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PANDEMIC INFLUENZA PREPAREDNESS

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BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

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PANDEMIC INFLUENZA PREPAREDNESS

TUESDAY, JANUARY 31, 2006

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 8:30 a.m., in room SH–216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Gregg, Stevens, Harkin.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will now proceed with this hearing on the issue of pandemic influenza preparedness at the Federal, State and local levels. The subcommittee had an initial hearing on this subject last November 2, the day following the presentation by President Bush at the National Institutes of Health, alerting the country to the potential of a very, very serious health problem.

At that time, the President asked for an emergency allocation of $7.1 billion, and the Congress responded with the first years' funding of $3.3 billion. This hearing is designed to acquaint the public with the scope of the potential problem.

It could be enormous, or it might not be a major problem. That will depend upon what happens in many distant places around the world, what happens in Asia, what happens in Turkey and what happens by way of an influenza-contagious outburst. We have already seen some 160 people infected by bird flu. We have seen some 85 die. We have seen the problem move in a number of directions from Asia to Turkey.

We are concerned about the problem of transmission from birds to humans and then from humans to humans and the complex question of mutation and the fact that we are not prepared at this moment for what could occur. We are looking at issues of vaccines where we are not prepared, and we'll get into the details of that. We're looking at antiviral drugs, again, where we are not prepared. The pandemics have a cyclical effect. In 1918, a pandemic—it is estimated it killed some 50 million people around the world. We have had one as recently as 1968.

We have a very distinguished array of witnesses today. We have the Assistant Secretary of Health of the Department of Health and Human Services (HHS). We have the Director of the Centers for

Disease Control and Prevention (CDC). We have Mr. John Barry, who wrote the book "The Great Influenza", who testified before the committee last November 2.

Regrettably, the vote on Judge Alito for the Supreme Court of the United States has been scheduled—well, it's not regrettable that it's been scheduled. The timing is troublesome. Speaking for myself, I practically lived in this room with the Alito hearings for many, many days. We have had an extended debate, which was curtailed yesterday afternoon. That has placed the vote on the agenda for 11 o'clock, and it is always a very difficult matter of scheduling. When it became apparent that was happening, we moved the time up to 8:30 a.m. So, when you came in this morning, the halls were all darkened, and the Senate's not quite awake, but Senator Harkin and I are, and so is a very large turnout for this very important hearing.

In yielding to Senator Harkin, I want to compliment him and thank him for his especial alertness on this issue. His voice was the first voice heard in the Congress of the United States in the Senate chamber on the problem here. When Senator Harkin speaks, everybody listens, but I listen first because we have a very important partnership, crossing party lines on this subcommittee, which has funding, I think, for the most important aspects of life in America, health, without which none of us is anything; education, which is the gold of the future and worker safety. I yield at this time to my distinguished colleague for his opening statement.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Mr. Chairman, thank you very much for those kind statements. Again, it has been just a pleasure to work with you for 16 years now on this important subcommittee of Appropriations, dealing with all the things that you mentioned about health and education, all the things that we've done to move this country forward. Again, I want to thank you for your leadership in providing the $8 billion that we put into the bill. It was under your leadership that we were able to take that lead and put that money in it. We didn't quite get it in the end, but at least, I think, we've paved the way with your leadership in putting that amount of money forward. I didn't realize that when I spoke, you listened. Now, if I speak about the Alito vote, will you listen about how I talk about how we ought to vote on Alito, coming up at 11 o'clock? I don't know.

Senator SPECTER. Well, you can filibuster if you want, Senator Harkin, but——

Senator HARKIN. No, I'm talking about how to vote on it. That's what I'm talking about.

Senator SPECTER. Do you want to call some more witnesses?

Senator HARKIN. No, not at all. I've had it with that one. Anyway, I just—again, thank you for having this hearing. Again, I know we had that vote at 11 o'clock, and I'll try to be brief, but, you know, we've had a couple of major disasters in the United States in the last few years, and what we found out is that we were just totally unprepared. We've been warned about this avian flu influenza. We know what the dimensions of it could be. This time,

we've got to be prepared, and time is running out. We know about H5N1. We know how it's been transmitted. We know that it's widespread now.

Scientists, doctors, public health people tell us that it's not a matter of if but when it will move into a pandemic stage. We worked together last year, as I said, under the leadership of Senator Specter to provide the funds for a possible pandemic. We put $8 billion in our bill to be used first for upgrading State and local capacity; second, stockpiling vaccines and antivirals; third, increasing global surveillance activities; and fourth, to expand the domestic production of flu vaccine.

Unfortunately, in the end, Congress only provided a little less than $4 billion for pandemic flu preparedness, about half of what was in our bill, more than $3 billion less than requested by the President. One of our witnesses today has said in his written testimony, "This shortfall did not send a positive message to manufacturers about the certainty and stability of the Government's efforts to fully address a public health threat of this magnitude."

On a more positive note, we are able to designate $350 million of the funds appropriated for upgrading State and local response capacity to a pandemic, and I am going to be kind of harping on that this morning. State and local public health agencies will be on the front lines of both surveillance and disease prevention should an outbreak occur.

So, Mr. Chairman, I'm glad to see that you've asked a number of State and local public health directors to today's hearings. In particular, I am pleased to see that Dr. Mary Hansen, director of our Iowa Department of Pubic Health, will be testifying before the subcommittee this morning. In fact, this Friday, Secretary Leavitt will be in Des Moines having a flu summit this Friday with the Governor, with me, with Dr. Hansen. I just wanted to mention—I will ask some people to comment on this. Speaking of State and local preparedness and getting enough flu vaccine, it occurred to me that we have the annual flu outbreak in the United States. We have a flu shot. I always get my flu shots, but not very many of our population do. They're pretty expensive, maybe $15 to $20 a shot. It occurred to me that if we really want to build vaccine capacity and other things, we ought to provide a free flu shot to everyone in the United States. So, I introduced a bill. It's now S. 2112—that would provide a free flu shot for every person in America. It would do the following things, I believe: Create demand for flu vaccines; second, stimulate the production facilities; third, lower the cost of the flu shot dramatically; four, it would stimulate public health agencies to build sustainable delivery systems.

In case of a pandemic, we're going to have to get this stuff out in a hurry, and we're going to have to have bigger delivery systems than we have right now, sort of the what I call the Wal-Martization of flu vaccines. Maybe we can give flu vaccines and shots in Wal-Mart or at churches on Sunday and places like that where there's a sustainable-type delivery systems so that if a pandemic hits you, you can get out there in a hurry; fifth, it would provide protection from the annual flu. We know 36,000 people die every year, 200,000 hospitalizations, lost time, lost productivity. So, we provide protection from the annual flu.

Last, there may be some major protection from the more virulent strains. There's some evidence that maybe an annual flu shot might provide some—build up some immunities that would help protect people in case of a pandemic. So, I will ask people to comment upon the possibility of having a free flu shot, for everyone this morning, in America.

I'm also pleased to see Dr. Julie Gerberding this morning. The Centers for Disease Control and Prevention is doing a great job in cooperation with the World Health Organization and governments in affected regions to detect the disease and help to stop its spread, and I will have some questions for Dr. Gerberding about that. Surveillance is the first line of defense; to find it, isolate it so that widespread infection does not occur.

So again, Mr. Chairman, thank you for calling this hearing. It is timely. It's important. And under your leadership, we're not going to let up on this. We're going to keep at this. We'll keep at it until we can assure the American people that in case of a pandemic, they are going to be protected. Thank you, Mr. Chairman.

Senator SPECTER. Well, thank you very much, Senator Harkin. We'll now turn to our first panel. Our first witness is Dr. John Agwunobi, Assistant Secretary for Health in the U.S. Department of Health and Human Services. He is an admiral in the Public Health Commission Corps. He received his medical degree from the University of Jos in Nigeria, holds an MBA from Georgetown University and a master of public health from Johns Hopkins University. Because we have to conclude this hearing about 10:30 a.m., we are going to have to stick very close to timelines and limit it very sharply to the testimony. If you're an admiral, you get 5 minutes. It's all yours.

STATEMENT OF DR. JOHN AGWUNOBI, ASSISTANT SECRETARY OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. AGWUNOBI. Thank you, sir. Thank you. Mr. Chairman and Senator Harkin, thank you so much for this opportunity, this invitation to testify on a topic which I know both President Bush and Secretary Michael Leavitt have made top priorities. As you know, Congress, and as you just stated, recently appropriated $3.8 billion as the first installment on the President's request. An amount of $3.3 billion was provided to HHS to allow us to further our efforts to prepare for a pandemic.

We appreciate the action and the expressed commitment of Congress. It definitely allows us to take this first essential step in our efforts to become the first generation in history to be prepared for a possible pandemic. The majority of the HHS appropriation will be spent in two major ways; first, the production of countermeasures, both vaccines and antivirals and other resources and supplies needed to respond; second, to enhance planning and preparedness, training and exercising across the Nation. Our vaccine strategy is to simultaneously stockpile a limited amount of what we call pre-pandemic vaccine. This is a vaccine that is developed today to the prevailing H5N1 virus that's available and also build a vaccine-manufacturing capacity that we can use to quickly ramp up and produce what we call a pandemic vaccine. That would be a vac-

cine that's used to protect against the pandemic virus once it rears its ugly head.

Roughly $1.76 billion of the HHS allocation will be spent on increasing vaccine production capacity. A portion of this funding will go to accelerate cell-based manufacturing technology. We will also fund projects to increase egg-based capacity, including buying prepandemic vaccine from existing egg-based manufacturers. We will develop strategies that allow us to retrofit existing non-flu manufacturing facilities for emergency production of influenza vaccine if it's ever called upon.

We will support advance development contracts that could extend the vaccine supply by decreasing the amount of vaccine needed to protect each individual. This is a strategy that would allow us to use adjuvants to extend the limited doses that might be available.

Finally, we intend to develop a vaccine registry to monitor vaccine safety, efficacy and distribution. Our antiviral drug strategy involves the stockpiling of, currently, two drugs, Tamiflu and Relenza. Currently, those two antiviral drugs provide clinical benefits against all of the H5N1 strains currently circulating in Asia, but it's important to note that that may not necessarily be true over time as the virus evolves.

HHS plans to acquire 20 million treatment courses in fiscal year 2006 with a goal of acquiring 44 million treatment courses by fiscal year 2008. This, obviously, will be subject to the availability of funds. The plan provides for States to purchase 31 million treatment courses for which the Federal Government would subsidize 25 percent of the costs. Let me restate that. This would be a methodology by which the States could purchase, at a subsidized price, antivirals on top of the distribution of antivirals that they would receive from the Federal Government. We also hope to fund advanced development in the development of new antiviral drugs as we move forward.

HHS intends to allocate $350 million directly to the States as per the instructions that we received from Congress. We want them to use this to enhance their State and local preparedness. This money will be divided into two pieces, with the first piece totaling $100 million to be divided amongst the States on a population basis.

We also intend to establish, and I'm sure my colleague will talk about this, increased laboratory surge capacity, enhance our strategic national stockpile with personal protective equipment and a number of other efforts designed to improve overall preparedness. The Secretary at the moment is working his way around the Nation visiting each State in order to participate in State summits, the goal being to try and drive the notion of preparedness into local communities. He often says a pandemic is a global phenomenon, but our response will, by definition, be local.

It's essential that we focus our efforts on county, city, community and State preparedness. Almost 30 of these summits have either been completed or scheduled, and we look forward to working with our State counterparts.

PREPARED STATEMENT

In conclusion, Mr. Chairman, although there has been much accomplished, continued vigilance and preparation is definitely need-

ed. We do have a journey. Preparedness is a continuum. There are many things that we will need to do into the future, and we look forward to working hard to make them happen. Thank you for this opportunity to share this information with you. I'm happy to answer questions at the appropriate time.

Senator SPECTER. Thank you very much, Dr. Agwunobi.

[The statement follows:]

PREPARED STATEMENT OF DR. JOHN AGWUNOBI

Mr. Chairman and members of the Subcommittee, I am honored to be here today to describe for you how the Department of Health and Human Services is working to improve preparedness for a potential human influenza pandemic. Thank you for the invitation to testify on this topic which Secretary Mike Leavitt has made a top priority. As you know, the President requested $7.1 billion in emergency funding for the National Strategy for Pandemic Influenza, of which $6.7 billion was requested for HHS. Congress appropriated $3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, $3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to become the first generation in history to be prepared for a possible pandemic.

As you are aware, the potential for a human influenza pandemic is a current public health concern with an immense potential impact. Pandemics are not new. There were three in the 20th century, the worst of which was the Spanish flu epidemic in 1918–1919 that is estimated to have killed over one half million people in the United States and 50 million worldwide. While we are focusing today on the impact of a possible pandemic of avian flu, many of the policy issues and preparedness measures that arise for avian flu apply as well to pandemics of other types of influenza, other infectious disease outbreaks and public health emergencies. To put the impact of a pandemic in context, the seasonal influenza that we have today causes an average of 36,000 deaths each year in the United States, mostly among the elderly, and adds more than 200,000 hospitalizations.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus currently circulating in birds in Asia and Europe, or the emergence of another influenza virus of pandemic potential. However, it is still useful to model possible scenarios based on analysis of past pandemics. In a report released in December 2005, the Congressional Budget Office presents the results of modeling a severe pandemic scenario similar to the 1918 Spanish flu outbreak and a more moderate outbreak resembling the flu pandemics of 1957 and 1968. In the severe scenario, roughly 90 million people become ill and 2 million die in the United States and the impact on the real Gross Domestic Product (GDP) is about a 5 percent reduction in the year following the outbreak. In the "mild" pandemic scenario, about 75 million people are infected in the United States and about 100,000 of them die. The impact on the GDP is approximately a 1.5 percent decline. While there is substantial uncertainty associated with these estimates, they illustrate the enormous public health threat of an influenza pandemic and the need for effective access to vaccines, treatments, and a robust public health infrastructure to meet the challenge.

There are several important points to note about an influenza pandemic:

—A pandemic could occur anytime during the year and could last longer than typical seasonal influenza, with possible repeated waves of infection.

—The capacity to prevent or control transmission of the virus once it gains the ability to be efficiently transmitted from person to person will be limited.

—Right now, the H5N1 avian influenza strain that is circulating in Asia and Europe among birds is considered the leading candidate to cause the next pandemic. However, it is possible that another influenza virus, which could originate anywhere in the world, could cause the next pandemic. This uncertainty is one of the reasons why we need to maintain year-round laboratory surveillance of influenza viruses. As is the case with the avian virus H5N1, pandemic influenza viruses often emerge in animals. As they are transmitted among animals the viruses can potentially mutate to a form that can be transmitted to humans. Thus, it is critical to maintain constant surveillance of viruses worldwide affecting animal populations and that can potentially be transmitted to humans.

—We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have

been many changes since the last pandemic in 1968, including changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes have made us more vulnerable.

THE CURRENT STATUS OF H5N1 VIRUS IN ASIA

Beginning in January 2004, the World Health Organization (WHO) confirmed reports of new outbreaks of HPAI H5N1 infection among poultry and waterfowl in several Asian countries. In 2005, outbreaks of H5N1 disease have also been reported among poultry in Russia, Ukraine, Kazakhstan, Turkey, and Romania. Mongolia has reported outbreaks of the H5N1 virus in wild, migratory birds. In October 2005, outbreaks of the H5N1 virus were reported among migrating swans in Croatia. In 2004, sporadic human cases of avian influenza A (H5N1) were reported in Vietnam and Thailand. In 2005 additional human cases have been reported in Cambodia, China, Indonesia, Thailand, Vietnam, and most recently Turkey. Turkey first reported confirmed H5N1 cases on January 5, with 3 cases (2 fatal) in eastern Turkey. On January 9, Turkey reported 10 H5 cases, and an additional 2 cases from Agri province on January 16. To date, Turkey has reported a total of 21 H5N1 human cases, 4 of them fatal, confirmed by a national laboratory in Ankara. Four cases (2 fatal) have been verified by a WHO lab in the United Kingdom. Of the 21 cases, 19 have been children aged 4–18 years. All cases seen in Turkey so far developed illness following direct exposure to diseased poultry. Cumulatively, as of January 30, 2006, 160 human cases have been reported and laboratory confirmed by WHO. These cases have resulted in 85 deaths, a fatality rate of approximately 53 percent among reported cases. Almost all cases of H5N1 human infection appear to have resulted from some form of direct or close contact with infected poultry, primarily chickens. In addition, a few persons may have been infected through very close contact with another infected person, but this type of transmission has not led to sustained transmission.

For an influenza virus to cause a pandemic, it must: (1) be a virus to which there is little or no pre-existing immunity in the human population; (2) be able to cause illness in humans; and, (3) have the ability for sustained transmission from person to person. So far, the HPAI H5N1 virus circulating in Asia and Europe meets the first two criteria but has not yet shown the capability for sustained transmission from person to person.

The highly pathogenic avian influenza A (H5N1) epizootic (or animal) outbreak in Asia that is now beginning to spread into Europe is not expected to diminish significantly in the short term. It is likely that H5N1 infection among birds has become endemic in certain countries in Asia and that human infections resulting from direct contact with infected poultry will continue to occur. So far, scientists have found no evidence to indicate that the virus has changed to make it easier to transmit from person to person. However, the animal outbreak continues to pose an important public health threat, because there is little preexisting natural immunity to H5N1 infection in the human population. It is quite certain that a threat anywhere in the world is a threat everywhere.

WORKING TO MEET THE EXISTING THREAT

On November 1, 2005, President Bush released the National Strategy for Pandemic Influenza, which outlines the roles of the Federal Government, State and local governments, private and international partners, and individual citizens in preparing for and responding to an influenza pandemic. The following day, Secretary Leavitt announced the HHS Pandemic Influenza Plan—a blueprint for all HHS pandemic influenza preparedness and response planning. The HHS Plan provides guidance to national, State, and local policy makers and health departments with the goal of achieving national readiness and the ability to respond quickly and effectively to a pandemic. The HHS plan also includes an outline of key roles and responsibilities during a pandemic. In the event of a pandemic and the activation of the National Response Plan, HHS has a critical lead role to manage the public health and medical response and support the Department of Homeland Security in their role of overall domestic incident management and Federal coordination.

On November 1, 2005, the President requested an additional $7.1 billion in emergency appropriations for fiscal year 2006, including appropriations for HHS totaling $6.7 billion to support implementation of the National Strategy for Pandemic Influenza.

In seeking this funding, the goals were to:

(1) Produce a course of pandemic influenza vaccine for every American within 6 months of an outbreak;

(2) Provide enough antiviral drugs and other medical supplies to treat over 25 percent of the U.S. population; and

(3) Ensure a domestic and international public health capacity to detect and respond to a potential pandemic influenza outbreak.

On December 30, 2005, President Bush signed into law the Department of Defense Appropriations Act of 2006 (Public Law No: 109–148) providing approximately $3.8 billion for pandemic influenza preparedness activities for fiscal year 2006, of which $3.3 billion was appropriated to HHS. The majority of the HHS appropriation will be spent in two major areas: the production of countermeasures (vaccines and antiviral drugs) and enhanced domestic preparedness. I would like to talk in depth about these areas, as well as describe other ongoing activities.

VACCINES

The optimal way to control the spread of a pandemic and reduce its associated morbidity and mortality is through the use of vaccines. Broadly speaking, vaccines may be divided into those that are developed against strains of animal influenza viruses that have caused isolated infections in human, which may be regarded as "pre-pandemic" vaccines, and those that are developed against strains that have evolved the capacity for sustained and efficient human-to-human transmission ("pandemic" vaccines). Because emergence in human populations necessarily reflects genetic changes within the pandemic virus, pre-pandemic vaccines may be a good or poor match for—and offer greater or lesser protection against—the pandemic strain that ultimately emerges. Thus, our strategy is to simultaneously stockpile a limited amount of pre-pandemic vaccine and also build vaccine manufacturing capacity so that we can quickly produce pandemic vaccine when and if a pandemic occurs.

Roughly $1.76 billion of the HHS allocation will be spent on increasing vaccine production capacity. A portion of this funding will go to accelerate cell-based manufacturing technology. Because the surge capacity needed for a pandemic cannot be met by egg-based production alone, cell-based technology, which is insensitive to seasons and can be adjusted to vaccine demand, is a critical supplement to our Nation's surge capacity.

At the same time, HHS believes that it is vital that investments continue to be made to increase egg-based vaccine production capacity, given the years of experience and proven success with this technology. Therefore, HHS will fund projects to increase egg-based capacity, including buying pre-pandemic vaccine from existing egg-based manufacturers. In addition, HHS will retrofit existing non-flu manufacturing facilities for emergency production of influenza vaccine.

In addition, HHS will support advanced development contracts for antigen sparing techniques. Antigen-sparing strategies, if successful, could extend the vaccine supply by decreasing the amount of vaccine needed to protect each individual. Finally, HHS intends to develop a vaccine registry to monitor vaccine use (safety/efficacy) and distribution.

ANTIVIRAL DRUGS

In the event of a pandemic, antiviral drugs will be the first line of defense before a vaccine is available and could delay the spread of the pandemic, particularly if the strain is not efficiently transmitted between humans. Their effectiveness will be limited to the accuracy of detecting pandemic influenza and whether the pandemic strain is sensitive to current antiviral drugs.

HHS funding will also be allocated to acquire antiviral drugs. Currently two drugs, Oseltamivir (Tamiflu) and Zanamivir (Relenza) provide clinical benefit against all of the H5N1 virus strains currently circulating in Asia. HHS intends to complete the "20/20 plan" of achieving 20 million courses in fiscal year 2006, with the goal of achieving 44 million courses by fiscal year 2008, subject to the availability of funds. HHS also intends to purchase 6 million courses of antiviral for purposes of containment, if feasible, in the event of 1–2 isolated, domestic outbreaks. The plan calls for States to purchase the remaining 31 million treatment courses, for which the Federal Government would subsidize 25 percent of the cost. Finally, HHS intends to fund the advanced development work on promising new antiviral drugs.

DOMESTIC PREPAREDNESS

HHS will allocate $350 million directly to States to enhance their State and local preparedness. This money will be divided into two pieces, with the first piece total-

ing $100 million to be divided amongst the States on a population basis. Secretary Leavitt announced this $100 million in funding for State and local preparedness on January 12. CDC is currently finalizing a self assessment tool for States to evaluate their readiness. This self-assessment tool will be sent to States, and as soon as the assessment is completed and sent back to CDC, each State will receive its portion of these funds. The second piece, the remaining $250 million, will be used to enhance State preparedness and will be allocated in the near future contingent on each State meeting specific preparedness goals, timelines, and targets as agreed to by HHS, CDC, and the State. These stipulations will be contained in an Agreement that each State governor will sign with Secretary Leavitt at the ongoing State summits.

Other fiscal year 2006 funds will be used to enhance the Strategic National Stockpile by increasing the quantities of personal protective equipment (PPE), ventilators, and other medical supplies needed in a pandemic outbreak. Approximately $50 million will be spent on establishing and increasing laboratory surge capacity. Funding has also been designated for the advanced development of rapid detection tests for human avian influenza. With regard to domestic surveillance, HHS plans to accelerate CDC's BioSense real-time surveillance system to enhance our ability to detect an outbreak early.

HHS will also direct funding to enhance international surveillance, expanding clinical trials in Southeast Asia, and implementing rapid outbreak response in currently affected countries. HHS plans to allocate funds for risk communications strategies and overall pandemic preparedness and planning within the Office of the Secretary.

STATE AND LOCAL PREPAREDNESS

In addition, at the direction of President Bush, Secretary Leavitt convened senior State and local officials from across the country on December 5, 2005 to establish an integrated Federal-State influenza-pandemic planning process. The White House Homeland Security Council, the U.S. Department of Homeland Security, and the U.S. Department of Agriculture also participated in the meeting. Secretary Leavitt asked participants to begin preparing for a series of in-state pandemic-planning summits to be held in each State over the next several months. The summits are intended to inform and involve public health, emergency response, political, economic and community leadership in the planning process.

Secretary Leavitt has since embarked on a Nation-wide tour to support State and local pandemic preparedness and planning efforts. His tour has the ambitious goal of visiting 50 States and 10 U.S. territories within 120 days. Thus far, the Secretary has completed summits in Minnesota, Arizona, Rhode Island, Vermont, Georgia, West Virginia, and Kentucky. These summits have been attended by hundreds of people at each venue and have brought together physicians, hospital executives, transportation workers, business owners, town officials, police officers, rescue squad volunteers, members of the agriculture sector and many other community leaders. In some States, the summit was broadcast to audiences in remote locations across the State as well. The central goal of the Secretary's visits is to raise awareness of pandemic preparedness in sectors which may have not been previously briefed on the current pandemic threat. The Secretary feels that it is essential that schools, universities, businesses, faith-based organizations, and various other community groups and organizations realize the impact that a pandemic may have on them.

In this regard, to assist in State and local preparedness, the Centers for Disease Control and Prevention has released a series of checklists to aid States in their preparation for a pandemic in a coordinated and consistent manner across all segments of society. At this time, a State and local government checklist, a business checklist, an individual & families checklist, and a checklist for community organizations have been released. The state and local government checklist, of note, is specifically aligned with the CDC Preparedness Goals and the HHS Pandemic Influenza Plan, Public Health Guidance for State and Local Partners. It delineates action items over a comprehensive range of issues, including community preparedness leadership and networking, surveillance, public health and clinical laboratories, healthcare and public health partners, infection control and clinical guidelines, vaccine distribution and use, antiviral drug distribution and use, community disease control and prevention, public health communications, and workforce support. In addition, there are a number of checklists pertaining to the education and healthcare communities that are in the clearance process and scheduled to be released in the coming weeks. CDC has also prepared a Pandemic Influenza Toolkit for health care providers which provides a compilation of resources and information to clinicians for their use in discussing pandemic influenza with patients and providing care in case

of a flu pandemic in the United States. Finally, www.pandemicflu.gov, the U.S. Government's official Web site for information on pandemic flu and avian influenza, contains updated information on international developments, the status of State summits, and on activities that can be initiated by various sectors of government and community to prepare now for a pandemic.

Finally, at each State summit, the Secretary and the Governor will be signing an Agreement laying the foundation for the financial assistance to be provided to States and also clearly delineating areas for mutual cooperation between the Federal Government and States as we jointly prepare for a potential future pandemic. For example, HHS will be providing substantial technical assistance to States in the areas of pandemic planning and logistical support and assistance to State and local health departments, health care agencies, and hospitals. The CDC will be particularly involved in support for epidemiological and diagnostic services, and distribution and storage of vaccines and antiviral drugs.

CONCLUSION

I hope my testimony today has provided you a summary of the current threat of pandemic influenza, the plans for which the Department of Health & Human Services intend to spend appropriated money to enhance domestic and international readiness, and the on-going activities and relationships being forged with States to enhance their overall preparedness for a potential pandemic. Although much has been accomplished, continued vigilance and preparation are needed for us to be ready for a pandemic.

Thank you for the opportunity to share this information with you. I am happy to answer any questions.

Senator SPECTER. We'll now turn to the distinguished Director of the Centers for Disease Control and Prevention, Dr. Julie Gerberding. She also serves as associate clinical professor of medicine at Emory, a bachelors' and doctorate MD from Case Western Reserve, a master's in public health from the University of California at Berkeley. Dr. Gerberding has testified before this subcommittee on many occasions and before many, many other committees of Congress and has been very, very responsive to our requests, and she's held in very high esteem. So, thank you for coming in today, Dr. Gerberding, and we look forward to your testimony.

STATEMENT OF DR. JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Thank you, sir. I have three points I'd like to make. The first is a thank you to the leaders of the committee as well as the committee members for your incredible support of this particular flu agenda and for all of our health protection activities. It matters. My second point will be to update you on the status of influenza. My third will be to summarize some of the things we're doing at the State and local level about it at this point in time. Our situation report in terms of avian influenza is serious. We have ongoing and spreading prevalence of H5N1 in migratory birds. We have continued outbreaks among domestic poultry in an increasing number of countries. We know the virus can infect animals, including cats and pigs. We had infected tigers at the Thai Zoo who were fed chickens, for example. We know pigs have been infected. We know the virus is evolving. Last year's virus strains collected in Vietnam are genetically distinct from the virus strains that are spreading this year. We've had more than 150 case reports confirmed by WHO to date and more that are in progress with the case fatality rate currently at 53 percent.

We have seen rare person-to-person transmission of the virus in at least two cases. We have basically everything of concern except for the last requirement for a pandemic, and that is we have not seen sustained and rapid person to person transmission. We hope we never check this last box, but we are certainly as close to checking it as we've been in the last several decades, and that is why we are focusing particularly on H5N1.

We have a couple of major concerns about this virus. One is that it is everywhere and that it is in common contact with people. These photographs show the mixing of the migratory birds, which are carrying it, and people literally sleeping in their chicken coop where they are at risk for inhaling the virus and acquiring it. This is one of the reasons why as the weather gets cold, people bring their chickens indoors. They sleep with them, and we're seeing an up tick in cases in places like Turkey.

But this virus is also especially bad. We know from research done at CDC and at the Department of Defense that the H5N1 virus is similar to the 1918 virus, which also emerged from birds. This chest x-ray illustrates how rapidly a person can go into total lung failure just over a couple of days because the virus is so aggressive and so invasive and causes very severe disease and requirements for intensive care and intubation. CDC along with our partners under Secretary Leavitt's leadership are doing many things including surveillance, laboratory support, development of international response capability in the priority countries, but we're also doing research on the front line.

The graphic at the top here, it shows one of the CDC scientists in Asia working, literally, on laboratory research in the field next to chickens and people who are exposed to those chickens. We are studying how we can best slow down and delay transfer of this virus in the context of the community. We're studying best ways to deliver vaccine, what systems are necessary, what kinds of things at the community level can prevent transmission. Certainly, we're studying how best to use the countermeasures like vaccines and antivirals that could save lives in the context of a pandemic.

Our planning protocol is going very deep. We believe that we are only as prepared as our weakest link, and we have developed a number of checklists for a whole variety of people outside the health community so that our businesses are prepared, our schools are prepared, our churches are prepared, our health system is prepared, our travelers are prepared. And these checklists apply even to people in their homes. We have a checklist for families and individual citizens so that people understand where they are on their preparedness and what they need to do to protect themselves and their families.

We hope we don't have an influenza pandemic, but if we don't, these preparations will still pay off because they will benefit us for seasonal flu. We will save lives during seasonal flu because of these investments. We'll have a better vaccine. We'll have more and better drugs. We'll have community health systems that are protecting against other threats.

I think most importantly, for the many people who couldn't get their flu shot this year or who suffered from influenza, we'll have

peace of mind that we, as a Government and as a citizen, we have done everything that we can to protect people against influenza.

PREPARED STATEMENT

Complacency is our worst enemy, and we appreciate you for making sure that that enemy is not at our doorsteps on this issue.

[The statement follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

Mr. Chairman and members of the Subcommittee, I am pleased to be here today to describe the current status of avian influenza around the world; CDC's role in the Department of Health and Human Services (HHS) Pandemic Influenza Plan; and CDC's pandemic influenza preparedness activities. We appreciate the support of the Members of this Subcommittee provided so that funding was included in the fiscal year 2006 Department of Defense (DOD) Appropriations Bill for HHS and CDC. A pandemic flu outbreak would have profound impacts on almost every sector of our society. Such an outbreak would require a coordinated response at all levels of government—Federal, State, and local—as well as the participation of the private sector and each of us as individuals. HHS and CDC have been leaders in this effort.

I am pleased to be here today with HHS Assistant Secretary for Health Dr. John Agwunobi who has articulated the pandemic preparedness planning underway. Both history and science clearly tell us that influenza pandemics are inevitable. The next pandemic could emerge from the current H5N1 strain affecting Asia and Europe, or it could emerge from another influenza strain. One of CDC's roles in protecting the Nation's health is to provide ongoing surveillance information for the United States on influenza strains circulating throughout the world.

THE CURRENT STATUS OF H5N1 VIRUS IN ASIA AND EUROPE

Beginning in January 2004, the World Health Organization (WHO) confirmed reports of new outbreaks of highly pathogenic avian influenza (APAI) A H5N1 infection among poultry and waterfowl in several East Asian countries. In 2005, outbreaks of H5N1 disease also were reported among poultry in Russia, Ukraine, Kazakhstan, Turkey, and Romania, in Mongolia among wild, migratory birds, and in migrating swans in Croatia.

In 2004, sporadic human cases of avian influenza A (H5N1) were reported in Vietnam and Thailand. In 2005 additional human cases were reported in Cambodia, China, Indonesia, Thailand, and Vietnam. Turkey began reporting human cases in early January 2006. Cumulatively, as of January 30, 2006, 160 human cases have been reported from a total of 6 countries and laboratory confirmed by WHO. These cases have resulted in 85 deaths, a fatality rate of 53 percent among reported cases. Almost all cases of H5N1 human infection appear to have resulted from some form of direct or close contact with infected poultry, primarily chickens. In addition, a few persons may have been infected through very close contact with another infected person, but this type of transmission has not led to sustained transmission.

CDC'S PANDEMIC INFLUENZA PLANNING PREPAREDNESS ACTIVITIES

On November 1, 2005, President Bush released The National Strategy for Pandemic Influenza, which outlines the roles of the Federal government, State and local governments, private and international partners, and individual citizens to prepare for and respond to an influenza pandemic. The following day, Secretary Leavitt introduced the HHS Pandemic Influenza Plan—a blueprint for all HHS pandemic influenza preparedness and response planning. Under the rubric of the HHS Pandemic Influenza Plan, CDC is developing a fully executable operations plan that will provide specific policies and procedures for each key area of CDC's involvement in the overall national response to a potential influenza pandemic. The development of the plan includes input from State and local partners through both formal and informal mechanisms. We anticipate completion of the operations plan by the spring of 2006, after which agency practice simulation exercises will begin.

CDC has encouraged States to use its preparedness framework as the foundation for their pandemic influenza plans. State plans were submitted to CDC as part of their 2005 Public Health Emergency Preparedness Cooperative Agreements. Key elements of these plans include the use of surveillance, infection control, antiviral medications, community containment measures, vaccination procedures, and risk communications. To promote pandemic influenza planning and awareness at the

State and local level, the Secretary is holding summits in all 50 States. These in-state summits will help the public health and emergency response community inform and involve their political, economic, agricultural and community leaders in this process. To date, summits have taken place in West Virginia, Vermont, Kentucky, Georgia, Rhode Island, Arizona, and Minnesota.

Congress recently included $350 million in the emergency appropriations to support efforts to upgrade State and local capacity to respond to pandemic influenza. On January 12, 2006, Secretary Leavitt announced plans for the release of the first $100 million of the funding. The remaining $250 million will be made available later this year when States and local governments have established benchmarks and met the performance objectives and timelines put forth in the guidance. These stipulations will be contained in an Agreement that each State Governor will sign with Secretary Leavitt at the summits.

PREVENTION

CDC's prevention activities intend to increase the use and development of interventions known to prevent influenza. CDC's roles in the research, development and manufacturing of vaccines and public health prevention activities as identified under the HHS Pandemic Influenza Plan encompass CDC's efforts towards our prevention goal.

Development and Manufacture of Vaccine

During an influenza pandemic, the existence of influenza vaccine manufacturing facilities functioning at full capacity in the United States will be critically important. The U.S. vaccine supply at present is particularly fragile; only one of four influenza vaccine manufacturers that sell in the U.S. market makes its vaccine entirely in the United States. In fiscal year 2006, appropriated resources to support pandemic preparedness will be used to encourage greater production capacity by enhancing the U.S.-based vaccine manufacturing surge capacity and developing antigen sparing technologies. This will help the United States prepare for a pandemic and further guard against annual shortages.

One of the main efforts by HHS in pandemic preparedness is to expand the Nation's use of influenza vaccine during inter-pandemic influenza seasons. In fiscal year 2006, $40 million was appropriated through the Vaccine For Children (VFC) program to purchase influenza vaccine for the national pediatric stockpile as additional protection against annual outbreaks of influenza. Increased annual production efforts should strengthen our capacity for vaccine production during a pandemic. We are also developing strategies to increase influenza vaccine demand and access by persons in high-risk groups that are currently recommended to receive vaccine each year.

DETECTION AND REPORTING

CDC's efforts are directed towards decreasing the time needed to classify an influenza outbreak, decreasing the time needed to detect and report an influenza outbreak with pandemic potential, and improving the timeliness and accuracy of communications regarding the threat posed by an influenza outbreak with pandemic potential. CDC focuses on detection and reporting by strengthening our national local laboratories, enhancing laboratory capacity and research, supporting our BioSense surveillance system and other real-time surveillance, studying human-animal interfaces to learn more about the zoonotic nature of pandemic influenza, and strengthening CDC's quarantine stations.

State Laboratory Preparedness

CDC is working to strengthen national local laboratory capacity by: (1) ensuring that States have sufficient epidemiologic and laboratory capacity both to identify novel viruses throughout the year and to sustain surveillance during a pandemic; (2) improving reporting systems so that information needed to make public health decisions is available quickly; (3) enhancing systems for identifying and reporting severe cases of influenza; (4) developing population-based surveillance among adults hospitalized with influenza; and, (5) enhancing monitoring of resistance to current antiviral drugs to guide policy for use of scarce antiviral drugs.

Collaboration with the Council for State and Territorial Epidemiologists (CSTE) has considerably improved domestic surveillance through making pediatric deaths associated with laboratory-confirmed influenza nationally notifiable, and by implementing hospital-based surveillance for influenza in children at selected sites. CDC will continue to work with CSTE to make all laboratory-confirmed influenza hospitalizations notifiable. Since 2003, interim guidelines have been issued to States and hospitals for enhanced surveillance to identify possible H5N1 infections among

travelers from affected countries, and these enhancements continue. Special laboratory training courses to teach State laboratory staff how to use molecular techniques to detect avian influenza have been held.

Enhanced Laboratory Capacity and Research

In fiscal year 2006, emergency supplemental resources will support laboratory capacity and research at CDC. Close collaboration with many partners will be vital to enhancing laboratory capacity and research at CDC. The following are among the steps our agency is taking:

—Applying advanced mass spectrometry techniques and analysis to examine structural changes in viral surface proteins that will help identify factors that alter the virulence of influenza viruses and to better characterize drifts and shifts in the influenza viruses.

—Enhancing pandemic influenza research in collaboration with the Laboratory Response Network (LRN). This includes determining the potential for increasing stocks of diagnostic reagents for influenza and accelerating research and development for diagnostic tests.

—Maintaining a library of pandemic influenza reference strains.

—Enhancing laboratory capacity to increase throughput and working with international partners to address critical issues that may affect the timely sharing of data.

BioSense and Real-time Surveillance

CDC's BioSense program improves the Nation's capabilities for monitoring community health by providing rapid access to timely data from hospitals and healthcare systems in several major metropolitan cities. It provides the immediate, continuous and comparable information needed to inform local, State, and national public health in participating areas, and to support national preparedness by using a network that includes hospital systems, Department of Veterans Affairs and Department of Defense facilities, poison control call centers, and the largest clinical laboratory in the United States. In responding to the threat of pandemic influenza with the support of additional funding in fiscal year 2006, CDC plans to further accelerate implementation of the BioSense program in 2006 by increasing the number of participating cities, the number of healthcare systems and real-time clinical data sources within those cites, and incorporating other existing health data sources of importance in monitoring influenza activity and the effectiveness of emergency response.

Human-animal Interface Studies

CDC will receive funds in fiscal year 2006 to support human-animal interface studies that will improve understanding of avian and other zoonotic-related influenza strains. CDC strategies in this area focus on studies of poultry and other domestic animals and on the potential impact of migratory wild birds. CDC will coordinate with partners to conduct epidemiological studies in countries that have documented H5N1 infection in poultry, especially those that also have confirmed human H5N1 cases. In addition, CDC works with its partners to coordinate surveillance between the human and animal health sectors in response to emerging zoonotic diseases of public health importance including avian influenza. In addition, CDC has established close working relationships with organizations such as the Wildlife Conversation Society, the American Zoological Association, and the International Species Information System to ensure that surveillance data about migratory bird and captive bird species can be shared in a timely and transparent manner to promote early detection of avian influenza.

Enhancement of Quarantine Stations

Under its delegated authorities, CDC is responsible for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States. This effort includes maintaining quarantine stations. Currently, CDC's Quarantine Stations are actively involved in pandemic influenza preparedness at their respective ports of entry. We have expanded the Nation's Quarantine Stations; currently, CDC has a presence at 18 Quarantine Stations, and is working to fully staff these stations. HHS and the Department of Homeland Security (DHS) have recently established a Memorandum of Understanding setting out specific cooperation mechanisms to combat the introduction and spread of communicable diseases. These include DHS assistance with passive and, in certain instances, active surveillance of passengers arriving from overseas, as well as information sharing to assist in contact tracing of passengers with communicable or quarantinable diseases. HHS/CDC will provide training and other necessary support to reduce the potential of disease to enter the United States.

Informing the Public

Risk communication planning is critical to pandemic influenza preparedness and response, and funds are budgeted in fiscal year 2006 in the Office of the Secretary to support communication preparation in the case of a pandemic. HHS and CDC are committed to the scientifically validated tenets of outbreak risk communication. It is vital that comprehensive information is shared across diverse audiences, information is tailored according to need, and information is consistent, frank, transparent, and timely.

In the event of an influenza pandemic, clinicians are likely to detect the first cases; therefore messaging prior to a pandemic includes clinician education and discussions of risk factors linked to the likely sources of the outbreak, in addition to information targeted for specific groups, such as businesses and State and local officials. Given the likely surge in demand for healthcare, public communications must include instruction in assessing true emergencies, in providing essential home care for routine cases, and basic infection control advice. This comprehensive risk-communication strategy can inform the Nation about the medical, social, and economic implications of an influenza pandemic, including collaborations with the international community.

INVESTIGATION AND CONTROL

CDC's investigation efforts focus on decreasing the time needed to identify causes, risk factors, and appropriate interventions for those affected by the threat of pandemic influenza and to decrease the time needed to provide countermeasures and health guidance to those affected by the threat of pandemic influenza. These efforts include activities that support rapid outbreak response and purchasing and stockpiling antiviral medications.

Rapid Outbreak Response

Rapid response to international outbreaks has been a part of CDC's mandate for decades, but recently published work suggesting challenges involved in slowing or containing an influenza pandemic makes the importance of such response more clear. For optimal response, a nascent influenza pandemic outbreak anywhere in the world must be recognized within 1 to 2 weeks and investigated and virologically confirmed within days. An unprecedented and well-coordinated response must be launched in stages in response to pre-planned trigger points, including deployment of dozens to hundreds of trained teams, public health messages, social isolation measures, movement restriction, treatment of patients, and tracing and prophylaxis of contacts.

In response to this challenge, CDC has developed a comprehensive Global Disease Detection (GDD) strategy. In fiscal year 2006, funding is included to expand international surveillance, diagnosis, and epidemic investigation efforts. Additional funding in fiscal year 2006 will build rapid outbreak response capability in 15 avian influenza affected countries. The strategy is integrated with WHO and other international partners. Regional workshops and other efforts have already begun that build local infrastructure for epidemiologic and laboratory disease detection, develop rapid outbreak and response teams, and establish and maintain appropriate stockpiles. The Investigation and Control goals during the next 3 to 9 months are focused on detection and rapid outbreak response to an avian influenza A (H5N1) outbreaks in Southeast Asia, Eastern Europe, and other affected areas. In the longer term, our rapid outbreak response will be focused on virtually any infectious disease threat anywhere in the world.

Antiviral Drugs

Acquiring, distributing, and using antiviral drugs is an essential preparedness activity for both seasonal and pandemic influenza. Congress provided funding of $525 million in fiscal year 2006 to purchase and maintain the materials for the Strategic National Stockpile (SNS), including antivirals. Recent studies at CDC have shown that 91 percent of currently circulating human strains of seasonal influenza in the United States and H5N1 isolates from people in Asia during the past 2 years indicate that these viruses are resistant to the cheaper and more available class of antiviral medications, the adamantanes, but are sensitive to the neuramidase inhibitor class of drugs such as oseltamivir (Tamiflu®) and zanamivir (Relenza®). Ongoing surveillance and monitoring of the status of antiviral sensitivity is absolutely critical as CDC continues its work to procure additional influenza countermeasures for the SNS. Information on antiviral sensitivity is important for developing the most up-to-date public health policy for effective use of antiviral medications.

RECOVERY

The U.S. healthcare system will be severely stressed by an influenza pandemic. In addition to critical preparation needed to respond successfully to the acute medical care needs of the population, the healthcare system will also need to resume normal services as rapidly as possible. CDC's work to improve the national healthcare system's capacity to respond is also included under this goal.

Healthcare System

Healthcare facilities need to be prepared for the potential rapid pace and dynamic characteristics of a pandemic. Medical surge capacity is limited, and could be vastly outpaced by demand. However, all facilities should be equipped and ready to safely provide care for a limited number of patients infected with a pandemic influenza virus early in a pandemic. Thereafter, recovery of necessary staffing and supply lines will be essential in order to provide for the large number of patients that would require care in the setting of escalating transmission. Preparedness activities of healthcare facilities need to be synergistic with those of other pandemic influenza planning efforts.

CDC has developed, with input from State and local health departments and healthcare partners, including other Federal agencies, guidance that provides healthcare facilities with recommendations for developing plans to respond to an influenza pandemic and guidance on the use of appropriate infection control measures to prevent transmission during patient care. Development of and participation in tabletop exercises over the past 2 years have identified gaps and provided recommendations for healthcare facilities to improve their readiness to respond and recover after a pandemic, as an integrated part of the overall planning and response efforts of their local and State health departments. The healthcare system has made great strides in preparation for a possible pandemic, but additional planning still needs to occur.

IMPROVEMENT

The investment required in preparing for an influenza pandemic is resource and time intensive. Iterative consideration and evaluation of activities funded by the U.S. Government are necessary to assure the development of best practices approaches to pandemic preparation.

CONCLUSION

Although much has been accomplished, from a public health standpoint, more preparation is needed to prepare for the public health response to a possible human influenza pandemic. As the President mentioned during the announcement of his National Strategy for Pandemic Influenza, our first line of defense is early detection. Although the present avian influenza H5N1 strain in Asia and Europe does not have the capability of sustained person-to-person transmission, we are concerned that it could develop this capacity. Because early detection means having more time to respond, it is critical for the United States to work with domestic and global partners to expand and strengthen the scope of early-warning surveillance activities used to detect the next pandemic.

Thank you for the opportunity to share this information with you. I am happy to answer any questions.

Senator SPECTER. Thank you very much, Dr. Gerberding. We'll now proceed with questions by Senators on 5-minute rounds. Dr. Gerberding, it is estimated that some 50 million people died in the pandemic in 1918. I know it is a delicate line to tread on, not over alarming people and at the same time, putting people on notice that there is a potential problem, that when we talk in terms of the kinds of deaths which occurred in 1918 and very substantial deaths in other times, the most recent pandemic in 1968, how would you assess the risk factor that we will have a pandemic and that it will be a serious health problem in the United States?

Dr. GERBERDING. History teaches us that pandemics do happen, and we need to expect one. We can't say that H5N1 influenza will be the cause of the next pandemic, and there is no way to really

predict that. What we can say is that compared to 1918, we're dealing with a virus that is similarly lethal.

We're dealing with a society that's much more mobile and can get from one corner of the world to another overnight, but we're also dealing with a society that has the capacity to plan and prepare and develop countermeasures and provide state-of-the-art medical treatment if we prepare in advance for how we could that.

So, the connection of worst-case scenario virus in a highly connected population, but also a system that is taking the time and the steps to prepare may put us in a position where we will be able to at least delay or slow down the impact of a future pandemic.

If we stay the course and get all of these things accomplished, we are really in a position in the future to take the threat off the table.

Senator SPECTER. Dr. Agwunobi, the President asked for $7.1 billion. We have come forward with $3.3 billion for the agencies within the jurisdiction of this subcommittee. Would a greater appropriation this year enable the Federal Government to do more now? Or stated differently, do you really need more money at this time?

Dr. AGWUNOBI. The President and the Secretary came up with that figure following extensive planning and thinking through what it would take——

Senator SPECTER. I only have 5 minutes. Do you need more money now?

Dr. AGWUNOBI. Sir, this first-year funding is absolutely welcomed.

Senator SPECTER. No—no, do you need more money now?

Dr. AGWUNOBI. As I said, sir, clearly, the President and the Secretary have a plan. This first-year funding was very, very gratefully received. We're going to work to make sure that it's extended——

Senator SPECTER. Oh, wait a minute. I'm sure it's gratefully received, but is it adequate?

Dr. AGWUNOBI. Sir, we continue to stay the course. Sir, our plan is to expand the $7.1 billion.

Senator SPECTER. Dr. Gerberding, when we move ahead to vaccines, how much do we need by way of vaccines, and when will we have an adequate supply for this country?

Dr. GERBERDING. We are not going to have a rapidly available adequate supply for several years even if we do everything we want to do with the $7.1 billion. It's going to take time to build that production capability, and we've got to modernize the vaccine so we don't depend on eggs. So, I would estimate 4 to 5 years at best to get where we need to be.

Senator SPECTER. On the antiviral drugs, what is the projection for an adequate supply of antiviral drugs?

Dr. GERBERDING. That's a tough one because we have to make some speculations, but our target is 25 percent coverage of our population based on the best models that we have.

Senator SPECTER. When will we get there?

Dr. GERBERDING. We estimate, based on what the manufacturer of Tamiflu has represented to us, that we would have that supply by 2008.

Senator SPECTER. 2008?

Dr. GERBERDING. We estimate that with the investment you just made, we would have enough to cover 20 million Americans in 2006.

Senator SPECTER. It's possible that this pandemic could get here long before 2008, isn't it?

Dr. GERBERDING. Yes, it is possible.

Senator SPECTER. Dr. Gerberding, we covered this at the hearing that we had last November 2, and I still haven't gotten an adequate answer. But we saw this problem going back to 1996, and should we have done more in 1996 and 1997 and 1998, that's 10 years ago, to be in a better shape than we are today for this very serious, potential problem?

Dr. GERBERDING. Absolutely.

Senator SPECTER. Well, it's not a satisfactory situation we find ourselves in now, but I'm out of time, so I'll yield to Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman. It was a great line of questioning. I want to ask Dr. Agwunobi that you mentioned in your testimony only cell based and egg based. In the amount of money in the document we have here on your funding you have accelerate cell-based vaccine and then buy courses from existing egg-based manufacturers.

I had in my office, I think, what, 2 weeks ago maybe, an individual informing me of another process using recombinant DNA, which is even faster. Well, at least according to them, I mean, I'm not—I approach it from a non-scientific basis, obviously, but in going through the steps that were necessary and the fact that these labs can be mobile, that they can be set up anywhere, I'm curious as to why you're not looking at recombinant DNA or any egg based vaccines.

Dr. AGWUNOBI. The fact that this is—there's a need for us to rapidly develop capacity forces us to look first to those existing situations where we know we can expand as quickly as possible, but it's not at the exclusion of science.

Indeed, we continue to work through our scientists, both at CDC and NIH and with industry, to look for other opportunities over time. Our investment today is focused, however, on finding the fastest ways to use existing industrial technology, existing opportunities to expand.

Senator HARKIN. Cell based is not existing.

Dr. AGWUNOBI. There are some industries—there are some companies within the industry that have already begun the process of rolling out their cell-based capability. Clearly——

Senator HARKIN. What can you tell me about RNA based?

Dr. AGWUNOBI. There is some science that would indicate that it is potentially one of the options we could use going forward. Now, we haven't ruled it out——

Senator HARKIN. Have any vaccines ever been developed using RNA based?

Dr. AGWUNOBI. I'm not sure that I know of any specific, but I believe there are. There are some.

Senator HARKIN. I think that's true.

Dr. AGWUNOBI. I believe there are.

Senator HARKIN. I think that's true. At least, that's what I'm told. I don't know. I mean, I don't know. I have—I'm asking the experts here.

Dr. AGWUNOBI. That's true.

Senator HARKIN. I was told that there have been RNA-based vaccines. Oh yeah, hepatitis for hepatitis.

Dr. AGWUNOBI. Yes, I believe there are and——

Dr. GERBERDING. Yellow fever——

Senator HARKIN. Pardon?

Dr. AGWUNOBI. Yellow fever and others.

Dr. GERBERDING. Yellow fever is another RNA virus vaccine.

Senator HARKIN. Well, you know, a virus is a virus. I mean, they're not all the same, obviously, but it would seem to me that the same kind of RNA-based production for these kinds of viruses, at least what I'm told, could be rapidly used for the production of the flu-based viruses.

Now again, I'm not a scientist. I can't speak to that, but if all of this is true, I'm just curious as to why you're not putting some money into RNA based. Why not? You don't have one cent in there.

Dr. GERBERDING. The NIH is supporting research that is looking at all of these recombinant technologies for——

Senator HARKIN. So, it's coming through NIH somewhere?

Dr. GERBERDING. Yeah, the research program there, and we also are working on how to build the recombinant seed virus strains that we would use for a large-scale vaccine. So, that technology is moving forward.

Senator HARKIN. Well, that's reassuring because if—is it true that if, in fact, this proves to be a viable methodology, that the timeframe then, you're talking less than 4 to 6 months, you're talking a matter of a couple of months is what I was told, in terms of ramping up and getting the vaccines developed.

Dr. AGWUNOBI. I think our strategy is to diversify as much as we can. Through advances in science, hopefully, one of our goals will be to shorten that time period.

Senator HARKIN. Well, I mean, I need more information, and maybe I'm just getting ahead of my schedule about what NIH is doing in this area. Excuse me, but we really have to push ahead on that.

Dr. Agwunobi, your pandemic flu plan would require States to pay 75 percent of the costs of the antivirals over and above the 26 million courses to be purchased by HHS. Your latest budget figures expect that States will spend $340 million to purchase antivirals. Where do you expect the States to find this money?

The $350 million provided in the DOD bill is meant primarily for the planning and exercising of pandemic response plans. It raises the question if one State finds itself unable to meet these objectives, doesn't this place all Americans at risk since the pandemic's not just going to stay in one State, it's going to move across State lines?

Dr. AGWUNOBI. I think it's important that we first State that the absolute number of antivirals on hand is a poor indicator of preparedness. It doesn't equate to preparedness. A diversified strategy is important.

Having said that, our first step is to provide 20 million doses—treatment courses rather, of antivirals to the States paid for 100 percent by the appropriation that we were given. The second strategy is then to allow States, if they wish, to augment that amount with this subsidized, 25 percent subsidized option.

In addition to that, States can also go one step further and purchase on our contract amounts of antivirals in excess of the subsidized and the 100 percent paid for Federal allocation of antivirals that each State will receive.

The bottom line is that States will have three options to add to and increase. Every State will receive antivirals in our plan.

Senator HARKIN. I know I'm out of time. I just have one question for Dr. Gerberding. How many people do you have on the ground? How many people do you have? Do you know? If you don't know right now if you—in Vietnam, Cambodia kind of, and do you have any people on the ground in China?

Dr. GERBERDING. We have people on the ground in all of those countries. I can't tell you exactly how many are in the priority countries right now, but we intend to put more people there. Yes, we do have people in China.

Senator HARKIN. Turkey?

Dr. GERBERDING. We have CDC scientists in Turkey in the association with the WHO team and, I believe, an additional person working in the lab in Istanbul.

Senator HARKIN. Thank you very much, Dr. Gerberding.

Senator SPECTER. Thank you, Senator Harkin. Senator Gregg.

Senator GREGG. Thank you. Thank you, Mr. Chairman. Let me join in your praise of Dr. Gerberding's work. Enjoyed working with her as Chairman of the Health Committee and she's an exceptional challenge for our Government. Doctor, let me ask you a couple of quick questions, and then I will move on here. But on quick preparation questions, I've been to a couple of meetings, you know, symposiums on this issue, and one thing that everybody seems to think it can be done quickly, should be done quickly, is get up to speed with what you'd call basic medical gear. You see those people with facemasks in your picture there. So, do we have enough facemasks, because they're produced out of the country and if there were an epidemic they'd be hard to get, and do we have enough facemasks? Do we have enough hypodermics in storage and in staging areas to handle an epidemic?

Dr. GERBERDING. We are still purchasing. We have enough in terms of the use that would be required to actually provide the medical care and treatment, but the reality is everyone will want a mask.

Senator GREGG. When do we get——

Dr. GERBERDING. So, there's going to be a run on——

Senator GREGG. How far do we come—how far are we from getting enough?

Dr. GERBERDING. In the money that was just appropriated in the President's emergency supplemental, we're going to spend $242 million to augment our stockpile with those items. We're going to need to continue to buy those over time. We're——

Senator GREGG. We buy them all overseas, I presume. They're all manufactured in China probably.

Dr. GERBERDING. Most of the manufacturing is offshore. So, for us, stockpiling makes sense because otherwise, we might not be able to secure what we need in the time of a pandemic.

Senator GREGG. All right. That's what I mean. We have to have it here because we're not going to get it if there's a worldwide epidemic. They're not going to sell it to us. They're going to keep it themselves.

Dr. GERBERDING. Absolutely.

Senator GREGG. But we are going to have enough by, say when, June?

Dr. GERBERDING. I'm not going to commit to that because I think, again, enough—one of the things that's going on is our scientists are studying if masks can be reused and how should masks be used. The $50 million toward CDC research that's in the appropriations is going to ask and answer these very practical questions so that we can have a better evidence base for planning and how much we need.

Senator GREGG. Could you get me a—I'm going to—I don't have much time. Sorry to be abrupt, but can you get me a letter that explains the timeframe for getting adequate supplies on what you'd call basic medical supplies?

Dr. GERBERDING. Absolutely.

Senator GREGG. Second, another thing that's been mentioned in these meetings has been the capacity to quarantine at the borders. Do you have all the legal authority you need to quarantine at the border, number one? Number two, do we have—have we set up the regime to accomplish that?

Dr. GERBERDING. I just visited one of our quarantine stations yesterday, so I can assure you that we are getting prepared there. We do have the legal authorities to quarantine. We have worked out the agreement with the Department of Homeland Security on who will enforce our authority because CDC, obviously, is not an armed service. So, we need the law enforcement component should we ever require that additional protection.

But I think, in general, as these systems are put up and exercised, we're discovering that this voluntary opportunity to evaluate, assess and isolate people is working quite well.

Senator GREGG. I'd also appreciate it if somebody and I don't want to have your staff just spinning wheels, but as chairman of the Homeland Security Committee, which mirrors this committee on this issue, I'd like to know if we need to do anything. So, if you could tell us, tell us.

Dr. GERBERDING. Thank you.

Senator GREGG. On a more philosophical level, the issue of vaccines has been something that we've been struggling with. We've been struggling on it with bioterrorism. Now, we're struggling on it with this. Is it not true that one of the reasons we don't have the vaccines is that we basically destroyed our vaccine industry in this country?

Dr. GERBERDING. It's absolutely true. We've seen a continued deterioration in the number of manufacturers and their capacity over time.

Senator GREGG. It's gone from approximately 35 manufacturers to 3 or 4, and isn't that a function primarily of the liability that

manufacturers simply don't seem—feel that there's enough return in considering the risk?

Dr. GERBERDING. I think there's a component of liability, but it's also a profit issue. Our manufacturers take a lot of risk and——

Senator GREGG. Profit is a function of liability—of your liability threat. I mean, if you're going to be liable for a vaccine that may impact millions of people in an instant—in a very instant period, and you've got no way of getting it to the market because you can't sell it to anybody but the Government, you're probably not going to produce that vaccine, right?

Dr. GERBERDING. I think manufacturers want a fair profit, and liability can certainly be a deterrent from their confidence in acquiring that.

Senator GREGG. So, if we're going to get our vaccine back on—vaccine industry back up and running, we're going to have to, and we have tried to address liability, and we're going to have to address revenue, but what we've seen so far is that we put revenue into the stream through bio—the bio, what, biotech effort. We put $5.6 billion in the stream. Now, we're going to put $7 billion into this stream for influenza potentially. Are we going to get a vaccine industry back up and functioning in this country as a result of those dollars, do you think?

Dr. GERBERDING. My understanding that when the President asked for the $7.1 billion, a major focus of that investment was to do everything we could to get the vaccine industry up and running for influenza.

Senator GREGG. Well, how is it going to happen? I mean, we are we going to see pharmaceutical companies engaging in the production of vaccine in this country, or are we still going to have to buy it from France and——

Dr. GERBERDING. We are seeing that. We are certainly seeing of the one manufacturer who's domestically based a willingness to commit to infrastructure and building capacity for vaccine production. We also, this year, have four manufacturers in the game as opposed to two manufacturers that we had 2 years ago.

Senator GREGG. How many are American based?

Dr. GERBERDING. Only one of the four is American based.

Senator GREGG. But don't we need this production in the United States because if there's an influenza outbreak in the world, and the production isn't in the United States, we're not going to have first call on that, right?

Dr. GERBERDING. Absolutely. We believe that for all of the essential countermeasures.

Senator GREGG. So, how do we get more than one vaccine in the—participant in this effort?

Dr. GERBERDING. Some of the investment that is included in the appropriation is going to be used to try to motivate additional manufacturers to come around the table. I know Secretary Leavitt and the President have met with the large list of manufacturers to see what else we need to do to get them collaborating. It's been an impressive commitment to scale this up, and I believe that our industry and our Government is working together to accomplish this, but it just can't happen fast enough. We also have to modernize what

we're doing, and that's the other lane here to bring modern technologies faster to the marketplace.

Senator GREGG. I think the one thing we can, and I know my time's up, I think the one thing we can take a little comfort from is that we got really talented people in your organizations working on this, and there is a focus on it. That's good, and hopefully we can get some results. We know it takes time, but we don't have a whole lot. Thank you.

Dr. GERBERDING. Thank you.

Senator SPECTER. Well, thank you, Senator Gregg. As you can see, Dr. Gerberding and Dr. Agwunobi, there's a lot of concern here as to how fast we're moving on these critical issues and what you need. There are only four of us here today, but there's a fair amount of clout.

Senator Stevens, who will have the next line of questioning, was former chairman of the full committee and chairman of Commerce, and Senator Gregg is chairman of the Budget Committee and chairman of the Subcommittee on Homeland Security. You know where Senator Harkin and I have been.

We want to be helpful to you, but we have to know what you need. When I ask if the money is adequate, I really want to know if the money is adequate and whether you are able to maximize activities at this time because when the President asks for $7.1 billion, then we give him $3.8 billion, there's a big gap. Now, maybe that's all you need at the moment. Now, there is some talk that that's as much as you want in the year. But you are high-level professionals, and we want to know what we can do to help you, but we can't do it unless you tell us. Senator Stevens.

Senator STEVENS. Well, Mr. Chairman, we tried. I've got a series of questions. First, when I was home, I had a meeting in Alaska with the people who were doing the testing of the migratory birds. I was very surprised that there's no laboratory in our State that can analyze those tests. They go down to Michigan or somewhere and eventually down to CDC headquarters. About 2 months later, maybe 3 months later, we find out whether these birds that have just come through are infected.

Why is there no laboratory up there? This is a massive amount of these birds that come into our State. In addition to that, we have half the cargo that comes in by air comes through Anchorage now, and we have the massive travel of people from Asia coming through in our passenger's planes. I find that strange to think it takes so long to deal with this testing. Why is it?

Dr. GERBERDING. The tests that you're talking about are actually not done at CDC. They're done by the U.S. Department of Agriculture at the University of Georgia, but we're fixing that. In fact, the appropriation to develop centers of excellence and other research relevant to human and animal health that was included in this emergency supplement—one of the things we want to do with that is get in the business of being able to test for these birds and test them faster. So, we will address that.

Senator STEVENS. Unfortunately, it's one of those things we tried to get that lab up there to speed up this process. From what I was told, there's no hope for it. Is that right?

Dr. GERBERDING. I disagree with that, and I think we do have a laboratory in Alaska through our laboratory response network, and we are training laboratorians to be able to test for H5——

Senator STEVENS. There's no laboratory. The specimens go down somewhere to Michigan and then go down South. By the time the people that are testing the birds, those—they don't get an answer back for months.

Dr. GERBERDING. I can't speak for the USDA or the Department of the Interior's project, but I can commit to you that CDC intends to be able to test in Alaska, and we are already able to do that for human infection. We can expand that.

Senator STEVENS. Okay. I had the task of managing that bill that had this money in it. I congratulate the Senators here, Senator Harkin, Senator Specter, for their advocacy to get the money that we did get.

I'm disturbed we didn't get the full amount, but the problem that I have is at the last minute, we did put in the provision concerning the liability portion of that bill. Has that liability portion been analyzed by your people? Is it adequate to give assurance to the manufacturers that they will move forward and have an American-based manufacturer of the vaccines?

Dr. AGWUNOBI. Staff and HHS are currently reviewing the language very, very closely. We are, as we speak, issuing RFPs and then requests for information to industry. We expect as those responses come in, that we'll be able to analyze what the actual and real impact of that language is on their responses. It's a little early yet to tell what their response to that is going to be.

Senator STEVENS. Well, respectfully you know, that was in December. We're approaching February, and had I been in your position, I would have had a meeting in January of all of the CEOs of the companies involved and asked them is this adequate.

Dr. AGWUNOBI. Sir, that——

Senator STEVENS. Did you do that?

Dr. AGWUNOBI. Yes. Sir, as you know, prior to——

Senator STEVENS. Did you do that?

Dr. AGWUNOBI. Sir, yes, we have met with industry, and they indicated to us that the liability issue is a significant roadblock to progress. That's what is——

Senator STEVENS. But that's not my question. What about the adequacy of what we put in the bill? Is that adequate to give the assurance to the industry that they can have the liability protection?

Dr. AGWUNOBI. Sir, my understanding is that as they respond to the RFPs and the RFIs that we'll have a better idea of that particular answer.

Senator STEVENS. I don't find that acceptable, Doctor. I think the timeframe on this is so short that we ought to know now whether we have to proceed in the next supplemental to improve that liability provision, and it won't do us any good if we get that in July.

We're going to move a supplemental some time in March or April. If that's not adequate, the threat of this pandemic is so great we ought to move to see if we can give the assurance to the American manufacturers of vaccines that they will have the protection that they demand in order to bring that industry back here.

Now from me, I do believe that that's your responsibility, yours and the Department of Health and Human Services'. Now, can we get any assurance at all we'll know whether that liability provision is adequate?

Dr. AGWUNOBI. Sir, it shouldn't take long. We are expecting responses very quickly hereafter. In our dialogue with the industry at that level, we'll be able to ascertain very quickly as to whether or not it's enough.

Senator STEVENS. Madam Secretary, what do you think?

Dr. GERBERDING. I'm not an expert in liability, but I do think that urgency is important because we have to get the show on the road.

We know that if we'd had the full appropriation, we probably could have reassured industry, and they would have been willing to move forward faster. You'll hear from them on the next panel whether or not our current situation is providing any additional barriers. But liability is one thing that several have cited as an issue, and we've got to get it out of the way.

Senator STEVENS. Well, I'm not as disturbed about not getting the full amount as other people because we did as much as we could in that one bill. There is a problem of budget control and what not. I think we'll get the balance of that money early this year if we get the assurance that, if putting it up will make the difference. Now, I don't think we'll get it unless we get that assurance. Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Stevens. As you hear the sense of urgency in Senator Stevens' questions and Senator Stevens' tone, and there's no doubt that we're on a short timeframe. We understand that you're focused on it, but we want to help you. When Senator Stevens raises the issue of adequacy of the liability issue, you've got to get some hard answers. We do have people coming in today to tell us about it, but we shouldn't have to wait until the subcommittee convenes a hearing. We've talked to Secretary Leavitt about it, and he's going to be coming in for the appropriation of the full department. We're going to be emphasizing this again, but may I compliment you, Senator Stevens, on the tone of your questions and the tone of your urgency.

Senator STEVENS. Mr. Chairman, my mind goes back to that night that was really very early in the morning when we had these arguments before, and I got you somewhere, I think, out of bed, probably on the telephone, and we have had the sense of urgency then. That was December. I still have that sense of urgency from the conversations I had at home. I hope we'll see some progress here before we mark up the first bill.

Senator SPECTER. Senator Harkin seconds that motion, and Senator Harkin wants to be heard some more.

Senator HARKIN. Yes, Mr. Chairman. Look, I had not raised the issue of liability, but since it's been raised, I want to weigh in on it. I believe that there ought to be some form of limited liability to the manufacturers. I think that's appropriate.

But in all this talk about liability, what about people? What about the individual out there that may get harmed because of either an accident that can happen in the manufacture or an acci-

dent in the delivery system or a carelessness on the part of a manufacturer?

That may happen. We're all human after all. Someone gets injured out there. Someone gets damaged. Well, if the manufacturer has got all liability protection, and we don't have a compensation package, what does that say to that person out there that got vaccinated? We want people to get vaccinated. We want them to have the assurance that if they get damaged and they get injured, even if there's liability protection of the manufacturer, there is a compensation package to help them out.

As it is right now in the bill that passed the Senate and the House and that the President signed, there's liability protection for the manufacturers, blanket liability. Blanket liability. There's zero. Zero money for any compensation to any individual that's injured out there. What about people? We want to assure people that they can get vaccinated without any fear, but if they get damaged, if they get harmed, you know, due to an accident, carelessness or whatever, there's going to be some compensation for them. Where is that side of the equation? Where is that side of the equation?

In the dead of the night, after the bill was passed, after manager signed off on it, this liability protection was slipped into the bill. Well, that's getting into the weeds on process around here. I don't need to bore anybody with process, but that's not the way to do things. We can have some limited liability.

I'm going to ask the manufacturers when they get up here about liability, but I want to ask them, and if you're sitting out there, and you're coming up here, be prepared, I'm going to ask you about compensation for people, not just protecting your company and your shareholders and your stockholders, but what about the people out there. How about giving them compensation? I'd like to see the manufacturers be as adamant—as adamant in saying yes, we want liability protection, but you must provide some compensation for people out there that get damaged. I'd like to see them as adamant about that, and I'm going to ask them about it.

Senator STEVENS. Well, Mr. Chairman, one last word. It'll take at least 2 years for the vaccine process to come back to the United States. There's plenty of time to deal with the liability. The question is getting the manufacturers back here now, and we can deal with liability. The timeframe for this vaccine to get to anyone, to even be heard, is more than 2 years, so I don't accept the delay on proceeding with the liability provision because of the lack of the compensation provision.

I support the compensation provision. I think that there should be adequate—but the question right now is do we have the vaccine capability here, or are we going to be dependent upon foreign countries releasing enough for us to deal with our population. So, that's the bottom line.

Senator SPECTER. I think we're all on the same page here on needing adequate protection for the companies so they proceed at having adequate compensation for the victims. We didn't get part B done because we were working very late. And we have a compensation program, but there are too many ifs in it. There's an if about a declaration of an emergency, and there's an if in it on the appropriation of the funds. Those are two big ifs. We do a lot of

talking about what we're going to do, and very frequently, the Congress is slow on doing it.

So that when Senator Stevens talks about the urgency of getting assurances that the manufacturers will go forward, he's right. When Senator Harkin talks about the necessity for having adequate compensation, he's right. This subcommittee does a lot of hearings, and we just may do a hearing on that subject as well because if it wasn't all tied up when we dealt with this, and Senator Stevens was at the core of it, and I was involved in it, and Senator Harkin was too, but we've got a lot of witnesses to cover and not very much time.

We very much appreciate your professionalism, Dr. Gerberding and Dr. Agwunobi, and let us hear from you before we summon you to another hearing. Senator Harkin wants to know if there's a possibility of getting one last fast question—I don't think so, Senator Harkin. We can have a question. I don't know that it'll be fast, but——

Senator HARKIN. Very quick, the Turkey—the outbreak in Turkey, I understand that the strain of flu found in Turkey includes three mutations in the virus's sequence that may make it more likely to be transmitted to humans. Is this true, and can you explain this very briefly?

Dr. GERBERDING. CDC has that virus right now, and we're studying it ourselves. But based on what we know from others, there are some signature mutations that have been associated with more affinity for humans. Whether or not that will prove to be true when we look at the actual virus in cells or in animals, it's too soon to speculate. So we are concerned, but we don't have the data yet to fully answer your question.

Senator HARKIN. Thank you.

Senator SPECTER. Thank you, Doctor Gerberding. Thank you, Dr. Agwunobi. We're now calling Mr. John Barry, Dr. Richard Webby, Mr. George Abercrombie, Mr. Daniel Soland, Mr. Chris Viehbacher, Dr. Mary Mincer Hansen, Dr. Calvin Johnson, Dr. Bruce Dixon and Dr. Joanne Godley.

We have a very limited amount of time, and I know you have been advised as to the limitations on your presentations. We would ask you to stick within those time limits, which you have been advised about so that we can leave the maximum time for questions for the panel on matters of specific interest to the subcommittee.

Our first witness is Dr. John Barry, author of "The Great Influenza", the epic story of the deadliest plague in history, author of four previous books, including the award-winning "Rising Tide: The Great Mississippi Flood of 1927 and How It Changed America". Mr. Barry is a graduate of Brown University with his bachelor's degree. Thank you for coming in, again, Mr. Barry. I think you ought to know at the start that my wife has bought several copies of your book to distribute to our friends. She is very concerned about this issue and is really a very heavy motivating force, and she just got complimented by Senator Harkin. Mr. Barry, the floor is yours for 5 minutes.

STATEMENT OF JOHN M. BARRY, AUTHOR, "THE GREAT INFLUENZA"

Mr. BARRY. Okay, well, thank you very much for asking me back, and I appreciate your wife's support. I think I'll probably take less than 5 minutes in the effort to save time and skip over most of the historical background. As you already said, according to a Nobel Prize winner, at least 50 million people died in 1918 and 1919. That was in a world population only 28 percent as large as today's. I think it's very important to note that a significant proportion of that, we don't know exactly how many, but perhaps one-third to almost one-half of those people died directly from the virus so that modern medicine, antibiotics and so forth, would not have had any effect.

Also, in the 1957 pandemic, 25 percent of the population died directly from the virus, which of course, you know, emphasizes how important a vaccine is since other medical technologies would be useless and also, of course, more research on antivirals. We don't really know how effective Tamiflu would be. We also don't know whether or not the virus would develop resistance to it.

I do want—I'm not an expert on the preparedness plans that the States have developed or for that matter, the Federal Government, although I certainly have familiarity with it, but I would like to make a couple of observations. I've participated in quite a few meetings in the last 1.5 years, workshops and so forth, on preparedness, most involving Federal agencies, but a few States, I do want to talk about two, what I think, are larger problems that I see as potential gaps. The first involves the lack of thinking about the wave phenomenon, the first wave, second wave, third wave.

There is some debate in the scientific community whether or not this virus actually did come in waves or whether they were different viruses. We've never seen another influenza pandemic where there were successive waves that followed upon each other so rapidly. We also haven't seen a lot of change in virulence in other viruses as we saw in 1918. This is not really an academic question. This is a very concrete question. Because you have a very different containment and communication strategy if when the virus first enters the human population as a human virus, it starts out as virulent as it's ever going to get. As opposed to what seems to have happened in 1918, that it starts out as really a very mild virus that looks absolutely no different from a normal influenza, and endemic influenza in terms of clinical illness, and then over a period of time becomes virulent.

Given the media attention, the firestorm that would erupt when we identify the next pandemic virus. You know it's very important if it starts out mild and becomes virulent and I don't think enough attention has been addressed to that wave phenomenon. Even if—we will never know probably for certain whether or not it was the same virus evolving, my own sense of the historical data, I feel somewhat qualified to look at this, because this is not strictly a laboratory question at this point. It really involves historical data, and I think I'm more familiar with historical data than many of the scientists who have weighed in on this subject. To me it does look like the same virus.

The other thing is I'm a little bit concerned about integration of planning. For example even—first I want to start off by—which I

do commend this committee for its attention to what I consider maybe the most serious threat to American lives and economic well-being that we face at the moment. I also commend this administration, I think they are trying to get ahead of the curve and as someone whose home is in New Orleans, I recognize how important planning and preparation is.

But having said that in terms of integration, even at HHS, for example, the communication strategy which in a pandemic is absolutely crucial. I mean in 1918 a very sober scientist not given to overstatement said if this continues for a few more weeks, "Civilization could easily disappear from the face of the Earth." That was I think intimately an outgrowth not only of the fear from the disease but from the poor communications strategy of all Government officials in 1918.

So I think the communication strategy needs—the people in charge of emergency preparedness at HHS, who I have very high regard for Stewart Simonson, are not intimately involved in developing the communication strategy. I find that troublesome. I think that's the last comment I'll make on my prepared remarks. I do want to weigh in a little bit on the liability issue. One of the meetings that I participated in——

Senator SPECTER. Mr. Barry, could you summarize at this point because you're over time.

PREPARED STATEMENT

Mr. BARRY. Okay. I thought I was—I was in a meeting which involved seven vaccine manufacturers including the CEOs of three or four companies. These were international companies, some in the United States, some overseas. The issue of liability was discussed, and what one of the CEOs of a U.S. manufacturer said is that "Liability is an irritant, it's not the biggest problem. The biggest problem is demand." So Senator Harkin's bill addresses that and I think that's an important part of the equation.

Senator SPECTER. Thank you very much, Mr. Barry.

[The statement follows:]

PREPARED STATEMENT OF JOHN M. BARRY

I thank you for the opportunity to testify, and to provide you with some background on a disease that, according to the Centers for Disease Control and Prevention, kills 36,000 Americans in a normal year. By definition, an influenza pandemic would not be a normal year; it would kill far more Americans than that.

I also want to commend this committee and this administration for trying to get ahead of the curve, to anticipate and plan for this serious threat to American lives and to the American economy. Now, we are here to discuss planning and preparedness.

However, since my home is in New Orleans and because of some personal involvement in flood control issues, I am well aware that anticipation and planning are not enough. Few disasters have been as well described in advance and as often warned about as Katrina, and yet Katrina happened.

Nature is perfect. Man is not perfect. Whenever a raging nature and humans collide, if humans make a mistake, nature will find it, and exploit it.

In the case of Katrina and New Orleans, we now know that human error, a serious design flaw in levees designed and constructed entirely by the Federal Government, caused the devastation of that city.

Obviously, in a conflict with an influenza virus, many more lives will be at stake than in Katrina. It will not be possible to eliminate mistakes, but we must exert every effort to minimize them. Oversight matters.

The first thing I want to do is give you some historical perspective on the disease. Then I'd like to make some comments about two areas that concern me.

HISTORICAL BACKGROUND

Influenza viruses are all bird viruses, not human viruses. But the virus mutates very rapidly and has some unusual genetic features which allow it to jump species to humans and other mammals. A bird virus can become a human virus—meaning that one person can infect another—both directly and indirectly. This ability to jump species makes it virtually inevitable that the virus will do so again.

We have no idea when the next pandemic will occur. It may have started 2 weeks ago and we just don't know it yet, or it may not come for 20 years. But for at least the last 500 years, pandemics have occurred three to five times a century, with the greatest duration between pandemics of 42 years. We are now at 37 years and counting. In several pandemics the virus has been quite lethal.

The most lethal pandemic that we know some details about occurred in 1918 and 1919. No one knows how many died, but Nobel laureate Macfarlane Burnet, who spent most of his career studying the disease, believed that the death toll was at least 50 million people, and possibly 100 million. This was in a world whose population was only 28 percent as large as today's. That is the equivalent of 175 to 350 million today. Yet even without adjusting for population and using Burnet's lower estimate, the 1918 influenza pandemic killed more people in 24 weeks than AIDS has killed in the 24 years that disease has been known. Well over half the deaths occurred in an incredibly short span of about 10 weeks, between late September and early December, 1918.

In the developed world, the overwhelming majority of victims suffered what we would today regard as a typical attack of the disease. For example, the case mortality rate in the United States was no more than 2 percent. But influenza attacks so many people that the U.S. death toll was an estimated 675,000, the equivalent of about 1.8 million today. But it is also important to realize that the virulence of the virus varied enormously from one town to the next, and from one country to the next; the continental United States was by no means among the hardest hit countries.

Even so, virtually every city, town, and village in the country ran out of coffins. People could die less than 24 hours after their first symptoms.

Federal, State, and local officials tried to reassure the public instead of telling anything close to the truth, people saw for themselves and what they were being told destroyed all trust in authority. People became alienated. In city and country victims starved to death "not from lack of food but because the well are afraid to help the sick." Streets emptied. In Philadelphia in a city of almost 2 million people, one medical student who was in charge of an emergency hospital saw so few cars on his way home every night over a drive of 12 miles that he started counting them; one night he saw not a single other car on the road, and wrote, "The life of the city has almost stopped." Doctors and nurses were kidnapped. A confidential Red Cross report noted "a fear and panic akin to the terror of the Middle Ages of the plague." One sober scientist, not given to overstatement, wrote that if the epidemic had continued "for a few more weeks, civilization could disappear from the face of the earth."

Particularly vulnerable were isolated populations. In Western Samoa, where we have good statistics, 22 percent of the entire population died. In Alaska and Labrador, an estimated one-third of the native population died.

More than half the dead were healthy young adults, people who are normally least susceptible to infectious disease. What little hard data we do have suggests that between 4 percent and 8 percent of the world's young adult population died.

It is also worth pointing out that, although the precise numbers are unfortunately soft, it is quite conceivable that between one-third and one-half the deaths came directly from the virus. We have better numbers for the 1957 pandemic, and in that outbreak it seems that 25 percent of the deaths came directly from the virus.

This is an important fact. Even if we had adequate supplies of existing antiviral drugs, which we do not have, we do not know how effective they really are, and the virus could very well become resistant to it. Since a pandemic would quickly fill all beds in intensive care units, we would quickly return to nature. Much of modern scientific medicine would have no impact on the disease until a vaccine became available.

Finally, we must recognize that influenza is one disease to which we have actually become more vulnerable than we used to be, not less. Medical developments have not kept pace with changing demographics. In addition, our economy has shifted to "just-in-time" inventory. In all sectors of society we have far less slack, which in ef-

fect translates into surge capacity, than we used to have; this is true from hospital beds to groceries—and to coffins.

In short, influenza is a serious threat, arguably the most dangerous threat we now face, both to American lives and economic well-being.

CURRENT PLANNING

I'd also like to make some comments about current planning. First let me say I was a little reluctant to testify because I do not purport to be an expert on Federal preparedness efforts, much less the plans being drawn up by the various States. But committee staff did convince me to come because you might have some questions for me that I am qualified to address.

Having said that, I have participated in quite a few meetings on influenza in the past year and a half involving Federal agencies or the National Academy of Sciences, and I have had a handful of conversations with public health leaders in several States. This experience has led me to tentative conclusions about two things that concern me.

The first is what seems to me to be inadequate preparation for the possibility of the pandemic coming in waves, particularly if the first wave is a mild one that does no more damage than endemic influenza, but that creates a media firestorm as soon as we have evidence that human to human transmission has occurred.

This is a complicated question. The 1918 pandemic seemed to come in three waves in rapid succession, far more rapid than any other influenza pandemic we know about. It also seemed to change in virulence, which also is unusual.

As a result, there is now some debate in the scientific community whether in fact the waves resulted from the evolution of the virus, or what seemed to be waves actually reflected almost simultaneous attacks by different viruses.

I am a historian, not a scientist. I have the highest regard for some of the scientists who have raised this question. Unfortunately, the only way we can know for certain is if we find and compare samples of viruses from the first, second, and third waves. That may never happen. Even if it does, in the meantime, we have only historical evidence.

I believe I am more familiar with a wider range of the historical data than many of the scientists who have raised this question, and I think the historical data does favor the interpretation that we faced only one virus in 1918, that it did evolve, it did change virulence, and it did so quite rapidly. Indeed, in 1918, medical journals published articles as late as July suggesting that the disease being reported could not be influenza because it was too mild, with too few complications. Only a few weeks later, medical journal articles said the disease could not be influenza because it was too lethal.

This question becomes more than an academic one when we think about how to respond to the first reports of human-to-human transmission, and as a new pandemic virus begins to spread.

If the virus starts out as virulent as it will ever get, that's one thing and calls for one containment and communication strategy.

But if it starts out as a virus so mild that it is clinically indistinguishable from endemic influenza, and it takes 6–8 months to become virulent, that may call for a different containment strategy. It will certainly require a different media strategy.

From the workshops and conversations with planners that I know about, insufficient attention has been focused on this problem.

My second concern is a lack of integration of planning. This of course is always a problem. Going back to Katrina, yesterday's Washington Post reported that immediately after the hurricane struck the Department of Interior offered FEMA boats, aircraft, law enforcement officers, and other resources. Only some of these resources were ever deployed, and only after long delays. Earlier the Department of Transportation had reported a similar experience. This problem is only compounded when State and local governments become involved.

Regarding the States's relationship with the Federal Government, I'm not sure what more the Federal Government can do besides what it is trying to do. Secretary Leavitt is trying to make it crystal clear to each State that they need to prepare themselves. They are not all getting the message.

But I'm also concerned about integration even within HHS. Let me say that I have high regard for both Secretary Leavitt and Assistant Secretary Stewart Simonson. And I am not just saying that out of courtesy. I mean it.

Nonetheless, in my opinion the people developing the communications strategy are not coordinating closely enough with the people actually planning the agency's emergency response.

In a pandemic, 1918 clearly demonstrated that the communications strategy is absolutely crucial to containing fear and keeping society functioning. It is not an afterthought, it is an essential.

Thank you very much.

Senator SPECTER. We turn now to Dr. Richard Webby, member of the Department of Infectious Disease at St. Jude Children's Research Hospital in Memphis, bachelor's and Ph.D. from University of Otago in New Zealand. You are a colleague of Dr. Robert Webster, Dr. Webby, correct? He was a renowned expert, hard to find unless you have a direct line to Hong Kong I understand. You have 5 minutes, Dr. Webby.

STATEMENT OF DR. RICHARD WEBBY, PROFESSOR, ST. JUDE CHILDREN'S HOSPITAL

Dr. WEBBY. Thank you Mr. Chairman, Senators, yes, Dr. Webster is actually on a plane now to Hong Kong, so you'd also need a line to the airplane as well.

I first want to spend a few minutes talking a little bit more about the current situation from the angle of I guess basic science, what the virus is doing, a couple of areas where we really need basic research as well you know to help us toward this goal of preparedness. Some of this information we've already heard this morning, so I can go through some of it fairly quickly.

The first is, and the most important fact is this virus is still full entrenched throughout Asia, Europe, and a likely now also moving into the Middle East. We certainly contend this virus is likely in migratory birds, and I think in the foreseeable future we're going to have to live with this virus, it's not going away. Talking about human cases, this year we've seen human cases in China, Indonesia, and in Turkey. More recently a suspected case in Iraq, and some of these figures are likely to increase as the WHO gets more information from these current outbreaks, more samples and can confirm some of the suspected cases.

Again that brings to the point that I want to spend a little bit of time on, is Turkey and what we're learning about the disease from the current outbreak in Turkey. How we're learning that, is again through the total cooperation of the Turkish authorities, as Dr. Gerderling spoke about this morning there are WHO teams in Turkey, we're getting a lot of samples coming out of that region in real time. You know some of the information that this is showing us is, there seems to be a few more perhaps mild cases, or "A" symptomatic cases of HDN1 in Turkey. Whether that's a property of the virus itself, the virus—I won't cover this again. The virus in Turkey is different than the viruses in some of the other parts of Asia.

So whether it's a property of virus, whether it's a property of the genetics of the host, or whether it's actually a property that we're just getting access to samples, or getting to people soon after they show symptoms, so we're getting the best samples to detect these cases. Again some of the data that was mentioned earlier, these particular changes that the WHO have described. We would consider looking at the sequence of these viruses in Turkey. They have signatures that we normally see in human flu viruses as opposed to avian flu viruses. We can do a lot of hand waving about what they mean, but the bottom line is we really don't know. And as far

as adapting to humans, is that why we're seeing these plight of human cases in Turkey, again we just don't know. We can certainly do these experiments in the lab, but again that's going to take having the funds to do those.

Again, moving onto the virus and to the expand a little bit on that point I've talked about, that the HDN1 outbreak is not one virus, it's actually a number of different viruses that genetically, and are anti-genetically distinct. And in general terms there's three groups of viruses out there, the viruses from Vietnam, Thailand, are one group. The viruses from Indonesia form another, and certainly the viruses that started off in migratory birds, at least that's when we first saw them, migratory birds in China are now moving through Europe, is actually another group of virus.

So practically what does this mean, it means that we've got to keep this in mind when making these preparations of these pre-pandemic vaccines. Now will a pre-pandemic vaccine from a virus in Vietnam, which is the virus that's a pre-pandemic certainly in the United States at the moment, will that protect against viruses from Turkey, will it protect against viruses from Indonesia. Again, we don't—we don't really know. We need a lot more basic research. This is not a the level of trials. It's at the level of animal studies, to look at these cross protection.

Also we need a lot more work, obviously the Holy Grail for flu is a broadly reactive vaccine and there are approaches such as a recombinant DNA approach that we heard a little about this morning, that could potentially lead to that end. Unfortunately they need—if that outbreak was here tomorrow, they need to be up here, at the moment they're only down here, in terms of development.

So the million dollar question I guess is with whether this virus will gain the ability to transmit human to human, and I know it's not a satisfactory answer, but the real answer is we have no idea at all. Even amongst experts in the field—actually I spoke to one expert in the field once and asked him this question, what do you think about this, and his answer to that was, you got more chance of getting kicked to death by a duck. So I think that explains that even with the experts in the field, there is a range of opinions about this virus.

PREPARED STATEMENT

What we do know is that a pandemic flu will occur, and that this H5N1 virus is a very, very nasty virus. It's not your ordinary run of the mill flu virus. It's highly pathogenic, and certainly my opinion in terms of a disease right up there with 1918. Thank you.

Senator SPECTER. Thank you very much Dr. Webby.

[The statement follows:]

PREPARED STATEMENT OF DR. RICHARD WEBBY

CIRCULATION

The H5N1 viruses continue to circulate in avian populations throughout Asia and parts of Europe. There are some unconfirmed reports of infected avian species in the Middle East. The most recent activity in humans has been reported in China (2 in 2006), Indonesia (3 in 2006), and Turkey (4 in 2006). These figures represent World Health Organization confirmed cases and the actual number, particularly in

Turkey (up to 21), is likely to rise as suspected cases are confirmed by reference laboratories.

TURKEY

The current outbreak in Turkey is receiving much attention. Due to the total cooperation of authorities in Turkey and hence a strong international presence, we are getting good information from this outbreak. Some of the preliminary data suggest that, at least in Turkey, there have been a number of asymptomatic or mildly affected people. Whether this is a property of the extra surveillance here or a difference in the viruses from Asian and Europe is still uncertain. It is very likely that both are playing a role.

Data released by the WHO collaborating center for Influenza in Mill Hill London shows that there have been some notable changes detected in viruses isolated from Turkey. Of particular importance is a change within a protein called the hemagglutinin. This change is more often seen in human influenza viruses than in avian viruses and could theoretically increase the binding of the avian virus for human cells. Practically, the consequences of this change are really unknown, and much more basic research needs to be done to examine this. Large scale influenza virus sequencing efforts such as that of TIGR (NIAID funded) and St Jude Children's Research Hospital are providing valuable information to help address issues such as what factors are blocking the effective human transmission of H5N1.

NATURE OF THE VIRUS

It should be stressed that this outbreak is not caused by a single type of H5N1 virus. Although all H5N1, there are three distinct groups of virus circulating. Generally speaking, and although there is much variability even within these 3 groups, the viruses can be separated into:

(i) many of the viruses from Vietnam and Thailand.

(ii) viruses from Indonesia and some from China.

(iii) viruses from outbreaks in wild aquatic birds in China, and those moving through Europe.

Good progress has been made with developing potential H5N1 vaccines, but the practical consequence of the above is that new vaccine reference strains will need to be produced (although we predict that substantial cross-protection will be generated from those already available) as the viruses continue to evolve. Recommendations on reference strains will continue to be provided by WHO. Basic research into more cross reactive vaccines and anti-virals should be encouraged.

SUMMARY

Unfortunately there is no way to predict whether H5N1 will become pandemic in humans. The virus is still poorly infectious and transmissible to humans and we do not know how it has to mutate to change this. The only things that we do know are that flu pandemics are inevitable and that this H5N1 is a particularly nasty virus. Regardless of the direction in which it goes, expenditure of money to prepare against H5N1 will help prepare for infectious disease emergencies caused my many agents.

Senator SPECTER. We turn now to Mr. George Abercrombie, president, CEO, Hoffmann-La Roche. Bachelors' degree from the University of North Carolina, MBA from Harvard, the time is very limited for your formal presentation, you have talked to staff, and will have a chance to talk further. We've only allocated 2 minutes Dr. Abercrombie. Proceed.

STATEMENT OF DR. GEORGE B. ABERCROMBIE, PRESIDENT, CHIEF EXECUTIVE OFFICER, HOFFMANN-LA ROCHE PHARMACEUTICALS

Dr. ABERCROMBIE. Thank you Chairman Specter, ranking member Harkin. I just want to share with the committee that my company Roche is proud of our history of partnership with the Government, and pandemic preparedness and response planning. I'd like to highlight three key points, Tamiflu our product is an effective influenza antiviral medication. Experts agree that immediate ac-

cess to Tamiflu and other antivirals are an essential part of any plan to help control the spread of a pandemic flu virus and my company Roche continues to accelerate production of Tamiflu to fulfill pandemic orders world wide.

The HHS pandemic influenza plan calls for stockpiling at least 81 million antiviral treatment courses. Enough to cover about 25 percent of the U.S. population. However the Tamiflu manufacturing process requires significant time and capacity and therefore surge production at the time of the beginning of a pandemic outbreak is not an option.

This is the reason why Tamiflu must be stockpiled in advance of a pandemic, and positioned for rapid distribution. Here in the United States Roche has filled pandemic stockpiling orders totaling about 5 million treatments. Until last week we were working under a letter of intent from the Government seeking an additional 15 million treatments to be delivered in fiscal year 2006. But last Friday at the end of the week, we received a revised a projection from HHS, indicating that the fiscal year 2006 stockpile purchases may total up to 46 million courses of treatment. Now according to that letter 18 million of the total would be purchased directly by HHS, 28 million would be dependent upon purchase decisions made by individual States.

We are ready to begin filling these orders as soon as we receive the final contract, and we are committed to ensuring that we can provide the full stockpile recommended to cover 25 percent of the U.S. population as outlined in the HHS plan.

PREPARED STATEMENT

However, given global demand we have sold Tamiflu to about 65 countries around the world, the U.S. Government must have the resources required to make an immediate and sustained contractual commitment for that full stockpile.

Senator, on behalf of Roche, thank you for highlighting the importance of this critical public health issue, and I'm pleased to answer any questions that you may have.

Senator SPECTER. Thank you very much Dr. Abercrombie.

[The statement follows:]

PREPARED STATEMENT OF DR. GEORGE B. ABERCROMBIE

Chairman Specter, Ranking Member Harkin and Members of the Subcommittee, I am George Abercrombie, President and Chief Executive Officer at Hoffmann-La Roche Inc. ("Roche"), a research-based pharmaceutical company. I am grateful for this opportunity to discuss with you the roles of Roche and antiviral drugs in pandemic influenza preparedness and response. I commend Congress, and specifically the Chairman and Ranking Member of this Subcommittee, as well as the Chairman of the full Senate Appropriations Committee, for making the protection of the American people against avian influenza a priority issue during the fiscal year 2006 appropriations process. We also applaud the President, Secretary Leavitt, and the Department of Health and Human Services (HHS) for the seriousness with which they have approached this issue.

There are three key points that I would like to leave with you today.

(1) Tamiflu® is an effective antiviral medication for use in the prevention and treatment of influenza, and it has been shown to have activity against the H5N1 influenza strain. Experts agree that Tamiflu® and other antivirals are an essential part of any plan to help control the spread of a pandemic flu virus and potentially reduce illness, hospitalizations, and deaths during an influenza pandemic.

(2) Achieving rapid patient access to antivirals in the event of an influenza pandemic will be critical; and

(3) Stockpiling antiviral drugs in advance of an influenza pandemic is the only way to ensure that they are available when and where we need them. Roche has been taking steps to prepare for a pandemic for three years and is prepared to produce Tamiflu® in sufficient quantities so that the drug will be accessible to the American people during a pandemic.

THE PANDEMIC INFLUENZA THREAT

Public health experts from around the world agree that we stand on the precipice of a new influenza pandemic. Pandemic influenzas are defined by three characteristics. First, little or no pre-existing immunity to the strain exists in the human population. Second, the strain causes illness in humans. Third, there is sustainable transmission of the virus from person to person. The avian influenza strain known as H5N1 currently satisfies the first two conditions, and public health officials such as Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) and Dr. Lee Jong-Wook, Director-General of the World Health Organization (WHO) have publicly expressed grave concern that H5N1 could soon acquire the capability of efficient transmission from person to person.[1]

Simply put, the threat of pandemic influenza is real. In the HHS Pandemic Influenza Plan (HHS Plan), HHS notes that an influenza pandemic "has the potential to cause more death and illness than any other public health threat."[2] Last year, Secretary Michael Leavitt testified before the House Committee on Government Reform that "[i]f a pandemic virus strain emerges, it is estimated that upwards of 30 percent of people exposed could become infected and the death rate will likely be considerably higher than that seen with seasonal influenza."[3] Studies cited recently by the CDC estimate that, without vaccines or drugs, a "medium level" pandemic would kill between 89,000 and 207,000 Americans, and sicken another 20 to 47 million—causing up to 42 million outpatient visits and 734,000 hospitalizations.[4]

The availability of adequate supplies of vaccines and antivirals is recognized as an essential component of pandemic preparedness by both the HHS Plan and the WHO Global Influenza Preparedness Plan.[5] However, there is no approved vaccine currently available, and it will likely take 3 to 6 months from the onset of a pandemic for an effective vaccine to be developed, produced and distributed widely. Once available, vaccines are expected to play a major role in bringing a pandemic under control. In the interim between the emergence of a pandemic strain and the development of a safe and effective vaccine, and during the course of a pandemic, antivirals will be an essential tool to treat influenza patients and limit the spread of the virus. Recently published models suggest that an influenza pandemic could be contained if 80 percent of those exposed to the virus used targeted antiviral drugs prophylactically.[6]

TAMIFLU® IS AN EFFECTIVE ANTIVIRAL MEDICATION

Tamiflu® (oseltamivir phosphate), licensed from Gilead Sciences and marketed globally by Roche, is the leading prescription oral antiviral drug for influenza. First approved by the FDA in 1999 for the treatment of adults with type A and B influenza, Tamiflu® is a neuraminidase inhibitor that directly attacks the influenza virus, compromising its ability to replicate, rather than simply addressing influenza

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[1] Pandemic Planning and Preparedness: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce, 109th Cong. (2005) (statement of Julie L. Gerberding, M.D., M.P.H., Director, CDC); Lee Jong-Wook, M.D., M.P.H., Director-General, World Health Organization, Address at the Health Ministers Meeting on Global Pandemic Influenza Readiness (Oct. 24, 2005) available online at http://www.who.int/dg/lee/speeches/2005/influenza_readiness/en/index.html.

[2] Department of Health and Human Services, HHS Pandemic Influenza Response and Preparedness Plan, Executive Summary 4, (Nov. 2004), available at http://www.hhs.gov/pandemicflu/plan/pdf/Overview.pdf.

[3] The HHS Pandemic Influenza Plan: Hearing Before the H Comm. on Governmental Reform, 109th Cong. (2005) 2 (statement of Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services).

[4] Centers for Disease Control and Prevention, Influenza Pandemic Fact Sheet (Mar. 8, 2005), available at http://www.cdc.gov/flu/avian/gen-info/pandemics.htm.

[5] Department of Health and Human Services, HHS Pandemic Influenza Response and Preparedness Plan, Executive Summary 4, (Nov. 2004), available at http://www.hhs.gov/pandemicflu/plan/pdf/Overview.pdf; World Health Organization, WHO Global Influenza Preparedness Plan 13 (2005), available at http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf.

[6] N.M. Ferguson et al., A Population-Dynamic Model for Evaluating the Potential Spread of Drug-Resistant Influenza Virus Infections During Community-Based Use of Antivirals, 51 Journal of Antimicrobial Chemotherapy 977 (2003); I.M. Longini et al., Containing Pandemic Influenza with Antiviral Agents, 159 Am. J. Epidemiology 623 (2004).

symptoms. As of December 2005, Tamiflu® is indicated for both treatment of uncomplicated acute illness due to influenza infection in patients one year and older who have been symptomatic for no more than 2 days and prophylaxis of influenza in patients one year and older. Fortunately, Tamiflu®, which is available in both capsule and oral suspension form, has a low likelihood of clinically significant drug interactions and is generally well-tolerated, with nausea and vomiting being the most frequently reported adverse events. To date, Tamiflu® has been used by about 33 million patients worldwide, 13 million of whom were children. Tamiflu® is available for the treatment of influenza in more than 80 countries.

At this time, Tamiflu® is the only oral antiviral shown to be active against the H5N1 avian influenza virus currently circulating in Asia.[7] Designed to be effective against influenza A and B types, Tamiflu® has shown activity against H5N1, a Type A influenza virus, in the laboratory and in animals infected with the H5N1 strain taken from humans. It was also reported that Tamiflu® was used successfully in the management of an outbreak of the H7N7 avian strain in the Netherlands in 2003, which infected around one thousand people. Tamiflu® was found to protect infected poultry workers from contracting this strain, where mouth and nose masks did not.

Tamiflu® works by blocking the action of the neuraminidase enzyme on the surface of the virus. When neuraminidase is inhibited, the virus is not able to spread to and infect other cells in the body. Consistent with labeling, WHO recommends use of Tamiflu® for treatment within 48 hours of symptom onset to reduce the duration of viral replication and improve prospects of survival.[8]

I would like to take this opportunity to address questions that the Subcommittee may have related to recent news stories about resistance. The potential exists for an influenza virus to emerge with decreased sensitivity to any antiviral treatment, and Roche has both internal and external mechanisms in place to monitor for emerging reports of resistance. The vast majority of data collected from patients worldwide who were treated with Tamiflu® for seasonal influenza indicate that the incidence of resistant virus is rare.

Even researchers, who recently reported on Tamiflu®-resistant H5N1 strains in two Vietnamese patients who subsequently died,[9] underscored that Tamiflu® "constitutes an important treatment option, and stockpiling of this drug is part of pandemic-preparedness plans."[10] Moreover, although resistant mutations of the H5N1 virus were detectable in these patients at the end of treatment with Tamiflu®, the viral mutation isolated in those patients is known to be less transmissible than the wild-type virus present in other subtypes of influenza viruses.

Human clinical trials have not yet been conducted with the H5N1 avian flu strain, and it is important that different treatment regimens be explored, including the possibilities of using a higher dose and/or a longer treatment duration. To that end, Roche is now collaborating with the National Institutes of Health (NIH) and WHO, who are undertaking clinical research to assess the efficacy of a higher dose of Tamiflu® in the treatment of severe influenza, including the H5N1 virus.

According to the Neuraminidase Inhibitor Susceptibility Network (NISN), the clinical and epidemiological implications of possible antiviral resistance in future pandemic influenza viruses are incompletely understood. However, neuraminidase inhibitors such as Tamiflu® should be effective for both prevention and treatment for such viruses, and concerns about antiviral resistance, particularly to neuraminidase inhibitors, should not dissuade countries from developing adequate antiviral stockpiles for pandemic response.[11]

THE ROLE OF TAMIFLU® IN AN INFLUENZA PANDEMIC

There are two ways Tamiflu® can be used in a pandemic setting. First, in infected patients, Tamiflu® begins working immediately and is active against multiple influ-

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[7] See The Threat of and Planning for Pandemic Flu: Hearing Before the Subcomm. on Health of the House Comm. on Energy & Commerce 109th Cong. (May. 26, 2005) (Statement of Dr. Julie Gerberding). See also M.D. de Jong et al., Oseltamivir Resistance during Treatment of Influenza A (H5N1) Infection, 353 New Eng. J. Med. 2667 (2005) (The benefit of oseltamivir antiviral treatment "is suggested by the rapid decline in the viral load to undetectable levels in all four survivors in the current series.).

[8] World Health Organization, Avian Influenza ("Bird Flu") Fact Sheet (Jan. 2006), available at http://www.who.int/csr/disease/avian__influenza/avianinfluenza__factsheetJan2006/en/index.html.

[9] M.D. de Jong et al., Oseltamivir Resistance during Treatment of Influenza A (H5N1) Infection, 353 New Eng. J. Med. 2667 (2005).

[10] Id.

[11] NISN Statement on antiviral resistance in influenza viruses. Weekly Epidemiological Record (2004); 33, 308–308.

enza types. Patients can still mount an immune response to the virus while taking Tamiflu®, which reduces duration and severity of symptoms when administered within 48 hours of symptom onset. Second, Tamiflu® can be used preventatively to help those exposed to the virus from becoming infected. When administered within 48 hours of exposure, clinical data demonstrate Tamiflu® is highly effective at preventing seasonal flu, a characteristic which, if replicable with a pandemic strain, would be key to controlling the spread in households, the workplace and healthcare settings.

Overall, experts agree that Tamiflu® is uniquely suited to pandemic stockpiling for several reasons: (1) Tamiflu®-resistant viruses appear rare and generally are not readily transmissible in humans; (2) the product has a five-year shelf life, and (3) unlike other antivirals, Tamiflu® is active throughout the entire body. This could be clinically important, as some of the reported H5N1 human cases have documented illness in the lungs, digestive tracts, mouths, and noses of victims.[12]

ROCHE HAS EXPANDED ITS CAPACITY TO RESPOND TO PANDEMIC PLANNING WORLDWIDE

Historically, Roche has produced enough Tamiflu® to meet the seasonal influenza demand, and we have marketed the product responsibly to avoid undermining public health messaging regarding seasonal vaccinations. U.S. prescriptions for Tamiflu® capsules have risen from roughly 700,000 in the 1999–2000 flu season to over 1.7 million in the 2004–2005 flu season. In contrast, the HHS Plan calls for the stockpiling of at least 81 million antiviral treatment courses, which is sufficient to cover 25 percent of the U.S. population.[13] To reach this goal, it is imperative that Tamiflu® be stockpiled and pre-positioned in advance of the outbreak of a pandemic. Surge manufacturing in the event of a pandemic is not an option. The manufacturing process for Tamiflu® requires a number of months to go from raw materials to finished product, and significant lead time is needed to build stockpiles at the magnitude called for in the HHS Plan.

As early as 2003, before we had received any firm governmental commitments, Roche recognized that responding to pandemic influenza would require enormous additional capacity. Since 2003, we have doubled our production capacity each year. By the end of the third quarter of 2006, we will be able to produce over 300 million treatments of Tamiflu® annually. We have reached this potential in part by adding capacity to meet specific production challenges. Roche recently granted sub-licenses for Tamiflu® production to two companies, one in India and one in China, for production for less-developed nations, and we continue active discussions with a dozen potential sub-contractors as part of our ongoing United States efforts to expedite production. This process has included an extensive evaluation of the technical capabilities of potential sub-contractors. Currently, the Global Tamiflu® Supply Network includes approximately 50 external suppliers and 7 external manufacturers.

We have now received and are on schedule to fulfill Tamiflu® stockpile orders from almost 65 countries. We are also particularly proud that we have been able to donate 5 million Tamiflu® treatment courses to WHO, three million treatments for their mobile rapid response stockpile and two million treatments for use against avian influenza outbreaks in developing nations.

We are also committed to expanding and enhancing our U.S. production processes. During discussions with HHS, which first began 3 years ago, HHS made three requests regarding U.S. production of Tamiflu®. Roche has fulfilled them all.

(1) Roche created a U.S. supply chain for Tamiflu® production, which is now operational, producing 15 million treatments per year. By the end of the third quarter of 2006, that chain will be capable of producing about 80 million treatments annually.

(2) Roche has developed special U.S. pandemic packaging for stockpiling Tamiflu® to ease distribution and administration; and

(3) Roche is providing Tamiflu® to Federal and State governments at a reduced pandemic stockpiling price.

Based on subsequent conversations with HHS, we are also bringing to the United States the ability to produce a synthetic form of the initial starting material for Tamiflu®, Shikimic Acid, reducing our reliance on scarce natural sources.

With respect to the U.S. stockpile, Roche has filled all U.S. Government pandemic stockpiling orders to date, which total approximately 5 million courses of therapy, less than 2 percent of the U.S. population. Until last week, we were working under

[12] World Health Organization, Avian Influenza ("Bird Flu") Fact Sheet (Jan. 2006), available at http://www.who.int/csr/disease/avian_influenza/avianinfluenza_factsheetJan2006/en/index.html.

[13] U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan, Part 1_Strategic Plan 24 (2005).

a letter of intent from the government seeking an additional 15 million treatments to be delivered in fiscal year 2006. On Friday, we received a revised projection from HHS indicating that fiscal year 2006 stockpile purchases may total up to 46 million courses of treatment. According to that letter, 18 million of that total would be purchased directly by HHS, and 28 million would be dependent upon purchase decisions made by individual States. Additional purchases are planned for fiscal year 2007 and 2008.

We are ready to begin filling these orders as soon as we receive a final contract, which we anticipate shortly. Thereafter, Roche is committed to ensuring that we can provide the full stockpile recommended to cover 25 percent of the U.S. population as outlined in the HHS Plan. However, given global demand, the U.S. Government must have the resources required to make an immediate and sustained contractual commitment for that full stockpile.

We are also meeting the seasonal influenza need for Tamiflu®. Recently, Roche lifted all restrictions on the distribution of Tamiflu® for seasonal orders and is now shipping product to all U.S. markets as part of its proactive inventory management plan. Roche had previously been distributing Tamiflu® only to U.S. cities where high incidence of influenza was being reported, based on the FluSTAR Surveillance System. This plan was implemented last fall following a huge spike in Tamiflu® demand, caused in part by fears of a potential flu pandemic. The decision to open distribution was based on recent developments, including increased flu reports from around the country and a Health Alert issued by the CDC recommending against the use of two other antiviral medications, amantadine and rimantadine, for the remainder of the 2005–2006 season, due to high levels of resistance.

FULL FUNDING OF THE PRESIDENT'S NATIONAL STRATEGY ON PANDEMIC INFLUENZA IS ESSENTIAL

The HHS Plan is a broad-based strategic document, which identifies the critical needs the United States must address to prepare adequately for the emergence of an influenza pandemic.[14] We applaud the HHS Plan's call for critical investments not only to improve domestic vaccine capacity and ensure sufficient antiviral supplies, but also to enhance national and international disease surveillance, and to develop appropriate Federal, State, and local response plans.[15] If integrated into a strong pandemic preparedness and response plan, such as is outlined in the HHS Plan, Tamiflu®—particularly in the early stages in a pandemic when a vaccine may not be available—can play a primary role in treating and preventing infections. During a pandemic, there will be heightened awareness of influenza and—with the type of functioning infrastructure and appropriate pre-positioning called for in the HHS Plan—we believe rapid response can be achieved.

We are appreciative of the substantial funding provided to date for the HHS Plan. However, it is absolutely essential that all parts of the HHS Plan be funded in full without delay. Piecemeal appropriations will only add an additional hurdle for pandemic planners to overcome. The currently circulating potential pandemic virus is a formidable foe, yet global public health surveillance has given us the rare benefit of a warning of what is likely to come. Today is our chance to invest in the future health of this Nation by implementing sound measures that will improve our overall public health responsiveness and help protect us from pandemic influenza. Based on our expansion to date, Roche is currently in a position to accommodate a U.S. stockpile order that would satisfy the coverage goals of 81 million treatment courses outlined in the HHS Plan. To fulfill such an order, however, requires an immediate and sustained commitment from the U.S. Government.

We at Roche want to continue to work closely with this Subcommittee, HHS, and governments around the world to assist in ensuring our pandemic preparedness. I can assure you that this effort is our highest priority. On behalf of Roche, thank you for highlighting the importance of this critical public health issue.

I am pleased to answer any questions you may have.

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[14] U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan, Executive Summary (2005). See also The HHS Pandemic Influenza Plan: Hearing Before the H Comm. on Governmental Reform, 109th Cong. (2005) (statement of Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services).

[15] See U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan, Executive Summary (2005).

HOFFMANN-LA ROCHE INC.,
Nutley, NJ, February 7, 2006.

Senator ARLEN SPECTER, *Chairman,*
Senator TOM HARKIN, *Ranking Member,*
Subcommittee on Labor, Health and Human Services, Education, Related Agencies, Senate Committee on Appropriations, Washington, DC.

DEAR CHAIRMAN SPECTER AND SENATOR HARKIN: Thank you for the opportunity to appear before your Subcommittee earlier this week to offer testimony and answer questions regarding the roles of Hoffmann-La Roche Inc. (Roche), and antivirals in pandemic influenza preparedness and response. We applaud your efforts to raise awareness about the urgent need for pandemic planning, and your leadership in ensuring that the U.S. Government has the necessary resources to protect our Nation from this looming threat.

As requested, we are pleased to answer the questions you posed prior to the conclusion of the hearing. Below please find a restatement of each question followed by Roche's response.

Question. Please provide more detail regarding the most recent letter of intent to purchase Tamiflu® for U.S. pandemic stockpiles that Roche has received from the Department of Health and Human Services (HHS). Specifically, please discuss what level of contractual authority Roche requires to begin acting on this order.

Answer. The most recent HHS letter of intent, dated January 27, 2006, projects procurement of Tamiflu® for the pandemic stockpile as follows:

The amount that HHS intends to purchase or order on behalf of State governments in fiscal year 2006 has been revised to up to forty-six (46) million courses, including amounts subject to pending discussions with State governments. HHS intends to purchase additional amounts in fiscal year 2007 and fiscal year 2008.

Current planning for these fiscal year 2006 purchases envisions eighteen (18) million courses to be purchased by HHS and an arrangement with State governments where HHS would subsidize State purchases of twenty-eight (28) million courses. The amount of State purchases is dependent on purchase decisions made by individual States.

While we fully appreciate the importance of this expression of intent, the letter specifically States that these purchase levels are both subject to change and contingent upon the availability of funding. Since Roche faces enormous demand for Tamiflu® from governments around the world, we cannot indefinitely reserve capacity on the basis of a non-binding letter of intent. To ensure that sufficient production capacity is reserved to meet the stockpiling goals of the HHS Pandemic Plan as rapidly as possible, it is essential that HHS proceed to finalize a binding contract with Roche for the maximum level of procurement permitted under current appropriations. Moreover, to ensure that HHS can enter into firm contractual commitments for the remainder of the required U.S. stockpile, it is critical that Congress appropriate the remaining funds required for stockpile purchases as soon as possible in 2006.

Question. Please comment on the proposed liability protections discussed during the hearing. Please indicate whether Roche believes the current provision is adequate and/or realistic; what obstacles, if any, Roche foresees; and any additional information that would be relevant given Roche's expertise in this area.

Answer. We believe the protections contemplated under the recently enacted Public Readiness and Emergency Preparedness Act of 2005 framework (Public Law 109–148) should address our significant concerns regarding the liability implications of the provision of Tamiflu® for the pandemic stockpile. Given the likely scenarios for pandemic use of Tamiflu®, including an unprecedented patient population, dosing at levels and for durations significantly in excess of labeling, and use under greatly reduced physician supervision, liability protections for pandemic use of Tamiflu® are reasonable and necessary. Thus, in addition to other contractual protections, we will be asking the Secretary of HHS to include Tamiflu® in any declaration triggering liability protections for pandemic countermeasure products. The protections under any such declaration should be comprehensive, and equivalent to those afforded to pandemic influenza vaccines.

Question. Please provide Roche's assessment of S. 2112, which would establish programs and activities to increase influenza vaccination rates through the provision of free vaccines.

Answer. Roche does not manufacture vaccines, and thus we defer to vaccine manufacturers' assessment of such legislation. However, please note that Roche strongly supports efforts to increase seasonal influenza vaccination levels, and we have consistently sought to ensure that the marketing of Tamiflu® is complementary to public health messages regarding the role of vaccines. We also note that, even with

greatly enhanced vaccination levels, increasing the seasonal use of antivirals would be beneficial in preventing and treating infections.

Roche is committed to working closely with your Subcommittee, HHS, and governments around the world to assist in pandemic preparedness. If you have further questions, please do not hesitate to contact me.

Respectfully submitted,

GEORGE B. ABERCROMBIE,
President and Chief Executive Officer.

Senator SPECTER. We'll turn now to Mr. Daniel Soland, president of the Vaccines of Chiron Corporation. Bachelor of Science and Pharmacy from the University of Iowa. We have another 2 minute allocation, the floor is yours Mr. Soland.

STATEMENT OF DANIEL SOLAND, PRESIDENT OF VACCINES, CHIRON CORPORATION

Mr. SOLAND. Thank you for the opportunity to appear before the committee, I will summarize three key points from my written statement. From Chiron's perspective as a vaccine manufacturer, we believe that there are three critical assets required for the United States to effectively prepare for pandemic influenza: one, technology and innovation; two, development capability to turn technology into effective products; and three, the capital investment to deliver new technologies in the shortest time possible.

My first point, technology and innovation: I think we all understand that vaccine research and development against new and deadly vaccines, is a long and very difficult process that requires sustained investment. Chiron initiated innovative research on avian influenza concerns back in 1997, after the H5NI outbreak in Hong Kong first infected humans. These studies reported in peer reviewed journals Lancet, Vaccine, and Journal of Infectious Disease, between 2001 and 2005 concluded that the use of Chiron's adjuvant a novel adjuvant, MF59 in an avian flu vaccine may allow dose-sparing, where using less vaccine adjuvant per person would allow more people to be immunized, and secondly to offer cross-protection, where the vaccine may offer protection against an avian virus even after it has changed or drifted over time.

This past October, Chiron reported promising data from an H9N2 another avian strain study which found that the vaccine formulations containing MF59 were highly used in the clinical trial were highly immunogenic, even at the lowest dose of 3.75 micrograms of antigen this is a quarter of the normal dose in seasonal flu vaccine. At the present time, we are in collaboration with the National Institute of Allergy and Infectious Diseases to evaluate the use of this adjuvant in a trial with H5NI.

Which brings me to the second point and that's development capability: Chiron is on track to deliver new technologies into innovative products with our adjuvanted vaccines which we just discussed. Our second-generation influenza manufacturing technology. Flu cell culture. Flu cell culture is an important technology for securing annual vaccine production and also for long-term pandemic preparedness. When approved by regulatory authorities it will provide significant advantages and flexibility over traditional manufacturing methods by eliminating the dependence on chicken eggs. Remember if we don't have chickens, we don't have eggs, we don't have——

Senator SPECTER. Mr. Soland, could you summarize at this point, please.

PREPARED STATEMENT

Mr. SOLAND. Sure. In my third and final point, I appreciate the uncertainties that Congress has faced with the question of if and when and relative to the global pandemic, juxtaposed against the need to act in a physically responsible way in tight economic times. However there is a sense of urgency growing everyday relative to pandemic influenza and the Government must engage in public private partnerships with all vaccine manufacturers to effectively prepare for the global pandemic. Thank you.

Senator SPECTER. Thank you very much Mr. Soland.

[The statement follows:]

PREPARED STATEMENT OF DR. DAN SOLAND

Mr. Chairman, Members of the Committee: Thank you for the opportunity to provide a statement to the Appropriations Committee to address the critical importance of funding for pandemic preparedness. I am Dan Soland, President of Chiron Vaccines, one of the three divisions of Chiron Corporation, a U.S. biotechnology company headquartered in Emeryville, California. Chiron Corporations two other businesses are: BioPharmaceuticals and Blood Testing.

CHIRON OVERVIEW

Chiron Vaccines is committed to the development and supply of vaccines to protect society against a range of important diseases, notably the possibility of a global influenza pandemic. We, and our predecessor companies, have a 100-year history in vaccine development and are the world's fifth-largest vaccines business with facilities located throughout Europe and Asia. Chiron Vaccines is the world's second-largest manufacturer of influenza vaccines and has important meningococcal, pediatric and travel vaccine franchises. We are the leading vaccine manufacturer in the United Kingdom, Germany and Italy. The company's portfolio of products includes vaccines for influenza, meningococcus C, rabies, tick-borne encephalitis. haemophilus influenzae B (Hib), polio, mumps, measles and rubella (MMR) and diphtheria, tetanus and pertussis (whooping cough).

CHIRON AND PANDEMIC INFLUENZA

I welcome the opportunity to discuss with you the uncertain environment that the very real threat of a global influenza pandemic creates, and the importance of stabilizing our public health capacity and manufacturing infrastructure through public-private partnerships to save the lives of millions of Americans,

From Chiron's perspective as a manufacturer, we believe that there are three critical assets required for the United States to effectively prepare for pandemic influenza: technology and innovation, the development capability to turn technology into effective products and the capital investment to deliver new technologies in the shortest time possible.

Technology and Innovation.—Vaccine development against new and deadly viruses is a long and laborious process. The erosion of our domestic vaccine manufacturing capacity over the past decade has placed us in a precarious position relative to protecting public health, The most recent avian influenza concerns first arose 9 years ago, in 1997, when the H5N1 avian influenza virus moved from birds into humans. The evolution of this virus during the past 9 years and its emergence outside of the Pacific Rim countries in the past several months has heightened concern about our preparedness to deal with a global influenza pandemic.

Chiron initiated innovative research on avian flu after the H5N1 outbreak in Hong Kong first affected humans. The high mortality of the H5N1 virus among birds, the quality that made it such a concern, also made it problematic to use in vaccine development—the virus tended to kill the chicken eggs that served as the first step of the vaccine production process. Chiron instead worked with a less pathogenic strain of H5 and consequently developed an H5N3 virus vaccine for testing against the H5N1 virus strain. Studies of this vaccine included Chiron's proprietary adjuvant, MF59. An adjuvant is a substance that is added to a vaccine to enhance the body's immune response to the vaccine's active constituent, called the antigen.

Our research found that, without the adjuvant, various tested doses of vaccine did not induce protective levels of antibodies. With the adjuvant, however, the vaccine induced protective antibody levels against the original H5N1 strain. Even at dose levels of 7.5 micrograms—half the dose of the seasonal influenza vaccine-protective levels were achieved. Importantly, people immunized with the adjuvanted vaccine in this trial showed protective antibody tilers not—just against the original H5N1 strain, but also against drifted strains of H5N1 that had changed over time.

These studies, reported in the peer-reviewed journals Lancet, Vaccine and the Journal of Infectious Diseases between 2001 and 2005, concluded that the use of Chiron's adjuvant MF59 in an avian flu vaccine may:

—allow dose-sparing, in which using less vaccine per person would allow more people to be immunized, and

—offer cross-protection, in which the vaccine may offer protection against an avian flu virus even as it changed over time.

These findings must be validated by additional research. We were pleased with the validating research recently announced as a result of our collaboration with the National Institute of Allergy and Infectious Diseases (NIAID). In October 2005, Chiron reported promising data from an H9N2 study which found that all vaccine formulations containing MF59 were highly immunogenic, even at the lowest dose of 3.75 micrograms (a quarter of the dose used in seasonal flu vaccines). At the present time, we are collaborating with the NIAID to evaluate the use of this adjuvant in a trial of our H5SN1 vaccine.

What is the lesson from Chiron's multi-year investment in pandemic vaccine research? Establishing the framework for the development of a pandemic vaccine is a long-term process that requires funding stability. Further, it is critically important the industry have the development capability to translate research into effective products.

Development Capability.—Chiron has pushed the frontiers of science with the development of second-generation technologies for influenza vaccines. We believe we are on track to turn new technologies into innovative products with our adjuvanted vaccines and our second-generation influenza technology, Flu Cell Culture (FCC).

I have already addressed our track record in innovation for adjuvanted vaccines relative to pandemic influenza. Chiron has an adjuvanted vaccine. Fluad, which has been approved and on the market in several European countries for seasonal influenza for almost a decade. Experience with the use of this product in millions of Europeans positions us to apply our knowledge with adjuvanted vaccines to pandemic influenza development.

Additional technologies and innovation, such as FCC, are also critical to stabilize manufacturing capacity and rapidly respond to a global influenza pandemic. FCC vaccines represent the next generation of influenza vaccine production, both for annual vaccines and for long-tern pandemic preparedness. FCC can provide significant advantages over traditional manufacturing methods by eliminating the dependence on chicken eggs for production. Removing egg supply lead times would enable flexible and faster start-up of vaccine production in the event of an annual vaccine supply shortfall or an avian influenza pandemic.

Chiron has completed its second pivotal phase III enrollment in Europe for our FCC vaccine and plans to submit for E.U. regulator approval in 2006. Chiron has a validated, full scale manufacturing facility for FCC in Marburg, Germany that is presently undergoing expansion in preparation for our launch in the E.U. This fall we initiated our FCC development program in the United States with the launch of our Phase I/II research program. We are engaged with the U.S. regulatory authority, the Food and Drug Administration (FDA) and its advisory bodies, to structure the pathway for development and regulatory approval in the United States.

Translating innovative technology into products on the market is not possible without a strong and well-resourced FDA. Over the past year, Chiron has had the opportunity to work closely with the men and women of the FDA as we proceeded through the remediation of our Liverpool facility. The FDA is to be commended for its professionalism, dedication and commitment to the vaccine industry. Having observed their dedication, it is regrettable that the funding for FDA under the recently enacted pandemic influenza supplemental appropriation is so limited. This agency will be pivotal in assuring that manufacturers can translate innovation into effective products and it is in the best interest of the United States that the FDA be appropriately funded to meet this important challenge. Mr. Chairman, Members of the Committee, this is one critical area where the government needs to provide additional resources to the FDA so they can carry out their mandate relative to pandemic preparedness.

The close collaboration of the FDA with European regulatory authorities enabled Chiron to supply influenza vaccine this season. In addition, HHS announced this

past fall the award of a contract to Chiron for the production of pandemic influenza vaccine for the government's stockpile, which will be a critical source of vaccine supply in the early days of a pandemic. Production of the pandemic stockpile vaccine is underway now.

Capital Investment.—The growing concern with regard to the inevitability of a global influenza pandemic, coupled with the erosion of our public health and manufacturing infrastructure in the United States, creates a precarious situation as we develop the technologies, tools and policies to deal with pandemic influenza. We are engaged in a monumental undertaking that may save the lives of millions of Americans. It is critically important that the capital investment be available to deliver innovative technologies to the U.S. market in the shortest time possible. I should add that meeting the technical challenges required to prepare for a possible pandemic influenza outbreak entails significant business risks for manufacturers such as Chiron, Even with the support of the government, Chiron will be obliged to make a significant investment of time and money before it is able to realize any return on that investment. And there is no guarantee that Chiron will recover its costs or turn a profit on that investment.

The political resolve and will to create an environment of certainty for vaccine manufacturers is crucial to create U.S. vaccine manufacturing capacity and enable it to flourish, I appreciate the uncertainties that Congress faces associated with the "it" and "when" questions relative to a global pandemic juxtaposed against the need to be fiscally responsible in tight economic times. However, we must have a sense of urgency—the U.S. vaccine capacity and our public health infrastructure has been eroded over several decades and they will not be restored in days, weeks or months. These assets will take years to rebuild.

Chiron Corporation strongly supported the administration's funding request for pandemic influenza of $7.1 billion transmitted to Congress in November 2005. The administration's request was structured to provide the Department of Health and Human Services (HHS) with the flexibility and resources to make the critical decisions about resource allocation to minimize the human and economic toll of pandemic influenza. Priorities that require full funding include:

—Improving our health care system capacity to identify and care for infected individuals;
—Global and national surveillance in order to allocate scare resources efficiently;
—International responsibilities to aid nations where H5N1 is endemic;
—Stockpiling to protect U.S. citizens; and
—The substantial challenge of restoring our vaccine industry in the United States.

We appreciate that Congress provided a significant down payment on the administration's request for HHS this past December as part of the Department of Defense Appropriations bill; however, the resources provided to HHS fell $3.4 billion short of the administration's request. This shortfall did not send a positive message to manufacturers about the certainty and stability of the government efforts to fully address a public health threat of this magnitude. The message of certainty and stability for the U.S. vaccine manufacturing industry needs to be clear and unequivocal in light of its erosion in past years.

The administration needs to include the remaining $53.4 billion for HHS in their fiscal year 2007 funding proposal and Congress must find the resolve to fully resource this program. These funds are vitally important for competitive research programs: resources to fund the FDA and HHS's pivotal role in vaccine development and facility validation; and establishing and expanding domestic manufacturing capacity of second generation technologies, among other important priorities, so that pandemic preparations can be effectively resourced.

The government must engage in numerous public-private partnerships to maximize U.S. investment. Preparing for a global pandemic requires the consistent, committed and full collaboration of all vaccine manufacturers. A December 2005 report issued by the General Accounting Office (GAO) cites the potential for substantial economic impact as a result of a global pandemic. In its analysis, the GAO developed two models to estimate economic impact: severe and mild. The modeling for a severe pandemic indicates that the estimated decrease in "real GDP" of 4.7 percent exceeds the impact of every post WWII recession except the one following 1981. In the event of a mild global pandemic, the impact on GDP will be significantly less; however, GAO has estimated that economic growth will slow.

We cannot afford to partially fund an effort of this magnitude—the human and economic consequences of inadequately preparing will be too grave. Of the three assets I described at the outset of my statement—technology and innovation; development capability; and capital investment—two are fully in place but the third, capital investment, is not fully present. Chiron stands ready to commit its scientific exper-

tise, innovation and resources in collaboration with the government to engage in effective public-private partnership to ensure that the resources are available and the United States is positioned to meet this global challenge.

CONCLUSION

In closing, let me thank Congress for enacting legislation last year to address the critically important issue of pandemic influenza vaccine liability. We are grateful for the leadership of Congress and the administration in addressing this issue. Pandemic vaccine products present unknown risks. Whatever regulator approval mechanism might be adopted for pandemic vaccine in the event of an avian flu outbreak, it is likely that testing of the pandemic vaccine in humans will be less extensive than that for traditional flu vaccines. As a result, there may be limited data available on safety and adverse events before the vaccine is put into use. Additionally, it may be difficult to predict the numbers of people who would receive the pandemic vaccine—in the event of a pandemic, the number could be far greater than the number currently vaccinated with the trivalent product, and could include subpopulations that would not normally be considered at high risk. For these reasons, and plan to prevent or treat pandemic influenza has the potential to present major liability risks to manufacturers and health care professionals. Products must be developed on an emergency basis and administered in a very short period of time to tens or hundreds of millions of people. The liability plan adopted by Congress was a critical first step in establishing a comprehensive liability program for pandemic influenza and Chiron looks forward to working with Congress to craft a compensation program to protect the interests of individuals who are immunized when a pandemic situation exists.

Mr. Chairman, this concludes my formal remarks and I will be happy to answer any questions you or the Committee might have for me. Thank you.

Senator SPECTER. Our next witness is Dr. Chris Viehbacher, president of U.S. Pharmaceuticals GlaxoSmithKline (GSK). Graduate of Queens University Ontario, with a degree in commerce. Thank you for joining us Mr. Viehbacher and the floor is yours for 2 minutes.

STATEMENT OF DR. CHRISTOPHER VIEHBACHER, PRESIDENT OF U.S. PHARMACEUTICALS, GLAXOSMITHKLINE

Dr. VIEHBACHER. Thank you Mr. Chairman, Senator Harkin, Senator Stevens. GlaxoSmithKline is unique as a manufacturer of both seasonal and pandemic flu vaccine, as well as the licensed antiviral Relenza. Now in 2005 alone, GSK committed over $2 billion to strengthen the long-term commitment we have made to the U.S. flu market and to position GSK to help respond effectively to a pandemic. As a result of those investments we'll be able to manufacture more than 150 million doses per year of seasonal flu vaccine by 2008, and about half of that will be based here in North America.

We will significantly expand U.S. manufacturing capacity for Relenza and clinical trials are due to start soon on two candidate H5N1 vaccines that use antigen-sparing techniques that may allow us to stretch the supply of vaccine. Our Seattle operations add to GSK's leadership in using novel adjuvants to improve vaccines. Thanks to your help Senator Specter we'll be able to base our cell technology at our newly acquired site in Marietta, Pennsylvania.

PREPARED STATEMENT

The threat of a pandemic cannot be met successfully without a robust private-public partnership. Our pandemic investments would not have been made without the financial investments from the Federal Government. I know that the administration and Congress appreciate these realities. We support the administration's

estimate of what is required to fully respond to the country's pandemic needs. Funding would be most effective if it is provided in multi-year commitments. We're making large investments to do our part to assist in preparedness, and we need to be able to plan around the Government's role and ability to partner with us. Thank you for the opportunity to appear before you today, I would be happy to answer any questions you might have.

Senator SPECTER. Thank you very much, Mr. Viehbacher.

[The statement follows:]

PREPARED STATEMENT OF DR. CHRISTOPHER VIEHBACHER

Mr. Chairman and members of the Committee, I am pleased to be here today to describe GSK's efforts, working with our partners in government, to help prepare for the next influenza pandemic. My name is Chris Viehbacher and I am the President of U.S. Pharmaceuticals at GlaxoSmithKline. I appreciate the opportunity to appear before the Subcommittee today and look forward to answering your questions.

As a leading global provider of vaccines and anti-viral medications, GSK stands ready to support governments, health authorities and our own employees around the world in planning to respond to a global influenza pandemic. We had the opportunity, with our other industry colleagues, to meet with President Bush on this subject last year and applaud his recognition of the integral role industry can play in preparing for a pandemic. At that meeting, and in earlier discussions with the Secretary of Health and Human Services, GSK expressed its commitment to being part of the collective effort needed to develop an effective global response to flu pandemic. During this interpandemic period, GSK is committed to developing products to respond to the threat. Should a flu pandemic occur, GSK would work with governments and health authorities to ensure the availability and appropriate distribution of vaccine and antiviral supplies.

As the only manufacturer of both candidate pandemic vaccines and a licensed antiviral that could be effective in an influenza pandemic, GSK has taken significant steps to prepare for a pandemic. We have committed over $2 billion in 2005 to expand our flu vaccine manufacturing capacity and increase production of the antiviral Relenza. This includes doubling vaccine manufacturing capacity at our Dresden, Germany site, acquiring Canadian vaccine maker ID Biomedical, acquiring a 90 acre vaccine research and development and manufacturing site in Pennsylvania, and expanding manufacturing capacity for Relenza, including adding capacity at our North Carolina facility.

VACCINES

In 2005 we made great progress in increasing our capacity for manufacturing of influenza vaccines and developing potential pandemic vaccines, strengthening the long-term commitment we have made to the U.S. influenza market and positioning GSK to be able to respond effectively in the event of a future influenza pandemic.

GSK manufactures Fluarix, an inactivated trivalent vaccine for seasonal influenza, prepared in eggs, which was approved for use in adults by the FDA in 2005, and is also marketed in 79 other countries. Fluarix is manufactured in Dresden, Germany. In June 2005, GSK announced plans to double the capacity of the Dresden facility from today's 35 million doses to 60–80 million doses by 2008.

In December 2005, GSK acquired ID Biomedical, an integrated biotechnology company that manufactures another egg-based, inactivated, trivalent seasonal flu vaccine, Fluviral, currently marketed in Canada. GSK plans to seek FDA approval for this seasonal influenza vaccine in 2006 in preparation for the 2006/2007 seasonal influenza season. ID Biomedical is in the process of expanding its flu vaccine manufacturing facilities in Quebec province, Canada, which are expected to produce around 75 million doses beginning in 2007.

In the event of a pandemic, existing facilities engaged in the manufacturing of seasonal flu vaccine would be the first and easiest facilities to convert to production of a vaccine against the pandemic virus. All combined, by 2008, GSK anticipates having capacity to manufacture more than 150 million doses per year of egg-based trivalent inactivated influenza vaccine.

GSK is also aggressively developing candidate pandemic influenza vaccines. We have previously demonstrated the feasibility of using an antigen-sparing pandemic vaccine composition based on clinical trial data generated with two influenza A subtypes having pandemic potential. The first is H2N2 virus, a human influenza strain

which caused the 1957 pandemic, and the second is H9N2 virus, an avian influenza strain implicated in several clusters of bird-to-human transmission with resulting mild illness in Southern China in 1998–1999. The basis for the vaccine's antigen-sparing property is inclusion of aluminum salt as an adjuvant. The company is planning clinical trials of a pandemic vaccine candidate made with the H5N1 strain and aluminum salts in the first quarter of 2006. Because GSK has developed another novel adjuvant system with potentially greater immunostimulatory properties than aluminum salts, a second H5N1 pandemic vaccine candidate with the novel adjuvant system has been manufactured and will be used in a clinical trial due to start soon. These antigen-sparing pandemic vaccine candidates may allow us to stretch the supply of vaccine, by requiring lower amounts of antigen.

We are also working to ensure that necessary regulatory files are in place prior to a pandemic. GSK submitted a "mock-up" dossier for the H5N1 flu pandemic vaccine composition to the European Agency for the Evaluation of Medicinal Products (EMEA, the European version of the FDA) in late December. The approval of this dossier in advance of a flu pandemic declaration by the World Health Organization will hasten licensing of a pandemic vaccine once a pandemic influenza strain is identified.

Lastly, we are investing in new vaccine production technologies, highlighted in the 2005 acquisition of two key domestic holdings. The first is a Seattle-based company called Corixa that specializes in developing novel adjuvants to boost the body's immune response to a vaccine; additional novel adjuvants from this organization may allow a new generation of pandemic influenza candidates to be prepared and evaluated. The second is a 90-acre vaccine research, development and manufacturing facility in Marietta, Pennsylvania, where we plan to base our work in cell culture flu vaccine. With additional Federal collaboration through competitive contracts, we hope to rapidly advance this new technology to supplement and eventually move away from the use of eggs in flu vaccine manufacturing. I would like to thank both Senator Specter and Governor Rendell for their valuable support in making the Marietta facility acquisition possible.

ANTIVIRALS

I mentioned that we also produce an antiviral called Relenza. Relenza is an inhaled medicine delivered through a device called a Diskhaler® to the surface cells of the upper respiratory tract. Relenza is a prescription medicine for the treatment of influenza A and B virus infections. In many countries around the world, Relenza is also approved for use to prevent seasonal flu. Last November, we filed with the FDA to expand Relenza's indication to include prophylaxis in the United States. Relenza has not been studied in patients who have H5N1 avian flu. However, there is laboratory data indicating that Relenza added to cultured cells inoculated with influenza virus, including the H5N1 avian flu sub-type, inhibits virus growth. Moreover, Relenza protects animals from illness when they are challenged with highly pathogenic H5N1 virus. Based on these data, experts believe that Relenza will be effective in treating influenza illness during a pandemic.

Our current supplies of Relenza are very limited, as orders are well in excess of historical demand for the product. GSK is investing heavily to increase its Relenza manufacturing capacity so we can expand supplies significantly in the future, including expanded domestic capacity at our plant in North Carolina. However, even with this investment, near-term demand is still likely to exceed available supplies.

THE ROLE OF GOVERNMENT

In my remaining time I would like to acknowledge the efforts of President Bush, the U.S. Department of Health and Human Services and this Congress in preparing the United States for the next pandemic. While GlaxoSmithKline is dedicated to doing its part to meet this public health need, GSK does not view its commitment to pandemic preparedness from a commercial perspective, and our investments in pandemic preparedness would not have been made without some financial investment and support from the Federal government. I know that the administration and the Congress appreciate these realities. It is appropriate and critical that a robust public-private partnership be fostered to meet preparedness needs. I would like to describe examples of how a strong government commitment is allowing us to make these investments and suggest additional areas where government assistance can help speed preparedness.

—To increase compliance with recommendations to administer the flu vaccine, the reimbursement amount was increased to approximately $18 for physicians who administer flu vaccine to Medicare beneficiaries. This increase, along with an educational campaign from the Centers for Medicare and Medicaid Services

(CMS) to increase flu immunization rates, was an appropriate recognition of the work involved in vaccination as well as a much needed encourage to help improve the uptake of flu vaccine among the approximately one in three Medicare beneficiaries who go without this critical yearly preventive intervention.

—To help address a potential unanticipated supply shortage, HHS has contracted with industry to purchase bulk monovalent seasonal flu vaccine. This is a sensible approach to incrementally increase flu vaccine capacity and supply while sharing the risk between government and industry.

—To foster growth and competition in the U.S. vaccine industry, Congress passed legislation that will reduce the risk of frivolous lawsuits and minimize litigation burdens on companies producing pandemic products. The new law provides avenues to punish any bad actor companies, as well as a compensation program for individuals who may be injured by a pandemic product. Passage of this pandemic liability protection has removed a major obstacle to industry participation in pandemic preparedness in the United States.

—To move technology forward, a series of Requests for Proposals for government grants in pandemic preparedness has been announced. For example, one grant seeks to enhance the development of cell culture flu vaccine, and another seeks "antigen sparing techniques" to stretch supply. GlaxoSmithKline, along with many of our industry colleagues, is participating in the grant process.

—To achieve basic preparedness, the government is stockpiling pandemic vaccine and antivirals. GlaxoSmithKline is currently working with HHS on these projects.

GSK believes that the government can further help by putting in place a series of measures aimed at creating sustainable demand for flu vaccines. For example, the US government could:

1. Increase seasonal flu vaccination programs and expand the public health recommendations for domestic seasonal influenza vaccination toward universal mass vaccination. Strategies to enhance annual influenza vaccination are good for public health and also would increase the amount of seasonal influenza vaccine the world produces, therefore building the necessary capacity that would be required in the event that seasonal influenza vaccine production would be switched to pandemic flu production were a pandemic to break out.

2. Continue support for the development of manufacturing methodology that moves away from the current techniques that rely on chickens and eggs. These methods have been used for over 50 years with little refinement because the existing economic model has not provided a reason to improve flu vaccine manufacturing.

3. Continue support for the development of vaccines using adjuvant technologies to improve both effectiveness of current vaccines and improve efficiency of pandemic influenza vaccine supplies. Adjuvants offer the promise of using less antigen and thus stretching existing supplies of pandemic vaccines.

4. Encourage development, licensure and use of new types of influenza vaccines with the potential for broad protection against severe influenza illness. These new types of vaccines could substantially reduce the threat of pandemic influenza.

5. Increase support for research into monitoring the developments of a potential flu pandemic outbreak. Industry will continue to rely on government supported research on the influenza virus and surveillance of how it may be changing.

6. In addition to acquiring and maintaining an appropriate stockpile of pandemic products, enter into advance purchases of prototype pandemic vaccines and antivirals to cover key front line workers and high-risk groups.

These are a few examples of how the public-private partnership has been working and can continue to work to ensure that the United States is prepared to face the next influenza pandemic. GlaxoSmithKline has been pleased with the dedication and commitment of the US government to addressing this threat. Last year, the President requested $7.1 billion in pandemic preparedness funding. Congress was able to provide about half that amount, or $3.8 billion, at the end of last year. GSK is not in a position itself to be able to quantify the total appropriate levels of funding required to fully meet the country's pandemic needs, but we do have confidence in the administration's ability to do so, and GSK supports the administration's estimates of what is required. From our perspective, funding would be most effective in advancing technology and ultimately ensuring preparedness if it is provided in multiyear commitments. Companies are making large investments to do their part to assist with preparedness, and we need to be able to plan around the government's role and ability to partner with us.

At GSK, we stand ready to assist the Subcommittee and the Nation on the critically important and challenging issues of global preparation for the next influenza pandemic. Thank you for the opportunity to appear before you today. I would be happy to answer any questions that the Subcommittee might have.

Senator SPECTER. Our next witness is Dr. Mary Mincer Hansen, director of the Department of Public Health in Iowa, bachelors' degree in nursing from Creighton University and her master's in nursing in Texas Women's University, and a Ph.D. in higher education from Iowa State. We have you on the docket for 3 minutes Dr. Hansen, proceed.

STATEMENT OF DR. MARY MINCER HANSEN, DIRECTOR, IOWA DEPARTMENT OF PUBLIC HEALTH

Dr. HANSEN. Thank you Senator Specter, members of the subcommittee, Senator Harkin, Senator Stevens. On behalf of Governor Vilsack, I am honored to be here today to address the pandemic influenza issue. I would like to first thank you for your support of public health and health care. As a result of congressional investments our department has received funding from the CDC and HRSA to prepare and respond to public health emergencies such as pandemic influenza.

Some of our accomplishments include a Health Alert Network which allows public health professionals, hospitals, laboratories, emergency management agencies, law enforcement, and veterinarians to receive health alerts.

Another important accomplishment is engaging the public. We launched an education campaign called "Protect Iowa Health" to increase awareness about the importance of personal preparedness and to inform Iowans of the role of public health with such issues as quarantine and isolation.

We have also established volunteer disaster medical assistance teams who can rapidly respond to any part of Iowa. Our ability to mobilize these teams was demonstrated when we deployed them to Florida and Louisiana.

Today we have an Emergency Capacity Reporting System that allows us to obtain information quickly about hospital bed capacity, pharmaceuticals, and other medical supplies. We increased isolation capacity in our hospitals; we have decontamination ability, as well as appropriate personal protective equipment.

We still need to be better prepared. If the expectation is for public health to be capable of responding to emergencies 24/7 then the Nation must invest in public health infrastructure, technology, medicines, and health care surge capacity. The pandemic appropriation for State and local public health is woefully inadequate. Funding must be commensurate with the roles and responsibilities public health agencies and hospitals are being asked to carry out now and into the future. We must be able to maintain and expand our workforce, without them we will not be able to get the vaccines and antivirals to our citizens. Expectations for protecting the public's health do not come and go with funding; rather these expectations will continue forever.

I would ask that you carefully review the expectation of States to independently purchase antivirals. Not only are the costs prohibitive, but the level of protection our citizens receive should be standardized across the country. The recent cuts to public health bioterrorism funding will directly impact public health and health care capacity that has been built since 9/11. Our alerting and communications systems will become obsolete. Exercises will dwindle;

equipment and technology will become outdated. The investment of our country in public health must be sustained to ensure a healthy future for all Americans.

In closing, I would recommend four things. Number one, increased and sustain funding. Number two, national preparedness standards and benchmarks developed with State and local input. Number three, consistent Federal interagency collaboration and coordination. A national program for vaccine and antiviral purchase and stockpiling.

PREPARED STATEMENT

Thank you again, for the opportunity to testify before the your committee. We in public health are grateful for the foresight you demonstrated in providing an initial investment in pandemic influenza preparedness and response. These investments are critical to fulfilling our mission of protecting the health of the citizens we all serve.

Senator SPECTER. Thank you very much Dr. Hansen.

[The statement follows:]

PREPARED STATEMENT OF DR. MARY MINCER HANSEN

INTRODUCTION

Good morning, Chairman Specter and members of the Subcommittee. I am Dr. Mary Mincer Hansen, Director of the Iowa Department of Public Health. On behalf of Governor Thomas J. Vilsack, I am honored to be here today to address the important issue of pandemic influenza.

I would like to thank you for your support of public health and health care as we and our Federal and local partners work together to protect the health of Americans. I also commend the U.S. Department of Health and Human Services for its development and release of the National Pandemic Influenza Plan. We have reviewed the plan and are working to assure that our State and local pandemic plans integrate seamlessly with the Federal guidance outlined in DHHS's plan.

FUNDING RECEIVED AND ACCOMPLISHMENTS

As a result of congressional investments since the tragic events of 9/11 our department has received funding from the Centers for Disease Control and Prevention (CDC) and the Human Resources Services Administration (HRSA) to prepare for and respond to public health threats and emergencies such as pandemic influenza. With this funding, the Iowa Department of Public Health and local public health partners have made significant progress in our preparedness efforts and have improved our public health and hospital response capability.

Some of our major accomplishments include the development and implementation of our statewide Health Alert Network (HAN) system. The HAN is a robust, redundant communication system allowing local public health agencies, hospitals, laboratories, hazmat teams, emergency management agencies, law enforcement, EMS, veterinarians and many others to receive health alerts, share documents, and post announcements We have also implemented a redundant communication system by placing 800 mega hertz radios in all licensed hospitals, local public health agencies, the State public health laboratory, poison control center, all EMS helicopter services, and the State emergency operations center and at the department. An excellent example of how the HAN system in Iowa fosters multidisciplinary relationships is that it is now used as an additional way to send Amber Alerts.

Another important accomplishment and ongoing effort is engaging the public in our preparedness efforts. In August 2005, the Iowa Department of Public Health launched an education campaign called "Protect Iowa Health" to increase awareness among Iowans about the importance of personal preparedness and to inform them of the role of public health during an emergency. This campaign includes a booklet that provides information on how to make a plan for communicating with loved ones and how to make an emergency kit to be used in the event of a public health emergency. It also informs the public about what types of actions public health may take during an emergency, such as quarantine and isolation.

Because we are a predominantly rural State we have also established volunteer disaster medical assistance teams who can rapidly respond to any part of Iowa. Issues relating to surge capacity are particularly difficult for rural areas with fewer public health and healthcare personnel. This places greater emphasis on building a network of qualified surge responders. Our ability to mobilize these teams was demonstrated by the fact that Iowa was one of the first States to deploy our volunteer medical teams to both Florida and Louisiana following devastating hurricanes over the last 2 years.

These examples show how current funding of public health has made a significant difference in our capacity to protect the health of Iowans and respond to pandemic influenza. Prior to receiving this funding we had two epidemiologists at the State level and one at the local level. Today we have one epidemiologist for every 500,000 population. Three years ago we did not have an emergency alerting system or redundant communication connecting all hospitals and public health agencies nor could we quickly gather information about hospital bed capacity, pharmaceutical or other medical supplies. Today we have an Emergency Capacity Reporting System that allows us to obtain this information quickly. We have increased isolation capacity in our hospitals and all hospitals have decontamination capability and appropriate personal protective equipment. Additionally all hospitals and public health agencies have participated in incident command training.

ROLES AND RESPONSIBILITIES OF PUBLIC HEALTH

Prior to a pandemic, local and State public health departments will function as an early warning system. State and local public health will be responsible for surveillance—detecting outbreaks of disease and identifying pandemic influenza strains. When pandemic influenza is detected, State, and local public health will be responsible for implementing appropriate prevention and control measures. These measures include providing timely, accurate, and consistent information on vaccine prioritization and use, antiviral use for treatment and prevention, infection control and treatment and care of patients. Public health laboratories will ensure proper collection, transport and testing of highly infectious influenza specimens. This is all done during a time when we must also help to ensure continuity of operations by keeping vital societal services going to mitigate the impact of a pandemic on human health, the economy, government and the private sector.

WHAT WE ARE DOING TO PREPARE FOR A PANDEMIC

The Iowa Department of Public Health has developed a pandemic influenza response plan working with our local public health and health care partners and other State agencies. Exercises have been completed in our six regions for hospital preparedness and a State exercise will be completed in February focusing on our incident command and management system to evaluate effectiveness of interagency coordination between homeland security, agriculture, law enforcement, public health, health care and others. Additionally a virtual functional exercise will be conducted in March to test our epidemiology response on the local and State level. Iowa will be holding our Pandemic Summit this Friday with Governor Tom Vilsack and U.S. Secretary Mike Leavitt, including Senator Tom Harkin and other Congressional representatives, to engage business, schools, faith-based communities and others in our pandemic preparedness activities. Other activities that are being planned include the development and implementation of operational procedures specific to pandemic influenza; ongoing public education regarding prevention and containment measures; development of antiviral stockpiling plans; development, implementation and exercising of off-site care facility plans for providing healthcare; and development and distribution of guidance for health care clinics related to surge capacity and review of stockpiling durable goods and supplies.

WHAT PUBLIC HEALTH NEEDS TO BECOME BETTER PREPARED

Our State and local public health system has been under funded for decades. We as a country now realize that public health is a critical asset and must be strengthened to provide the foundation for a strong America. Federal, State, and local public health entities have assumed preparedness responsibilities that require a strong system foundation. If the expectation is for public health to be prepared and capable of responding to emergencies 24/7 then the Nation must invest in public health infrastructure, the technology, medicines, and health care surge capacity that are necessary to save lives and mitigate suffering from pandemic influenza and other public health threats and emergencies. An adequately funded, coordinated Federal, State, and local public health response is essential if we are to care for the public during an influenza pandemic.

The pandemic appropriation for State and local public health is woefully inadequate to build the infrastructure that is necessary to protect the citizens of our Nation against this potentially lethal virus. Funding must be commensurate with the roles and responsibilities State and local public health agencies and hospitals are being asked to carry out now and into the future. We must be able to maintain and expand our workforce, without them we will not be able to get the vaccines and antivirals to our citizens. Expectations for protecting the public's health do not come and go with funding; rather these expectations will continue forever.

I would ask that you carefully review the expectation of States to independently purchase antivirals. Not only are the costs staggering and an unrealistic expectation, but the level of protection our citizens receive should be standardized across the country. There must be a national commitment for antiviral purchase and stockpiling. In addition, all Federal inter-agency preparedness activities must be coordinated at the national level prior to dissemination and request for implementation at the State level. Federal partners need to obtain State and local input when defining policy, developing plans and making funding decisions. Clear well defined baseline national preparedness standards that are measurable and sustainable must be developed.

Lastly, proposed cuts to the public health bioterrorism program will directly impact public health and health care capacity that has been built since 9/11. Our alerting and communications systems will become out of date and we will not be able to maintain the systems. Planning meetings and exercises will dwindle, equipment will age and technology will pass us by again. Education and training of public health professionals will no longer be a priority and there will be minimal investment in public information and education. The reinvestment of our country in public health must be sustained to ensure a healthy future for all Americans.

CLOSING

Thank you for the opportunity to testify before the Senate Appropriations Subcommittee. We in public health are grateful for the funding you have allocated for the CDC and HRSA Bio-terrorism programs and for the foresight you demonstrated in providing an initial investment in pandemic influenza preparedness and response. These investments are critical to public health and health care fulfilling our mission of protecting the health of the citizens we serve.

Senator SPECTER. Our next witness is Dr. Calvin Johnson, secretary of the Pennsylvania Department of Health. Graduate of Morehouse College with a degree in chemistry, M.D. and masters in public health from John Hopkins University. I thank you for joining us Dr. Johnson and we have you down for 3 minutes.

STATEMENT OF DR. CALVIN B. JOHNSON, SECRETARY, PENNSYLVANIA DEPARTMENT OF HEALTH

Dr. JOHNSON. Thank you Senator, good morning Chairman Specter, Senator Harkin, Senator Stevens. On behalf of Governor Ed Rendell, from Pennsylvania thank you for this opportunity to address the committee about pandemic influenza planning. For States preparing, preparing for, and responding to, a pandemic means coordinating the response, maintaining essential health, public health and other general services; and obtaining and distributing vaccines and antivirals, among other activities.

The national plan unveiled in November places the majority of responsibility for prevention, protection, response and recovery, on State and local health departments. For States to minimize illness, and death in an influenza pandemic, there must be a sound public health infrastructure. This includes the capacity to detect disease, disseminate timely and accurate information, and to maintain a well trained public health workforce.

Pennsylvania has used Federal preparedness funding to further develop and improve disease surveillance, rapid health communications, and workforce training. All of which are components of public health infrastructure. Electronic disease surveillance improves the

timeliness and accuracy of disease reporting. We have developed the Pennsylvania National Electronic Disease Surveillance System (PA-NEDSS), and have built it into a nationally recognized surveillance system. Timely and accurate information delivered to health professionals and the public saves lives. In Pennsylvania our health alert network, provides real time health information and updates to public and private health partners based on reports from PA-NEDSS. A well trained public health workforce is crucial to an effective plan and response to pandemic influenza and other public health emergencies.

Pennsylvania learning management system provides online training and continuing education in many areas including bioterrorism and hospital preparedness among others. These examples of Pennsylvania's investments in influenza pandemic and overall public health preparedness are also examples of what States can do with dedicated resources.

Preparedness relies on more than one time investments and sustain funding is necessary to ensure long-term improvement. Just as the virus changes its makeup to adapt to whatever threatens its survival, we have to find new and better ways to address ever changing and emerging threats to our health and safety.

In Pennsylvania we saw the value of preparing for all hazards in responding to Hurricane Katrina aftermath and managing the Nation's largest ever hepatitis A outbreak. Each State faces individual challenges based on geography, demographics, and resource availability. One size will not fit all. So States must inform the planning process at the highest policy levels, and from the beginning in order to—for guidance to be clear useful and effective.

PREPARED STATEMENT

There are still gaps in preparedness, and States will need to fill those gaps and have the funding flexibility to do so. We recognize and appreciate Congresses support of the Department of Health and Human Services, in providing the guidance and resources they have to this point to State and local health departments. We also thank you for recognizing that States and their public health agencies are vital links in ensuring that this Nation is prepared for any crisis.

Senator SPECTER. Thank you very much Dr. Johnson.

[The statement follows:]

PREPARED STATEMENT OF DR. CALVIN B. JOHNSON

On behalf of Governor Edward G. Rendell, the Pennsylvania Department of Health is honored to testify before the Subcommittee on Labor, Health and Human Services and Education to address the important issues surrounding influenza pandemic planning from a State's perspective. Thank you for this opportunity.

Preparing for, and responding to, a pandemic will involve every aspect of our lives. For States, this means providing a coordinated response of the State and local governments, hospitals, and other local responders to care for the sick; addressing the issue of isolation and containment; maintaining essential health, public health and other general services; and obtaining and distributing vaccines and antivirals directly to the people, among other activities.

The national influenza pandemic response plan unveiled in November 2005 places the majority of responsibility for prevention, protection, response and recovery, including those just mentioned, on State and local health departments. To meet these demands, adequate and sustained support from our Federal partners is required to build up a long neglected public health system. And, because each State faces dif-

ferent challenges and possesses different assets, the type and level of this support must not be determined without solid State representation.

SOUND INFRASTRUCTURE IS CRITICAL TO MEETING RESPONSIBILITIES

The success of a national response to an influenza pandemic depends upon many factors. Arguably, one of the most important components is the preparedness and coordinated response of State and local governments, hospitals, and other local responders. When an influenza pandemic spreads worldwide and across the United States, the Federal Government will not be the ones to care for the sick, enforce a quarantine order, maintain essential public services in the community, or distribute vaccines and antivirals directly to the public. This is not meant to lessen the role that the Federal Government has played and will continue to play in public health emergencies. Rather, it is designed to ensure that we all keep in perspective the roles that all levels of government, as well as the public health system, have in responding to a public health emergency, specifically, an influenza pandemic.

In the case of an influenza pandemic, the affected population will be too widespread for the Federal Government to attack the issue alone. State and local institutions will be largely responsible for critical functions and ultimately for the health and safety of their citizens. State public health agencies will be responsible for, among other things: (1) coordinating the distribution and administration of vaccines and antivirals at designated locations; (2) providing public health nurses and other clinical staff to administer the vaccines and antivirals to the public; (3) communicating with local, State, and Federal officials to make sure all are kept abreast of the most recent information and status; (4) working with the local health care system to ensure that adequate beds and staff are available to care for those who are sick; (5) maintaining a presence with State emergency management agencies to ensure emergency management officials at all levels have the necessary information to act; (6) managing communication with the mass media to provide the public with the most up-to-date information regarding the outbreak, vaccine locations, precautions, and other facts to minimize the risk of panic, illness and death among the public; (7) tracking the spread of the disease within the State to arm officials with the information to identify vaccine locations and bed capacity; and (8) issuing, in a worst case scenario and as a last resort, quarantine orders if necessary.

To fulfill these and the vast array of additional day-to-day responsibilities, States must have a strong public health infrastructure. State and local governments recognize and take very seriously these enormous responsibilities. Many States, including Pennsylvania, have already made significant investments in their public health infrastructure and emergency preparedness thanks to some generous Federal support. Examples of a public health infrastructure include:

—*Health care facilities*.—Hospitals, nursing homes, and other health care facilities will be swarmed with individuals requiring clinical services for influenza symptoms. Hospitals will face an influx of individuals on a day-to-day basis. Nursing homes must deal with the challenges of ensuring systems are in place to address the needs of their residents, who, as we all know, are among the most vulnerable when it comes to influenza. Pennsylvania's pandemic plan estimates up to 38,000 residents would be hospitalized for presence of the influenza virus and nearly 1.6 million people would require outpatient care for flu-like symptoms;

—*Bed capacity*.—States must ensure they have the necessary bed capacity to care for not only those afflicted with the influenza virus—what is sometimes referred to as surge capacity—but also the other day-to-day illnesses that require hospitalization;

—*Emergency response system*.—States like Pennsylvania rely on their Emergency Management Systems (EMS) to not only respond to citizens who fall ill and require medical attention, but also provide prompt medical transport to the nearest hospital system that meets their acute medical needs;

—*Informed health care network*.—A State health department is responsible for disseminating timely and accurate information to health professionals, hospitals, laboratories, other public health partners and the general public. In Pennsylvania, we utilize an electronic Health Alert Network (HAN) that provides real-time health information and updates to key public and private health partners. So, if our PA-NEDSS alerts us to a sudden or unusual increase in a particular type of infection or a cluster of clinical symptoms, health care professionals can be informed of what to look for and how to treat, so lives can be saved. To date, there are approximately 3,250 HAN users in Pennsylvania.

—*Workforce*.—No influenza pandemic plan, or other public health emergency plan, can function without a dedicated, competent, and robust public health and

health care delivery workforce. Public health nurses will be called upon to organize and administer vaccines and antivirals at mass immunization clinics. Private nurses and physicians will be stretched thin as their offices and hospitals are flooded with citizens seeking medical attention for their symptoms. Epidemiologists will be called upon to maintain the highest level of accuracy and diligence as they survey and track the spread of disease. There are many other examples of public health workers that will be called upon in such a crises and States must be ready with a strong workforce that is capable of implementing its plan. Pennsylvania has created a Learning Management System (LMS) that offers on-line instruction, training and continuing education in a variety of topic areas, including bioterrorism and hospital preparedness, weapons of mass destruction, and response and recovery. LMS offers 250 courses and now has over 31,600 registered users in Pennsylvania; and

—*Surveillance.*—States will require a sophisticated surveillance system that allows for early detection and close monitoring of infectious diseases and other potential bioterrorism-related conditions. The PA DOH continues to enhance the Pennsylvania National Electronic Disease Surveillance System (PA-NEDSS), a national award winning system for real-time, electronic reporting of communicable diseases. The CDC has cited PA-NEDSS as the "gold standard" for disease surveillance. The PA DOH has also implemented the first-in-the-nation Real-time Outbreak Disease Syndromic Surveillance System (RODS) that tracks symptom clusters in both emergency room complaints and through pharmacy purchases. For example, if unusual clusters of people present with stomach pains and purchases of diarrhea medicine in a particular area in the State, PA DOH can immediately investigate to determine if an act of bioterrorism or other public health threat is occurring. RODS was also recognized in 2005 by the RAND Corporation as one of 12 exemplary practices in public health preparedness in a national study prepared for the U.S. Department of Health and Human Services (HHS).

The aforementioned certainly underscores the complexity and depth of a public health infrastructure. What should also be evident is that a public health infrastructure is not dependent on one-time investments of equipment or "bricks and mortar." While these very tangible items are certainly necessary, an effective public health infrastructure is something that must be sustained with ongoing commitments from all levels of government. Such investments will ensure that States can continually prepare and respond to a variety of public health threats with improved surveillance, communication systems and laboratories. However, we should not be satisfied with the assurance that we can mount a response; we must now set our sights higher with the goal of achieving minimal human illness and morbidity and minimal social and economic disruption in every State and every community.

PREPAREDNESS REQUIRES SUSTAINED SUPPORT

Furthermore, if at any point we become complacent and believe that we have "done enough" or "invested enough" to prepare for a pandemic influenza, we will ensure a failed response. For States, this means enforcing a coordinated response of state and local governments, hospitals, and other local responders to care for the sick, enforce quarantine orders, maintain essential public health services in the community and distribute vaccines and antivirals directly to the people, to name a few. To meet these demands, adequate and sustained support from Federal partners is required to build up a long neglected public health infrastructure. Because each State will face different challenges and will possess different assets, the type and level of this support must be determined with solid State representation.

An investment in preparedness is never wasted. Whether public health crisis is natural or manmade, there will be substantial return on that investment. The tragic events of 2005—particularly the lives lost and destruction caused by Hurricanes Katrina, Rita and Wilma and the Asian Tsunami—are a grim reminder of the unpredictable nature of weather caused calamities and other public health emergencies. Reaction to these disasters is a perfect example of how implementing an all-hazards approach and multiplied benefit of investment in preparedness provides a return on investment by saving lives and money.

Pennsylvania, along with the rest of the United States, recognizes government's core responsibility to protect its citizens; and the role that public health and safety plays in helping to determine the quality of our lives and the shape of our communities.

STATES MUST INFORM THE PROCESS

Our generation has not experienced an influenza pandemic—however, our not so distant history reveals that three pandemics occurred in the last century in 1918, 1957 and 1968. These pandemics killed approximately 40 million, 2 million and 1 million people respectively worldwide. An influenza pandemic is a global issue that will challenge our health care systems, impact our work force, temporarily change the way we travel, purchase goods and interact. The HHS likens the potential pandemic risk from avian influenza to the 1918 Spanish Flu which was devastating, costing us 20–40 million lives world wide—HHS anticipates with modern treatment and prevention that the U.S. death count could result in 2 million lives lost with over 10 million people requiring hospitalization. In Pennsylvania, we estimate that nearly 9,100 lives will potentially be lost during an influenza pandemic. Clearly, all States must continually prepare for such a threat. Policy decisions that determine and direct resources to planning efforts must fully engage all levels of government.

From Pennsylvania to Florida to Texas to Alaska, all States will face different challenges in preparing for a pandemic. State's public health systems will vary from State to State with some having intricate, fully-developed local or county-based health systems, while others will rely mainly on the State public health entity. Still others, like Pennsylvania, face the task of working in a mixed environment where some areas have a local health department and others will lean on the State. States will have different procurement processes, different administrative policies, different private health care delivery systems, different levels of authority, and, of course, different legislatures and governors. This diversity must be recognized and supported with Federal funding that provides States with the discretion and flexibility to develop plans and invest dollars in a manner that best suits the organization, capacity, geography, and resources that each State possesses.

The greatness brought about by the diversity of our Nation manifests itself in so many ways. Each State has unique characteristics that are relevant to pandemic planning and response. Each faces particular challenges based on geography, demographics, and resource availability, to name a few. These differences demand that State, local, and Federal governments maintain open and effective communication. One size will not fit all, so States must inform the planning process at the highest policy levels and from the beginning in order for guidance to be clear, useful and effective and for resources to be adequate.

A STATE'S INVESTMENT IN PUBLIC HEALTH PREPAREDNESS AND RESPONSE

It is important to understand what activities and systems a State has developed as part of pandemic preparedness efforts. Pennsylvania's ability to respond to such public health emergencies is enabled by intense planning, guided by decisions made with input from all levels of government and cross-agency coordination. This planning has noticeably improved Pennsylvania's readiness capabilities over the past three years. The PA DOH has been working with the Pennsylvania Emergency Management Agency, the Pennsylvania Department of Agriculture and other State, local, and Federal agencies and numerous volunteers to establish a coordinated approach to pandemic planning. To put a finer point on the discussion, history, particularly in Pennsylvania, demonstrates the need for a sustained investment of dollars and other resources to preparedness.

Avian Influenza (AI) is not new to Pennsylvania's poultry. In 1983, an avian influenza outbreak in Pennsylvania's poultry industry led to the destruction of 17 million birds. It is important to note that, like human disease, there are numerous strains of avian influenza and there are dozens of detections of low risk (to humans) strains of avian influenza in Pennsylvania each year by the Pennsylvania Department of Agriculture. The detection of the disease leads to a determination by the Department of Agriculture of the most appropriate response—a response that could include quarantine of the farm or destruction of the fowl.

As a result of the outbreak in 1983 and the ongoing surveillance efforts implemented by the Pennsylvania Department of Agriculture, Pennsylvania has become a leader in the prevention, detection and response of AI in the country's poultry population.

Nonetheless, there remain two main categories of threat to Pennsylvania, and other States alike—the threat to our poultry industry and the threat of a global human influenza pandemic outbreak. It could be a virus that spreads more easily, is more deadly, or may cause more health complications. With no "weapon" available for a State or Nation to stop the influenza virus from spreading so rapidly, coordinated response and recovery efforts are essential for saving lives. Perhaps one point that has been overlooked so far is the inevitability of a pandemic influenza. This

is not an "if" scenario. Preparing Pennsylvania, and the Nation, for a pandemic is a "when" proposition.

Under the direction of Governor Rendell, Pennsylvania has taken numerous steps in preparation for this threat. They include:

Establishment of Task Forces to Address Agricultural and Health Preparedness.—Two task forces have been created to prepare for the increased threat of an H5N1 outbreak in Pennsylvania's bird population and one to ensure that the Commonwealth is preparing to detect, prevent and respond adequately and timely to this potential threat. The goals of both task forces are to identify any potential gaps in Pennsylvania's planning efforts and develop unique and integrated ideas for closing the gaps.

Agriculture—Avian Influenza Response Plan.—The Pennsylvania Department of Agriculture has developed an Avian Influenza Response Plan which describes the procedures for potential or actual presence of AI in poultry in the Commonwealth. The plan does not just focus on response, but addresses all aspects of preparation including prevention, protection, response and recovery. This plan is now the basis for ongoing discussions, planning sessions and activities with State, local, and Federal partners. The plan is available on the Department of Agriculture web site.

Health—Pennsylvania's Pandemic Plan.—The PA DOH has released Pennsylvania's Pandemic Influenza Response Plan for the public to review and use for planning purposes. Again, this plan focuses on prevention, protection, recovery and response. This document is the basis for six work groups that are addressing remaining details and policy questions that have arisen through the creation of Pennsylvania's Plan. The Plan is available on the PA DOH's web site at www.health.state.pa.us.

Health—Detection, Prevention and Response Efforts.—The PA DOH has upgraded its State public health laboratory to Biosafety Level 3 capabilities and recently renovated it so that it is now equipped with a level 2 chemistry laboratory that has successfully participated in proficiency testing events. In addition, the PA DOH continues to enhance two key surveillance systems—PA NEDSS and RODS—that provide Pennsylvania with the latest disease surveillance technology.

Communications to Local Government.—As part of its preparedness activities, PA DOH has been fully engaged with local partners from throughout the Commonwealth to assure local needs and community capacity are met.

Continuity of Government.—Each agency under the Governor Rendell's jurisdiction has been directed to develop and maintain a continuity of government plan to determine essential resources and key business functions and to review work force policies and procedures that may require modification.

However there is more that Pennsylvania will do.

For example, the PA DOH is currently working with HHS to conduct a pandemic summit in Pittsburgh that will include businesses, hospitals, local government, schools, universities and other groups. The purpose of the summit will be to provide outreach and education to all Pennsylvanians on the activities underway across the State, but more importantly outline what all Pennsylvanians can do to prepare. Sessions will address the following areas:

—Human Avian Influenza Prevention Detection Policies and Processes;
—Work Force Planning;
—Isolation and Quarantine Procedures;
—Vaccine and Medication Distribution;
—Incident Coordination and Response (Command and Control);
—Surge Capacity; and
—Public Communications and Outreach Planning.

Despite substantial progress in Pennsylvania, and the continued work with local and Federal partners that lies ahead, there are several gaps in the system that need to be addressed to enable a more seamless response. The biggest gap is in the public health infrastructure. Pennsylvania has a small census of public health staff that is already stretched to meet their routine daily challenges. This gap leaves little time for grass-roots public health staff to work with communities and individuals for pandemic planning activities such as planning, education and evaluation of readiness. Other areas that Pennsylvania will continue to address once Federal guidance is provided are as follows:

—Enhance systems and capabilities for large scale dissemination of public information, including public and health professional awareness;
—Develop and disseminate shelter-in-place guidelines;
—Enhance and sustain a well coordinated regional and State surge planning effort;
—Convene a panel to explore the issue of alternative care sites, including staffing and supplies;

—Identify core competencies for health professionals during a large scale emergency and develop training programs;
—Refine hospital staff credentialing and operationalize mutual aid agreements;
—Inventory available equipment purchased through HRSA funds; and
—Identify intrastate and interstate (EMAC) mutual aid agreements.

CONCLUSION

Pennsylvania and its Department of Health recognize the enormous challenges that lie ahead. We also recognize that we have been given significant resources, particularly through Federal funding, to help us meet these challenges. We understand that each State will face different challenges, possess different resources, and have different needs for effective preparedness.

These differences demand that State, local, and Federal government maintain open and effective communication. When a disaster occurs, whether it is a pandemic influenza, other natural disaster or act of terrorism, all levels of government will have a role and responsibility. Funding should be based on State's needs to ensure that what is being allocated is adequate to meet those needs. The State variety also requires that funding be based on individual State's needs to ensure that what is being allocated is enough to meet individual needs. One size will not fit all, so States must inform the planning process at the highest policy levels and at the beginning in order for guidance to be clear, useful and effective.

Pennsylvania commends Congress's support of Health and Human Services agencies in providing guidance and support to State and local health departments, and strongly encourages these agencies to involve State and local health departments at every level as new guidance and initiatives are developed. We also strongly and respectfully encourage Congress to continue these wise investments in public health preparedness so that States, and the Nation as a whole, can continue to enhance preparedness efforts for a pandemic influenza as well as other public health emergencies. State public health agencies can meet their responsibility with sustained commitments from all levels of government. This will assure that the differences in State's infrastructures and needs are accounted for and States are not left to face a "one size fits all" quandary.

Pennsylvania and all other States are committed to using these resources wisely. After all, the same resources that will enhance our ability to deal with preparedness will also support our day-to-day efforts to improve the health of all Americans, and provide an infrastructure to successfully detect and cope with any public health preparedness situation—whether that emergency results from an influenza pandemic, a natural disaster, the accidental release of toxic material, or a terrorist attack using a chemical or biological agent.

On behalf of Governor Rendell, thank you for inviting the Commonwealth of Pennsylvania to present this testimony.

DEPARTMENT OF HEALTH,
Harrisburg, PA, March 8, 2006.

Hon. ARLEN SPECTER,
U.S. Senate, Washington, DC.

DEAR SENATOR SPECTER: On behalf of Governor Rendell and the citizens of the Commonwealth, I would like to again thank you for extending an invitation to the Governor to testify before the U.S. Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing on influenza pandemic.

During the hearing, you asked that I follow-up with you in writing to provide information on what resources Pennsylvania needs in order to protect its 12 million residents in the event of an influenza pandemic. In addition, you asked for information on what State resources have been, and will be, dedicated to influenza pandemic planning.

Question. Have the Federal allocations for Pennsylvania's pandemic planning been enough to support planning efforts to protect its over 12 million citizens? If not, what is needed and how much will this cost?

Answer. Pennsylvania has been notified that it will receive $3,508,291 in Federal funds for the first phase of State pandemic influenza response initiatives. By contrast, just the cost of providing antiviral medications to critical emergency responder personnel and their families will triple this amount, reaching closer to $11 million. This figure estimates a cost of $24 per course of antiviral medication, which is multiplied by: 1,300 public health workers; 5,875 State police officers; 56,000 EMS; and 81,000 firefighters and volunteer firefighters. Please note, this figure does not take into account the number of physicians, hospital personnel, sheriffs and other critical personnel necessary to maintain order and ensure the public's safety during a pandemic.

Clearly, the amount allocated for the first phase is not sufficient to continue planning efforts in Pennsylvania. For instance, the following is a list of pandemic planning activities and activities that will require additional resources and on-going funding:

—Keeping the public health workforce and the emergency response infrastructure in place in order to care for the sick and manage the pandemic response. This includes resources to keep the families of first responders healthy during a pandemic.

—Administrative costs for recruiting and organizing non-medical volunteers to assist with special needs populations; mass decontamination; post hospitalization mass movement; mobilization of burn/trauma/pediatric specialists; and coordination of services during isolation/quarantine, and other activities.

—Mass prophylaxis protocols for distribution of antivirals.

—Administrative costs for staffing Point of Dispensing Sites.

—Stockpiling of potential vaccines and antivirals, and managing shelf life and medication rotation.

—Development of a State-specific Pennsylvania Emergency System for the Advance Registration of Volunteer Healthcare Professionals (ESAR–VHP) System to allow for the advance registration and emergency credentialing of volunteers.

—Training and participation in the ESAR–VHP System.

—Professional liability and workers compensation protection for all emergency volunteers enrolled in ESAR–VHP in the event of a governor-declared emergency.

The Department estimates that the above-mentioned activities alone will cost approximately $393,000,000 to fully implement. Attached for your review is a detailed breakdown of what the Department estimates it will cost to fully engage Pennsylvania's planning and response efforts for an influenza pandemic.

PENNSYLVANIA COST PROJECTIONS FOR PANDEMIC RESPONSE: Wave 1

Categories	Line Items	Unit Price	Needed	Total for First Wave	Explanation
Purchase of Antivirals	3 million courses	$24 per course at 75%	2,302,698	$41,448,564	Enough Tamiflu is needed to innoculate 25% of the PA population (.25 x 12,281,054 = 3,070,264 citizens). PA will receive 25% of the total 3,070,264 from Feds (or 767,566 free treatment courses). States should purchase the remainder at 75% of cost.
Purchase of Equipment	Masks (N95)	$2	56,000	$112,000	10 items/day x 7 days/week x 8 weeks x 100 public health employees
	Gowns	$.58 each	56,000	$32,480	10 items/day x 7 days/week x 8 weeks x 100 public health employees
	Gloves	$0.14	56,000	$7,840	10 items/day x 7 days/week x 8 weeks x 100 public health employees
Personnel for Vaccination Clinics	Salary/Wage	$30 per hour	896,000 hours	$26,880,000	50 people x 8 hrs x 20 clinics x 56 days x $30 hour x 2 shifts
	Lodging	$75 per night	11200	$840,000	$75x10x56x20=$840,000
	Subsistence	$28 per day	11200	$313,600	$28x10x56x20=$313,600
	Travel	$0.485 per mile	100,000	$48,500	$.485x100,000=$48,500
Laboratory Response	Equipment/supplies			$67,576	Includes tissue culture, lab disposables, gowns, N95 respirators, gloves, shipping kits, infectious waste disposal box
	Transport cost			$8,000	
	Sendouts/referrals for tests			$30,000	
Communications	800 Mhz Radios	$5,000	20	$100,000	
	Health Alert Network	$40 per license	3000	$120,000	
	Hotline costs			$1,112,166	
	Written communications			$15,000	1.5 million copies @0.01 per copy for flyer/fact sheets

	Radio campaign			$500,000	Statewide for one month
Death Management	Processing Deaths Certificates	$18	10,938	$196,884	
	Body bags	$10	10,938	$109,380	
Planning and Preparedness	Conferences	4 per year	$20,000	$80,000	
	Pandemic Planning Meetings	2 per year	$2,000	$4,000	
Epidemic Case Investigation and Surveillance	Personnel for Epi Teams	5 staff per 500 cases for initial case finding/outbreak investigation/ exposure assessment for active surveillance during the 2 first weeks of the outbreak (~6,000 cases) @ $50,000 per staff.	60 new staff	$3,000,000	Staff request included communicable diseases nurses, Epidemiology Program Specialist, Master level epidemiologists, doctoral level epidemiologists, public health physicians and clerical/administrative staff for data entry, phone interviews, answering phones, etc. This request takes into consideration adequate staffing levels for field staff.
	Data Management	Application to assist with Incident Management.		$2,000,000	
	Lodging for Epi Teams	$75	5 staff x 3 days x 8 trips	$9,000	
	Subsistence for Epi Teams	$28 per 24 hr	5 staff x 3 days x 8 trips	$3,360	
Transportation		500,000 miles	$.485 per mile	$242,500	

Education and Training	Training via Learning Management System for 105,000 Public Health, EMS, EMA, Hospital, Allied Health			$343,500	Planning phase: 50K users on current licenses =$0; curriculum development = $1,000; satellite broadcast = $2,000. Response phase: 55K additional users @ $6 = $330K; curriculum development = $3,000; Satellite broadcasts = $7,500
Quarantine Support/Self Containment		1,968,510 cases not hospitalized	$20 a day per 7 days	$275,591,400	The $20 may cover for any site visit or provision of medical care.
Points of Distribution (PODS) for Antiviral					165 PODs will be needed. 3,282,634 divided by 20,000 per POD = 164.14 PODs
	Core Staff (Station personnel)	204 staff per 24-hour shift	Volunteers	in kind costs	
	Support Staff (Security, Maint., EMS, etc.)	88 staff per 24-hour shift	Volunteers	in kind costs	
	Supplies (PODs in a Box)	$24,000	165 PODS	$3,960,000	Each box is $1,500 to start with and will need to be replenished, on average, twice a week ($3,000 per week) times 8 weeks for wave 1 ($24,000).
	Subsistence for staff	$28		$457,856	292 volunteers times $28 per day ($8,176 per day) times 7 days ($57,232 per week) times 8 weeks ($457,856).
	Lodging	$75		$693,000	165 POD supervisors times $75 per day ($12,375 per day) times 7 days ($86,625 per week) times 8 weeks ($693,000).

Mental Health Support	State/county Mental health counselors	7 MH staff at each PODx3 shifts per day x 56 days x $20/hour	3,465	$30,983,250	Responsibility of Department of Public Welfare
HealthCare Support		0	0	$0	Department of Health does not fund any state-based hospitals.
Local Health Support		0	0	$0	Financial support for local health jurisdictions has been included in all the individual line items.
Other	EMS Transport Units	$250	9,240	$2,310,000	165 Transport Units times $250 per day ($41,250 per day) times 7 days ($288,750 per week) times 8 weeks ($2,310,000).
	Department of Health Emergency Operations Center (EOC)		25 staff (two shifts for 56 days)	$1,123,178	This includes meals, overtime, conference calls and misc. expenses needed to staff and run the Department of Health EOC.
	Health Desk at State Emergency Operations Center (SEOC)		3 staff (two shifts for 56 days)	$124,797	This includes meals, overtime, conference calls and misc. expenses needed to staff and run the Health Desk at the SEOC.
TOTAL				**$392,867,831**	

QUESTION. What State resources have been used to help support efforts? What does the Governor plan to do to support these resources?

Answer. The success of a national response to an influenza pandemic depends upon many factors, and requires, as its foundation, a strong public health infrastructure. The Pennsylvania DOH, and its sister agencies, including the Pennsylvania Department of Agriculture (PDA) and the Pennsylvania Emergency Management Agency (PEMA), have invested a significant amount of time and resources to protect against the spread of an influenza pandemic.

Governor Rendell has proposed to invest $500,000 for State fiscal year 2006–2007 for PEMA to coordinate with DOH on the Commonwealth's avian flu and pandemic preparedness efforts. In addition, the State has dedicated staff resources to pandemic planning efforts. Over the past 6 months, an estimated 2,300 hours in personnel time have been spent on pandemic planning which translates into over 300 working days directed to this important issue. At this point, the associated costs, including salaries, are approximately $80,000. As you know, pandemic planning will be an ongoing priority, and the State will continue to use the resources necessary to protect the citizens of Pennsylvania.

In order to protect the citizens of this Commonwealth from an influenza pandemic, States, such as Pennsylvania, will need continued Federal investments and greater flexibility in using Federal resources. I am confident that with your sustained support and our commitment to planning, Pennsylvania will be well-positioned to meet the demands of an influenza pandemic and a variety of other public health emergencies. Again, on behalf of Governor Rendell, I thank you for your interest in this important issue. Should you have questions or need additional information, please do not hesitate to contact me directly, or Mike Yantis, Director of Legislative Affairs at (717) 783–3985.

Sincerely,

CALVIN B. JOHNSON,
M.D., M.P.H.

Senator SPECTER. We now turn to Dr. Bruce Dixon, director of the Allegheny County Health Department, Associate Professor of Medicine at the University of Pittsburgh School of Medicine, bachelors' and MD degrees from the University of Pittsburgh. We welcome you here Dr. Dixon and look forward to your testimony, we have you down again for 3 minutes.

STATEMENT OF DR. BRUCE W. DIXON, DIRECTOR, ALLEGHENY COUNTY HEALTH DEPARTMENT

Dr. DIXON. Thank you Senator Specter and Senators Harkin and Stevens. It's a pleasure to speak before you. All public health to my mind is basically local, because it's at the local level that we interact with our citizens. If we do a good job, we do it well, if we don't all of the preparedness that we put into it doesn't work terribly well.

I have some concerns as does Senator Stevens about laboratory capacity. I would start with that, because basically we do not have a laboratory in western Pennsylvania of a public health sort that can identify an infectious agent, whether avian flu or anything else.

We've tried to get one up, but it's been stymied in a lot of ways and funding is certainly necessary to get this in place. In Pennsylvania the only public health laboratory is located outside Philadelphia, where the technology is available to identify something within 15 or 20 minutes, it takes us about 36 hours to get a specimen over there and to get results back. So it's incumbent that we do get this laboratory up, because not only do we want to recognize something such as avian flu, we want to be able to tell our citizens that there is not a risk, and that negative result is probably as important as a positive result in many instances in calming the panic

that sometimes occurs around this. So that's my first point I'd like to make.

Second of all, I want to point out that we really need to regionalize our efforts. You're familiar with region 13, Allegheny County and surrounding 12 counties have joined together so that we will work collaboratively to try to deal with any sort of an emergency, whether we're talking avian flu, or anything else. We really need to regionalize even further than that, unfortunately we craft geopolitical lines for public health purposes and patients don't work that way. They cross those lines, we should really, if we get a laboratory up be looking at doing things for eastern Ohio, and northern West Virginia as well.

So this is a new way of thinking about how we approach public health. It's important I think that we recognize also that we have a dynamic relationship with the emergency management. Sometimes those lines get a little bit confusing as to who does what. It's very clear in the case of avian flu, this is a public health issue, but we need to work with our emergency management agencies as well to deal with that.

One of the things that I think that we have in Allegheny County that works quite well is two major health institutions, the University of Pittsburgh and the Allegheny West Penn System. We work very closely with our partners so I feel that we're probably as well prepared as any region of this country to deal with avian flu, although we do have our gaps.

We've demonstrated that last year when we had a shortage of a routine flu vaccine, we were able to in a very short period of time; in five days medicate over 20,000 people at a single site. We feel we have a medical reserve corps that has over 10,000 volunteers of a public health nature who have volunteered for that, we feel with multiple sites, and we would use our school districts, we could immunize our population within 48 hours. We would set up also satellites areas where we could evaluate people, to keep people from going to the hospital and allow those healthcare institutions that we have to remain on the alert for people who are seriously ill.

PREPARED STATEMENT

So I think we're quite well prepared, we certainly though, and I would echo Dr. Johnson's comments, we need a steady stream of funding, because we've had peaks and valleys and the public health infrastructure is tremendously lacking throughout this country, including western Pennsylvania, and we need increased funds to do some of the things that we need to do. I thank you for the opportunity to talk with you.

Senator SPECTER. Thank you very much Dr. Dixon.

[The statement follows:]

PREPARED STATEMENT OF DR. BRUCE W. DIXON

Senator Specter and Other Distinguished Dignitaries: I am honored to be speaking before your distinguished committee. I have been the Director of the Allegheny County Health Department for over a decade and during that time have seen several accomplishments, both regionally and locally, which I feel positions our region to be as well or more equipped to handle either a man-made or naturally occurring emergency than any other region of the country. We have regularly risen to any oc-

casion and worked together, whether an emergency due to flooding or infectious disease, has occurred. Our approach to avian influenza would parallel our efforts in dealing with any other public health emergency. Having said that, however, there are several inadequacies which prevent us from being totally prepared to deal with this problem.

First and perhaps central is the lack of adequate laboratory facilities to rapidly identify an infectious agent such as H5N1 (avian) influenza. Unfortunately, we received funding to begin construction of a Bio-Safety Level III laboratory in 2002, and I regret to say that there has been no construction of such a laboratory to date. The only Public Health laboratory in Pennsylvania is that of the Pennsylvania Department of Health located in Lyonville, outside of Philadelphia. While the technology exists to identify a hazardous agent in as little as twenty minutes, it takes us a minimum of 24 hours to submit a specimen to this laboratory due to travel time, and there is concern if we were to have a serious event in Pennsylvania that the capacity of that laboratory would be exceeded. If constructed, a laboratory in Pittsburgh would in the event of an emergency serve all of Western Pennsylvania including the northeast, and conceivably could accept specimens from eastern Ohio and Northern West Virginia as well. Any emergency response starts with identification and even a negative result allows for better dissemination of information that there is not a serious threat, which is an important factor in preventing hospital emergency rooms from being overcrowded with worried patients and in reducing panic. The lack of such a laboratory is unconscionable and must be addressed soon.

As you may be aware, Southwestern Pennsylvania counties have joined together in an agreement to support each other in the event of emergency and this arrangement known as Region 13 made up of Allegheny and the surrounding 12 counties has attracted national attention. There is a dynamic interplay in this collaboration, however, between Emergency Response as manifest by County and local Emergency Response Coordinators, and the public health component served by the Allegheny County Health Department and the Pennsylvania Department of Health, which has responsibility for the public health needs of the surrounding 12 counties. Both the ACHD and Pa DOH are severely limited in personnel—Allegheny County Health Department, at present, has more personnel than the Southwest District of the Pa Department of Health, which must serve a much larger geographic area—and neither has sufficient personnel to handle an infectious disease emergency without large numbers of external personnel to lend assistance. The problem of Southwestern Pennsylvania is further compounded at least for Allegheny County in that we need to interact with elected officials and emergency response coordinators in 130 different municipalities, unlike Philadelphia where there is a single municipality and single Emergency Management coordinator. The ability to communicate electronically and by means such as hand held devices remains a problem with all these myriad agencies using different frequencies and needs to be addressed. A similar lack of consistency exists with our Federal agencies including law enforcement. It is actually easier to communicate with our State public health partners where we share radio frequencies. The public health infrastructure of the State and region must be strengthened or at least the erosion of personnel stopped. Salaries are a major factor in attracting and retaining trained personnel.

At the Federal level there is confusion between the roles of Emergency Management and Homeland Security and the roles of Public Health, as represented by the Centers for Disease Control and Department of Health and Human Services. It is not clear who is ultimately "in charge" and this same confusion exists at the State and local level. While we work collegially well, there needs to be better clarification of role and responsibility. As an example, during the Anthrax scares of 2003 the FBI was put in charge since this might have been an act of terrorism. Their role was to develop a case which would stand for prosecution regardless of the time necessary to do so. The role of Public Health on the other hand was to as rapidly as possible determine whether there was an infectious agent present so that in the event there was, the public health measures of isolation and treatment could be instituted to reduce the likelihood of additional infections, as well as control panic by announcing negative results. Public Health was comfortable with 95 percent accuracy in the shortest possible time; law enforcement required 100 percent accuracy regardless of the time needed. We solved the problem locally by initially splitting specimens and after some discussion law enforcement was comfortable with Public Health taking the lead, but valuable time was wasted in negotiating the responsibilities of each which could be better served if there was better delineation of responsibility.

In planning for avian influenza (or any respiratory infectious agent) we have worked closely with our hospital partners, and have developed carefully considered plans to deal with large numbers of people who might become ill. We would establish centers to provide prophylaxis—either oral or injectable medications including

vaccines—using our local high schools. We plan on establishing, again with our hospital partners and medical community, evaluation sites where individuals with symptoms can be evaluated, separate geographically from sites, administering preventive medication to prevent potential infectious individuals from spreading an infection to asymptomatic or non infected ones. This should help to keep individuals from seeking care primarily at an emergency room and allow our hospitals to care for those most severely afflicted and in need of intensive hospital care. We are the recipient of a Medical Reserve Corps Grant and have enrolled several thousand medical volunteers, including physicians, nurses, pharmacists and support personnel to help in this effort. We have inventoried equipment and supplies which may be needed and continue to plan for contingencies. Our partners in other counties of Region 13 would be called upon to assist if the system should be overwhelmed.

I should note that there is a need for better coordination of funds. Multiple funding streams from the Federal Government seem to arise with little coordination which results in duplication and unnecessary expenditures which could be more profitably used.

Lastly, I should comment on the Pa Department of Health. The present Secretary is very talented and has been a refreshing addition to the Department, being the first physician secretary in almost a decade. However, his short tenure—they change usually after 4–8 years—does not allow for long term planning and this is an essential ingredient in assuring a consistent plan and message for the citizens of Pennsylvania. A mechanism needs to be developed to allow for a longer term.

Thank you for the opportunity of commenting on our readiness and problems which we face. We look forward to working with you and our local, regional, and State partners to continue to assure exemplary service for our citizens in time of need.

Senator SPECTER. Our next witness is Dr. Joanne Godley, acting commissioner of the Philadelphia Department of Public Health, bachelors' degree from Stanford, M.D. and master of public health from Neil University. Thank you for coming in today Dr. Godley. We have you on the agenda for 3 minutes.

STATEMENT OF DR. JOANNE GODLEY, ACTING COMMISSIONER, PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH

Dr. GODLEY. Thank you Senator Specter, Senator Harkin, Senator Stevens. Thank you for inviting me to participate in this hearing regarding our national preparedness for an influenza pandemic.

I am going to speak to you as a bioethicist, I recently got that from the University of Pennsylvania and as Public Health Commissioner. I'm passionate about issues that deal with the equitable allocation of health resources, and social justice in health. As a scientist I analyze problems and ask, where are the gaps and where are the opportunities.

Senators, if we use the analogy of the influenza pandemic as a train, I would say that it's heading straight for us, and that we are not prepared. Where are the gaps? We have a multitude of pandemic influenza preparedness plans. There are several Federal plans, the States and local jurisdictions have been charged with the responsibility of developing plans, but there is a lack of integration. The lack of cohesiveness in our healthcare system is reflected in the fragmented approach that we've taken toward this impending pandemic.

I won't spend much time discussing vaccines; I would say that we should not rely on vaccines to see us through this. With regard to antivirals, the need to begin an antiviral within the onset, the immediate onset of symptoms speaks to having public stockpiles of antivirals. I say public because the virus will infect individuals indiscriminately. An inability to pay for medication should not be a

barrier to receiving effective treatment. Early effective treatment of one individual could critically impact an entire community's health.

I would say that the three biggest gaps at the local level are our inability to augment local medical care, from the outpatient level, from the hospital level, from the mortuary level. Second would be our inability to have developed a continuity of business plan, and involving public partnerships at the local level. Third is the lack of a public health campaign around this issue.

After Hurricane Katrina hit the gulf coast and the tragic flooding ensued, within hours the tiny island of Cuba mobilized more than a 1,000 medical care practitioners. These were nurses and doctors who were trained in medical relief operations and who were literally placed on call to travel to the United States even with supplies.

The country whose GNP is a mere fraction of ours can respond to an emergency in that fashion, why can't we? I would ask that the Federal Government provide oversight in integrating the many pandemic influenza plans and assume leadership in developing a truly cohesive response.

I think standardization is a good concept. For example, Philadelphia does not have a Federal quarantine office, within Philadelphia, it is at JFK airport, so that the cross jurisdictional issues would be a factor in Philadelphia. Federal Government should create a funding stream to provide stockpiling of durable medical goods such as mechanical ventilators and personal protective equipment.

Philadelphia has a shortage of nurses, and doctors. Federal legislation would make it easier to rely on retired physicians for personnel surge capacity. Federal legislation could facilitate the mobilization, and deployment of a medical reserve corps——

Senator SPECTER. Dr. Godley, could you summarize at this point?

PREPARED STATEMENT

Dr. GODLEY. Sure. Finally the Government could take the lead in the development of a social marketing campaign about pandemic influenza, the public needs to be informed about what is coming and educated about what actions are expected of it.

I want to thank you for the opportunity to share my concerns with you and I'd be happy to respond to questions.

[The statement follows:]

PREPARED STATEMENT OF DR. JOANNE GODLEY

Chairman Specter, Senator Cochran, Subcommittee Members, thank you for inviting me to participate in these hearings.

I appreciate the opportunity this subcommittee has afforded me to testify here today. I want to thank you and your staff for investigating the issue of our national preparedness for a pandemic of influenza. Your subcommittee's forward thinking in gathering information and facts on this issue will serve to identify our national strengths and also to highlight areas where improvements must be made. I am honored to be part of this process.

I have the pleasure to serve as the Health Commissioner of Philadelphia. Philadelphia is a vibrant and active City, recently named by National Geographic Magazine as "America's Next Great City." We have a thriving business community and are privileged to have some of this great country's leading hospitals and medical facilities located in our city. Our city is a destination for national and international tourists. In 2004, the Philadelphia airport accommodated 28.5 million passengers,

including 4 million international passengers. Philadelphia provides services to a diverse urban population, many of whom are struggling to make ends meet.

Today, I am here to discuss what impact pandemic influenza would have on Philadelphia and how we can work together to best protect the health of our citizens and our economy from this threat.

IMPACT OF AN INFLUENZA PANDEMIC ON PHILADELPHIA

Pandemic influenza would have a substantial impact on Philadelphia. Public health experts estimate that, should pandemic influenza reach our shores, approximately 35 percent of the population would exhibit symptoms of the flu. In Philadelphia, with our population of about 1.6 million persons, 560,000 people would fall ill over the 6 months that the epidemic is likely to last. Our city could also expect to face the following challenges:

—Hospitals would be overwhelmed: We could see approximately 2,000 inpatient hospital admissions due to influenza during the first month of the epidemic. Based on an average length of stay of four days, this means that hospitals would need to cope with about 8,000 additional patient days during the first month of the epidemic.

—Healthcare providers would be overwhelmed: During the first month of an influenza pandemic, doctors and other health care professionals could expect to see an additional 227,8000 outpatient visits.

—Our mortuary capacity would quickly be overwhelmed. Based on estimates from the U.S. Centers for Disease Control and Prevention's (CDC) FluSurge software program, Philadelphia could expect 2,400 additional deaths during the first six weeks—amounting to almost 60 additional deaths each day.

Businesses would be impacted not only by the number of ill persons, but also by the likely need to implement quarantine and containment measures to limit the spread of the disease. Such measures could include asking the city's population to stay home—for as long as 10 days.

Despite the estimated large numbers of ill and dead, our city would have to ensure continuity of its operations. Our city government would need to continue to function. Our responsibility is to ensure that essential services are provided to our citizens, such as heating, transportation, clean water, safe food, and others.

The economic impact of pandemic influenza on the city of Philadelphia would be substantial. We would suffer from loss of business revenue, including loss of tourism. Our health care system would face tremendous expenses. Our city, as would all large cities in the United States, would be greatly and negatively impacted by an influenza pandemic.

STEPS PHILADELPHIA IS TAKING TO PREPARE FOR PANDEMIC INFLUENZA

Philadelphia's health department is preparing for pandemic influenza. We have developed a Pandemic Influenza Preparedness Plan (with guidance from the Department of Health and Human Services' (DHHS) plan and information distributed by the CDC and the World Health Organization (WHO) to help guide our preparations and our response actions. This plan focuses on key areas:

—Ensuring good surveillance and laboratory capacity, so that we can rapidly detect the disease and take steps to limit its spread. Our current surveillance for influenza uses several methods: outpatient, hospital, laboratory, and mortality-based approaches;

—Healthcare planning, to cope with the expected surge in patients. The health department plan includes distributing public stocks of antiviral drugs and vaccines, providing local physicians and hospital administrators with updated guidance on clinical management and infection control;

—Distribution of vaccines and antiviral medications, so that we can rapidly treat and protect people, with a special attention to making sure that we can reach the most vulnerable among us. Last year, Philadelphia was funded as part of CDC's Cities Readiness Initiative Pilot Program to enhance its ability to rapidly dispense life saving drugs to our population. At the conclusion of the pilot, Philadelphia received a 78 percent increase in its preparedness level. As a test of the Public Health Emergency Response Plan, Philadelphia Department of Public Health recently conducted a mass vaccination clinic at a community health center that provided influenza vaccines to the elderly. During 2.5 hours, 2,059 doses of influenza and pneumococcal vaccine were administered to 1,550 people at a vaccine administration rate of 800 doses per hour;

—Communications, to ensure the mechanisms to communicate our messages to health care providers and communities during such a situation;

—Recognition of travel-related risk of disease or importation, particularly via our busy international airport; and

—Providing psychosocial support to a community that would be in turmoil.

We will continue working with key partners in critically reviewing this public health plan so that we can continue to improve our preparedness to handle an influenza pandemic. Additionally, the mayor of Philadelphia, John F. Street, has developed an Emergency Preparedness Review Committee (EPRC) that brings together key government cabinet members, city leaders (academic, business, and professional) and national emergency preparedness experts to strategically analyze the city's hazard risks and evaluate gaps in the city's various emergency preparedness plans, including the pandemic influenza preparedness plan. Only by working with our partners at the local, State, and Federal levels before an event can we best coordinate our efforts during an event.

SUPPORT NEEDED BY PHILADELPHIA TO COPE WITH PANDEMIC INFLUENZA

Philadelphia is preparing for pandemic influenza, but we need assistance in several key areas:

—Philadelphia needs a public stockpile of vaccine when it becomes available. We have the capacity to administer large quantities of vaccine to our city's population in a timely manner. However, since the pandemic influenza virus has not yet appeared, it has not been possible to manufacture a vaccine in advance. We applaud recent Federal efforts to speed production capacity of a vaccine, because during a pandemic we would quickly need a large supply of vaccine to protect our population. As is true for other large American cities, our public health planning has identified significant numbers of residents who are uninsured and underinsured and who would be less likely to seek health care quickly if they developed symptoms of influenza. Since the influenza virus would infect Philadelphians indiscriminately, inability to pay for the vaccine cannot be a barrier to its administration.

—Philadelphia needs a public stockpile of antiviral medications. There is a shortage of antiviral medication in this country. Should pandemic influenza appear, we would need a substantial supply to protect our citizens.

—Philadelphia needs the ability to augment local health care, both hospital and outpatient services, and mortuary services. With the onset of a pandemic, our health care facilities would need additional medical supplies (such as mechanical ventilators and N95 respirators) to cope with the tens of thousands of additional ill people. Development of this surge capacity requires a substantial investment of resources, preparation, and cooperation between agencies.

—Philadelphia needs assistance to reduce travel-related importations of pandemic influenza. The Philadelphia International Airport must be prepared to screen millions of travelers to identify those with pandemic influenza. Our airport would benefit from the establishment of a local Federal/CDC quarantine station to coordinate this process.

—Philadelphia needs support for the development of a citywide business continuity plan to ensure no interruption in public services.

—The establishment of a new laboratory in Philadelphia with the biologic safety level (III) to handle influenza viral specimens and that could be certified to be part of the CDC's public health laboratory network would improve the Philadelphia Department of Public Health's capacity for rapid identification of unusual influenza strains. Presently, viral specimens for laboratory analysis are taken to a State laboratory requires transport outside of city limits.

—Philadelphia's public health infrastructure needs support. Over the past five years, there has been a significant attritional loss of core personnel. The health department lacks capacity to simultaneously respond effectively to an influenza pandemic and maintain continuity of health department operations.

Should pandemic influenza become a reality, Philadelphia—and indeed the Nation and the world—would face substantial challenges. We need to learn our lessons on prevention from the past—using our national response to Hurricane Katrina as an example. Working together and working proactively can better prepare us for pandemic influenza.

I appreciate the opportunity to address this subcommittee and am ready to answer any questions that you may have at this time.

CITY OF PHILADELPHIA,
DEPARTMENT OF HEALTH,
Philadelphia, PA, February 10, 2006.

Hon. ARLEN SPECTER, *Chairman,*
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR SENATOR SPECTER: Thank you for the opportunity to present testimony on hearing held by the Committee on Appropriations, Subcommittee on Labor, Health and Human Services and Education on Pandemic Influenza Preparedness at Federal, State, and Local Levels on January 31, 2006. Because of time constraints at end of the hearing, I agreed to provide information to questions or requests for further information that were raised during my testimony. I offer the following additional information concerning the Philadelphia Department of Public Health:

(1) Provide a delineation of how the Homeland Security monies have been spent by the Department.

While the Department does not received funding specifically identified as "Homeland Security" funding, a breakdown of funding from other Federal agencies received by the Philadelphia Department of Public Health is as follows:

The Department has received 3 types of grants related to Bioterrorism/Emergency Preparedness:

1. CDC Bioterrorism Awards—funds totaling $4.85 million received from 2003 to date received, indirectly, through a contract with Pennsylvania Department of Health. An approximate breakdown of the expenditures is as follows:

—60 percent was spent on personnel costs, including clinical, epidemiology, planners, sanitarians, and support persons.

—15 percent was spent on supplies for the City Readiness Initiative PODs, and related supplies.

—15 percent was spent on technology, including communications equipment, computers, and contract services.

—10 percent was spent on consultants for trainings, education materials, and tabletops exercises.

2. HRSA Award—funds provided indirectly through a contract with Pennsylvania Department of Health: $600,000 one-time grant award for 2004–05. Project involved assessment of hospital surge capacity, development of a mental health reserve corps, and Medical Reserve Corps planning project.

3. Congressional "earmark" funds, awarded through a direct contract with CDC: $150,000 one-time award for 2005–06. Project is to build a web-based public health/medical community communication interface with security enhancements to all Department of Public Health networks and data exchange processes.

(2) Provide a delineation of how the Influenza preparedness monies to be distributed by the States will be spent by the Department of Public Health.

Although the Philadelphia Department of Public Health does not yet know what the flu preparedness award amount will be, anticipated expenditures include:

—Personnel (planning, training, clinical, epidemiology);

—Facility preparations (inspections and improvements related to quarantine/isolation/morgue);

—Technology (expand immunization registry to capture flu vaccination info);

—Supplies (respiratory masks, protective equipment); and

—Hospital Support (contracts to support planning efforts, exercises, preparedness).

(3) Provide a delineation of the additional needs and estimated costs of the Department that would render Philadelphia pandemic flu-ready.

The Philadelphia Department of Public Health can identify four specific needs. The costs associate with them depend on the solution:

—*Laboratory*.—A local laboratory is needed for surge capacity to detect novel influenza strains. Cost could be $1–$3 million for renovation/construction.

—*Isolation/Quarantine*.—A facility or facilities are needed to house persons who are not sick enough for hospitalization. Cost could be up to $5 million to purchase/renovate/prepare facility or facilities.

—*Medications/Vaccines*.—Not currently available, but ideally these items should be stockpiled in preparation. The cost of vaccine is undetermined. The cost of antiviral medication could be $1.0 million.

—*Medical Care surge capacity, especially as it relates to staffing*.—No identified solution at present.

I hope this provides the additional information requested. Should any additional information be needed, feel free to contact me.

Sincerely,

JOANNE GODLEY, MD, MPH,
Acting Health Commissioner.

Senator SPECTER. Thank you very much Dr. Godley. The information has been very helpful in focusing our attention on where we have to go next. Regrettably we do not have enough time to ask all the questions here, so I would like to direct some questions to Dr. Hansen, and Dr. Johnson, Dr. Dixon, and Dr. Godley for some written responses. We've allocated $350 million, State and local government.

Now I would like to know Dr. Hansen how that squares with Iowa's needs about 3 million people in Iowa, so that we can project to other States. Dr. Johnson, with 12 million Pennsylvanians I'd have the same question.

For Dr. Dixon and Dr. Godley, I'd like to know what you have done on the flu issue. The pandemic flu issue. What you have done also on homeland security which may interface as I've visited Allegheny County Dr. Dixon, I see what you have done on isolation wards for example. What you need for a county the size of Allegheny, about 1 million. What you need for Philadelphia, which is about 1.4 million now and the surrounding areas. When you talk about a laboratory, I'd like to know what you need. Thirty-six hours is not adequate, and we can try to help you on that. When it comes to the pharmaceutical companies, you gentlemen have focused the issue, and again I'd like written responses, because of the inadequacy of time. But tell us more about the memorandum of understanding as opposed to a contract. What you have to by way of contractual authority and commitment to—Dr. Abercrombie which you mentioned.

What you need Mr. Viehbacher when you talk about multi-year contracting, what will that do for you. Address for us if you will in writing because we don't have time to probe the intricacies of limited liability, whether it's adequate now, and whether it's a hang-up, and what you think is realistic because you know what the exposure may be. As Senator Harkin points out the people who will be injured, give us an idea on your expertise.

Dr. Webby, you said I think that it will happen, were those your words that the pandemic will happen.

Dr. WEBBY. I think a pandemic will happen yes.

Senator SPECTER. You think it will happen?

Dr. WEBBY. Whether it's H5 or not is the question.

Senator SPECTER. I know you work with Dr. Robert Webster who is a world travel, and I want to compliment the switchboard at your hospital trying to get a hold of him through Hong Kong I think. Several calls, and have gotten better treatment than at most switchboards, treated personally to get some insight. So we'd like to know more from you on the specifics an in writing as to—what you base your projection on, that it will happen. When you talk about stage five, what are the projections. I know this is a judgment call, it can't be scientific, and what you see in Iraq on the young girl who's in today's newspaper who has it, and what you see in Vietnam, and what you see in Turkey. Given the—I hear there are 70 flights from Istanbul to Hamburg, Germany everyday. So

there's a lot of interaction and a lot of risk factor, and Dr. Webster and your hospital have been projecting all around the world. From what I read you have about as good a handle as anybody does in what you think is going to happen and what we ought to be doing by way of protecting ourselves. You've heard the limitations to funding we have. Mr. Barry, you have the best perspective I think, having written so extensively, and you cite the figure, when we talked briefly before the hearing about 50 million could be afflicted. Here again it's a judgment call we don't want to panic anybody, but we also want to put people on notice as to what they might have to do to protect themselves, talk about schools, and public gatherings, and isolating, and the contagious aspect, how long the pandemic flu stays on objects, what the water supply is like.

But from your historical perspective, and my red light will go on, after you started your answer, what do you think. How likely are we to find something which comes near 1918?

Dr. BARRY. Well as Dr. Webby said, nobody can predict what virus is going to jump species. However, it seems almost inevitable from everything we know scientifically, that some virus will jump species. When that happens, we don't know. I mean, it could have already happened, and we don't know about it. It might not happen for 20 years. It's almost a random event. But we do know as far back as we can look in history the longest gap between pandemics is 42 years. And we're now at 37 years and counting.

Senator SPECTER. Thank you very much, Senator Harkin.

Senator HARKIN. Again I just join with Senator Specter in thanking you all very much for your excellent testimony and I read most of it last night. We're under a time constraint right now, but just about three things I want to cover. Again I want to just repeat for emphasis sake. That and perhaps if I can't get the answer here from the manufacturers, maybe in writing, about this demand poll.

Mr. Barry you mentioned it. As I said, I have this bill S. 2112. I want you to take a look at it. Maybe it's not perfect, nothing's every perfect around here. But the idea was to provide for a free flu shot for every single American. Now if we did that, as I said I think it would create demand and therefore we hope that flu manufacturers would build manufacturing capacities. It would stimulate that production facility, it would lower the cost of the flu shot dramatically. It would stimulate public health agencies to build sustainable delivery systems. Now if we're going to face a pandemic, we can't just have people lining up to go to the local public health office someplace to get shots. They're going to have to get it at Wal-Mart, Target, at sports games, at churches on Sunday, or whatever day people go to church, or synagogues. There's going to have to be numerous places. We're going to have to create that system. I mean you can't just ask someone here, go out and give shots. They have to be trained. They have to be supervised. You have to build that system. So if we have that in place to give a free flu shot to every American, every year, we could have that system in place.

It would also provide protection from annual flu. Lost lives 36,000—200,000 hospitalizations. Think of the money that we would just save from all the hospitalizations every year. As I said, and I'm on a little thin ice on this, but I've checked with some sci-

entists that there may be some measure of immunity built up from this, for a possible pandemic flu that might come. So I hope that you will take a look at that and let me know what you think about that.

Second, Dr. Dixon, on regional labs, I'm shocked when I heard Senator Stevens say that they don't have that in Alaska. Now Pennsylvania, east, west, go to Philadelphia, I can't—I don't know how long that takes, but my gosh, Alaska is way in the heck out there, and they ought to have that capability. So you've raised a question of regional labs. I think we ought to look at that. How many we need, where they ought to be located, I don't know.

Dr. DIXON. We need to have a plan though, so that we have them strategically located throughout this country.

Senator HARKIN. We need some type of regional labs. I believe that. I just don't know exactly what the structure would look like. But certainly we need to address what Senator Stevens asks. Because it actually may start, Senator Stevens, in your State, it may start with those birds and stuff coming across that flyway. It could actually start in his State, and if we're talking about immediate isolation, and coverage and stuff, that may be the first place where we have to address it nationwide. For our Nation. So I thank you for bringing that up.

Dr. Abercrombie, you mentioned that HHS revised their request for courses, now $46 million for this fiscal year. That $18 million will be HHS and $28 million will be the States. Dr. Hansen, here's what you said: "I would ask that you carefully review the expectations of States to independently purchase antivirals. Not only are the costs staggering, and an unrealistic expectation, but the level of protection our citizens receive should be standardized across the country. There must be a national commitment for antiviral purchase and stockpiling."

Again I raise the question, Dr. Abercrombie, if we're asking the States to pick up 75 percent, that would be $28 million, what happens in a State like Louisiana? They don't have any money, or Mississippi, they don't have any money. They've been answering—in Florida they've been answering the costs of Hurricane Katrina and stuff, they don't have any money. Shouldn't we focus—and shouldn't we, if we have a stockpile, shouldn't we be able to focus where the outbreak occurs to get the antivirals out there immediately?

Now what happens if we have State stockpiles? Let's say Pennsylvania, let's say they come forward, they're rich. They got a lot of money, they come in, they build a stockpile; we don't have that much in Iowa. If the outbreak occurs in Iowa, will Pennsylvania send its antiviral—would it send its Tamiflu to Iowa. Of course not. Their Governors are going to want to protect their own States. So you'll have all these States stockpiling, the outbreak that occurs in Louisiana where they don't have any money, are we going to send—will the States step forward, and say we'll just send them out. The citizens of that State will say, wait a minute, we paid for this, we got to keep them here. That's why I think it's got to be a national type of a stockpile.

Dr. Abercrombie, I hate to put you on the spot, but could you just address yourself again to that. About the $18 million HHS, and $28

million States. Just from your expertise, is that the proper way to proceed. Or should we do it on a national basis?

Dr. ABERCROMBIE. Well, first of all, I think the first step, Senator, is to commit to purchasing enough to cover a significant portion of the U.S. population. The HHS plan calls for enough for 25 percent of the population.

Senator HARKIN. Is that enough?

Dr. ABERCROMBIE. Well, we're not public health experts, but if you listen to the World Health Organization, they advocate stockpiling for 25 percent. Countries in Europe are stockpiling, for between 20 and 40 percent. The Infectious Disease Society of America advocates 50 percent. So certainly 25 percent is in that range. So once the right amount is ordered, clearly we will work with HHS to make sure it is delivered, distributed to the right point. We are not distribution experts. We manufacture and sell, and discover and research medicines. We have been working with HHS, and in fact recently had a discussion with Secretary Leavitt to help coordinate State purchases to ensure that States can benefit from the cost sharing proposed in the pandemic plan from the President.

Senator HARKIN. Well, I still question if this is even—one, if this is the right way to proceed. Second, if the States have the money to purchase it, what do we do about a Louisiana that simply won't have the money? I just don't know what we do in that case.

Last, on the issue of adjuvants, and moving ahead with adjuvants. All the briefings I've had indicate that this is something that we ought to pursue very aggressively. In terms of making sure that our stockpile will be—will be expanded and used more. Can you address yourself again, Dr. Soland, to the issue of the adjuvants.

Dr. SOLAND. Sure. Through the work that we started back in 1997, what we've found is that adjuvants are antigen-sparing, or it spares the amount of vaccine or is spares the amount of vaccine that is necessary in order to protect an individual. So that in theory from this last study that was conducted with the NIAID on a H9N2 virus, it was suggested that you could use one-fourth of the normal antigen with adjuvant and have them protected.

That's the first part. The second part is that the adjuvant seems to offer additional protection as the virus changes or drifts, that you would get a sort of cross protection that might allow for protection as the virus continues to drift. So those are the two potential benefits of adjuvants.

Senator HARKIN. Do you feel that NIH is moving ahead aggressively enough on adjuvants?

Dr. SOLAND. Both the NIH and the FDA have been very helpful in this regard, and as I mentioned both in the written and oral testimony that we're undertaking the next trial with an H5N1, with our novel adjuvant that we'll be starting relatively soon.

Senator HARKIN. Mr. Viehbacher, what do you think about a free flu shot for every American?

Mr. VIEHBACHER. I certainly support the notion that we want to have broad based vaccination because as you say, that would encourage the production capacity of seasonal flu. That capacity could then be used if you needed to produce pandemic. Whether or not you want to pay for every American to have a $15 to $20 shot, I mean I would submit that there's no more cost effective healthcare

intervention than a flu shot. I mean save the valuable Government resources for those who can't afford it. That's really I think the question up for Government, I think the sense of having a broader based vaccination is a good one.

Senator HARKIN. I've heard that if we did that, that the cost of the flu shot might even come down to less than $5, simply because of the massive production that would be caused, does that—I don't know, do you have any idea—you probably don't have any idea.

Mr. VIEHBACHER. I couldn't answer that question. It's speculative.

Senator HARKIN. I see. Thank you.

Senator SPECTER. Thank you Senator Harkin, Senator Stevens.

Senator STEVENS. Well Mr. Chairman, I don't know about questions this late in the day here, but I don't think we have enough of a sense of urgency. I don't know if you heard about the fact that in Nome last year, a body of an Eskimo woman who died in 1918 was disinterred and tested and we were told it was a similar—the cause of her death was similar to the virus that has the world worried right now. Now, the birds that come across the Pacific, our Eskimo and Native people rely on them for food. They intersect with the flyways that affect the whole Nation in terms of the contact of those birds throughout our enormous State. I just think that when we look at the degree of preparation we've had right now to face a similar circumstance, it's just grossly inadequate. I'm sad that we didn't put up the $7.1 billion last year; I hope we get the balance of it this year. But I'm worried about the allocation of that money, I know that there's a great demand from every city and every State for Federal money to meet the necessities of each one of those localities, but I don't hear really much coming from the States, and localities who have their own money yet. I don't think it's something that the Federal taxpayer can finance all of it. I think we ought to finance the basic infrastructure, as many people have mentioned, to get the vaccines and the viral out to all our people. But it is a difficult thing for me right now to see that come about, all of you have talked about cooperation, integration, and basic infrastructure here. My hope is that Mr. Barry's going to write another book. Because I think his last one got the attention of the public and we need even more. You need to be a greater Paul Revere, my friend. I think we're more excited about this here in Washington than the rest of the country, is what I'm saying. I do hope we can find some way, beyond trying to get the money, to get the public aware of the threat that may face this country. I'm just at a loss for the answers, except that we should find some way to get a greater emphasis on everything all of you have mentioned. I can't believe we can find Federal money to do everything you've asked.

Senator SPECTER. Well, thank you very much, Senator Stevens. I agree about the necessity for more attention from the country, and I think we have spent more attention here because the President had this special speech on November 1 and we had a hearing and we've appropriated a lot of money, and we have to see whether it is adequate. I think we caught the attention of the Federal agencies and the authorities today, and very illuminating to hear what Mr. Barry and Dr. Webby say about the urgency of the problem and what's happening with the pharmaceutical companies, and

what's happening at the State and local level. Including your answers, Dr. Hansen and Dr. Johnson, what your Governors are going to do, and your Senators will help your Governors, but Senator Stevens raises a valid issue, what it's going to take for Pennsylvania with 12 million and what it's going to take for Iowa with 3 million people and then we can project it further. This is a continuation of what we're going to be doing, but there will be more coming out of this subcommittee and the full committee and the Congress.

STATEMENT FROM SENATOR LARRY CRAIG

We have received the prepared statement of Senator Larry Craig which will be made part of the hearing record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR LARRY CRAIG

Thank you, Mr. Chairman. I appreciate you convening this hearing today. It is of utmost importance that we fully asses our level of preparedness for an avian flu pandemic.

Last Congress, while I was Chairman of the Special Committee on Aging, we held hearings to address an impending shortage of seasonal influenza vaccine—which was compounded by the uncertain market demand and liability concerns faced by vaccine manufacturers.

Now, these concerns are resurfacing as we encounter the threat of pandemic flu. In addition to underscoring our need for a stable vaccine supply, the possibility of pandemic flu ushers in a new set of serious considerations. It forces us to confront such realities as staggering mortality rates and workforce shortages—translating into a devastating economic impact in the hundreds of billions of dollars.

Avian flu has been characterized as both an "urgent" and "uncertain" threat. We do not know where or when an outbreak will strike, but consensus is growing among disease experts that it is an all-too-likely outcome over the next few years.

However, compared with the three flu pandemics that occurred last century, we are much better equipped to ward off a full-fledged pandemic. Unlike in previous years, we now have the scientific capability to provide advance warning of an impending outbreak. Many public health experts claim that by emphasizing surveillance and preparedness—and effectively distributing our supply of vaccines and antivirals—we have the potential to minimize and contain an outbreak in the event one does occur.

This presents a tremendous challenge. We must strive for the seamless coordination of preparedness and response efforts at the local, State, and national levels. Doing so will not only maximize the funds appropriated for avian flu relief, but will also help us to save precious time if the pandemic threat becomes a reality.

That is why today's hearing is so vital and so timely—it is focusing our efforts exactly where they need to be. I hope that we can capitalize on this opportunity to have local, State, and Federal health officials all under one roof—along with a diverse set of industry perspectives.

With that, I want to extend a welcome to the witnesses who are here today. I look forward to hearing your testimony.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much, and that concludes our hearing.

[Whereupon, at 10:21 a.m., Tuesday, January 31, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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