

THE ADMINISTRATION'S FLU VACCINE PROGRAM: HEALTH, SAFETY AND DISTRIBUTION

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 29, 2009

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THE ADMINISTRATION'S FLU VACCINE PROGRAM: HEALTH, SAFETY AND DISTRIBUTION

TUESDAY, SEPTEMBER 29, 2009

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

The committee met, pursuant to notice, at 2:05 p.m., in room 2154, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the committee) presiding.

Present: Representatives Towns, Cummings, Kucinich, Clay, Watson, Connolly, Quigley, Van Hollen, and Issa.

Staff present: Kevin Barstow, investigative counsel; Jean Gosa, clerk; Velginy Hernandez, press assistant; Adam Hodge, deputy press secretary, Carla Hultberg, chief clerk; Marc Johnson, assistant clerk; Chris Knauer, senior investigator/professional staff member; Mike McCarthy, deputy staff director; Julie Rones, counsel; Christopher Sanders, professional staff member; Leneal Scott, IT Specialist; Ron Stroman, staff director; Lawrence Brady, minority staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Adam Fromm, minority chief clerk and Member liaison; Ashley Callen, minority counsel; and Molly Boyd, minority professional staff member.

Chairman TOWNS. The committee will come to order. Let me begin by thanking you for being here today. This past March, a novel strain of H1N1 influenza [swine flu], was reported in Mexico. Several people died, and the virus spread quickly. Just 3 months later, in June, the World Health Organization declared this strain of swine flu to be a pandemic, the first global pandemic declared since 1968.

According to the CDC, by the end of August, this new virus had spread throughout the United States resulting in more than 9,000 hospitalizations and over 600 deaths. At first, some scientists feared that this could be a pandemic disaster on the scale of the Hong Kong flu of 1968; or, worse, the Spanish flu of 1918. At this point, however, it appears to pose much less of a threat. Nevertheless, there is great uncertainty about the course of this flu. It is this very uncertainty that I think concerns people most.

If there is any good news, it is that so far this flu strain has not caused the number of deaths that some had feared. But why? What did the experts see then that they are not seeing today? And what does this foretell regarding how this virus may behave? Although dangerous mutations have not yet occurred, is this still a possibil-

ity? What do the experts expect and what do the best assessments now suggest?

Public Health officials believe that vaccination is the best means to protect against this flu. We understand that a vaccine has been approved and is in production. But ever since the swine flu vaccine fiasco of the late 1970's, people have been cautious.

Today we want to discuss questions that I believe the public has about the benefits and risk of the new vaccine. We want to understand whether it is necessary, whether it is available, who will get it, and when will they get it. The more information that can be made available regarding these questions, the better the public and other key stakeholders can assess both the risk and the benefits of receiving this important vaccine.

With the swine flu virus spreading rapidly, hundreds of thousands of health-care workers, many in my State of New York, are now being required to get flu shots. Concerns have been raised about mandatory immunizations. In fact, there is a protest underway right now in Albany, NY, which highlights the concerns that some have regarding mandatory vaccinations. I want to carefully examine these concerns today with our witnesses.

In addition, the Chamber of Commerce estimates that during a normal year, the U.S. economy loses an average of \$10 billion as a result of the flu. It could be double that this year, and many businesses that are not adequately prepared may not be able to function given the number of workers that could be absent.

Fortunately, we have the three leading experts on these issues with us today and we are happy to have them. I welcome all of you and look forward to your testimony.

[The prepared statement of Hon. Edolphus Towns follows:]

**OPENING STATEMENT
CHAIRMAN EDOLPHUS TOWNS
COMMITTEE ON OVERSIGHT AND
GOVERNMENT REFORM**

**“The Administration’s Flu Vaccine Program:
Health, Safety, and Distribution”**

September 29, 2009

Good afternoon, and thank you for being here today.

This past March, a novel strain of H1N1 influenza, commonly known as “swine flu,” was reported in Mexico. Several people died and the virus spread quickly. Just three months later, in June, the World Health Organization declared this strain of swine flu to be a pandemic, the first global pandemic declared since 1968.

According to the CDC, by the end of August, this new virus had spread throughout the U.S., resulting in more than 9,000 hospitalizations and over 600 deaths.

At first, some scientists feared that this could be a pandemic disaster on the scale of the Hong Kong Flu of 1957, or worse, the Spanish Flu of 1918. At this point, however, it appears to pose much less of a threat. Nevertheless, there is great uncertainty about the course of this flu. And it is this very uncertainty that I think concerns people most.

If there is any good news, it is that so far, this flu strain has not caused the numbers of deaths that some had feared. But why? What did the experts see then that they are not seeing today and what does this foretell regarding how this virus may behave? Although dangerous mutations have not yet occurred, is this still a

possibility? What do the experts expect and what do the best assessments now suggest?

Public health officials believe that vaccination is the best means to protect against this flu. We understand that a vaccine has been approved and is in production. But ever since the swine flu vaccine fiasco of the late Seventies, people have been cautious.

Today we want to discuss questions that I believe the public has about the benefits and risks of this new vaccine. We want to understand whether it is necessary, whether it is available, who will get it, and when.

The more information that can be made available regarding these questions, the better the public and other key stakeholders can assess both the risks and benefits of receiving this important vaccine.

With the swine flu virus spreading rapidly, hundreds of thousands of health-care workers—many in my state of New York—are now being required to get flu shots. Concerns have been raised about mandatory immunizations.

I want to carefully examine these concerns today with our witnesses.

Finally, it should be said that no matter how much we try, the current—or an even a more virulent flu strain—may eventually spread to large portions of the population. Should a worst-case scenario occur, are we prepared? What plans does the Administration have for controlling the spread of this flu should it become more virulent? Would there be a need for quarantines and if so under what circumstances? Would they be voluntary or mandatory? Clearly, none of us hope to test such plans, but these are questions of great importance.

In addition, the Chamber of Commerce estimates that during a normal year U.S. businesses lose an average of \$10 billion as a result of the flu. It could be double that this year, and many business that are not adequately prepared may not be able to function given the number of workers that could be absent.

Fortunately, we have the three leading experts on these issues with us today. I welcome all of you and look forward to your testimony.

Chairman TOWNS. I will now yield to the ranking member, Mr. Darrell Issa of the State of California, for his opening statement.

Mr. ISSA. Thank you, Mr. Chairman. Thank you for holding this always timely hearing.

Today we will examine the H1N1 pandemic flu, and many will say we're not examining it for the first time, and that is true. As a matter of fact, we are not examining it and other causes of pandemic outbreaks for the last time or the second-last time or perhaps the thousandth last time.

It is very clear that the flu—the flu virus can mutate as it migrates; it has, in all the years since the many outbreaks, including the so-called Spanish flu that was so devastating to our soldiers from Fort Riley, Kansas, two generations ago.

Unlike then, we understand now that there are steps that must be taken. Today, we'll hear not just about the virus and not just about vaccines, but about a series of steps that must be taken now and in the future in preparation for an effective response.

If we have an effective vaccine today, we have it for today. Tomorrow is yet another day, and those vaccines that worked yesterday, likely, do not respond next year. Moreover, this committee has previously talked about and heard witnesses on the annual flu shots people receive and the questions about that.

This committee was very, very involved, and properly so, in the provisions of the Public Readiness and Emergency Preparation Act [PREP] Act, which, in fact, went a long way toward creating an environment in which our government could encourage the development of these vaccines, at great cost, without the liability of being beyond economic advice of their counsel. We must continue to do so. We must work on a bipartisan basis to recognize that, for example, the Veterans Administration, which plans to make available more than 3 million H1N1 doses this year, does so to Federal workers and veterans without fear of lawsuit, because in fact they have a liability exemption. But that's not true of the broader market.

So as we talk about the requirements we have—and the chairman is talking about protest against these vaccines—we must bear in mind that there will always be two schools: those who will rightfully sue us or threaten us if we don't respond and we don't prepare and we don't have vaccine, and those who will respond and protest and sue if we do.

Mr. Chairman, I hope that this committee will, in fact, dedicate itself as the premier oversight committee of the Congress to do this on an annual basis, because as much as people may say, "well, we've heard about it before," the flu of next year is not the flu of this year, the pandemic of this year may pale in comparison to the pandemic of next year. And as we as a Congress support the efforts of various organizations, both public and private, to implement an international strategy to make us invulnerable as possible, we have to realize that nothing changes faster than the flu.

With that, I yield back and look forward to the hearing.

Chairman TOWNS. Thank you very much.

[The prepared statement of Hon. Darrell E. Issa follows:]

EDOLPHUS TOWNS, NEW YORK
CHAIRMAN

DARRELL E. ISSA, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED ELEVENTH CONGRESS
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Statement of Rep. Darrell Issa, Ranking Member

“The Administration’s Flu Vaccine Program: Health, Safety, and Distribution.”

September 29, 2009

Thank you, Chairman Towns, for holding this important hearing to examine the Administration’s response to the H1N1 pandemic flu and specifically the flu vaccine program. I would like to thank our witnesses for taking time out of their busy schedules to discuss these important issues, and look forward to hearing from them.

As vaccines represent the most effective strategy to combat the flu virus and mitigate the effects of a pandemic, it is important that we have a robust flu vaccine program. First and foremost, we must make certain that any vaccines given are safe and effective. We must also ensure an efficient mode of delivery and distribution of the vaccine.

Working with the FDA, the CDC, and private and public scientists – on a tight timeline – drug manufacturers developed and are producing an H1N1 vaccine, the first doses of which will be available in just a few days. At a time when the politics of the health care reform debate have created a contentious environment in the health sector, I am encouraged by the cooperation between the government and the private sector during the pandemic. This level of cooperation would likely not be possible without provisions such as the Public Readiness and Emergency Preparedness Act (PREP Act), which, under declaration of a public health emergency, waives liability for manufacturers, distributors, program planners and persons who prescribe the vaccines. As a result of this liability waiver, safe and effective vaccines are better able to be developed, produced and distributed without their manufacturers hampered by litigating frivolous tort claims. The next public health crisis will undoubtedly come any day and scientists and manufacturers need to focus on innovating, not litigating.

The Veterans Administration (VA) plans to make available more than 3 million H1N1 vaccine doses to veterans, and potentially some other federal workers. Additionally, many private health insurance providers have made arrangements to cover the H1N1 flu vaccination for their members. As both private sector and government-run health care systems continue to prepare for vaccine distribution and administration, I am interested to hear from our witnesses about the level of coordination between the Department of Health and Human Services (HHS) and these agencies and companies.

I will also be interested to hear what our witnesses have to say about the integration of information technology into the Administration's pandemic flu response strategy. Yesterday, it was reported that HHS is starting intensive tracking of vaccine side effects. In addition to the surveillance provided through the existing Vaccine Adverse Event Reporting System (VAERS), the government is partnering with Harvard Medical School to electronically link insurance databases so vaccine-related complaints can quickly be studied. Examples like this one illustrate how important health information technology is to patient safety, and the role it can play in keeping costs down in the health care sector, while ensuring better patient outcomes.

Finally, I hope our witnesses will help us determine what Congress can do to ensure the best response possible in the face of the H1N1 pandemic. Although the H1N1 flu may prove to be a mild pandemic, the lessons learned from the planning and implementation of the National Strategy will prove invaluable for tackling future public health crises.

Chairman TOWNS. Any other Members seeking recognition? The gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. Mr. Chairman, I certainly thank you for holding this hearing today on the administration's flu vaccine program. The H1N1 virus has been taking the world by storm since April 2009. The U.S. Secretary of Health and Human Services, Kathleen Sebelius, renewed the declaration that a public health emergency exists nationwide involving this virus.

As the government prepares for the 2009 flu season, we must take every measure to ensure that all Americans, but especially populations of concern including children and the elderly, are well prepared for the increased spread of H1N1.

At least 46 U.S. children, under the age of 18, have died from the H1N1 swine flu infection since April. H1N1 flu is a new virus, so people may have little or no immunity, which means that the virus may spread more easily from person to person.

In my State of Maryland, we are on a widespread activity alert, meaning that outbreaks of the flu or flu-like illnesses have been reported in at least half of the regions in the State, and there is recent evidence of lab-confirmed influenza in the affected regions. In fact, H1N1 is now the predominant strain of flu in the State of Maryland.

Currently, Maryland has had eight deaths and over 170 hospitalizations due to H1N1. So, I'm curious to learn from our witnesses how the administration will address the areas that have been hit the hardest. And we have 135 days left in the flu season, and vaccinations are expected to be available within a few weeks. Education around the importance of the seasonal flu vaccine has helped millions of Americans see the importance and value of receiving this treatment. However, with something as common as a flu shot, people are still resistant. People are afraid of potential side effects. They are concerned they will actually get the flu from the inoculation. And there are those who just do not believe that the flu shot will be effective.

Last year in a RAND Internet-based survey of some 4,000 U.S. residents results showed that 46 percent of adults for whom flu vaccination is strongly recommended, meaning those with underlying conditions, those over 50, those in close contact with infants, the ill, Mr. Chairman, and the elderly had no intention of getting the vaccine. Similarly those especially vulnerable to flu are not getting the vaccine either.

In that study, it was reported that 52 percent of people with asthma had no intention of getting the flu vaccine. With the current state of apathy toward the seasonal flu vaccinations, I am worried that there will be the same or even a worse case of apathy toward the H1N1 vaccine.

As I close, since the initial outbreak earlier this spring, the media has put a strong emphasis on H1N1 virus and the need for children to get vaccinated. However, there are some concerns about whether all of the hype is really necessary.

The Centers for Disease Control and Prevention estimates that an average of 36,000 people die from seasonal flu each year, while the CDC's own data shows that so far there have been fewer than

1,000 H1N1 deaths. Certainly, I know that this hearing will shed light on this subject. And one thing we need to keep in mind, Mr. Chairman, is that it is better that we be cautious and err on the side of caution in making sure that our people are protected, no matter what their reluctance might be.

If we have a safe vaccine, which I do believe we have, we need to make sure that we do everything in our power to convince the public that it is important that they take advantage of it.

And with that, Mr. Chairman, I thank you and I yield back.

Chairman TOWNS. I would like to thank the gentleman from Maryland for his statement.

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

**Representative Elijah E. Cummings, D-MD7
Committee on Government Reform
U.S. House of Representatives
111th Congress**

**Hearing on “The Administration’s Flu Vaccine Program: Health, Safety, and
Distribution”**

September 29, 2009

Mr. Chairman,

Thank you for holding today’s hearing on the
Administration’s Flu Vaccine Program.

The H1N1 virus has been taking the world by storm
since April of 2009. In the United States, Secretary of
Health and Human Services, Kathleen Sebelius renewed
the declaration that a public health emergency exists
nationwide involving this virus. As the government
prepares for the 2009 Flu season, we must take every
measure to ensure that all Americans but especially
populations of concern, including children and elderly are

well prepared for the increased spread of H1N1. At least 46 U.S. children under the age of 18 have died from the H1N1 flu infection since April. H1N1 flu is a new virus, so people may have little or no immunity, which means that the virus may spread more easily from person to person.

In my state of Maryland, we are on a widespread activity alert, meaning that outbreaks of the flu or flu-like illnesses have been reported in at least half of the regions in the State and there is recent evidence of lab confirmed influenza in the affected regions. In fact, H1N1 is now the predominant strain of flu in my State. Currently, Maryland has had eight deaths and over 170 hospitalizations due to H1N1. So I am curious to learn from our witnesses how the administration will address the areas that have been hit the hardest.

We have 235 days left in the flu season and vaccinations are expected to be available within a few weeks. Education around the importance of the seasonal flu vaccine has helped millions of Americans see the importance and value in receiving this treatment. However, with something as common as a flu shot, people are still resistant. People are afraid of potential side effects, they are concerned that they will actually get the flu from inoculation, and there are those who just do not believe the flu shot is effective.

Last year in a RAND Internet-based survey of some 4,000 U.S. residents, results showed that 46% of adults for whom flu vaccination is strongly recommended, meaning:

- those with underlying conditions;
- those over 50;

- those in close contact with infants;
- the ill;
- and the elderly

had no intention of getting the vaccine. Similarly, those especially vulnerable to flu are not getting the vaccine either. In that study, it was reported that 52% of people with asthma had no intention of getting the flu vaccine. With the current state of apathy towards the seasonal flu vaccine, I am worried that there will be the same or even a worsened case of apathy towards the H1N1 vaccine.

Since the initial outbreak earlier this Spring, the media has put a strong emphasis on the H1N1 virus and the need for children to get vaccinated. However, there is some concern about whether all of the hype is really necessary. The Center for Disease Control (CDC) estimates that an average of 36 thousand people die from the seasonal flu

each year while the CDC's own data shows that so far there have been fewer than one thousand H1N1 deaths in the United States.

However I am encouraged by the steps taken so far by the Department of Health and Human Services in raising public awareness on encouraging better hygiene among young children. Elmo and other characters from Sesame Street have been working to stress the importance of basic healthy habits such as frequent hand washing, sneezing into the bend of your arm, and not touching your mouth, nose, and eyes.

The flu is one of the most unpredictable diseases and we must continue to educate the public by reiterating preventative care, hygiene basics and encouraging our most vulnerable populations to get vaccinated. I look forward to

hearing the expert testimony of today's witnesses on how to combat this disease and protect ourselves and our children.

I thank you again Mr. Chairman for holding this vitally important hearing. With that, I yield back the remainder of my time.

#####

Chairman TOWNS. And I now yield 5 minutes to the gentleman from Ohio, Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman. I want to welcome our witnesses.

This is an opportunity for still another civics lesson through this committee, and that is that we have public health officials here who are once again demonstrating the primacy of the government's role in matters of public health; that we have here, oh, yes, a government-run flu vaccine program. Why? Because the government has the resources and the ability to distribute in the public interest and to protect the public health, medical means and materials, in this case, flu vaccines, that can be important to protecting the health of the people of the United States. This is one of the purposes of the government.

At this very time, Mr. Chairman, a Senate committee is meeting on a public option for health care. And I want to connect the two, because the fact of the matter is with tens of millions of Americans without access to primary care, if you don't have access to primary care and you get the flu, the effects of the flu can be much more damaging. You don't have to be a doctor to understand that. You also may be more medically compromised than other people and therefore even more vulnerable to being able to contract an influenza.

So we have to use this opportunity to explore cause and effect here as well, because what we have to do with the influenza issue here—swine flu is one thing and the more generalized type of flu another—but we also have to realize this occurrence in the context of a health-care system which is, in itself, a weakened system. And we reflect that it is Congress' responsibility to strengthen it.

So, I want to thank Dr. Frieden, Dr. Fauci and Dr. Goodman for their presence here today. We look forward to your testimony as to how we can prepare the American people for this influenza season. But we also have to understand that there are things happening in health care in America which make our constituents even more vulnerable to every manner of flu and the generalized pandemic that can ensue, not just this season, but any season. And to look at the underlying question here is one of the things Congress will certainly be involved in in the next few months.

Mr. Chairman, with that I yield back. Thank you.

Chairman TOWNS. I thank the gentleman from Ohio for his statement. I yield to the gentleman from Illinois, Mr. Quigley.

Mr. QUIGLEY. Waive.

Chairman TOWNS. He waives.

Let me introduce our witnesses today. Dr. Thomas R. Frieden, good to see you. Director of the Centers for Disease Control and Prevention. Dr. Frieden has been trained in internal medicine, infectious diseases, public health and epidemiology. Before being named the Director of the CDC in June 2009, Dr. Frieden was the commissioner of the New York City Department of Health and Mental Hygiene.

Dr. Fauci, Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases, at the National Institutes of Health. Dr. Fauci, a native of Brooklyn, NY, advises the White House and the Department of Health and Human Services on med-

ical and public health preparedness against emerging infectious disease, such as pandemic influenza.

Our next witness is Dr. Jesse Goodman, the Food and Drug Administration Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs. Previously, Dr. Goodman, an infectious disease expert, was the Director of FDA's Center for Biologics, Evaluation and Research.

Gentlemen, it is a longstanding policy that we swear all of our witnesses in, and so if you would stand and raise your right hands.

[Witnesses sworn.]

Chairman TOWNS. You may be seated. Let the record reflect they answered in the affirmative.

Dr. Frieden, we will start with you and come right down the line, OK? And let me just say that we have 5 minutes. When you start, the light is green and then as you move forward it becomes yellow, which is saying you have 1 minute to summarize. And then after that it becomes red. Red all over the United States means stop. OK, you may proceed.

STATEMENTS OF THOMAS R. FRIEDEN, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; AND JESSE GOODMAN, M.D., ACTING CHIEF SCIENTIST AND DEPUTY COMMISSIONER FOR SCIENTIFIC ADMINISTRATION AND MEDICAL PROGRAMS, FOOD AND DRUG ADMINISTRATION

STATEMENT OF THOMAS R. FRIEDEN, M.D.

Dr. FRIEDEN. Thank you very much. Members of Congress—

VOICE. Turn your mic on.

Dr. FRIEDEN. Thank you very much, Mr. Chairman, Ranking Member Issa, and members of the committee. In the spring, I was New York City health commissioner and we had hundreds of thousands of cases of H1N1 influenza. At that time, we didn't have as clear an understanding as we do today of the level of illness it causes. We had health-care settings that had a great deal of difficulty dealing with the large number of patients coming in. We had intense media interest. And tragically, we had some people who became very severely ill, and some people who died. So, H1N1 influenza is something that we have to take extremely seriously. And what I would like to do is update you briefly on the situation and our response.

As of today, H1N1 really never went away from the spring until now. It continued to spread over the summer, in summer camps and elsewhere. And when schools came back into session and kids went to college, we saw large numbers of cases.

Influenza is now widespread across the United States and, in fact, this is uncharted territory for an influenza season. We've had already many millions of cases and we will have many millions of cases more.

So far, there has been no change in the pattern of illness, so the level of illness with H1N1 is no more severe than seasonal influenza. And intensive laboratory studies have shown no change in

how deadly the virus is and no significant change in the genetic makeup of the virus. That's good news, because it indicates that so far, it doesn't seem that it will become more deadly in the immediate future. And so far, it seems like the vaccine, which Dr. Fauci will speak about more, will be an excellent match against the specific virus that's spreading now.

However, influenza is probably the most unpredictable of all infectious diseases. There are many variables, and only time will tell what will happen, whether it will become something that becomes more deadly is something we just don't know until the time comes. Therefore, the role of the CDC, much of which is made possible because of the support of the Congress over several years, is several-fold.

We currently have more than 1,500 staff working on H1N1 response. The activities include the identification and characterization of the virus, identifying a candidate strain, monitoring the spread of disease in the United States, and globally, and responding through communications with the public; guidelines for schools, businesses, health-care providers, and a vaccination campaign.

The vaccination campaign is an unprecedented effort. It's a public-private partnership, with substantial amount of vaccines coming available in the weeks to come. Production is rolling and our choice was to let it buildup in warehouses then send it out; or what we decided to do is send it out as soon as it becomes available off the production line and its safety and potency has been verified. That means that over the next several weeks, there will be some vaccine in the system, but there will also be some roughness as it gets distributed.

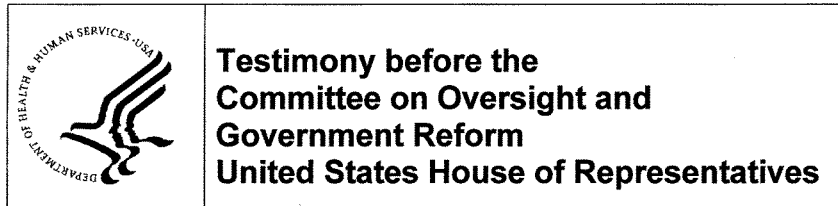
Eventually, there will be vaccine for all who want to be vaccinated. The priority of people who are at higher risk of becoming severely ill, pregnant women, those with underlying conditions, school children, contacts of people under the age of 6. The vaccine will be free in public settings and in private settings. There will be no cost of the vaccine, although some settings will charge an administration fee. There will be up to 90,000 providers across the country providing vaccine, and the challenges are significant.

This is a shared responsibility of the Federal, State and local governments of the health-care system, of individuals, of businesses, and, of the manufacturers who are partners in this process.

Progress has been possible because of the ongoing investment by Congress. We are working hard with our partners in HHS, under the leadership of Secretary Sebelius, and the U.S. government generally, and State, local tribal governments, as well as health-care providers; and we are committed to regular open communications with the public and the Congress. It's an evolving situation. We're committed to staying open and answering your questions. Thank you.

Chairman TOWNS. Thank you very much.

[The prepared statement of Dr. Frieden follows:]



**Responding to the 2009-2010 Influenza
Season**

*Thomas R. Frieden, M.D., M.P.H.
Director,
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services*

**For Release upon Delivery
Expected at 2:00 p.m.
September 29, 2009**

Chairman Towns, Ranking Member Issa, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. I am Dr. Tom Frieden, Director, Centers for Disease Control and Prevention (CDC). As the former Commissioner of the New York City Department of Health and Mental Hygiene, and an infectious disease doctor by training, I am pleased to have been asked to work under the leadership of Secretary Sebelius to ensure that the Administration is implementing a comprehensive plan to address H1N1 throughout this fall and winter. CDC and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned this spring, as well as on preparedness for pandemic influenza during the past several years. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, the federal government has been actively preparing for the ongoing influenza pandemic.

Since the initial spring emergence of 2009-H1N1 influenza, the virus has triggered a pandemic and has become the dominant strain of influenza in the southern hemisphere during its winter season. The virus has not changed to become more deadly. The viruses characterized at CDC and the other World Health Organization (WHO) Collaborating Centers have shown very little genetic variation with no acquisition of genetic markers known to be associated with increased virulence in other strains. Viruses collected worldwide have been very similar both genetically and antigenically.

In the United States, we saw unusual levels of influenza activity over the summer, and have seen early increases in 2009-H1N1 influenza activity in many states beginning in late August, and expect this to continue to spread across the United States during the coming weeks. We anticipate that even more communities may be affected than during this past spring and summer. In addition, seasonal influenza viruses could cause illness this fall and winter. Influenza is unpredictable, and only time will tell how long the current wave of infection with the H1N1 continues, whether there is another wave, whether the virus becomes more deadly and whether seasonal influenza causes widespread illness this winter.

Shared Responsibility and Science-Based Guidance

Slowing the spread and reducing the impact of H1N1 and seasonal flu is a shared responsibility, and we all need to plan for what should be done when the flu impacts our communities, schools, businesses, or homes this fall. Given that influenza is already circulating in the United States, it's important for every American family and business to prepare their own household and business plans and think through the steps they will have to take if a family member or co-worker contracts the flu.

CDC has provided specific recommendations for what individuals, communities, clinicians, and other professionals can do. Each individual can take actions to prevent respiratory infections. At the current level of disease in the community, we emphasize three personal actions: (1) When sick, stay home and don't go to school, work, or public places. It is very important for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, the mall or other places children and teenagers gather. If a child becomes sick with the flu, CDC

recommends keeping the child at home for at least 24 hours after there is no longer a fever or signs of a fever (without the need for fever-reducing medicine). (2) Cover the nose and mouth with a tissue when coughing or sneezing (or a shirt sleeve or elbow if no tissue is available) (3) Wash hands frequently, especially after coughing or sneezing. Use soap and water when possible or alcohol-based hand sanitizer otherwise. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory viruses.

CDC has issued guidance for schools, child care settings, colleges and universities, and large and small businesses. The guidance contains information about strategies to prevent the spread of flu, especially important in the remaining time before large scale vaccination with 2009-H1N1 vaccine can begin. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. CDC also has issued guidance for healthcare providers about appropriate use of antiviral medications to treat patients who are at highest risk of complications from influenza. Additional work is being done on critical guidelines to address infection control and worker safety in healthcare settings.

Our recommendations and action plans are based on the best scientific information available to help our nation respond aggressively and effectively to the 2009-H1N1 virus. We are working to ensure that Americans are informed and consistently updated with information in clear language. In this rapidly changing situation, it is essential that the American people are fully engaged so they can be part of the response. CDC will continue to conduct weekly and, when necessary, more frequent briefings that will be available at flu.gov and other media to get critical information to the American people.

Vaccination Campaign

The federal government is taking strong, proactive steps to control the spread of the 2009-H1N1 virus, including preparing for a voluntary national vaccination campaign starting in October.

With unprecedented speed, we have completed key steps in the vaccine development process: we have characterized the virus, identified a candidate vaccine strain, through our HHS partners expedited manufacturing, and performed clinical trials. The speed of this vaccine development was possible due to the investments made by the Congress over the past five years in advancing research and development and building infrastructure. Two types of vaccine will be available: vaccine made from inactivated virus for injection (flu shot) and a live attenuated virus vaccine administered by nasal spray. Some vaccine manufacturers will be producing 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

The vaccines are being manufactured by the same companies using the same methods used for the production of the seasonal flu vaccines administered every year. Dr. Fauci will describe in more detail the results from clinical trials which are very encouraging and have allowed us to move forward rapidly. Continued characterization of circulating strains of 2009-H1N1 suggests the vaccines being produced should be an excellent match with the circulating virus at this time, and are expected to be highly effective if the virus doesn't change. One of the major determinants in effectiveness of influenza vaccines is how closely the strains used to create the vaccine match the strains being transmitted and causing illness in our communities. The

circulating strains of 2009 H1N1 virus have not undergone major mutations and match the vaccine strains very closely. Therefore, we have every reason at this time to expect that the vaccine will produce good antibody responses and provide protection against H1N1 illness.

Adverse events from the 2009 H1N1 vaccine in the clinical trials are similar to those seen with seasonal flu vaccine—mainly, mild pain, tenderness, redness, or swelling at the injection site. No severe adverse events have been identified in the clinical trials, but we will remain alert for the possibility of rare, severe adverse events. Ensuring a vaccine that is safe as well as effective is our top priority. CDC and the Food and Drug Administration (FDA) have been working with other agencies to establish and enhance surveillance systems to detect as rapidly as possible any unexpected adverse events among persons who are vaccinated and to adjust the vaccination program to minimize risks and maximize benefits from vaccination. Two primary systems that will be used are the Vaccine Adverse Events Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations with more than nine million members designed to determine whether any reported adverse events are occurring among vaccinated persons more than among unvaccinated persons.

Our goal is to make vaccine available to every American who wishes to be vaccinated, beginning with population groups at greatest risk. The federal government has been working in close partnership with states, territories, tribes, and local communities as well as with the private sector to help distribute and administer the new H1N1 vaccine. Thanks to support from Congress, the

federal government has made a significant investment in states and hospitals to support planning and preparation efforts.

We expect initial shipping of 2009-H1N1 vaccines from our central distributor to sites where it will be administered to begin as early as the end of this week. During these initial days of the program, vaccine will be available in limited quantities. However, vaccine production is continuing and the amount of vaccine becoming available will increase throughout the fall, and we expect sufficient quantities to be available for all who want to be vaccinated through the end of the year. Vaccine production is a complex and demanding process with many variables—CDC is working with other agencies and with the manufacturers to provide as much vaccine as possible as soon as possible. Projections for the amount of vaccine available at any given time during the fall may change as more information on the production process becomes available from the manufacturers. This is a challenging process; because we want to speed the delivery of vaccine as quickly as it becomes available, we need to depart from the traditional process of warehousing and distribution of a more complete inventory.

The 2009-H1N1 vaccine will be distributed to providers and state and local health departments in a manner similar to how federally purchased vaccine are distributed in the Vaccines for Children program. The amount of vaccine allocated to each state is based on the total population of that state. This system follows state-developed plans for delivery to up to roughly 90,000 locations, and is designed to provide maximal flexibility to meet the differing needs in various parts of the country. States will have vaccine delivered directly to clinics and other sites of vaccine administration and some will also receive, repackage, and redistribute some of the shipments

according to local needs. The number of doses shipped will be reported to the CDC daily, and states have been asked to report the number of doses administered to the CDC weekly. The planning for this vaccine campaign has been informed by experience working with States and localities through the Vaccines for Children program. We have been able to provide significant new resources to States and localities to facilitate their ability to rapidly deliver vaccine as it becomes available and we were fortunate to be able to take advantage of preliminary findings from a recent HHS Inspector General report on preparedness for vaccine and antiviral distribution as we worked with States on their final vaccine planning.

The vaccine, which was purchased with Federal funding, will be available free of charge to the American people, but some private providers may charge an administration fee or bill the administration fee to a third party payer. Administration of vaccine in public settings will be free of charge and we have been working with public agencies and the insurance industry to insure that no American goes unvaccinated because of lack of insurance and inability to pay administration fees.

The virus has not changed compared with the spring in terms of the illness that it causes or who is most likely to become ill. This virus is infecting more young people, including children and younger adults than is typical for seasonal influenza; and pregnant women are more severely affected with H1N1 flu than the general population. CDC's Advisory Committee on Immunization Practices (ACIP) recommended providing initial doses of the 2009-H1N1 vaccine to five groups—totally approximately 159 million people. CDC endorsed these recommendations. These groups are:

- people ages 25 through 64 years who are at higher risk for complications from 2009 H1N1 infection because of chronic health disorders like asthma and diabetes or compromised immune systems.
- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel, and
- persons between the ages of 6 months through 24 years of age.

However, an effective vaccine against 2009-H1N1 does not mean that we can become complacent about other control measures. We need to remind all Americans about the things they should be doing right now: stay home if you're sick, cover your cough or sneeze, and wash your hands often. Flu.gov has good tips for what you need to do to avoid getting the flu as well as information about both the 2009-H1N1 vaccine, as well as the seasonal flu vaccine. While the 2009-H1N1 flu virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by the seasonal flu viruses. It is estimated that about 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all people 50 years of age and over, all adults with certain chronic medical conditions, as well as infants and children. More than 60 million doses of seasonal flu vaccine had been distributed as of last week.

Closing Remarks

CDC is working hard to limit the impact of the pandemic and we are committed to keeping the public and the Congress fully informed about the situation and our response. We are

collaborating with our federal partners as well as with other organizations with unique expertise that helps us provide guidance for multiple sectors of our economy and society. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge. Our nation's current preparedness is a direct result of the investments and support of the Congress over recent years as well as in recent months, effective planning and action by Federal agencies, and the hard work of state and local officials across the country. While we must remain vigilant, it is important to note that at no time in our nation's history have we been more prepared to face this kind of challenge.

We look forward to working closely with the Congress to best address the situation as it evolves in the weeks and months ahead. Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to taking your questions.

Chairman TOWNS. Dr. Fauci.

STATEMENT OF ANTHONY S. FAUCI, M.D.

Dr. FAUCI. Mr. Chairman, members of the committee, thank you for giving me the opportunity to review for you, the role of the National Institutes of Health, their research endeavor, and the preparedness and response to the 2009 H1N1 influenza pandemic, particularly in the arena of the development and testing of vaccines against this new virus.

The National Institute of Allergy and Infectious Diseases has been involved in basic and clinical research related to seasonal influenza for several decades. And we have the responsibility for the development of rapid diagnostics for the flu, the development and testing of antiviral drugs, the understanding of how the influenza viruses evolve, how they mutate, how they transmit, what immune responses are induced. And, importantly, we are deeply involved in the development of the testing of vaccines to prevent seasonal and pandemic influenza.

This latter effort is a collaborative process among several agencies of the Federal Government, particularly the sister agencies represented here in the Department of Health and Human Services, in partnership with the pharmaceutical companies that actually manufacture the vaccines.

As schematically shown on the first poster over there on the right, the development of an influenza vaccine is a step-wise process, starting with the isolation of the virus up to and including the actual development of the new vaccine for distribution. In this regard, the 2009 H1N1 pandemic influenza virus was first isolated by the CDC and made available to a number of parties, including us at the NIH, for purposes of studying its characteristics. Pharmaceutical companies, with which we have longstanding relationships in the development of influenza vaccines, were given what we called "seed" or reference viruses for the purpose of developing pilot lots for the NIH to test in clinical trials.

Historically, our Institute has set up a network of vaccine and treatment evaluation units throughout the country. These groups have extensive experience in the conduct of vaccine trials and were called upon, again, to answer several important questions that would inform how we would use the H1N1 vaccines in this country and worldwide.

The important information gained from these clinical trials involve safety, even though we have safety data from decades of experience with seasonal vaccines made in the same manner. Also immunogenicity; or, simply put, does the vaccine elicit a response that will be predictive of protection against this virus? For example, what is the correct dosage and the number of doses? If we require the use of an enhancing substance called an "adjuvant" to amplify the response in spare doses, would this be safe and effective.

Also, we need to know about the effectiveness of vaccine in special populations, such as the elderly, children and pregnant women.

As shown in the next poster, we have several ongoing trials that have already provided extremely valuable information for the implementation of our vaccination program. I can report today some

good news regarding these clinical trials. For example, it was unclear at first whether this vaccine would induce a protective response at all. And if so, would it require an unreasonable dosage and/ or a number of doses to achieve this effect? We now know that a single dose of the standard 15 micrograms of vaccine in adults and the elderly, without the need of an adjuvant, is, not only well-tolerated, but induces a robust immune response in a high percentage of recipients.

This is a very important finding and has important implications for the supply of vaccine, as well as, for effectiveness in protecting our citizens, as well as, people throughout the world against the pandemic influenza.

In addition, we found that, very similar to the seasonal flu vaccines, one dose of the 2009 H1N1 vaccine induces a robust response in children 10 to 17 years old, indicating that they will require only one dose, while younger children will likely require two doses, which is quite similar to the case with seasonal flu vaccine.

Current studies are ongoing in pregnant women, and we hope to have preliminary data within a few weeks. In addition, we are planning to conduct vaccine trials in individuals who might have particular difficulty with the H1N1 virus, such as asthmatics and individuals with HIV infection.

In summary, the NIH research effort, in the development and testing of the 2009 H1N1 vaccine, is an important part of the collaborative effort among the sister agencies of the Department of Health and Human Services, and we look forward to continuing this effort as we face the challenges ahead of us this fall and winter.

Thank you very much, and I would be happy to answer questions later.

Chairman TOWNS. Thank you very much, Dr. Fauci.

[The prepared statement of Dr. Fauci follows:]



Testimony
Committee on Oversight and Government Reform
United States House of Representatives

**The Role of NIH-Supported
Research in the Response to 2009
H1N1 Influenza**

Statement of

Anthony S. Fauci, M.D.

Director

National Institute of Allergy and Infectious Diseases

National Institutes of Health

U.S. Department of Health and Human Services



For Release on Delivery
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Tuesday, September 29, 2009

Mr. Chairman and members of the Committee, thank you for the opportunity to discuss the NIH research response to the public health threat that the Nation and world face with regard to the pandemic caused by the novel 2009 H1N1 influenza A virus.

Over the past several years, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS), has conducted a major research effort that builds on long-standing programs related to seasonal influenza in order to improve our preparedness for pandemic influenza. Although in this decade we have focused a good deal of attention on H5N1 avian influenza, it always has been clear that the next pandemic threat could come from another influenza virus altogether.

The new pandemic influenza is now here. In response, NIH has intensified the implementation of the research agenda that underpins the development of countermeasures for all influenza subtypes, and in particular, the 2009 H1N1 virus.

In my remarks today, I will discuss the research response being mounted by NIH that is complementary to—and synergistic with—the efforts of other components of HHS such as the Biomedical Advanced Research and Development Authority

(BARDA) within the Office of the Assistant Secretary for Preparedness and Response, and our sister agencies, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), as well as other organizations throughout the world.

Seasonal and Pandemic Influenza

Influenza viruses affect many animal species, including birds, pigs, and humans. As influenza viruses circulate, the genes that determine the structure of their surface proteins undergo small changes called mutations. These genetic changes accumulate over time to cause a gradual “antigenic drift” that allows an influenza virus in a typical influenza season to largely evade the preexisting immunity we may have developed from prior exposure to influenza viruses or from prior vaccinations. Antigenic drift in human influenza viruses is the basis for the predictable patterns of seasonal influenza seen in most years and is the reason that we annually reassess the strains to be included in the seasonal influenza vaccine.

In humans, seasonal influenza epidemics in the Northern hemisphere usually occur in winter months. These seasonal events cause symptomatic illness in 15 to 60 million people in the United States every year; they result in an average of approximately 200,000 hospitalizations and 36,000 deaths. Background immunity from prior exposure to related influenza viruses or from prior immunizations tempers the number of illnesses, hospitalizations, and deaths we

see each year. Most of the severe outcomes from seasonal influenza occur among people aged 65 years and older, in very young children, and in those with chronic health conditions. Globally, seasonal influenza causes 3 million to 5 million cases of severe illness each year, and an estimated 250,000 to 500,000 influenza-related deaths, according to the World Health Organization.

Influenza viruses also can undergo more extensive changes that lead to what is called an “antigenic shift,” which can pose a more serious threat to human health. One way antigenic shifts occur is through the infection of humans by a novel influenza virus from a non-human source. For example, influenza viruses infecting birds can, on rare occasions, also infect humans. Although the result is usually a “dead-end” infection that does not spread further, the virus might undergo mutations that allow limited human-to-human transmission. Once transmission begins, further mutation can make human-to-human transmission more efficient and sustainable. Another way that antigenic shifts occur is through a process called reassortment, in which two virus strains co-infect a host and exchange genes resulting in a hybrid virus. Whatever the mechanism, the result may be the evolution of a new virus to which the human population has little or no immunity. If this new virus is able to efficiently transmit from human to human, then an influenza pandemic may result. Pandemic influenza is an unpredictable and rare event that can occur at any time of year.

In the 20th century, influenza pandemics occurred three times—in 1918, 1957, and 1968. The pandemics of 1957 and 1968 were serious infectious disease events that killed approximately two million and 700,000 people worldwide, respectively. The 1918-1919 pandemic, however, was catastrophic: epidemiologists estimate that it killed more than 50 million people worldwide, including more than 500,000 people in the United States, and caused enormous social and economic disruption.

Given this history, we long have expected that a new influenza virus would emerge and another pandemic would occur. Since the initial spring outbreak of a novel influenza, the 2009 H1N1 influenza, the virus has triggered a worldwide pandemic and has emerged as the dominant influenza strain in the Southern hemisphere during its winter influenza season. Here in the United States, we continued to see influenza activity over the summer, which is totally unlike the pattern with typical seasonal influenza. More recently, we have seen a marked increase in 2009 H1N1 influenza activity in many states associated with the return of students to school, a trend we expect will continue in the coming months.

The U.S. Government, and HHS in particular, has been preparing for an influenza pandemic for a number of years. These efforts were bolstered after H5N1 avian influenza reemerged in Southeast Asia in 2003. U.S. Government pandemic preparedness plans assign to the NIH the primary responsibility for

scientific research and clinical trials needed to develop and test pandemic influenza vaccines and therapies.

NIH, for a considerable period of time, has supported basic influenza research to understand better how influenza viruses replicate, interact with their hosts, stimulate and evade immune responses, and evolve into new strains. Results from these basic research studies lay the foundation for the design of new therapies, diagnostics, and vaccines, and are applicable to seasonal epidemic and pandemic strains alike. NIH has worked with our partners in the biotechnology and pharmaceutical industries to speed development of new influenza vaccines, diagnostic tools, and anti-influenza drugs. We also have built a substantial infrastructure of research centers, NIH intramural and NIH-supported extramural laboratories, highly trained personnel, and clinical research networks to rapidly conduct research should a virus with pandemic potential emerge.

NIH is presently engaged in an accelerated effort to fully understand the currently circulating 2009 H1N1 influenza virus and to rapidly develop effective countermeasures. Scientists already have learned a great deal about the biology of the 2009 H1N1 virus, and we are taking numerous steps to learn more. NIH also has been fulfilling its role in developing vaccines and testing therapeutics to counter this newly emerged virus.

Basic Science

When news of the emergence of 2009 H1N1 influenza was first reported, scientists at CDC, FDA, NIH, NIH-supported laboratories, and elsewhere around the world obtained samples of the 2009 H1N1 virus. NIH immediately began a thorough and rapid characterization of the virus in cell culture and laboratory animals, as well as genetic and structural studies of the virus. That effort involved intramural researchers on the NIH campus, researchers in preexisting NIH research networks such as the Centers of Excellence in Influenza Research and Surveillance (CEIRS) and Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), as well as industry partners and individual NIH grantees.

These efforts already are yielding important information about the virus. For example, NIH-supported CEIRS researchers have found that the novel 2009 H1N1 influenza virus may have a biological advantage over seasonal influenza viruses in animal models. Preliminary findings in ferrets suggest that the levels of 2009 H1N1 influenza virus rise more quickly than seasonal influenza virus strains and that the 2009 H1N1 virus causes more severe disease. We expect that NIH-supported research will continue to provide critical insights into the mechanisms by which the virus causes disease, the viral molecular signatures of virulence and enhanced transmission, and the major viral and host factors important in mounting an immune response to the virus. NIH-supported researchers also are implementing a number of clinical studies to provide crucial

information about how the virus behaves in humans, how the human immune system responds to it, and how much cross-protection, if any, is provided by antibodies to previously circulating human H1N1 viruses.

Vaccines

Working with its partners in industry and academia, HHS has completed key steps in the development of vaccines for the 2009 H1N1 influenza—we have characterized the virus, identified a candidate strain, expedited manufacturing, and conducted clinical trials. HHS has contracted with five vaccine manufacturers who are producing either inactivated or live, attenuated H1N1 influenza vaccines by the same methods that are used annually for the production of the seasonal influenza vaccine; the 2009 H1N1 vaccines from four of these manufacturers were recently approved by the FDA for use in the United States. Inactivated vaccines are based on chemically killed influenza viruses and are injected intramuscularly, whereas live, attenuated vaccines are based on a weakened influenza virus and are administered as a nasal spray. Initial lots of the 2009 H1N1 influenza vaccines are expected to be available in early October.

NIH is using its longstanding vaccine clinical trials infrastructure—notably our network of Vaccine and Treatment Evaluation Units (VTEUs)—to conduct a series of clinical trials to quickly evaluate pilot lots of vaccines to determine whether the vaccines are safe and to assess their ability to induce immune responses that are predictive of protection. Data from these trials will help inform

the development of recommendations for immunization schedules, including the optimal dosage and number of doses for individuals in different age brackets and for specific groups such as pregnant women. Close collaboration among NIH, FDA, and BARDA was critical in launching these studies quickly while ensuring the usual high standards for the conduct of clinical trials.

Trials to evaluate the safety and immune response of two different dosages (15 micrograms versus 30 micrograms) and one versus two doses of vaccine in healthy adults and the elderly began in the first week of August. Complete immune response data from these first trials—those studying two doses in healthy adults—are expected in late October. As NIH announced on September 11, preliminary data indicate that the vaccines are safe and that a single 15-microgram dose induces what is likely to be a protective immune response in healthy adults between the ages of 18 and 64 years. For adults aged 65 and over, the preliminary data indicate that the immune response to the 2009 H1N1 influenza vaccine is somewhat less robust, as is the case with seasonal influenza vaccine. These data are consistent with early data from independent studies conducted by several of the vaccine manufacturers. NIH is conducting similar trials in populations who are at higher risk of influenza complications, including children, which began in mid-August, and in pregnant women, which began earlier this month. Early data from the pediatric trials suggest that one dose of vaccine in older children, aged 10 to 17 years, may be adequate to induce a robust immune response. Younger children may require a second dose, as is

the case with seasonal influenza vaccine. NIH is planning additional studies of the vaccines in other populations, including HIV-positive individuals and people with asthma.

A concurrent set of trials will determine whether the 2009 H1N1 influenza vaccine can be safely administered at the same time or sequentially with the seasonal influenza vaccine and whether both vaccines will induce protective immune responses. These trials are being conducted in healthy adult, elderly, and pediatric volunteers.

Finally, NIH is supporting trials of 2009 H1N1 influenza vaccines that contain adjuvants. Adjuvants are additives that help create a more vigorous immune response to a vaccine, thereby reducing the amount of antigen required per vaccine dose. Currently, it is not expected that adjuvants will be used in a U.S. vaccination program against 2009 H1N1 influenza. However, clinical trials are being conducted with adjuvanted vaccines as a contingency plan; an adjuvanted product might be needed, for example, if the virus mutates to become different from the vaccine virus, if certain populations do not mount an adequate immune response to vaccination, or if we require more doses of vaccine. The adjuvant trials are expected to begin in late September, with the first preliminary immune response data expected in mid- to late October.

NIH and its industry partners have been developing several other kinds of influenza vaccines that are not yet licensed for use. These include recombinant DNA technologies that yield subunit vaccines, in which various influenza virus proteins are selectively produced in cultured cells and are then purified and used in a vaccine; DNA vaccines, in which influenza genetic sequences are injected directly into a person to stimulate an immune response against the proteins coded for by these genetic sequences; and approaches that insert the genes of influenza virus into a different virus (a "vector") that is used as a vaccine. A study of a prototype 2009 H1N1 influenza vaccine that relies on one of these experimental strategies is underway; the NIAID Vaccine Research Center is enrolling healthy adults in a clinical study of its DNA-based H1N1 influenza candidate vaccine. However, because such "next-generation" vaccines will require additional safety and efficacy testing before they can be deployed, they will not reach the public during the upcoming influenza season.

Antiviral Therapies and Diagnostics

Antiviral medications are an important counterpart to vaccines as a means of controlling influenza, by treating infection after it occurs and, under certain circumstances, by preventing illness prior to or immediately after exposure. Although the 2009 H1N1 influenza virus is sensitive to oseltamivir (Tamiflu®) and zanamivir (Relenza®), experience tells us that resistance to influenza antiviral medications frequently emerges. Indeed, over the past two years the circulating

seasonal H1N1 influenza viruses have become widely resistant to oseltamivir, even while other influenza viruses have remained sensitive to the drug.

In recent years, NIH has been working to develop and test the next generation of influenza antivirals. Three drugs are now in clinical testing, including a long-acting neuraminidase inhibitor, an inhibitor of viral replication, and a drug that prevents the virus from entering human lung cells. NIH has begun evaluating how well these candidate antiviral drugs block the 2009 H1N1 strain and screening other compounds for activity against the virus. NIH intends to conduct clinical trials of antivirals, including new formulations and combinations of licensed drugs and investigational antiviral candidates, in individuals infected with the 2009 H1N1 influenza virus.

Improved methods of diagnosing 2009 H1N1 influenza infection at the point of care would be of substantial value in the months ahead, helping to differentiate people with the new influenza strain from those with other conditions who present with similar symptoms. Prompt and precise point-of-care diagnosis would help to slow the spread of the influenza virus and maximize the efficiency with which stockpiled antivirals are used. NIH has been developing diagnostic platforms capable of rapidly identifying a wide variety of pathogens in clinical samples, including specific subtypes of influenza, and we are now working to accelerate the development of these platforms to provide improved diagnostics for 2009 H1N1 influenza.

Shared Research Resources

When infectious diseases emerge, NIH serves an important role in providing research materials, support, and expertise to scientists and to the public health community. These research resources include blood samples from infected patients, immunological assay reagents, animal models, genomic sequencing and information resources, and isolates of the virus.

NIH intramural and extramural researchers, in turn, depend on materials and information shared by CDC, FDA, and other public health agencies around the world. For example, CDC provided NIH intramural investigators and NIH-supported researchers with samples of the 2009 H1N1 virus, while NIH has made available to CDC researchers archived blood samples from people vaccinated against 1976 swine influenza as well as influenza reagents from an NIH research reagent repository. From my perspective, the coordination and cooperation among government agencies, and with private industry, has been outstanding.

Conclusion

It is important to recognize that, even months into this worldwide pandemic, we are still only at the earliest stages of understanding how the 2009 H1N1 influenza virus emerged and what impact it might have. Influenza viruses are highly unpredictable, and it is unwise to make predictions about how a virus might

behave in the future. For example, although the virus at this time has caused relatively mild influenza symptoms for most people in this country, we do not know whether that might change in the coming months. Nor do we know whether the virus will become resistant to the antiviral drugs we have stockpiled. In short, we simply cannot predict at this time whether the 2009 H1N1 pandemic will become more or less severe than we have seen thus far. For these reasons, the NIH and other government agencies have been preparing for any possibility.

The ongoing, collective efforts of HHS, including the NIH, to prepare for an influenza pandemic—with surveillance, research, vaccine manufacturing infrastructure and clinical trials, antiviral drugs, public health measures, effective infection control, and clear public communication—have given us a valuable advantage in responding to the current worldwide pandemic, however it may unfold in the future.

I would be pleased to answer any questions you may have.

Chairman TOWNS. Dr. Goodman.

STATEMENT OF JESSE GOODMAN, M.D.

Dr. GOODMAN. Mr. Chairman and members of the committee, I very much appreciate the opportunity to be here today and describe FDA's role in this public health response. This ongoing collaborative response is the product of hard work and continuing investment made possible by Congress's support for preparedness activities in the Department of Health and Human Services.

When the H1N1 virus emerged in the spring, we immediately established an incident-command system to speed and coordinate our response. This allowed us to work hand in hand with HHS and my partners at the table here to rapidly mobilize what has been an emergency public health response. And this included not just the vaccine enterprise that we began at that time, but allowing emergency use authorization for antivirals for ill children under 1-year old, deploying a new diagnostics, so both the public health and health-care system could accurately diagnose this infection.

The very good news is that the initial doses of licensed vaccines will be available very, very soon and that full-scale production is continuing. And these vaccines are made in exactly the same manner as the 100-plus million doses of seasonal vaccine that are made and used safely every year to help protect American people.

Well, immediately after this virus was detected—and as you saw on Dr. Fauci's chart—we all began working together to generate all the tools, including the virus reference strains' reagents necessary to manufacture the virus. And we worked with our colleagues at NIH to design and mobilize those clinical studies, as well as, with the manufacturers that you've heard about.

Fortunately, this occurs on a background—and it's been mentioned here—of substantial investment that has helped us prepare better. We engaged for several years in an effort to strengthen influenza in public health system preparedness. And this has truly helped in this response.

In the last 5 years, we've been able to virtually double the number of U.S. licensed manufacturers of vaccine and also their production capacity. And some examples of some of these activities, undertaken by us in conjunction with the Assistant Secretary for Preparedness and Response and the Biomedical Advance Research and Development Authority under that office, have included having resources as mundane as chickens—having a large flock of chickens available year round, not to mention the roosters, to help produce large numbers of eggs. And this, in fact, was called into play in this very response.

In addition, in May, we approved a new facility for a U.S.-based manufacturer that markedly increased the ability to produce vaccine.

Well, as a result of some of the work you've heard about, on September 15th, FDA approved what we called "supplements" to the licenses of four U.S.-licensed manufacturers of vaccines made to protect against the pandemic influenza "A" strain. This approval is consistent with how strain changes are approved each and every year for identically manufactured, licensed seasonal flu vaccines.

FDA is very experienced with the development and production of these vaccines which were produced, as I said, by identical license processes; and have an extensive track record of safety and effectiveness in the United States.

And as Dr. Fauci mentioned, and as with the currently licensed seasonal flu vaccines, none of these vaccines contain an adjuvant, because none was needed.

Well, given the lack of measured background, immunity to the 2009 virus circulating, as Dr. Fauci mentioned, clinical studies were undertaken so that we could be as informed as possible on how to use these vaccines. And as you have heard, the data available, to date, are very positive and show that again, like seasonal vaccines, a normal 15-microgram dose induces a great immune response that's likely to be protective both in healthy adults and older children. And the vaccine has been very well-tolerated.

I want to stress that these pandemic vaccines are subject to the same stringent manufacturing and quality oversight that's in place for licensed seasonal influenza vaccine. Make no mistake, we've worked very hard to get vaccine available as quickly as feasible, but no corners have been cut in this process. Each facility is inspected annually for compliance with good manufacturing practices. Extensive in-process controls and product testing are required at multiple stages of manufacturing. And each lot of vaccine must be reviewed and tested by the manufacturer, and results and samples of every lot provided to FDA. No lot of vaccine could be used until testing is completed and it's released by the manufacturer and FDA.

I'm a bit over my time, but I do want to mention something about safety and safety monitoring, since this is very important to everyone. We expect the potential side effects for the H1N1 vaccines to be mild and to be similar to those that follow the use of seasonal vaccines. Following a flu shot—which, in answer to the chairman's comment, you cannot get flu from the flu shot, the flu shot is a killed virus that has been purified to get the component of the virus that can help protect you. The most common side effect of a flu shot is soreness at the site of immunization. Some individuals may develop mild fever, body aches or fatigue that typically just last a few days.

From the nasal spray vaccine, which is a live, weakened virus that similarly cannot cause flu in an individual, side effects may include runny nose, nasal congestion, sore throat and fever. Although these kinds of mild reactions are to be expected, unexpected adverse events are a potential risk of any medical product, even those associated with such a long and excellent record of safety.

It is important to realize that every day in the United States, some previously healthy people will have serious and unexpected medical events, regardless of whether or not they have received a vaccine or any medical product. These are what we call "background rates," or cases of a disease that we would expect to see whether somebody receives a vaccine or not. It's important to realize that when a large number of people are going to get a product in a short period of time, we're going to see many people who, by chance alone, may experience serious events which coincide with the time period following immunization.

It will be challenging, but very important, to keep aware of this, and to distinguish such events from those that are expected to occur coincidentally from somewhere, or an unexpected event that could occur from immunization.

Therefore, we are working with multiple partners, in particular CDC and HHS, to not only do the rigorous vaccine safety monitoring that we do every year and with every vaccine, but with this vaccine to expand that monitoring, including numerous other partners of Federal agencies—the Department of Defense, Veterans Affairs, Centers for Medicare and Medicaid Services, our international partners, our State and local partners, and many others. So we're going to have a very augmented safety surveillance system in place.

While we are gratified that this vaccine will soon be available, there are many opportunities to further develop the science and capacity that we need to enhance our preparedness. And I particularly appreciated Mr. Issa's comments that this a continued—that while this is an event this year, it is continuing work to be prepared for this and similar other events that's going to keep our public-health system and our people best protected.

We clearly need more capacity, both in the United States and globally, to produce vaccines. Major investments by NIH at the basic science end, by HHS in advanced development on newer kinds of flu vaccines, are already kicking in. Cell-culture-based vaccines, recombinant vaccines, will provide us with increased capability. With your support, in FDA's laboratories, we are working on methods that will speed the evaluation and testing of the vaccine so it can help make vaccines available sooner.

Vaccines, though, are only part of the picture here. So while people tend to focus on them, we need to keep clear that there are lots of other opportunities. We need to take the opportunity to promote the development of new antivirals, rapid diagnostics' and enhanced safety surveillance, and a variety of public health tools. All of this will better prepare us to respond to the future threats that we know will also occur.

So, in conclusion, we are fully committed to and engaged in protecting public health during this very challenging time. Working together with our partners, we have made important progress in providing vaccines and other tools to help safely protect our population.

Again, I thank you for the opportunity to be here today, and we welcome your questions.

Chairman TOWNS. Thank you very much.

[The prepared statement of Dr. Goodman follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT OF
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
HEARING ON
"THE ADMINISTRATION'S FLU VACCINE PROGRAM: HEALTH,
SAFETY, AND DISTRIBUTION"
SEPTEMBER 29, 2009
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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Jesse Goodman, the Food and Drug Administration's (FDA or the Agency) Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs. In that capacity I have been leading FDA's efforts to respond to the novel 2009 H1N1 influenza virus. Previously, I directed the Agency's Center for Biologics Evaluation and Research (CBER), and have extensive experience in the development and evaluation of influenza and other vaccines. I have served as an advisor to the World Health Organization (WHO) on immunization programs and I am a practicing infectious disease physician.

I appreciate the opportunity to be here today to describe FDA's role in this continuing public health response. The ongoing collaborative response to this pandemic, including the success in producing vaccines, is a product both of hard work and continuing investment, including the support of Congress for the preparedness activities of the Department of Health and Human Services (HHS). These initial results have been gratifying, although significant challenges remain. Today, I also will highlight opportunities to continue to enhance our nation's pandemic vaccine preparedness and response capacity.

FDA plays a vital role in U.S. and global preparedness for, and response to, challenges such as those presented by the 2009 H1N1 influenza virus. FDA is part of a team of HHS agencies. When the 2009 H1N1 influenza virus emerged in the spring, FDA immediately established an incident command system to speed and coordinate our response and to facilitate collaboration with and outreach to our external partners. All FDA Centers are engaged in this incident

command system, which includes several focused teams (e.g., Vaccine, Antiviral, Diagnostics, Personal Protection, and Consumer Protection), as well as Operations, Logistics Communications, International and Legal components. This approach allowed us to work hand in hand with our sister HHS agencies, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), to rapidly mobilize the emergency public health response. This effort included FDA's issuance of Emergency Use Authorizations for needed antiviral and diagnostic products, and enabled us to immediately initiate the complex process of preparing a vaccine. As you have heard, the good news is that the vaccine development effort has succeeded. The initial doses of licensed vaccines will be available very soon. These are made in the same manner as the millions of doses of seasonal influenza vaccines that are made and used safely every year.

Developing Vaccines

From the beginning, FDA worked tirelessly with our sister HHS agencies, other U.S. government agencies, WHO, foreign governments, regulatory agencies, and vaccine manufacturers to facilitate the production and availability of safe and effective vaccines against this virus. FDA/CBER and CDC are WHO Collaborating Centers, and as such, have a long history of working together and with global partners. Each year, based on surveillance data about influenza strains circulating throughout the world, WHO and FDA typically recommend changes in some of the three influenza strains contained in seasonal vaccine. Every year new influenza vaccines are made and each year can present new challenges. While we have both exercised our plans and built our capacity, our intense activities preparing for the seasonal

influenza every year, have been excellent preparation for us to handle the demands of an influenza pandemic.

Immediately after this novel H1N1 virus was detected, FDA began working with CDC and other laboratories around the world to generate the influenza virus reference strains that were needed to begin vaccine manufacturing. FDA and other key international regulatory laboratories developed and calibrated the vaccine potency reagents needed by manufacturers to make their vaccines. We worked with NIH and all U.S.-licensed manufacturers to design and help rapidly mobilize efficient clinical studies to evaluate candidate vaccines. These studies were designed to help determine the optimal number of doses (one or two) needed to protect people of different ages, and whether a higher-than-normal dosage of vaccine or vaccine-containing adjuvants (which can boost the immune response) might possibly be needed.

Enhancing Influenza Vaccine Infrastructure and Capacity

With the support of Congress, FDA and our sister HHS agencies have been engaged for several years in a continuing effort to strengthen influenza vaccine infrastructure and pandemic preparedness. This has helped significantly in the response to the 2009 H1N1 influenza virus. After 2004 when a major manufacturer could not provide vaccine to the U.S. market, we took several important steps to enhance the capacity and diversity of our supply, as well as to better prevent and detect potential manufacturing problems. We encouraged manufacturers of influenza vaccines licensed elsewhere to work with us and seek licensure in the United States. As a result of such efforts, in the last five years the number of U.S.-licensed influenza vaccines

increased from three to six, and seasonal vaccine production increased from 55 million doses in 2004 to an estimated 115 million for this 2009/2010 season.

The Biomedical Advanced Research and Development Authority (within the HHS Office of the Assistant Secretary for Preparedness and Response), working closely with FDA, has taken a number of additional steps that have put us in a much better position to respond to a pandemic. Examples include keeping a year-round egg supply to allow vaccine production at any time and supporting the retrofitting of a U.S.-based manufacturing facility, licensed on May 6, 2009, that substantially increased manufacturing capacity. Throughout the spring and summer, we actively engaged with HHS colleagues and manufacturers to increase capacity in order to speed and increase vaccine availability. In addition, FDA and our sister HHS agencies have worked with WHO to support global regulatory, technical, and manufacturing capacity, including HHS support of grants to developing countries to build influenza vaccine manufacturing capacity.

Licensure of the Influenza A (H1N1) 2009 Monovalent (Single Strain) Vaccines

On September 15, 2009, FDA approved supplements to the existing biologics license applications of four U.S.-licensed manufacturers for vaccines made against the Influenza A (H1N1) virus. These vaccines are made by CSL Limited, MedImmune LLC., Novartis Vaccines and Diagnostics, Ltd., and Sanofi Pasteur, Inc. As with the currently licensed seasonal influenza vaccines, none of these vaccines contain an adjuvant.

Each year the new seasonal influenza vaccine formulation is licensed as a “strain change supplement” to each manufacturer’s existing U.S. license. FDA is very experienced with the

development and production of these influenza vaccines, which are produced by the identical licensed egg-based manufacturing processes and which have an extensive track record of safety and effectiveness in the United States.

FDA determined that a monovalent influenza vaccine manufactured according to the same process as licensed seasonal influenza vaccines, but formulated to contain the pandemic 2009 H1N1 influenza virus strain antigen, could be approved as a strain change supplement to existing licensed influenza vaccines. This is consistent with how strain changes are approved each year as supplements to licensed influenza vaccines, which include seasonal H1N1 strains. This proposed regulatory pathway to licensure was discussed in an open public meeting of FDA's Vaccines and Related Biological Products Advisory Committee (the Committee) on July 23, 2009. Presentations were made by representatives from FDA, our sister HHS agencies, NIH and CDC, and industry. The Committee supported FDA's proposed regulatory strategy for approving the pandemic H1N1 strain change.

FDA does not require clinical studies for strain changes for U.S.-licensed inactivated influenza vaccines. However, clinical studies were undertaken with vaccines made from this strain, because it was important to determine the optimal dosage and number of doses, given the lack of measured background immunity to the 2009 H1N1 influenza strain. The clinical studies were intended to inform whether the 2009 H1N1 influenza vaccine, when given at the usual dose used in seasonal vaccines, is optimally immunogenic (able to generate an immune response likely to protect against infection), and whether older children and adults, who normally need one dose of seasonal vaccine, might need two doses. FDA worked with manufacturers and NIH to design these clinical studies. As mentioned, the data available to date from several of the trials,

including from our colleagues at NIH, show that a single dose induces a good immune response in healthy adults and is well-tolerated. Preliminary data from NIH trials in children were released on September 21. These results indicate that the immune response in 10 to 17-year-old children also is similar to the seasonal influenza vaccine in that a single dose produces a good result. As is the case with seasonal influenza vaccines, younger children generated a less robust immune response to one dose of vaccine, and are likely to require two doses. Again, the vaccine was well-tolerated. Trials in pregnant women have just begun and preliminary results will be available in late October. As with seasonal vaccines also recommended for pregnant women, it is expected that a single dose will be immunogenic and well-tolerated.

VACCINE QUALITY AND SAFETY

Manufacturing and Quality/Safety Oversight

While FDA has been a key participant in building capacity and helping the vaccine enterprise to meet public health needs, we have a particularly important and unique role in the oversight of vaccine quality and safety. These pandemic 2009 influenza vaccines are subject to the same stringent manufacturing and quality oversight processes that are in place for licensed seasonal influenza vaccines. Each facility is inspected annually for compliance with current Good Manufacturing Practices. Extensive in-process quality control and product testing (such as for potency and purity) are required at multiple stages of the manufacturing process. Each lot of vaccine manufactured must be reviewed and tested by the manufacturer, and results and samples of every lot must be provided to FDA. No lot can be used until testing is completed and it is released by the manufacturer and FDA.

Vaccine Safety and Safety Monitoring

We expect potential side effects for the H1N1 vaccines to be similar to those seen following vaccination with seasonal vaccines. Following injection, the most common side effect is soreness at the injection site. Other side effects may include mild fever, body aches, and fatigue for a few days after inoculation. Following inoculation with the nasal spray vaccine, the most common side effects include runny nose or nasal congestion (for all ages), sore throats (in adults), and fever (children two to six years of age). Although we expect potential side effects to be similar to seasonal vaccine, unexpected rare adverse events are a potential risk of any medical product, even those associated with a long, excellent record of safety. Therefore, FDA and CDC, working with multiple partners, will very closely monitor the safety of the 2009 H1N1 influenza vaccines.

Every day in the United States some previously healthy people will have serious and unexpected medical events, regardless of whether or not they have received a vaccine or another medical intervention. These are what we call “background rates” or the cases we would expect to see whether people are vaccinated or not. It is important to realize that given the large number of people who are likely to receive the 2009 H1N1 influenza vaccines, some previously healthy people will, by chance alone, experience serious and unexpected medical events which will coincide with the time period after immunization. It is challenging, but important, to distinguish such events that are coincidental and not caused by vaccine from unexpected rare events that may be related to immunization. Therefore we recognize the need to prepare for a possible increase in the number of reports of potential adverse events and to rapidly detect and accurately evaluate those reports associated with the use of these vaccines.

FDA is collaborating with CDC and other components of HHS, and with other government agencies, to enhance the capacity for adverse event safety monitoring during and after the 2009 H1N1 influenza vaccination program. Efforts are underway to establish a robust network to share information in real time. The network will build on the well-established Vaccine Adverse Event Reporting System and Vaccine Safety Datalink by integrating capabilities from the Department of Defense, Department of Veterans Affairs, and Centers for Medicare and Medicaid Services, as well as state, territorial, tribal, and local public health medical and private sector health care entities. FDA also is engaged with international regulatory partners on pharmacovigilance planning efforts. This is part of an over-arching effort by the Federal Immunization Safety Task Force led by the HHS Assistant Secretary for Health and the HHS Assistant Secretary for Preparedness and Response. FDA also is participating with others in a preparedness exercise to improve coordination and collaboration between agencies once reports begin to come in.

Looking Ahead

Much has been accomplished in a very short time by the strong collaborative efforts of those working inside and outside our government. While we are facing and responding well to this public health challenge, we should ask ourselves, even in the midst of it, what can we learn to do better? While we are gratified that vaccine will soon be available, there are many opportunities to continue to develop the science and capacity needed to enhance our pandemic vaccine preparedness for potentially even more serious outbreaks.

First, we need more capacity, both in the United States and globally, to produce vaccines. In the United States, major investments in advanced vaccine development and manufacturing capacity, which include vaccines manufactured in cell culture systems or by use of recombinant

technologies, may offer a number of advantages in scalability and reliability. These efforts are ongoing. There are instances in which adjuvanted influenza vaccines may be needed or desirable, for example, when an antigen alone cannot induce an adequate protective immune response, or to help address dramatic shifts in strains that might occur as an outbreak evolves. HHS is funding the development and careful evaluation of such adjuvanted vaccines. At FDA's laboratories, we are conducting collaborative applied regulatory research to improve the assays, reagents, and tests needed to more rapidly and accurately evaluate, produce, and test the quality of current and future influenza vaccines. This work has the potential to expedite vaccine development, speed availability, and ensure vaccine quality using the most modern scientific methods. Ongoing scientific efforts at NIH and FDA are evaluating even more advanced approaches, such as DNA vaccines and "universal" influenza vaccines, which potentially may protect against multiple and evolving influenza strains. Although we already participate in collaborative work and technical assistance through WHO, a much broader global collaborative effort would be desirable.

Vaccines are only part of the picture. As we respond to this pandemic, we also should take the opportunity to learn from this novel virus and the public health response, in order to promote the development of needed antivirals, rapid diagnostics, and enhanced safety surveillance capacities, and identify remaining scientific and public health questions. Our continued work, from basic and applied science to the medical products and public health interventions that may be used to protect people in the United States and around the world, will benefit us in preparing for and responding to future biological threats.

CONCLUSION

FDA is fully committed to and engaged in protecting the public health during this challenging time. We believe we have an exceptional team in place to handle the challenges of the 2009 H1N1 influenza virus and continue to receive excellent cooperation and input from other government agency partners. I thank you for the opportunity to testify today and will be pleased to answer any questions from Members of the Committee.

Chairman TOWNS. Let me thank all three of you for your testimony.

Let me begin by asking you, Dr. Frieden and Dr. Fauci, should the American public be more frightened about the H1N1 influenza than the seasonal influenza?

Dr. FRIEDEN. H1N1 influenza is what we have spreading widely in the United States today. And so that's what is the dominant strain. But the bottom line is that anyone who has a mild illness should know that for most people, neither testing nor treatment will be indicated. If, however, you are severely ill, you have difficulty breathing, or if you have an underlying condition, such as diabetes, or heart disease or lung disease, children with certain neuromuscular problems that make it harder for them to breathe, or women who are pregnant, then it would be quite important, if you have fever, flu-like symptoms, to get to see your doctor and get treated promptly, because that can make a big difference.

And over the coming weeks, vaccine will become available and it is recommended that people get vaccinated. Seasonal flu kills approximately 36,000 people each year in our estimates. Although the pandemic influenza, or H1N1 influenza, is not affecting the same age groups, it is making many millions of people sick. Vaccine is our best tool, and until vaccine is available, and even afterwards, there are some simple things that people can do to protect themselves, their families and their community.

Stay home if you're sick, it doesn't do yourself or others around you a favor to go out if you've got a fever or are coughing and could make others sick as well. Cover your cough—cover your mouth when you cough or sneeze, and wash your hands frequently. These three simple steps can make a big difference in how rapidly and widely flu spreads in a community.

Up until now, we see that H1N1 is spreading more widely than seasonal flu generally does and in somewhat different age groups: more young people affected, fewer older people affected, and the level of severity is no more than seasonal flu, but we also don't see it as being less than seasonal flu.

Chairman TOWNS. Dr. Fauci.

Dr. FAUCI. Yes, I just—to reiterate, we should take all influenza seriously, both seasonal flu as well as the situation we are facing now with H1N1 pandemic influenza. As Dr. Frieden mentioned, the burden of disease in seasonal flu is 36,000 people each year die, and 92 percent of them are elderly individuals. And the majority of those—when I say “elderly,” I mean older than 65—and the majority of them are 80 and older. So that is an important burden of disease in that age group.

The difference, as you've heard from all of us with regard to H1N1, although it doesn't appear to be more severe in general in the big picture than a seasonal flu, it has a propensity to infect younger individuals in greater quantities. And a certain percentage of them, unfortunately, would go on—a very small percentage, but nonetheless any death in a young person is a tragedy. And under these circumstances we're trying to avoid people getting infected by vaccination. And you know the target groups include pregnant women and younger individuals who are more vulnerable to what we call the complications of influenza, and that's the reason why

we want to stress the importance of people within those priority groups of getting vaccinated.

So, you asked should we be worried and concerned? I would say that we should pay attention to it and follow the guidelines of the Centers for Disease Control and Prevention.

Chairman TOWNS. This is to you, Dr. Goodman. This vaccine, how can we be assured of its safety and its effectiveness?

Dr. GOODMAN. Well, the good news is we were able to get vaccines made that are completely made in the identical way, in the same licensed FDA overseeing manufacturing facilities with all the same testing as the seasonal flu vaccines we use in over 100 million people every year. So these are very tried and true vaccines. The safety record of them has been outstanding over many years.

In terms of their effectiveness, there are circumstances, such as when the flu virus is different in the vaccine than what's out there, where the vaccine is sometimes not as effective as we like.

In this case, we believe that the vaccine is likely to be highly effective. We won't know until it's used, but that's our belief, based on the best science. And the reason for this is No. 1, as Dr. Fauci has said, it induces a really strong and good immune response in the people who have been getting it. It is an immune response that typically correlates with protection against the virus and protection against some of the serious complications, like ending up in a hospital or worse.

The other reason is that, as Dr. Frieden said, all of our surveillance shows that up to now this virus hasn't changed. So the virus and the vaccine strain used to make the vaccine is virtually identical to what's circulating out there. And under those circumstances, we expect vaccine to be effective.

Chairman TOWNS. Thank you very much. My time has expired.

I yield 5 minutes to the gentleman from California, Congressman Issa.

Mr. ISSA. Thank you, Mr. Chairman.

I think all the witnesses did spend some time talking from terms of safety, perhaps because there has been so much additional concern for this new vaccine.

Let me go through a couple of quick questions and I'm going to try to be as accurate as I can in who answers them. But the idea that health-care professionals, first responders, and hospital personnel would be required to mandatorily receive these shots, can somebody make the case for that, because there seems to be a very specific pushback from that industry of people who find the odds versus the side effects unacceptable?

Dr. FRIEDEN. The first thing I would make clear is that there is no Federal mandate for any individual to get vaccinated.

Mr. ISSA. OK. So the Washington Post, "Mandatory Flu Shots Hit Resistance" is premature?

Dr. FRIEDEN. There is no Federal mandate.

Mr. ISSA. OK.

Dr. FRIEDEN. At least one jurisdiction has mandated that unless there is a religious exemption or a medical exemption, such as an allergy to eggs, that health-care workers be vaccinated.

Mr. ISSA. Since all of you are at this level, can you make a case for whether the State has a compelling interest for that one State

versus the other? In other words, if the State is right, then why aren't we doing it from this dais? And if the State is wrong, then are the people being adversely forced to do something that is probably outside the need of government?

Dr. FRIEDEN. This is something that has been debated for some time, even before pandemic influenza came along this time around. In fact, the mandate that the State of New York implemented was prior to the emergence of H1N1 influenza and unrelated to it.

The argument is a simple one and an important one. The evidence is clear that many patients become ill because they get infected with influenza from health-care workers. Furthermore, health-care workers are themselves at risk of contracting influenza at their workplaces and of bringing it home to their families. There are other vaccinations such as measles, which are required of health-care workers, and other annual programs such as testing for tuberculosis infection, which are required of health-care workers. Our sense is that this particular season, in the midst of a pandemic, is not the time at the Federal level where we would start a new mandate along those lines, but the important point to make is we really do want health-care workers to get vaccinated for their own protection, the protection of their families, and the protection of their fellow workers.

Mr. ISSA. So to view the cliff notes in my short 5 minutes, you are not prepared to support it at this time but you are not ruling out supporting it at a national level?

Dr. FRIEDEN. Not this year.

Mr. ISSA. OK. And I'm going to leave all of you a copy of H.R. 1478, which is from the gentleman from New York, Mr. Hinchey, and I just would like you to followup. It's a bill that would make the Armed Forces and ultimately all government—the goal is to make all government entities liable for litigation for their actions; in other words, open them up to malpractice suits and the like.

And I would like you to respond on specifically, relative to your agencies which enjoy liability limitation as government entities over and above all over narrow ones, how it would impact your agencies if you were fully able to be sued by the public, by class action lawsuits for any and all things which you decide to do.

And I'm doing this for a reason, at a time of—first of all, because I'm on the dais and it is my 5 minutes. But second, because at a time in which we're talking about health care—and Mr. Kucinich talking so boldly about your public option—there's a number of pieces of legislation coming through that would open up the government option to litigation. And I'd like each of you to give me your view of how you are able to do your job without having to worry about, excessively, the fact that you might be sued for anything that goes wrong. And if you could respond in writing, because I realize that's far more than you might be able to do.

Last question. The H1N1 vaccine is for a different group than the flu virus vaccination, as a whole. Could you give us your breakdown of, in an ideal world, if you only had 10 million or 12 million or 15 million doses, who should get it first? And I say this because we're dealing with seniors versus non-seniors, children who have been reported actually having a lower incident or problem, and this unusual bulge called "Middle America," healthy young people who

seem to be at the highest risk, and how that plays for our consideration of dollars and the public message.

Dr. FRIEDEN. We're confident that eventually there will be enough vaccine for everyone to receive it who wants to receive it, in terms of H1N1 influenza. Each year for seasonal flu, we vaccinate about 100 million people. There is also going to be enough seasonal flu vaccine around, and anyone who wants seasonal flu vaccine can receive it, really.

For the H1N1 vaccine, there are five key priority groups. This doesn't mean that we deny it to other people, but we prioritize these groups: pregnant women, people with underlying conditions, health-care workers, people who are contacts of people, infants under the age of 6 months, who cannot themselves be vaccinated, and then children and young adults 6 months to 24 years.

Mr. ISSA. OK, Mr. Chairman, I think others may want to respond, but I do want to thank you and mention that in this case, since there is a controversy, I intend on getting one of these shots if for no other reason than to show that I believe that it's safe and effective. If anyone else wants to respond.

Thank you, Mr. Chairman.

Chairman TOWNS. Thank you very, very much.

At this time, I yield 5 minutes to the gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Thank you very much. And thank you, gentlemen, for your excellent testimony.

Dr. Fauci, one of the things that I'm very concerned about is the elderly. We have in my district probably 100 senior houses with at least 400 or 500 elderly. And I'm just wondering—they are locked into a situation, they don't have isolation and things of that nature. I was with two groups of elderly people yesterday, and they expressed some concerns about the vaccine. And I'm just wondering, how—what is your advice to that population? You have some people who—like one gentleman said, he said, I'm stuck in my ways and I'm not sticking a needle in my arm." And I mean, that's what he said. And so I'm just—how do you deal with that population?

Dr. FAUCI. Well, what we try to do is to explain to them in a way that's clear, that they can understand, the risk at their age of getting—let's start with seasonal influenza first, because seasonal influenza is available right now. And since the elderly are the ones that suffer most from serious consequences, I mentioned a while ago, just a moment ago, 36,000 deaths each year, 92 percent of which are in individuals 65 years of age or older. I would encourage them to get this vaccine as soon as they can, even though they may have skepticism about vaccine.

Whenever you make a decision about an intervention versus what it might do for you, you do what is called the "risk-benefit" analysis. And I think if you look at the risk of the vaccine that has decades of a good track record for safety, and the risk of an elderly individual who gets influenza coming up with serious complications which might trigger a very difficult clinical course for them, in my mind and in the mind of people who do this every day, it overwhelmingly weighs toward getting vaccinated if you are an elderly individual.

If you are thinking about H1N1, as Dr. Frieden just mentioned, there are five target groups. Of those target groups, since the elderly individuals greater than 65, if you look at what's happened over the spring and in the summer and in the southern hemisphere over the year, the individuals who are in that elderly group do not appear to be particularly susceptible to the H1N1. That doesn't mean that they shouldn't get it. We just would like to get the people who are in the five target groups vaccinated first, and then virtually anyone can get vaccinated.

And as we all mentioned, we feel confident that we will have enough vaccine at the end of the day for everyone.

Mr. CUMMINGS. The other population was the HIV population.

Dr. FAUCI. Right.

Mr. CUMMINGS. As you know, being from Maryland, that 50 percent of all our HIV cases are in Baltimore. Ninety percent of them are African American.

Dr. FAUCI. Right.

Mr. CUMMINGS. And you talk about trials still being conducted, and I know you're not—you don't have a magic ball, but do you predict that they are going to—I mean that it will be safe for people with—suffering from HIV?

Dr. FAUCI. Yes, I have little doubt that there would be any difference in the safety profile, Mr. Cummings, between the H1—excuse me, the HIV-infected individuals and uninfected individuals. The issue when you're immunosuppressed—which is what HIV does, it diminishes your ability to respond immunologically—that they may not have as robust a response to the vaccine, but they can still get considerable benefit of it. And since they are an immune-compromised group, even without clinical trials, I would like to see them get vaccinated as part of the group that's particularly susceptible for getting complications from it.

Mr. CUMMINGS. Thinking back on some comments of Mr. Kucinich and Mr. Issa, are you concerned that our health system will be able to appropriately—or any of you can answer this, address these issues? I mean, we've got a lot of people, of course, with no insurance. We have folks underinsured. We have people who don't have as much access as others do to sufficient health care. Is this a concern of yours? Is there a certain point where you can see us getting sort of overloaded with regard to these cases? It seems like it takes—you get to a certain point with the disease, and it seems it takes some intensive medical care.

And I was just wondering, where are we on that and what do you predict? And if such should take place, what plans do you have ready to go into operation? I don't want us to have another Katrina-type situation where we say that we're ready for something, and then when the time comes, there is—we say wait for the rubber to meet the road, and then we discover there is no road.

Dr. FAUCI. There will be challenges for sure, particularly when you have widespread outbreaks in various regions of the country, as we are seeing even right now in certain regions of the country. Tom.

Dr. FREIDEN. I think that the reality is that our health-care system doesn't currently have a good information system that would allow us, for example, to call back everyone who needs to be vac-

minated. It doesn't have good coordination that would allow us to share information and share resources within areas in most parts of the country, and it doesn't emphasize prevention. So we have vaccination practices that aren't as good as we would like in some groups of doctors, for example, obstetricians, as we try to get pregnant women vaccinated. So I think the challenges that we face in health care, and I think everyone can identify many of those, are going to be played out in this.

Also the response is going to be a State-specific response. So States that are better prepared to operate a vaccination program, or which have more resources for surge, will be better prepared to deal with it.

Health and Human Services, with support of the Congress, has provided more than \$3 billion in hospital preparedness over the past 7 years for additional ventilators, for exercises, for surge planning and preparations, and I think we are much better off with those preparations that have occurred so far.

But the challenges are real. The virus is potentially spreading rapidly. We do want to encourage people who are not severely ill and don't have underlying conditions not to go to emergency departments, because we have seen in parts of the country where that happens, that can make it very difficult for the emergency departments to manage. It is a shared responsibility between many different parties.

Chairman TOWNS. The gentleman's time has expired, but we will have another round.

The gentleman from Ohio.

Mr. KUCINICH. You know, that is precisely the point, though. We have a primary health-care system which is not widely available to all Americans, with 47 million Americans without any insurance and emergency rooms generally ending up as the place where people go to get care, at least those 47 million people.

So you may say that we spent \$3 billion to try to improve the surge capacity of America's hospitals. But so many of America's hospitals right now are locked into a system where they are actually rewarded for turning people out of a hospital bed in a few days, whereas if people are hit with H1N1, they are quite likely to require hospitalization.

I just want to go back to the point that I made, Mr. Chairman, which I appreciate my colleague Mr. Cummings reiterating, and that is we cannot forget the broader context of health care in America, where people are actually in a weakened state because of this for-profit system, because they don't have access to health care until they get really sick and then the costs go through the roof. So let's politicize this moment, because this is one of those moments where we need to look at the bigger picture at the same time we are looking at H1N1.

I also want to ask Dr. Freiden, we are talking about H1N1 vaccine here. Let's for a second go to the seasonal flu vaccine. We lose about 36,000 people every year because of seasonal flu. The CDC Web site says that the initial distribution of vaccine every year at the beginning of the season is critical to protect those who are most vulnerable, such as the elderly, that Mr. Cummings is mentioning.

Now I am hearing from one of our staffers, who is a physician, Dr. Lopez in our Cleveland office, says that in Cleveland, chain pharmacies will have an ample supply of the flu vaccine, while doctors are still waiting for shipment that they would want to give to their patients.

Have you heard about anything like this and is this a nationwide problem?

Dr. FREIDEN. In terms of the seasonal flu vaccine, there will be something on the order of 114 million doses available this year. There have already been more than 50 million doses distributed throughout the country. And while there may be some focal areas with shortages, there is going to be plenty of seasonal flu vaccine for anyone who wants it.

The seasonal flu vaccination program is 90 percent through the private and voluntary sector, and not through the government sector. The H1N1 response will be ordered a little differently to try to ensure that there is access and efficiency to the system.

In this, the seasonal flu vaccine, whoever orders first gets first, so there sometimes are focal shortages in different areas. But the big picture is, at least for this year for seasonal flu vaccine, there is plenty available.

Mr. KUCINICH. We are hearing from doctors who say they ordered it and drugstore chains are getting it ahead of the doctors. Do you know how it happens?

Dr. FREIDEN. It has to do with when it is ordered. So the earlier in the season that a provider or pharmacy orders, the earlier they are likely to get it. As we have the H1N1 system, we are not using that system. We are using a different system which will give the State health department or the State government the authority to authorize where within the State it would go, and provide equity across the State and the country in terms of availability, as well as, to try to get it out to places that don't usually vaccinate for H1N1, such as schools.

Mr. KUCINICH. Who is paying for that vaccine, the seasonal vaccine?

Dr. FREIDEN. The seasonal vaccine is paid for as the health-care system generally pays for things, a mix of payers. For H1N1, it is entirely paid for by the Federal Government.

Mr. KUCINICH. So when it comes to the seasonal flu vaccine, if it goes to the drugstores first, or the chain stores, is it possible that people could end up paying more for that than if they just went directly to their doctors?

Dr. FREIDEN. It would depend on the original charges, doctors versus other providers.

Mr. KUCINICH. I really think you should look into this thing where doctors who deal with patients on a regular basis are having difficulty getting flu vaccine, and the chain drugstores somehow are getting in ahead of the doctors. That doesn't seem logical and it doesn't seem fair.

Now, the CDC Web site says, "Influenza vaccine production and distribution are primarily private sector endeavors. The Department of Health and Human Services and CDC do not have authority to control influenza vaccine distribution nor the resources to manage such an effort."

Can you please clarify who in the private sector controls who gets the vaccines first?

Dr. FREIDEN. The CDC provides guidance and some resources for planning. Ultimately, it is a decision of each doctor, each medical provider, each patient, of whether or not to order the vaccine and whether or not to give it or receive it.

Mr. KUCINICH. Who in the private sector controls who gets the vaccine first? You didn't answer the question.

Dr. FREIDEN. It depends on when it is ordered. So the earlier orders get filled first, in general.

Mr. KUCINICH. Thank you, Mr. Chairman.

Chairman TOWNS. Thank you very much.

I now yield 5 minutes to the gentlewoman from California, Congresswoman Diane Watson.

Ms. WATSON. Thank you, Mr. Chairman, for holding this most significant and critical hearing. I just have to followup on something that my colleague Mr. Kucinich said.

You know, this has to be a teaching moment as well, because I just saw a television advertisement saying we don't want government to run health care.

What would happen if this particular flu spreads across, as it is doing now, and if government wasn't there? We are indeed the safety net.

Let me get into what I was prepared to say. As a result of the Nation's economic conditions and ensuing budget crisis, my State, the State of California, has had to make millions of dollars in cuts to our State and our local health departments and programs.

Is there any fear that the economic crisis that States such as California—and there are others too—are facing will have an effect on pandemic preparedness, or their ability to effectively and efficiently distribute the H1N1 vaccine?

And thank you so much, experts, for using "H1N1." We are trying to teach our constituents that it is not the swine flu. So thank you for reinforcing H1N1.

Can you respond?

Dr. FREIDEN. Yes. We are quite concerned about the State and local public health departments. We have seen decades of under investment in public health and the public health infrastructure that has been exacerbated over the past couple of years with the economic crisis, so we are seeing layoffs, attrition, furloughs, freezes, in terms of hiring. This makes it even more challenging to implement the vaccination and overall response program.

We have provided now, or are in the process of providing now, nearly \$1.5 billion to State and local governments for preparation, planning and vaccine administration. We are providing the vaccine free of charge, along with needles and alcohol and disposable equipment that would be needed with it. We are providing technical assistance and guidance.

I think we will inevitably see some variability in the separate States, with some better prepared and some less well prepared. The CDC has staff on the ground, in the field, in virtually every State in the country, and we provide whatever assistance we can. But again, it is a shared responsibility, and the State government

does have responsibilities, as does the local governments, as does the Federal Government.

Ms. WATSON. My concern is that being the largest State in the Union, and California being the first State that is a majority of minorities, and most of our immigrants come across the Pacific and not always over our southern border, and people are coming already infected, or not having 1 day of health care, so it hits our State with a greater wallop than a lot of others because of the demographics.

During the initial H1N1 outbreak in the spring, it is important to note that there are probably a lot of people who actually contracted the H1N1 virus but never got it specifically diagnosed, and that relates to what I just told you about the demographics, believing it to be the usual seasonal flu virus.

Do those people who have unknowingly had the H1N1 flu have the potential of any extra risk or complications when getting vaccinated?

Dr. FREIDEN. For most people with average flu, there is no reason to be tested or treated. So the fact that they weren't is not going to harm them. However, anyone who is severely ill, or has underlying conditions, should be promptly attended to, to reduce the risk of severe illness. So most people who had the flu in the spring won't know whether it was H1N1 or not. We recommend that they all get vaccinated. And there is no reason to suspect that the vaccine would be risky or riskier for people who have had the infection before.

Dr. Fauci.

Dr. FAUCI. Actually not at all. I agree completely with Dr. Freiden. If you have gotten H1N1, for example, in the spring in school, we'll say, and then we come back now and you want to vaccinate a child—first of all, the vast majority of times, you won't definitely know that you had H1N1, though you could assume that if it was rampant in the community. But there is no evidence scientifically at all that suggests if you then get vaccinated with a vaccine against H1N1, you are at any greater risk for toxicity or any adverse event.

Ms. WATSON. Thank you very much.

Chairman TOWNS. Thank you very much.

I now yield 5 minutes to the gentleman from Virginia, Mr. Connolly.

Mr. CONNOLLY. Thank you, Mr. Chairman, and thank you for holding this hearing on a subject that is so important to the American public and to American public health. And welcome to the panel.

In 1917, the original influenza strain that struck in Kansas was mild, not severe, eerily similar to the way you described this strain, and involved initially in the town it hit no fatalities; is that not correct?

Dr. FREIDEN. The best available evidence is that the first wave or waves of the pandemic in 1917 to 1919 were mild, followed by more serious waves.

Mr. CONNOLLY. As I understand it, what changed, what allowed the strain to become lethal, was it jumped into mustering camps? It just so happened that the United States was now mustering

large groups, concentrated groups in overcrowded conditions, of young men who were being trained to go to the trenches in France in World War I. And when the influenza strain went from that Kansas town to the nearby military camp, it transmuted into something far more lethal that led to many deaths and then spread around the country.

Is that true?

Dr. FREIDEN. There are a lot of different theories about what happened in 1918–1919. It is clear that crowded conditions such as barracks are breeding grounds for influenza, as well as, other infectious diseases. There are some theories that it was actually demobilizing individuals coming back to the United States that may have brought the flu.

Why there was apparently a mild spring wave followed by a severe fall wave is, as far as I know, not definitively known. Perhaps Dr. Fauci would like to comment further.

Dr. FAUCI. No, it really is all theory and hypothesis. Of note, which people don't fully appreciate, is that the virus that was in that early spring wave, as they call it, that virus has never been isolated or identified.

The virus that hit like a vengeance in the late summer and fall of 1918, that virus has been dug up and sequenced, and we know what that virus is. We have no idea what the relationship between that virus is and the virus from the spring, because we have never had any isolates that have been molecularly analyzed. So it really is just a big theory.

Mr. CONNOLLY. So, Dr. Fauci, they could have been actually two different strains?

Dr. FAUCI. It absolutely could be two.

Mr. CONNOLLY. Now, you touched on the fact that you have sort of five targeted groups for vaccination for H1N1, and I was heartened to hear you say that the recognition included in there that actually it seems to affect the over 65 population less severely than some of the others. That was the characteristics of the pandemic of 1918 as well, was it not, that actually the most affected group in terms of severity and lethality was actually the sort of 15 to 5, when young people's immune system was at the peak performance, but it kind of went into hyperdrive and overreacted to the introduction of this, and a lot of young people turned out to be more vulnerable. Is that correct?

Dr. FAUCI. It is a very interesting question. There are two aspects to what you said. If you have a 65- or 70-year-old person who is less susceptible to getting infected in the first place, it is likely that person during the experience in their lives, decades and decades before, came into contact with a virus that had some degree of similarity, which provided for them a background type of immune response so that they were able to avoid infection with the particular virus.

In fact, this may be exactly what is going on right now with elderly individuals who seem less prone to get infected with H1N1 because of prior experiences that they have had during their years either of previous exposures to viruses, or even previous vaccinations that they may have had. That is one issue.

The other issue, which dates back to the hypothesis from 1918, is that young people who do get infected have such a vigorous inflammatory immunological response, that it is conceivable, though not completely proven but not an unreasonable hypothesis, that the actual response to the virus in a vigorous, healthy young person allows for a greater damage to the lung tissue and an outpouring of inflammatory cells. So there are two issues going on; there is prior exposure, and the strength of your immune response.

Mr. CONNOLLY. Certainly the accounts from 1918 are legion of precisely that: young people healthy in the morning and dead by night.

Dr. FAUCI. Right.

Mr. CONNOLLY. Let me just ask a final question. This has implications for, if you will, triage and the distribution of vaccines should it be in short supply. A few years ago, for example, we had a scarcity of flu vaccine, as you will recall. Automatically the protocol was, all right, whatever supply we have is targeted for the most vulnerable, people over 65 and very young.

In this particular case, that would be the wrong model, would it not?

Dr. FREIDEN. Right. And that is exactly what we are most concerned about and exactly what we are doing, which is to prioritize to the groups that would be at highest risk of severe illness, and also to monitor very intensively. So every day, samples are sent to CDC and we analyze the data to see whether we see any change in the level of severity or in the genetic pattern of the virus that would suggest that it could become more deadly. And the good news is that up until now, we have not seen any significant change in the pattern of the virus, nor in the pattern of illness in people.

Mr. CONNOLLY. I thank the Chair.

Chairman TOWNS. Thank you very much.

I now yield 5 minutes to the gentleman from Maryland, Congressman Van Hollen.

Mr. VAN HOLLEN. Thank you, Mr. Chairman. I also want to thank all of the witnesses for their testimony.

I want to pick up on the question of Mr. Connolly. First, to get some of the facts in terms of the age distribution of the impact of this disease, because that does seem to be very different than the kind of flus that we have been used to addressing.

With respect to the 593 deaths so far from this H1N1, first, is that the number that you have? Is that correct; 593 deaths in the United States?

Dr. FREIDEN. We continue to count deaths each week, so the number continues to increase.

Mr. VAN HOLLEN. What is the age distribution? Dr. Fauci said with respect to seasonal flu, as I understood it, about 92 percent-plus deaths were in the 65-plus age range, with a lot of those being in the 80-plus.

With respect to the deaths so far from H1N1, what is the age distribution?

Dr. FREIDEN. We have seen very few deaths in people over the age of 65, there have been about 50-plus deaths in children over the age of 18, and the bulk have been in that young-to-middle age group. About two-thirds to 70 percent have been among individuals

who have underlying medical conditions, such as diabetes or lung disease, asthma or other problems.

The level—the hospitalizations have followed a similar pattern, although slightly different in terms of people with asthma maybe being hospitalized more, but less likely to die, people with diabetes or underlying conditions more likely to unfortunately, tragically, die.

Mr. VAN HOLLEN. So based on those figures, it sounds like almost the reverse of the normal seasonal flu in terms of age impact?

Dr. FREIDEN. It is the reverse of most flu seasons. There are different types of flu, and the “H1,” that particular type of flu characteristically does affect younger people more than older people, even if it is not the pandemic strain.

Mr. VAN HOLLEN. Right. Now, if our theory that one of the reasons elderly people aren’t as severely impacted is because they have had earlier seasonal flus or they have had earlier vaccines that may have helped them, it does suggest that this strain is very different than the strains we have been seeing for a very long period of time. Because otherwise, I assume, that is why young people are feeling it.

Dr. FAUCI. Well, it is very different, but there is some strong suggestion that individuals who are elderly have percentages as high as—30–35 percent of them have antibodies that actually would cross-react with this flu, even though we have never seen in our history anything like this in the sense of an identical virus like this.

There have been other H1N1’s. There have been people that have gotten vaccinated against the swine flu in 1976. There are people who were exposed to H1N1 years and years ago.

It is highly likely that those individuals do have some degree of subliminal background immunity, that when they see this virus they mount a reasonably good immune response. Whereas the youngsters, children, adolescents, people in their twenties, that doesn’t seem to be the case. It spreads very widely through them.

Mr. VAN HOLLEN. Just in terms of the rate of transmission right now, how does it compare to the seasonal flu?

Dr. FREIDEN. There a fair amount of data, some of it conflicting, about that. What we do know is we don’t see the kind of explosive outbreaks in schools and colleges in most flu seasons that we are seeing now. In New York City we had one school that had over 1,000 kids that had H1N1. We just don’t see that. So certainly in some populations, the younger adults and children, it seems to spread quite readily sometimes. But the overall rate of spread is not entirely clear.

Mr. VAN HOLLEN. Just following up on that and getting to the question of the adequacy of our State and local public health response, I hope that although the distribution happens at the local and State level with the support that you are providing at the Federal level, I hope that you will monitor very closely the local impacts and in some ways hold people accountable.

As you said, there is going to be some variability, but it seems to me we have a responsibility at the Federal level to make it clear where we do not think that the local response is adequate. I hope

that all of you will agree that is a responsibility of the Federal Government.

Sometimes it is not easy, you are going to have to be calling out shortcomings in terms of the local response. But in the interest of the public health, it seems to me we should have some kind of grading system or some kind of way to identify who is responding adequately, and who is not, especially with respect to schools where you have a lot of young people obviously gathered, and this is a strain of the flu that has a very severe impact potentially on young people.

Dr. FREIDEN. We will certainly do everything we can to support States and localities to respond effectively and to provide whatever support is possible. I think that there will be attention to the areas that are not vaccinating large numbers or where vaccine is more difficult to obtain.

There are going to be real challenges, particularly in the next few weeks as the vaccine program just begins to roll out, including to places that don't usually vaccinate, such as schools.

Mr. VAN HOLLEN. Thank you.

Chairman TOWNS. The gentleman's time has expired. We will have a second round. I thank all of the witnesses.

You know that vaccinations often bring fear to many groups, and the ability to spread false information is also prevalent. What information have you come across regarding this flu strain or this vaccine that you believe is false or confusing? Do you wish to clear that up today?

I received a call earlier today from farmers saying, "please stop referring to this as the 'swine flu' because people think they get it from pork." So I think that these are things that I would like for you to clear up. This is an opportunity for you to do so, because we want to make certain that accurate information is getting out there. We have the experts here. We want to make certain that people know exactly what is going on.

The other thing people are saying, and I find this one very interesting, is that if you want to avoid it, don't live in the South. Go to a cold area and you don't have to worry about it. So I guess if you went to Niagara Falls, it would not be a problem, according to what information is being passed out there by people.

I would like for you to take this opportunity to clear this up, so people will know exactly what we are dealing with here. Because, as you know, there's some people when it comes to vaccinations, anything of that sort, they just don't want to participate.

So right down the line.

Dr. FREIDEN. I will start, and then my colleagues I am sure will add to it.

First, in terms of the spread, it is very different in different parts of the country and it will change from time to time. Currently it is more prominent in some States than others, but it is widespread across the United States. There is more in the south of the United States, possibly because schools went back into session sooner.

There are at least three common myths about flu which are important to confront.

First, you cannot get the flu from a flu shot. It is not possible. It is killed vaccine and there is no way you can get the flu from

it. You can get a sore arm, but you can't get the flu from a flu shot. That is perhaps one of the more common misconceptions.

The second, which is common and problematic, is that flu is not necessarily a mild illness. It is not the common cold. It can knock you flat on your back and make you quite sick for a while. You can miss school, work, and if you are unfortunate or have an underlying condition, it can put you in the hospital or even kill you. So flu needs to be taken seriously.

You can't get the flu from a flu shot, and the flu shot is highly protective against what can be, and is for many people, a moderate illness that is unpleasant.

Third, in the public settings for the H1N1 vaccination program which will start in a few weeks, the public settings, immunization clinics, schools, vaccine administration and the vaccine itself will be free to the person being vaccinated. They may bill your insurance company or Medicaid, but no one will have to pay for it out-of-pocket in the public sector vaccine clinics.

It may be that the private sector sometimes has copayments, and we have encouraged them to waive those for H1N1 vaccination, and many insurers have agreed to do that. But at least for the public sector it will be free, and the vaccine itself will be free everywhere. There may be some administration fees in the private sector.

Dr. FAUCI. Just to add another one to Dr. Freiden's, is we have heard, and I am sure you have, Mr. Chairman, about some people who feel that maybe it is a good idea to actually deliberately expose yourself to get infected.

You have heard about flu parties, people getting people together like you have these chicken-pox parties. That is really a bad idea. It is a bad idea because, like Dr. Freiden said, influenza can be a very bad disease. Even at its best, sometimes it makes you very uncomfortable and puts you out of sorts, if not out of school and out of work. And also, even though there is a very small percentage of people who go on to real serious complications, you can't predict who that is going to be. So the idea about getting infected deliberately is a real bad idea.

What is a real good idea, is to get vaccinated.

Dr. GOODMAN. I think one very important myth here is that somehow vaccines in general, and in particular this vaccine, may be unsafe for pregnant women. I think it is very important to realize that pregnant women have been among the groups most over-represented in having serious outcomes for themselves and their offspring with this flu.

These vaccines, although there aren't a lot of formal studies in pregnant women, have been safely used every year in hundreds of thousands of pregnant women and studies that have been performed about their use have not shown any increases in adverse outcomes for the moms or their babies.

So there is not a known risk to pregnant women. We certainly continue to collect more data. There is certainly a known risk to pregnant women and their babies from getting this flu.

Chairman TOWNS. Just very quickly, because my time has expired, I know that it is not a Federal policy, but as you know, some States are requiring that public health workers receive vaccination.

Let me ask you, are you monitoring this? Because I think that is something that really needs to be looked at and to see whether or not there is any value to this. So, are you monitoring it?

Dr. FREIDEN. There are a lot of important studies, and they are ongoing, that we continue to track, that identify what are the risks to patients if the health-care workers who provide their care don't get vaccinated. And perhaps the experience from the jurisdictions that are doing this will be helpful in trying to understand that further.

Chairman TOWNS. OK. The gentleman from California.

Mr. ISSA. Thank you, Mr. Chairman.

I will reiterate a question for emphasis here. Pregnant women are among the most vulnerable. They are the ones that have the most natural reluctance to take any and all substances that are not grown in the ground, cutoff and freshly cleaned.

How is it when I hear the list of who should get it first, that isn't first? Why isn't that the group that most of you need to make sure are first heard? Because they have a reluctance, even if they are only among the top, shouldn't they be the first that you say, pregnant women or those who expect may become pregnant, shouldn't that be the first group, with their high immune—and particularly with H1N1 they are likely to fight more aggressively the disease?

Dr. FREIDEN. We don't distinguish among those five priority groups. All of them are equally high priority. And for each of them we have—

Mr. ISSA. That is like going to school and A through F being equal. I know there is a subtle difference between a 91 and a 59, but it made all the difference in the world when I was going to school.

Dr. FREIDEN. For each of them it is important that we reach out, so we work with the American College of Obstetrics and Gynecology to help get vaccine out and promote vaccination for pregnant women. We are working with magazines, mothers' magazines, net resources and others.

For each of those groups I think there is a special effort. There is a special effort to try to reach out to them most appropriately. The bulk of the people who have severe illness and death from H1N1 are not pregnant women, but pregnant women are at six or eightfold increase risk of severe and negative outcomes. So we do want to really prioritize vaccination in this and other groups, although we do understand that there is reluctance and will be.

Dr. FAUCI. Besides, it would be logistically really a problem to have you're first, you're second, you're third, because if you have distribution centers that are actually giving vaccines, and someone is among those five target groups that we have all mentioned during this testimony, that if a pregnant woman walks in and says I want to get vaccinated, she will get vaccinated, because not only is she among the five target groups, she is even among the five priority groups within the target groups.

Mr. ISSA. And within that, is there a difference in trimester? Has there been any study showing that level of vulnerability just before delivery versus early gestation?

Dr. FAUCI. Of when you could have it? No. There is no difference at all.

Mr. ISSA. Just all pregnant women.

Let me do one followup question. Since the former chairman of this committee isn't here and since he has been an outspoken critic of the side effects, real and/or alleged, of heavy metals in vaccines, can you discuss the level of—you would know the right term for the small amount of metal that is sort of part of the carrier in many vaccines, as to both today's flu vaccines and obviously the H1N1, and particularly as to the claim that autism can often be caused by that, and other birth defects?

Dr. FREIDEN. I think we will all comment briefly. Thimerosal is what you are referring to. The amount of Thimerosal in vaccines has fallen substantially in recent years. We will have a substantial amount of Thimerosal-free vaccine in this H1N1 program.

Mr. ISSA. A substantial amount. Some yes, some no. So a patient can say I want metal-free or Thimerosal-free?

Dr. FREIDEN. Thimerosal is used as a preservative in multidose vials. In single-dose vials it is not necessary, by and large. There have been a series of scientific studies that have not linked Thimerosal with autism. Autism is a very serious problem, and it is a tragic problem for the parents who have to deal with it, often. But we need to continue to make efforts to identify the causes and ways of preventing it.

There is good data that suggests or indicates that there is no link between vaccine and autism. However, because we want to accommodate the concerns of people who believe there may be, and we want as many people to get vaccinated as possible, we have made a Thimerosal-free vaccine available, to the extent possible. Since you have to have a preservative in a multidose vial, it is not possible to eliminate it completely.

Mr. ISSA. So those who might otherwise not get a shot should ask for a single dose, Thimerosal-free dose, and it should be reasonably available on request?

Dr. FREIDEN. Yes.

Mr. ISSA. Yes, sir? Yes, Doctor?

Dr. FAUCI. I would just add to that while there is an effort, as Dr. Freiden said, to get as much preservative-free vaccine as possible, I think that particularly for people in risk groups, if there is—you make your own choice, but given that there is no known risk and that the scientific community, including the Institute of Medicine in 2004, found there was no connection between Thimerosal and autism, that people should consider carefully the idea of not getting vaccinated because of this concern.

Mr. ISSA. In closing, Doctors, I asked the question, one, because one Member not here at the dais is terribly supportive of the theory that there is still a connection. And I don't want to say that he is wrong, because I am not qualified. But I think for everyone that will look at this hearing, being aware that if you have a young child or a pregnant woman who has that concern, that there is a way to get us past that concern. And understand that if you are a Member of Congress, you get hit every day or every month by somebody who wants the fluorine out of the water too; that in fact there is an interest group against almost anything you can name. And if it spreads into a portion of society that would not protect

themselves, then I think that is where we have the interest for the question.

I appreciate your understanding. And I thank you, Mr. Chairman, for giving us this opportunity. I yield back.

Chairman TOWNS. I yield to the gentleman from Maryland, Congressman Cummings.

Mr. CUMMINGS. Thank you, Mr. Chairman. I want us to put a microscope for a moment on the first category of people at high risk, between 25 through 64, who are at a high risk for complications of H1N1 infection because of chronic disorders that compromise the immune system.

You are on C-SPAN here. Why don't you tell us exactly what those diseases are? Because, one, the reason why I am saying that is we have 26.6 million people in the United States with diabetes who probably, unless a doctor tells them that they are high risk, they may not know it. We have people who are on chemo with cancer. And, of course, chemo, you are the doctor, I never spent 1 day in medical school, but I do know that chemo can compromise the immune system; is that right?

Dr. FREIDEN. Yes.

Mr. CUMMINGS. Of course, we have already talked about AIDS. I want you all to tell the American people—see, if I got 8 percent of the population that has diabetes and doesn't even know that they are at high risk, I want to make sure that the other folks, using this wonderful opportunity we have here, we need to let them know that they are at high risk right now.

Could you tell us what those diseases are that we are most concerned about?

Dr. FREIDEN. Anyone who, as you say, has diabetes; anyone who has a chronic heart condition, such as congestive heart failure; anyone with a chronic lung condition that would make it harder for them to breathe, such as emphysema or asthma; anyone who has immune compromise, such as being on cancer chemotherapy or someone with HIV; anyone with a neuromuscular disorder; someone who has trouble breathing on their own; myasthenia gravis or other problems that cause a weakening of the musculature; people with underlying health conditions which give them less reserve to call upon if they have become infected with influenza are more likely to end up in the hospital and more likely to die.

That is why these groups are so important to be vaccinated when vaccine becomes available, and if someone in one of these groups becomes sick with fever, with cough, it is so important that they get treated promptly; ideally, within 48 hours.

Mr. CUMMINGS. And how are we getting that word out? Are we telling doctors that? I am telling you. I am sure there are people watching this right now saying, wait a minute. Diabetes? The reason why I am so concerned about that is because there is so much diabetes in my district, and, I am sure, a lot of districts. When you say somebody who is in that top category, when you said diabetes, it automatically jumps out at me.

But go ahead, Dr. Fauci.

Dr. FAUCI. We are trying, and we appreciate the opportunity to say what Dr. Freiden just said at a hearing like this that is on C-SPAN. That is one way of getting it out.

Virtually every day we talk about this. The CDC has a—and I can say this because I am not from the CDC—has a beautiful Web site that you click open and they just list them all. And we keep talking about it, from Secretary Sebelius herself, down to the people doing the clinical trials in the trenches. This is something we constantly talk about.

But I agree with you; we have to keep shouting it from the hills so people understand that, because a lot of people who are in the risk categories don't really fully appreciate that they are. I think you mentioned one of the most important ones, the diabetics.

Mr. CUMMINGS. Probably, you know, if diabetics are 8 percent, and then when we put in all the other people that you all just mentioned, we may be talking about 25 percent of the population. Is that an unreasonable figure? Is it?

Dr. FAUCI. No, that is close.

Mr. CUMMINGS. That is just in the the first category.

In your testimony, I think it was you, Dr. Fauci, you said that—and correct me if I am wrong—that currently the H1N1 vaccine does not contain adjuvants which would increase the potency of vaccines, but you are testing them as well. We include adjuvants in our seasonal flu shots; is that right?

Dr. FAUCI. No.

Mr. CUMMINGS. We don't?

Dr. FAUCI. No.

Mr. CUMMINGS. OK. There is a rumor that we will run out of this vaccine as soon as we produce it. That is not true either?

Dr. FAUCI. That is not the right rumor. That is a rumor, it is not correct. We fully expect that we will have enough vaccine of the H1N1 2009 for all who want or need it, and we certainly will have enough of the seasonal influenza vaccine, based on the history of uptake of seasonal flu vaccine. So we feel confident that we will have enough for everyone who wants and needs it, without the use of adjuvants.

Mr. CUMMINGS. I go back to what I said a little bit earlier. I do believe that sometimes—it is not your office—I will be very brief, Mr. Chairman—that we operate, sadly, in a culture of mediocrity in our country, and I will never forget Katrina as long as I live.

I just want to make sure, going back to my friend and colleague from Maryland, what Mr. Van Hollen said. I just want to make sure that we hold our entire, all of our agencies, accountable. I know that may be difficult to do. But I agree with him, we cannot have another situation where we think we have everything under control and we don't.

Thank you very much, Mr. Chairman.

Chairman TOWNS. Thank you very much. Let me just ask one question, because I think, Dr. Fauci, you sort of mentioned it. Who has the best and most current information for the public in terms of Web site, videos, Twitter, whatever? Who has that? I think we need to put that on the record and let people hear it.

Dr. FAUCI. I go to the CDC Web site every day. They are a fountain of information. I would recommend that if anyone wants to know anything about the kinds of things we are talking about right now, it is very, very easy. It is flu.gov, F-L-U dot G-O-V. Just click on that and it is there. You could just search anything you want

that has to do with flu, all of the things we are talking about, risk categories, vaccines, etc.

Chairman TOWNS. Because I think that is important. We are trying to make certain that people have accurate information, and that is what this is all about.

So I want to thank the witnesses again for being here today. Of course, we want to get this information out. I would also like to thank you for the work that you are doing on this issue as well. I am certain that the American people will thank you, also.

Let me thank you again for the time that you have spent here with the committee, answering all the questions that we have raised.

So at this point in time, without any further questions or objections, the committee stands adjourned.

[Whereupon, at 3:45 p.m., the committee was adjourned.]

[The prepared statement of Hon. Gerald E. Connolly and additional information submitted for the hearing record follow:]

Opening Statement of Congressman Gerald E. Connolly

Oversight and Government Reform

"The Administration's Flu Vaccine Program: Health, Safety, and Distribution"

September 29th, 2009

Thank you, Chairman Towns for holding another important hearing on swine flu. I look forward to learning more from today's witnesses about safety precautions that were taken prior to vaccine distribution and logistical challenges associated with distributing the vaccine.

First, we need to ensure that all practical measures have been undertaken to ensure that swine flu vaccines are safe. Excusing pharmaceutical manufacturers from legal liability through administrative determination under the Public Readiness and Emergency Preparedness Act, while facilitating its development and distribution, could have the unintended impact of heightening public concern about the safety of the swine flu vaccine. Some may wonder why legal immunity is necessary if the vaccine has undergone proper testing overseen by the Food and Drug Administration. I hope we can establish that the testing process was sufficiently rigorous.

Second, I look forward to learning about obstacles and opportunities for ensuring efficient distribution of vaccines. We need to have an understanding of obstacles to distribution so that the federal government can work with our state and local partners to avoid distribution bottlenecks when swine flu vaccine starts arriving in October.

Finally, I would appreciate the opportunity to learn more about the long term prospects for pandemics that are similar to swine flu. During the 1918 influenza pandemic an unusually high proportion of deaths were among young to middle aged adults, in contrast to mortality rates for most strains of flu, which are most deadly for the very young and very old. We need to be prepared to prioritize vaccine distribution appropriately, so that vaccines are distributed to those who are most susceptible in the event of limited supplies. We have spent over \$1 billion to purchase 195 million vaccines, so it is appropriate to make plans to distribute all of it. We must also be prepared to distribute smaller quantities in a more targeted manner if the entire supply is not available for distribution on schedule.

Thank you again for holding this hearing. I look forward to the witnesses' testimony.

Response of the Centers for Disease Control and Prevention

Kucinich Questions:

During questioning, you mentioned that the vaccine manufacturers control the order of receipt of the vaccine every year. As I mentioned, I am concerned because chain pharmacies are getting the shot before doctors.

A. Is there any mechanism to ensure that the vaccines are actually distributed on a first come, first served basis?

For seasonal influenza vaccine, the vast majority of orders are placed directly by providers with the manufacturers. In contrast, the vaccine manufacturers are not involved in vaccine distribution to or within the states and territories for 2009 H1N1 vaccine. The vaccine manufacturers only ship the finished 2009 H1N1 vaccine to the vaccine distributor. Public Health Emergency Response (PHER) grantees (this includes all U.S. states, territories, and tribes) designate distribution points for their project areas. Vaccine is allocated to each project area in proportion to its population (pro rata). CDC's contractor for centralized distribution ships vaccine to hospitals, clinics, doctor's offices, health departments, and other providers of vaccines that have been designated as 2009 H1N1 vaccine-receiving sites by the Project Area. Available vaccine is shipped as orders are received.

B. If not, are we entrusting the pharmaceutical companies to distribute the vaccine as they see fit?

See answer to the previous question.

I see that the injectable vaccines come with or without a mercury based preservative called Thimerosal. I am concerned that people will not have a true choice even though those versions may be available to all, especially since these vaccines will be in high demand.

C. Can you tell me whether each facility administering the vaccine will have ample supplies of the non-mercury vaccines for those that want it?

Of the 41.6 million doses of 2009 H1N1 vaccine available for ordering by states on 11/12, approximately half of the formulations were thimerosal free or had trace thimerosal. The remaining doses contained thimerosal because they were in multidose vials that require preservative to prevent contamination. Studies consistently have shown that vaccines containing thimerosal are safe, and the Advisory Committee on Immunization Practices (ACIP) recommends that high-risk groups and others may receive vaccine with or without thimerosal.

D. I have been working on providing funding for Gulf War Veterans Illnesses for a number of years now. In November of last year, the Congressionally-mandated

Research Advisory Committee on Gulf War Veterans Illnesses at the Department of Veterans Affairs released a 454 page scientific review of the diseases. The Committee found that one potential cause of these diseases, which have a neurological and an immune system component, for which there is growing evidence is the concurrent receipt of multiple vaccines - not ne vaccine - but multiple vaccines at once.

Are you aware of this report or these findings?

I encourage you to explore it.

CDC is aware of the Research Advisory Committee's report and its recommendations for epidemiologic research concerning health effects associated with exposures during the Gulf War including associations between Gulf War illness and individual vaccines, combinations of vaccines and total number of vaccines received. To our knowledge, there exists no known threshold of immune stimulation in humans that has been scientifically observed to be excessive and no conclusive scientific evidence has been found that the concurrent receipt of multiple vaccinations among adults represents a health risk. CDC supports the Research Advisory Committee's specific recommendations for future research related to exposure to vaccinations and in particular that epidemiologic studies of Gulf War veterans control for potential confounding by other Gulf-War related exposures.

E. As we enter the flu season along with a surge in H1N1 at the same time:

Can you tell me if any precautions are being taken to help guard against any potential long term consequences of people receiving multiple vaccines at once?

Seasonal and 2009 H1N1 flu shots can be given on the same day, but should be given at different sites (e.g. one shot in the left arm and the other shot in the right arm). The seasonal and 2009 H1N1 influenza nasal spray vaccines should not be taken at the same time. The nasal vaccines should be separated by three to four weeks. A vaccine shot and a vaccine spray can be taken at the same time. While we do not expect that receiving these vaccines at the same time will result in any increase in adverse events, new and existing systems are being used to monitor for any problems.

F. Can you tell me whether there are any conditions under which an individual will be forced to take the H1N1 vaccine?

The federal 2009 H1N1 vaccination campaign is a voluntary program. Some state and local health officials may decide to make the vaccine mandatory for certain populations, such as health care workers, but those decisions are made at the state or local levels.

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Congress of the United States House of Representatives

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October 29, 2009

Dr. Thomas R. Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333

Dear Dr. Frieden:


Thank you for appearing before the Committee on Oversight and Government Reform on Tuesday, September 29, 2009, at 2:00 p.m., at the hearing entitled, *The Administration's Flu Vaccine Program: Health, Safety, and Distribution*. We appreciate the time and effort you gave as a witness before the Committee.

Pursuant to the Rules of the Committee on Oversight and Government Reform, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from Representative Dennis Kucinich, a Member of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question(s) and include the text of the Member(s) question along with your response.

Please provide your response to these questions by November 13, 2009. The response should be sent to the Committee office at 2157 Rayburn House Office Building, Washington, DC 20515. We would also appreciate it if an electronic version of your response was sent by e-mail to Carla Hultberg, Chief Clerk, at carla.hultberg@mail.house.gov in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Carla Hultberg at (202) 225-5051.

Sincerely,


Edolphus Towns
Chairman

Attachment

H1N1 Questions
Congressman Dennis J. Kucinich
September 29, 2009, Hearing

Dr. Frieden (CDC):

During questioning, you mentioned that the vaccine manufacturers control the order of receipt of the vaccine every year. As I mentioned, I am concerned because chain pharmacies are getting the shot before doctors. Is there any mechanism to ensure that the vaccines are actually distributed on a first come, first served basis? If not, are we entrusting the pharmaceutical companies to distribute the vaccine as they see fit?

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I encourage you to explore it. As we enter the flu season along with a surge in H1N1 at the same time, can you tell me if any precautions are being taken to help guard against any potential long term consequences of people receiving multiple vaccines at once?

Can you tell me whether there are any conditions under which an individual will be forced to take the H1N1 vaccine?