federal resources added to this effort through the CDC cooperative agreements with the states for public health preparedness since September 11, 2001 have greatly assisted. However, local preparedness activities necessarily engage many more local health department staff than the federal funds can subsidize. Localities are doing their part.

NACCHO concurs with the Administration's assessment that we are better prepared now and that improvements will continue. We are also very pleased that the HHS plan clearly recognizes the central roles of local and state public health departments in pandemic influenza preparedness and response. We look forward to collaborating closely with HHS and the Centers for Disease Control and Prevention to achieve the plan's objectives. However, NACCHO does not believe that local and state health departments can do all that the Administration asks with barely an extra 30 cents per U.S. resident.

Local health departments are the linchpins in protecting every community. They must carry out enhanced disease surveillance to detect cases early, distribute stockpiles of vaccines and drugs, implement a broad range of measures to prevent disease from spreading, and communicate rapidly and effectively with their communities to engage everyone – from doctors and hospitals to schools and businesses - in understanding and cooperating with the community's response. Accomplishing this requires trained people with technical sophistication in epidemiology, public health nursing, health planning, health education and communication, information technology and database management.

Communicable diseases like influenza cross city, county and state lines. It is most appropriate for the federal government to provide the resources that will assure that every local community has the capacity to respond. The federal pandemic influenza response plan will not succeed, even with plentiful new vaccines and antiviral drugs, unless every community can use them to stop an outbreak and save lives.

NACCHO is the national organization representing the nation's nearly 3,000 local public health departments. These agencies work every day on the front lines to protect and promote the health of their communities. NACCHO develops resources and programs and promotes national policies that support effective local public health practice.

American Public Health Association
800 I Street, NW • Washington, DC 20001-3710
(202) 777-APHA • FAX (202) 777-2534 • comments@apha.org • http://www.apha.org

November 3, 2005

The Honorable Tom Davis
Chairman
House Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member
House Committee on Government Reform
B350A Rayburn House Office Building
Washington, D.C. 20515

Dear Representatives:

On behalf of the American Public Health Association (APHA), the oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans, their families and communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States, please accept the attached document as testimony for the record to the House Committee on Government Reform for its November 4, 2005 hearing "The National Pandemic Influenza Preparedness and Response Plan: Is the U.S. Ready for Avian Flu?".

Thank you for your attention to and leadership on the important public health issue. We look forward to working with the Committee as it discusses the national capacity to prepare for and respond to pandemic influenza. If you have questions, or for additional information, please contact Courtney Perlino at (202) 777-2436 or courtney.perlino@apha.org.

Sincerely,

Georges C. Benjamin, MD, FACP
Executive Director

The American Public Health Association (APHA) is the oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans, their families and communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States.

For over 130 years, APHA has been in the forefront of numerous efforts to prevent disease and promote health. The Association has affirmed the importance of immunizations as one of the most effective means of preventing infectious disease. Influenza presents a grave threat to the public's health, even in this pre-pandemic period, causing an average of 36,000 deaths and 114,000 hospitalizations per year. Preparing for an influenza pandemic on the local, state, national and international levels is essential to ensure the health and safety of the American people.

Funding of HHS Plan Activities and Recommendations

The American Public Health Association welcomes the HHS Pandemic Influenza plan as an ambitious blueprint that could save the lives of millions of Americans in the event of a pandemic. However, this plan will not be successful in saving thousands of lives without the necessary funding. The $7.1 billion request submitted by the Bush Administration and the $8.0 billion allocated to pandemic influenza by the Senate are signals that there is political will for preparing our nation to be able to comprehensively respond to a pandemic strain of influenza. It is now essential for the House of Representatives to follow suit.

However, considering the amount of dollars currently committed to cell-based vaccine development and vaccine and antiviral stockpiles within the administration's request and the Senate Labor-HHS-Education appropriations bill, there will continue to be insufficient funds for states and local governments to fulfill their responsibilities as defined in the HHS plan and the national strategy. The HHS plan largely depends on hospitals, public health labs and state and local health departments to carry out both preparedness and response activities. However, funding provided to labs through CDC Epidemiology and Laboratory Capacity Cooperative Agreements and to hospitals through HRSA's Hospital Preparedness Program is inadequate to support the scaling-up of their efforts during a flu pandemic, including being able to stockpile certain medical necessities, including lab supplies, masks and gloves that are potentially life-saving and will be in high demand. The public health infrastructure in general is already in dire need of additional money and employees, and under this plan, those shortfalls will continue and be exacerbated without a larger federal commitment.

Vaccine Production, Purchase, Distribution and Tracking

The HHS plan and the national strategy outline the need for the federal government to invest in cell-based vaccine technology, and to purchase 20 million doses of the current bird flu vaccine, with hopes that it will provide some level of protection against the next pandemic flu strain. APHA supports the significant investment in cell-based vaccine technology, which will not only facilitate mass, expedited manufacturing of millions of doses of flu vaccine, but has the potential to create vaccines for other diseases and to make current vaccines more effective. However, APHA is concerned that the HHS plan did not outline a more significant federal purchase of influenza vaccines as well as centralized public distribution. Our current system of private purchase, reliant on supply and demand, will not give vaccine manufacturers ample incentive to produce pandemic influenza vaccine. There needs to be a guaranteed, substantial federal purchase, with some buyback provision included, so there are a number of vaccine manufacturers committed to produce the vaccine most effective against the pandemic flu strain. Also of concern is that the distribution of pandemic vaccine to health departments and providers will occur through private-sector vaccine distributors or directly from the manufacturer. The federal government would only distribute the pandemic vaccine that has been stockpiled. The HHS plan also calls for the creation of a vaccine database by CDC, which we hope will build on existing systems and be able to import relevant information from state immunization registries to help us more efficiently track the immunization of high-risk groups. However, without federally-led vaccine distribution efforts, this database will not provide timely enough information regarding vaccine distribution, as manufacturers and private vaccine distributors will be relied on to provide the necessary information. This, in

the end, has the potential to serve as an obstacle to ensuring that individuals most at risk receive the pandemic vaccine.

Antiviral Purchase
The HHS plan, considering that an effective pandemic vaccine will not be in circulation during the first months of an influenza pandemic, wisely calls for the purchase of enough antivirals—oseltamivir and zanamivir—for 25 percent of the United States population. However, it is of concern that states—who are already financially strapped—are relied on to purchase antivirals for their populations. The plan seems to assume that all states have the capacity to purchase antivirals and will be equally affected by an influenza pandemic. This is not the case, especially considering that Louisiana, Mississippi, Alabama and Florida will not have the funds to dedicate to antiviral purchase following the devastation of Hurricanes Katrina, Rita and Wilma. States should not be required to divert funds from general public health resources that support core public health programs nor from state bioterrorism and emergency response programs to purchase antivirals, as that will leave ultimately leave a major hole in their ability to effectively prepare for and respond to pandemic influenza.

Surveillance
APHA agrees with the HHS plan on the need to implement enhanced surveillance activities on the local, state and federal levels during a pandemic to accurately monitor disease spread, which will complement the activities occurring at the international level by the International Partnership on Avian and Pandemic Influenza. At the time that we experience human-to-human transmission of pandemic influenza in the United States, there is a need to report new cases daily to the CDC. However, before this is the case, there is a need to clarify that influenza is a mandatory reportable disease, which will ensure not only that local and state health departments and the CDC are immediately contacted, but also that all isolates are sent to public health laboratories for confirmation.

Public Health and Risk Communications
APHA is pleased that the HHS plan, including the HHS Pandemic Influenza Risk Communication and Public Outreach Strategy, provides guidance to state and local partners in what information needs to be communicated to the public, how to develop appropriate messages and the importance of language and reading-level appropriate material that is culturally sensitive. A comprehensive training and education program for all potential influenza responders, their household contacts and appropriate coworkers who may be exposed to pandemic flu is essential. The plan depends on hotlines and the existing communications infrastructure. However, state and local governments and health departments and public health laboratories need more than the status quo—one-way communications from CDC and communications to CDC through a hotline or by fax. There is a need to invest in two-way communications systems and in general, strengthen the public health and emergency communications infrastructure. This requires a substantial investment, which was not included in the president's request.

Surge Capacity
APHA is pleased that the plan identifies actions that healthcare facilities and laboratories must take to increase surge capacity, including staffing, bed capacity, consumable and durable supplies and security. The convening of local and statewide pandemic influenza planning meetings to identify public and private sector roles related to surge capacity is a first step in preparing for an influenza pandemic. Ultimately, there needs to be substantial funding dedicated to efforts to increase surge capacity, which was lacking in the national strategy. Also, states and localities will not be able to increase their capacity to respond to an influenza pandemic if there are no clear guidelines on what needs to be included in state and local pandemic influenza plans, and how often they need to be tested.

Liability/Compensation Concerns Regarding Vaccination
The HHS plan does not comprehensively address what the course is if a person is injured following the administration of the pandemic vaccine. If a person is injured following administration of a vaccine or antiviral medication, in connection with his/her employment, the plan states that compensation may be available under a

state's worker's compensation program. For federal employees, compensation may be available under the Federal Employees' Compensation Act. However, what can the general public do should they become injured following the administration of the vaccine for pandemic flu?

Liability concerns associated with widespread distribution of pandemic influenza vaccine, which may not be FDA-approved, need to be outlined. Mechanisms should be developed to compensate individuals for health care costs incurred as a result of adverse events resulting from a pandemic influenza vaccination. We recommend that a federally-funded compensation program be established for those who become ill or are injured, disabled or die as a result of receiving the vaccine. Worker's compensation programs are not enough. State and federal workers' compensation programs vary greatly in application and benefit and are inadequate. Also, it needs to be ensured that individuals who lack health insurance or have inadequate coverage should have access to care for complications as a result of the vaccination. For those without any coverage or with inadequate coverage, timely and accessible care must be ensured.

Public Health Containment Methods

APHA is pleased that the HHS plan includes clearer guidelines on when state and local governments should implement various public health containment methods, ranging from posting reminders to cover one's mouth during coughs and sneezes to closing schools to imposing voluntary quarantines. The plan is also careful to note that certain methods, such as quarantine, are only effective in certain stages of a pandemic. For every containment method, the plan includes its definition, examples of the method, its application, benefits and challenges, and the resources required for implementation—specificity that is needed for local and state implementation. At each stage of an influenza pandemic, the plan provides necessary guidance to state and local governments and health departments as to the best time to utilize and implement certain public health containment methods, with the goal of slowing and preventing transmission of influenza.

APHA emphasizes that the public health system and services must be consistently supported in order to adequately implement and respond to the myriad of public health problems and emergencies, including, but not limited to, pandemic influenza. Important health systems issues include traditional public health infrastructure such as the strength of the public health workforce, the effectiveness of our surveillance systems and the reach of our education and communications efforts. Ultimately, the strength of our health system in general and our ability to respond to the leading causes of death and provide quality health services for all Americans will determine our ability to protect our citizens from intentional and unintentional illness, death and disability. The health and safety of our nation go beyond preparing for and responding to influenza, and I urge the Committee to take a comprehensive, long-term approach to our nation's health.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
1275 K Street, NW, Suite 800, Washington, DC 20005-4006
(202) 371-9090 Fax: (202) 371-9797 www.astho.org

Statement of the Association of State and Territorial Health Officials

Submitted for the Record

Hearing on "The National Pandemic Influenza Preparedness and Response Plan: Is the U.S. Ready for Avian Flu?"

House Committee on Government Reform

November 4, 2005

The Association of State and Territorial Health Officials (ASTHO) commends the US Department of Health and Human Services for its development and release of the long-awaited HHS Pandemic Influenza Plan. We recognize and appreciate all of the hard work that went in to creating the document. We are gratified to see that the HHS plan identifies strengthening state and local public health preparedness as one of its major priorities.

States have developed and tested pandemic flu plans. These activities have been supported by the CDC preparedness cooperative agreement awards to states. Now that the HHS Plan has been released, states will review the federal plan to see what changes need to be made in their current plans to be consistent with national guidance.

An adequately funded, coordinated federal, state, and local response is essential if we are to protect the public during an influenza pandemic. The proposed state and local influenza pandemic appropriation of $100 million is far less than adequate to protect the citizens of our nation. Funding must be commensurate with the functions state and local public health agencies are being asked to carry out.

Public Health Agencies' Responsibilities

In an influenza pandemic, public health agencies will be responsible for surveillance - detecting outbreaks of disease, identifying pandemic influenza strains, and implementing appropriate intervention strategies. We will implement disease containment measures including travel restrictions, isolation and quarantine. State and local public health will work with public officials, other governmental agencies (such as law enforcement and transportation), businesses, schools, healthcare facilities and others to assure appropriate community disease containment strategies such as closing schools and limiting public gatherings.

State and local public health departments must provide timely, accurate, and consistent information on vaccine prioritization and use, antiviral use for treatment and chemoprophylaxis, infection control, and the treatment and care of patients. The public, media, health professionals, and business leaders will look to their state and local public health departments for information and guidance.

Public health laboratories will ensure proper collection, transport, and testing of highly infectious influenza specimens. Public health professionals must be able to distinguish between infection caused by traditional influenza strains and infection caused by the pandemic strain. Tracking the occurrence and rate of transmission of the pandemic virus through molecular sub-typing methodologies is public health's responsibility.

Assuming that influenza vaccines and antivirals are available, public health agencies will take the lead in vaccine and antiviral management – assessing the population size and locations within states that will need vaccines and antivirals and working with healthcare providers, pharmacies and others to ensure distribution, tracking, and coordinated administration of vaccines to priority groups. Public health workers will also help to ensure that vaccines and antivirals are stored and handled properly. It is public health that will provide informational materials on safety, use, and supply of these products as well as track, document, and report adverse events related to vaccines and antivirals.

It is public health that will be responsible for identifying medical, nursing, and other healthcare staff who may be called upon to assist in a pandemic. State and local public health agencies will identify alternate facilities where overflow cases from hospitals and well persons needing quarantine away from home can receive care.

Last, but not least, public health must have the capacity to assure the continuation and delivery of essential public health services during a protracted pandemic. Children will still need to be immunized against measles, mumps, and rubella. Rapid identification and response to food borne outbreaks must continue. Individuals needing cancer screenings must receive them in a timely fashion. Maintenance of essential health and medical services is of paramount importance.

State Purchase of Antivirals

The assumptions behind the expectation that states will purchase over $500 million worth of antivirals need to be carefully reviewed. What will happen to the citizens who live in a state that chooses, for whatever reason, not to purchase antivirals? Should decisions about the availability of antivirals be based on what state you live in? Equally important is the fact that when funds are identified to purchase antivirals, they must not come at the expense of other critical governmental public health services. This aspect of the national strategy needs careful examination.

Closing

Extraordinary efforts will be required to deal with an influenza pandemic. A strengthened public health infrastructure is essential. Investments in that infrastructure have been made and must continue to be made. The entire public health system at the federal, state, and local levels will be held accountable for protecting the public against this serious public health threat. It is up to all of us to ensure that each level of public health has the necessary resources to get the job done.

Thank you.

TESTIMONY

THOMAS R. FRIEDEN, M.D., M.P.H.
COMMISSIONER OF HEALTH
NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BEFORE THE

U.S. CONGRESS
HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM

THE NATIONAL PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN: IS THE U.S. READY FOR AVIAN FLU?

NOVEMBER 4, 2005
10:00 AM
2154 RAYBURN BLDG.

The National Pandemic Flu Plan provides a framework for how the nation would prepare for and respond to a pandemic influenza. It is encouraging that the federal government is taking the potential impact of a pandemic flu seriously and will increase resources to address this potential public health threat. The Pandemic Flu Plan provides recommendations and guidelines, which are important to our preparedness efforts.

While many of the proposals in the plan are welcome, particularly increased funds for vaccine development, the Federal Government needs to do much more to strengthen and protect resources at the local level. The Federal Government has appropriately recognized that avian flu could have a devastating impact, and the City urges a greater federal investment in local preparedness efforts. The Administration's plan assumes a great deal of responsibility on the part of State and local governments, but without matching resources. There also need to be assurances that resources to fund the plan do not come at the expense of reduction in assistance for other key programs such as preparedness.

The plan addresses several critical concerns, including creation of pandemic influenza vaccine production capacity and stockpiles and expanding the number of licensed domestic egg-based influenza vaccine manufacturers. Since the Administration's goal of meeting a surge capacity of 300 million courses of vaccine cannot be achieved from egg-based production alone, it proposes to invest in the advanced development of cell-based techniques for manufacturing pandemic influenza vaccines. While we enthusiastically support the expansion of vaccine production, we believe that it should not be limited to one technology. Cell-based influenza vaccine production will take several years to develop and implement and may not succeed. Multiple methods of increasing surge capacity should be considered and explored in more depth.

The Administration's plan also proposes an increase in international surveillance and collaboration in outbreak investigations. We support the increase of surveillance capabilities of our international partners, but believe that much, much more should be done. Our international plans should not be limited to surveillance development and enhancement. It will be infinitely more effective and cost effective to prevent the emergence of a pandemic strain abroad than to try to deal with the consequences of it at home. Critically important international prevention initiatives that do not appear to be addressed nor adequately addressed in the plan include:

- Reimbursement for farmers' losses for culling of flocks;
- Longer term improvement in poultry farming practices;
- Urgent work on the development and implementation of animal vaccines. The fewer infected animals, the less likely it is that pathogenic mutations will develop.
- Human vaccination among high-risk workers in Asia. The fewer infected humans there are, the lower the risk of pathogenic mutations.

While we support the enhancement of surveillance systems for early detections of various outbreaks of infections, the implementation and enhancement of the Administration's BioSense program raises serious concerns. Local syndromic surveillance systems can provide high quality timely surveillance from outpatient encounters, emergency department visits, ambulance runs, and hospital admissions, with the added benefit of strengthening the ability of local official ability to monitor community health more broadly. However, the pandemic flu plan is based on

the assumption that in order to increase this capacity, public health surveillance functions must be centralized and federalized. Adding a hospitalization surveillance component to the national BioSense system seeks to create a national system with direct reporting from hospitals into a vast centralized database at CDC without state/local intermediation. While we agree that the development of a national network of near real-time syndromic surveillance system is necessary, the best way to achieve this is not by federalizing public health surveillance but rather by strengthening capacity and links at local, state, and federal levels. Not only will this be consistent with the traditional, and Constitutional, U.S. approach to public health, but it will be more effective, since local and state health departments are better positioned to interact effectively with local institutions, it will be more complete, since local and state institutions can achieve a larger population coverage, it will be more accurate, since local and state institutions will be better able to interpret local data, and it will be more effective, since local and state institutions will be responding to the information. Furthermore, it will provide meaningful data just as rapidly, using a tiered reporting system. HHS' appropriate role is to identify case definitions and standards, support state and local health departments' informatics expertise and capacity, and set competency standards.

Another component in the Administration's plan provides for stockpiling antiviral medications sufficient to treat 25 percent of the U.S. population. The plan would allocate $1.4 billion to stockpile 81 million courses of antivirals, and to develop new antivirals. The first six million courses are reserved for an initial outbreak in the U.S., and of the remaining 75 million courses, HHS would fully fund procurement of 44 million courses, and the remaining 31 million treatment courses would be funded in part by HHS at 25% and by the States at 75% of the procurement cost. This provision pertains only to the HHS-negotiated contracts. It would seem that any purchases exceeding the 31 million treatment courses might exceed the cost previously agreed to by HHS and manufacturers, and that states will be responsible for 100% of a cost not yet determined.

Moreover, it appears a portion of funds proposed for pandemic flu preparedness may be funded by reducing other federally-funded emergency preparedness projects in New York City, such as the HRSA funded Hospital Preparedness Program and CDC funded Cities Readiness Initiative and the Bioterrorism and Public Health Preparedness Program. Congress is currently preparing to cut the CDC BT preparedness funding by roughly $130 million, the third consecutive cut to this program by Congress. This will seriously undermine our preparedness capabilities. The plan requests $555 million for surveillance and public health infrastructure, of which only $100 million is specifically for State and local pandemic preparedness efforts. It is unclear whether this will be in addition to the existing appropriations proposed by Congress for the federal fiscal year 2006, or whether it redirects existing funds. It is important that federal support strengthen the entire emergency preparedness infrastructure to address any pandemic or public health threat, rather than focus all our resources on one potential pandemic.

In short, if the current plan as it relates to state and local health departments amounts to a net reduction of $30 million ($130 million reduced from preparedness, $100 million provided for influenza), and a need to purchase hundreds of millions of dollars worth of antivirals, its net result will be a weakening, and not a strengthening, of local public health capacity.

In addition, the plan does not provide for liability protections for healthcare workers, State and local governmental entities, and others involved in the distribution or administration of countermeasures, nor for compensation for those injured in connection with the program. As we learned during the smallpox program, sufficient liability protections need to be in place for the public to buy in to and participate in the program.

Furthermore, while the Administration's plan mentions the need for surge capacity in intensive care units, funding for excess respiratory support capacity such as ventilators and staff does not appear to be sufficient. Lack of adequate ventilators and staff can turn a bad situation into a potentially fatal one in the care of patients if a pandemic were to occur. In addition, the funding does not account for needs in other medical care delivery systems such primary care centers and long-term care facilities.

In the meantime, New York City will continue to press forward with its preparations. We have excellent systems in place to detect a problem if it occurs, and excellent systems and institutions to respond in the case of an emergency. This includes readying hospitals and health services, planning for continuity of essential services, and educating the public about the personal precautions they can take in the event of a pandemic, all of which are relative to annual flu seasons. We appreciate the Administration's proposal overall and hope that the Administration will expand support for international pandemic influenza prevention, which is where the epidemic can be stopped, if anywhere, and for local and state public health response, which is where the epidemic would be managed, if it were to occur.

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Pandemic Planning

Friday, November 4, 2005; A22

THE PRESIDENT has called it a "crash program." Mike Leavitt, the secretary of health and human services, used the word "blueprint." Unfortunately, the administration flu pandemic plan released this week is neither of those things.

On a general level, the plan and the funding request accompanying it show that the administration is taking preparedness seriously. Particularly important is the president's recognition that the United States needs to learn how to speed up production of vaccines, because they offer the best hope for protection against any pandemic. By far the largest chunk of the president's $7.1 billion funding request is devoted to vaccine and antiviral drug research and building up vaccine stockpiles, and rightly so. Nevertheless, the earliest date by which the government could meet its goal of having the capability to produce a vaccine for every American within six months of the beginning of a pandemic is 2010 -- hardly a "crash program."

In the meantime, the flu plan mainly consists of a long list of things that local governments and public health officers should be doing, such as building surge capacity in laboratories and hospitals, carrying out "preparedness planning" and identifying potential isolation and quarantine facilities. But there is only a small slice of funding for such measures, and no real explanation of how they will be implemented. At times, the plan seems divorced from reality, such as when it points out that people could, in case of a pandemic, be asked to remain at home for a certain period. But does that include utility workers? Grocery store workers? Is any locality really in a position to feed and care for a quarantined population -- and if not, should that even be an option under consideration?

The same implementation issues plague the discussion of vaccine distribution. At the onset of a pandemic, HHS says it will "work with the pharmaceutical industry" and vaccine distribution will occur "via private-sector vaccine distributors or directly via manufacturer." Yet at the moment, manufacturers cannot distribute ordinary flu vaccine in a timely manner. How will they do so during a mass panic?

Finally, both the plan and the funding proposal ignore the benefits to Americans of working with countries in Asia and possibly Africa, where the virus could break out first and be halted or slowed before it gets here. The president has called for about $250 million to be spent internationally, but that won't suffice either to acquire vaccines and antiviral drugs in sufficient numbers or to enable rickety health care systems abroad to help prevent a pandemic. If a flu epidemic begins abroad, one of the first moral and practical issues this country will face is whether to share American stockpiles with others: Aside from proposing a small program to manufacture and hold clinical trials of flu vaccine in Vietnam, it doesn't seem as if the administration has confronted that issue at all. While not a bad start, the administration's flu plan is still too vague to be reassuring.