Testimony
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Preparing for Pandemic Flu

Statement of

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Mr. Chairman and members of the Committee, I am honored to be here today to describe for you how the Department of Health and Human Services (HHS) is working to improve the nation's preparedness for a potential human influenza pandemic. Thank you for the invitation to testify on this issue, which is one of our highest priorities at HHS.

Strategy and Threat Assessment

On November 1, 2005, President Bush released the *National Strategy for Pandemic Influenza*, which outlines the roles of the Federal government and sets expectations for State, local, and tribal governments, private and international partners, and individual citizens in preparing for and responding to an influenza pandemic. The following day, I 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 HHS roles and responsibilities during a pandemic. In the event of a pandemic, under the National Response Plan, HHS will lead the public health and medical response with the Department of Homeland Security carrying out its responsibility for overall domestic incident management and Federal coordination. However, ultimately, the center of gravity for such a response will be at the state and local level.

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 becoming the first generation in history to be prepared for a possible pandemic.

We must also continue to prepare against a possible pandemic influenza outbreak. The President has proposed $2.3 billion for the 2007 portion of the emergency funding request to fulfill the next phase of the Strategy. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including producing pandemic influenza vaccine for every American within six months of detection of sustained human-to-human transmission of bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness.

The President's FY 2007 budget also requests more than $350 million for important ongoing pandemic influenza activities at HHS such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs, and diagnostics (NIH).

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 U.S. and 50 million worldwide. While we are focusing today on the impact of the H5N1 avian flu virus from a strain currently circulating in birds in many parts of Asia and Europe, many of the policy issues and preparedness measures that arise for this

strain of influenza apply as well to pandemics of other types of influenza, other emerging infectious disease outbreaks and public health emergencies. For example, pandemic preparedness offers tangible benefits in the fight against seasonal influenza which causes an average of 36,000 deaths each year in the United States.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus 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 presented 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. The potential impact on the real Gross Domestic Product [GDP] is about a 5 percent reduction in the year following the outbreak. 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 is unlikely to behave like a typical seasonal influenza. Rather, past pandemics have occurred in multiple "waves" of infection and could persist in the world for over a year.

- In the absence of effective vaccines and antivirals, 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, the Middle East, Africa, and Europe among birds is a significant concern, but there is no way to know whether this virus will in fact lead to a human pandemic. Whether or not the H5N1 adapts itself to the human host, we know that influenza viruses are constantly evolving, and it is possible that this strain or 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 surveillance of influenza viruses to be able to determine if there are genetic changes that may signal a potential pandemic, to develop reference viruses that can be used to develop pandemic vaccines, and to assess whether influenza viruses have developed resistance to antiviral drugs. As is the case with the H5N1 that is currently in birds around the world, pandemic influenza viruses often emerge in animals. Like other viruses, they tend to remain within a species. However, as we have seen already in the more than 200 documented cases of human infection of H5N1 confirmed by the World Health Organization, they do have the ability to infect humans who have been exposed to infected birds. Of greatest concern for human health is the question of whether the viruses will develop the ability to readily infect people and whether these viruses will be able to transmit efficiently from person to person as is the case with seasonal flu. For all of these reasons, 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 in society since the "great influenza" of 1918, including dramatic 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 may have made us more vulnerable.

HHS Preparations for Pandemic Influenza

As you know, the President announced the *Implementation Plan for the National Strategy for Pandemic Influenza* on May 3, 2006. The purpose of this plan is to ensure that the efforts and resources of the Federal, State, local, and tribal governments and the private sector will be brought to bear in a coordinated manner against the pandemic threat. The *Implementation Plan for the National Strategy for Pandemic Influenza* confirms HHS' role as the lead federal agency for the public health and medical preparation and planning for and response to a pandemic.

The timing of the release of this Plan does not signal that a pandemic is imminent. The Plan is the result of much work in many Federal Departments and agencies to further prepare the government for a pandemic, whenever it might occur. It is important to note that the H5N1 avian influenza is a disease of birds, the virus has not yet appeared in the U.S., and there is no influenza pandemic in the world at this time.

HHS has already started to make progress on many of the tasks delineated in the plan.

The Department's key tasks outlined in the plan include:

- Building stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat;
- Expanding domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire U.S. population within 6 months of a pandemic declaration;
- Building stockpiles of antivirals adequate to treat 25% of the U.S. population, divided between Federal and State stockpiles;
- Building a Federal stockpile of 6 million antiviral treatment courses reserved for domestic containment efforts.
- Developing clear guidelines and decision criteria to assist State, local, and tribal governments, community service providers, and the private sector in defining groups that should receive priority access to existing limited supplies of vaccine and antiviral medications and other critical medical care, including a framework

to help maintain life-sustaining community-based services for frail and vulnerable older people in their homes.

- Working with State and tribal entities to develop and exercise influenza countermeasure distribution plans and to include the necessary logistical support of such plans, including security provisions.
- Establishing a strategy for deploying Federal medical providers from across the USG, including expanding and enhancing programs such as the Medical Reserve Corps and supporting the transformation of the Commissioned Corps of the Public Health Service.
- Creating plans to rapidly credential, organize, and incorporate volunteer health and medical providers as part of the medical response in areas that are facing workforce shortages.
- Supporting local and national efforts to:
    - establish "real-time" clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories;
    - link hospital and acute care health information systems with local public health departments; and
    - advance the development of the analytical tools necessary to interpret and act upon these data streams in real time.
- Establishing a single interagency hub for infectious disease modeling efforts, and ensuring that this effort integrates related modeling efforts for transportation decisions, border interventions, economic impact, etc. HHS will also work to

ensure that this modeling can be used in real time as information about the characteristics of a pandemic virus and its impact become available.

- Providing guidance to all levels of government on a range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

Impact of a Pandemic Influenza on the Elderly

A severe 1918-like pandemic would have a profound effect on all segments of the population. Though risk groups for severe and fatal infections cannot be predicted with certainty, it is likely to include the elderly. For this reason, in 2005, two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) provided recommendations to the Department of Health and Human Services to prioritize elderly populations, particularly those with 1 or more influenza high-risk condition, for vaccine administration and antiviral drug use. As described in the National Strategy for Pandemic Influenza Implementation Plan released in May 2006, these recommendations will be reviewed and possibly revised.

HHS has advocated that states understand the needs of special populations, including the elderly, when devising and exercising their pandemic influenza plans. Through the Pandemic Influenza State Summits as well as through the CDC grant guidance to states

for pandemic flu dollars, HHS has urged states to consider and plan alternative care sites, such as home care. HHS has also asked states to take into account the special needs of the elderly when developing vaccine and antiviral distribution plans. Finally, it will be essential that local and state plans take into account how the chronic medical conditions of the elderly will be managed during a pandemic. HHS, through CMS, will work with the elderly to allow supplementary refills of medication during a pandemic, as it has done in prior health emergencies.

HHS is trying to promote individual preparedness within all segments of population, including the elderly. The Pandemic Flu Planning Checklist for Individuals and Families is relevant to the elderly in outlining how to plan for a pandemic, how to limit the spread of germs and prevent infection, and how to decide which items to have on hand for an extended stay at home.

Additionally, many older adults will be receiving home health services or long-term care. Consequently, HHS and CDC have published two checklists of particular importance to this population – a Home Health Care Services Pandemic Influenza Planning Checklist, and a Long –Term Care and Other Residential Facilities Pandemic Influenza Planning Checklist. Both checklists provide detailed suggestions on the structure for organizational planning decision making, and guidance for developing a written plan of action. Elements of a written plan of action address issues such as communication, surveillance, staff training, infection control, and planning for absences.

Current HHS Progress

In December 2005, Congress appropriated $3.8 billion to help the Nation prepare for pandemic influenza preparedness activities. Of that total, Congress allocated $3.3 billion to HHS for the first year of funding of the HHS Pandemic Influenza Plan. HHS will use these emergency funds to help achieve five primary objectives:

1. Monitoring disease spread to support rapid response;
2. Developing vaccines and vaccine production capacity;
3. Stockpiling antivirals and other countermeasures;
4. Coordinating Federal, State and local public health preparation and medical response; and
5. Enhancing outreach and communications planning.

HHS is working both domestically and internationally to monitor the spread of H5N1 and other possible pandemic viruses. HHS is spending $125 million of its FY 06 allowance to promote international pandemic preparedness and planning and augment existing capabilities in areas such as international surveillance, epidemiological investigation, and diagnosis of illness. Through collaborations with the World Health Organization (WHO), the United Nations Food and Agriculture Organization, the World Organization for Animal Health, and numerous national governments, HHS is working to build capacity in other countries to detect outbreaks early and to contain the spread of the virus. Overall, HHS is supporting influenza activities in approximately 40 countries and has assigned influenza staff to the World Health Organization (WHO) Secretariat, Regional, and country offices in Europe and Southeast Asia.

On the domestic front, CDC is devoting $50 million to strengthen local laboratory capacity and capability and $35 million to accelerate the implementation of the national BioSense program to enhance our ability to detect an outbreak early. On January 1, 2006, BioSense RT (Real-Time) was launched in 10 select cities and 32 healthcare institutions across the country. Real-time transmission of existing clinical diagnostic and health information is being sent to CDC and analyzed. In April 2006, CDC launched a new data visualization and analysis tool for the use of all jurisdictional levels of public health (hospital, city, county, state, national). The BioSense implementation timeline is to link up to several hundred hospitals in over 30 cities by the end of 2006.

In the event of a pandemic, infection control practices and social distancing measures (such as school closures, cancellation of public gatherings, etc), and antiviral drugs will be the first line of defense before a vaccine is available and could limit and delay the spread of the pandemic. Currently, the Strategic National Stockpile (SNS) has over 5 million treatment courses of antiviral drugs on hand. On March 22, I announced the purchase of additional antiviral drugs that could be used in the event of a potential influenza pandemic. With these purchases, the SNS will have 26 million treatment courses of antiviral drugs that will be available to the States when an influenza pandemic is imminent. Our strategy is to procure an additional 24 million treatment courses of antiviral drugs through FY 07 and FY 08 funds and to offer a 25 percent federal subsidy for state purchase of another 31 million treatments courses. Thus, additional money will be needed to meet our goal to have enough antivirals for 25 percent of the population during a pandemic. Congressional support of $2.3 billion for the second year of the President's Pandemic Influenza plan will be critical to meet this goal.

The cornerstone of the HHS Pandemic Influenza Plan is to create domestic manufacturing capacity sufficient to produce 300 million vaccine courses within 6 months of the onset of a pandemic outbreak, and to maintain a stockpile of pre-pandemic vaccine. We currently have approximately 4 million courses of pre-pandemic vaccine against a clade 1 H5N1 avian influenza strain. Plans and procedures are also underway to manufacture pre-pandemic vaccine against a clade 2 H5N1 avian influenza strain that is currently circulating the globe.

On May 4, 2006, I announced the award of $1 billion for five contracts to support the development of advanced techniques using a new cell-based, rather than an egg-based, approach to producing influenza vaccines. We had previously awarded a five-year contract to Sanofi-Pasteur in FY 2005 for $97 million to develop cell-based influenza vaccine technology and conduct clinical trials, so we now have six companies working under government contract to produce domestic cell-based pandemic vaccines. Using a cell culture approach to producing influenza vaccine is a promising technology and offers a number of benefits. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. In addition, cell culture-based influenza vaccines will help meet surge capacity needs in the event of a shortage or pandemic, since cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as the potential for egg supplies to be contaminated by various poultry-based diseases, including pandemic influenza strains.

Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently licensed vaccines.

A total of $1.7 billion in FY 2006 funding is allocated for vaccine development to increase vaccine production capacity by accelerating cell-based manufacturing technology, increasing egg-based vaccine production capacity, and supporting the advanced development for antigen sparing technologies that could extend the vaccine supply by decreasing the amount of antigen needed to protect each individual.

Progress has also been made in the SNS purchase of medical supplies and equipment essential to pandemic readiness. HHS has purchased over 150 million N95 respirators and surgical masks with approximately $50 million of FY06 funds. Other planned procurements include personal protective equipment (PPE), ventilators, IV antibiotics, and other medical supplies. Advanced development for rapid diagnostic tests also continues through the use of FY06 funds. A request for information (RFI) was issued for a point-of-care diagnostic on March 30, 2006 and a request for proposal (RFP) will be issued soon.

State and Local Preparedness

Pandemic influenza preparedness requires the active planning and participation of States and local communities. If a pandemic were to occur in the U.S., it would likely affect thousands of communities at the same time over the course of many weeks. The Federal

Government is working to provide guidance regarding how state, local, and tribal governments can develop pandemic preparedness plans and respond in the event of a pandemic. As part of the Administration's effort to enhance State and local pandemic preparedness, HHS has held pandemic influenza summits in 47 States and the District of Columbia so far. These summits have brought together State and local officials, public health, schools, businesses, and other stakeholders to discuss pandemic preparedness. With the FY 2006 emergency funding, HHS has awarded $100 million of the $350 million allocated for State preparedness for pandemic influenza preparedness planning activities. The remaining portion of these funds will be awarded based on benchmarks that will measure States' progress.

It is important to note that HHS funding to enhance State and local preparedness for public health emergencies, including pandemic influenza, has existed since 2001. Principally through CDC and HRSA funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting. Including the funding we have requested for FY07, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost $8 billion.

To achieve a coordinated preparedness and response system for a pandemic, states, area agencies on aging and local administrators of aging programs will need to work together to develop plans that can help protect the safety and well-being of vulnerable older

individuals. HHS's Administration on Aging has issued a call to action to the network of national aging services organizations to seek to enhance coordination and accelerate preparedness for continuing community-based services to older adults in the event of a flu pandemic.

Communications and Outreach

Effective communications and outreach are essential to pandemic preparedness at the Federal, State and local levels. President Bush called for the development of a single, comprehensive web site to be the official Federal source of pandemic and avian influenza information. This web site, www.PandemicFlu.gov, includes a wide range of information on pandemic influenza and preparedness activities. In addition, HHS has developed a series of checklists intended to aid preparation for a pandemic in a coordinated and consistent manner across all segments of society. Thus far, ten checklists have been released and are aimed at State and local governments, the business community, the education sector, the health sector, community organizations, and individuals and families.

Conclusion

Thank you for the opportunity to share this information with you. Although much has been accomplished, continued vigilance and preparation are needed for us to be ready for a pandemic. I am happy to answer any questions at this time.