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Safeguarding our Nation: HHS Response to the H1N1 Outbreak

Statement of

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Good afternoon Chairwoman Clarke, Mr. Lungren, and Members of the Subcommittee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). As Secretary Sebelius emphasized in her testimony before the Senate last week, slowing the spread and reducing the impact of 2009 H1N1 is a shared responsibility and we all need to plan for what would need to be done when the flu impacts our communities, schools, businesses, and homes this fall. I appreciate the opportunity today to discuss our role in response efforts as well as some of the challenges and successes we have encountered in responding to the 2009 H1N1 influenza outbreak.

Overview of the Outbreak

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during its winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza), with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications, so early treatment with antivirals is recommended for them, as it is for pregnant women and others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in almost all states. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year. We are already observing that more communities are affected than those that experienced outbreaks this past spring and summer, reflecting wider transmission and potentially causing greater impact. For example, as of October 10, 2009, 86 pediatric deaths related to 2009 H1N1 flu have been reported to the Centers for Disease Control and Prevention (CDC) since April 2009, a level that has only been seen at the peak of past influenza seasons. During the week of October 4 - 10, 2009, 11 deaths were reported. In each of the past three years, between 46 and 88 children died from seasonal influenza.

Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close

monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

Office of the Assistant Secretary for Preparedness and Response (ASPR)

The Pandemic and All-Hazards Preparedness Act (the Act) designated the HHS Secretary as the lead Federal official for public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan, and created the Assistant Secretary for Preparedness and Response. Under the Act, ASPR plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

2009 H1N1 Task Force

In July 2009, the White House National Security Staff (NSS) released the *National Framework for 2009 H1N1 Influenza Preparedness and Response (National Framework)* to ensure a coordinated and focused national strategy. In response, ASPR created the 2009 H1N1 Task Force to: coordinate and consolidate H1N1 strategic program activities; serve as the focal point for policy coordination; and ensure that HHS's National Framework activities and accomplishments are reported to DHS according to NSS timelines.

The Task Force addresses the National Framework's four key capability "pillars:" surveillance, mitigation measures, vaccination, and communication and education. The Task Force meets daily with me and the HHS Chief of Staff to review ongoing activities to ensure our successful execution of the National Framework strategy. The Task Force has closely collaborated with DHS to establish a Common Operating Picture (COP) for 2009 H1N1, a single display of relevant information to facilitate collaborative planning and to achieve situational awareness.

ESF #8 Response Activities

Under the National Response Framework, ASPR is responsible for coordinating the Emergency Support Function (ESF) #8 response – Public Health and Medical Services. ASPR provides the mechanism for coordinated federal assistance to supplement State, local, territorial and tribal resources in response to public health and medical care needs during an emergency.

Specifically with regard to the 2009 H1N1 influenza outbreak, ASPR coordinates the interagency public health and medical response activities through a series of twice-weekly Emergency Support Function #8 calls. During these calls, HHS regional health administrators and regional emergency coordinators report updates on their regions' pandemic influenza preparedness and response

activities. Federal interagency partners, including DHS, also report their activities for group discussion and integration.
Other coordination activities include weekly calls between ASPR and the State health departments to discuss any challenges and issues that might necessitate federal assistance. ASPR has also conducted calls with intensive care physicians to better understand the clinical picture of patients requiring extensive care in hospitals and to share information and experience to help identify best practices to improve patient outcomes.

Hospital Preparedness

Since its inception in 2002, ASPR's Hospital Preparedness Program (HPP) has provided more than $3 billion to fund the development of medical surge capacity and capability at the State and local level. HPP funds are awarded to State and territory departments of public health, which in turn fund projects at hospitals and other healthcare entities. As a result, hospitals can now provide more beds; actually communicate with other responders through interoperable communication systems; track bed and resource availability using electronic systems; protect their healthcare workers with proper equipment; decontaminate patients; train their healthcare workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises. Over the past three years, HPP awardees have been required to conduct at least one pandemic preparedness exercise each year.

Congress's investment in the Hospital Preparedness Program has resulted in our hospitals being better prepared to respond to the current 2009 H1N1 outbreak. In 2007, $75 million was awarded to States and territories specifically for pandemic influenza planning, including pandemic exercises and purchases of equipment, such as ventilators, that would aid in their response to a pandemic. Of the grantees receiving these funds, 79% conducted pandemic influenza exercises to hone their preparedness capabilities. In 2009, $90 million was awarded for purchase of personal protective equipment, such as N-95 masks and ventilators. Each program recipient also was required to develop plans for alternate care sites. Pandemic influenza preparedness and development of alternative care sites have been two priorities of the HPP program since the inception of funding

HPP has required recipients to implement a system of bed counting, called the "Hospital Available Beds in Emergencies and Disasters" (HAvBED). This system requires reports of available beds, including a count of available adult and pediatric general beds and ICU beds, to State and HHS emergency operations centers within four hours of request. For the past six weeks, HAvBED has been operational and collecting information from States about hospital status that has enhanced our 2009 H1N1 medical surge response needs.

Furthermore, based on the lessons learned from the spring 2009 H1N1 response, HAvBED was modified to also collect information on emergency department stress and hospital stress. ASPR worked with the HPP grantees, the American Hospital Association and private vendors to develop a core set of measures (including daily census counts and equipment shortages) for the level of stress on the healthcare system. Within 48 hours of receiving information, we have senior ASPR experts discuss the analyzed data to determine if any hospitals are showing signs of stress or if there are indicators of equipment shortages. On occasions where the data indicates stress, we engage our Regional Emergency Coordinators to work with State health departments in conducting an investigation. To date we have not uncovered any instances of additional stress due to 2009 H1N1, but we remain vigilant and are prepared to act should the need arise.

Other Activities

ASPR has worked with CDC and Emory University to develop a web-based triage algorithm that enables people with flu symptoms to determine if they need to seek medical care and where this care should be sought. This tool is currently posted on the *flu.gov* website for public use.

ASPR also worked with the American College of Emergency Physicians (ACEP) to develop 2009 H1N1 influenza guidance for emergency departments and emergency physicians. This tool is available on the ACEP website. (http://www.acep.org/WorkArea/DownloadAsset.aspx?id=46870)

ASPR is working with the Society for Critical Care Medicine and is conducting a ventilator survey that will enable HHS to understand how many ventilators are available and where any regional shortages might exist. We are also working with professional organizations to train physicians in taking care of patients on ventilators.

The National Disaster Medical System (NDMS) is training personnel to become vaccinators to assist State and local jurisdictions in that activity. Additionally, NDMS teams have received training on the 2009 H1N1 outbreak and are standing by ready to assist States/locals in the delivery of care to pandemic influenza patients.

Responding to H1N1

Responding to 2009 H1N1 influenza has provided challenges and valuable lessons that will assist our response efforts going forward. As this emergency unfolded it became clear that significant resources would be necessary to respond to the pandemic with potentially large impacts. Further, based on a number of factors such as state readiness and vaccine effectiveness, we would not be able to plan response requirements with certainty and thus, how

resources would need to be allocated. As a result, we greatly appreciated the flexible funding that the Congress provided for these efforts.

As we learn from the experiences of 2009 H1N1, we look forward to working with you to improve strategies to ensure that our Nation has the right assets at the right time to minimize the health impacts of an influenza pandemic, hurricane or bioterrorism event. The timely access to a flexible response fund has provided us with a nimbleness to quickly augment capabilities – such as hiring personnel on the front line of public health – where the speed of our response translates to lives saved.

Now, I will briefly discuss a few of the challenges we encountered in our biosurveillance efforts, vaccine research and development, antiviral stockpiling, situational awareness, private sector collaboration, and international assistance.

Biosurveillance Efforts

Several additional systems have been put in place or modified to more closely monitor data on the impact of 2009 influenzas. These changes include the following:

- *Enhancing Hospitalization Surveillance:* Using the 198 hospitals in the Emerging Infections Program (EIP) network and six additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and to monitor the clinical course among persons with severe disease requiring hospitalization. The EIP sites also track vaccine effectiveness.

- *Expanding Testing Capability:* HHS continues to support all States and territories with test reagents, equipment, and funds to maintain laboratory staff and ship specimens for testing. CDC serves as the primary support for public health laboratories around the globe and has provided test reagents to 295 laboratories in 147 countries. Accurate testing is essential for monitoring any changes in the virus that may indicate increases in severe infection, resistance to antiviral drugs or a decrease in the match to circulating vaccine strains. To further enhance availability of testing, FDA has evaluated and provided emergency use authorization for several diagnostic tests specific for the 2009 H1N1 virus.

- *Monitoring severe illness and mortality of women who are pregnant:* Pregnant women are at higher risk of severe disease and death from the 2009 H1N1 influenza virus. CDC is in the process of implementing a new system to collect data on severe illness (intensive care hospitalization) and mortality among pregnant women, which will improve our ability to monitor this group.

- *Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA).* Initiated on September 1, 2009, AHDRA collects information from all 50 States to identify hospitalizations and deaths due to influenza or influenza-like-illness (ILI) nationally and within each State. This new collection activity will contribute to a more complete picture of the burden of serious influenza and pneumonia illness and deaths during the pandemic and let each state examine trends in the course of the pandemic in their areas.

Vaccine Research and Development

ASPR's investment over the past six years in medical countermeasure advanced research and development enabled the Department to complete 2009 H1N1 vaccine development with unprecedented speed. ASPR's Biomedical Advanced Research and Development Authority (BARDA) has worked with industry to build and sustain a domestic manufacturing infrastructure. Under the *HHS Pandemic Influenza Plan* (November 2005), the Department's key goals for vaccine preparedness were:

- Stockpile enough pre-pandemic influenza vaccines to cover 20 million persons in the critical workforce;
- Develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million persons within six months of pandemic onset.

To establish domestic pre-pandemic influenza vaccine stockpiles, BARDA supported the development and manufacture of vaccines against different H5N1 avian virus strains. Today, BARDA continues to support a secure supply of raw materials, including eggs for domestic manufacturing of seasonal and novel influenza vaccines and the development and manufacturing of novel influenza vaccine candidates for clinical evaluation. BARDA also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing vaccine manufacturing facilities and building new cell-based influenza vaccine manufacturing facilities. Additionally, FDA was fully engaged with industry to substantially increase the number of US licensed seasonal influenza vaccine manufacturers and their overall production capacity, a necessary infrastructure for pandemic vaccine development and production. It was through the licensed seasonal influenza vaccine framework that we were able to license and rapidly make available H1N1 vaccine.

The rapid responses of HHS agencies, including CDC, the National Institutes of Health, and the Food and Drug Administration, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by

the H5N1 outbreak in 2003. Stockpiling for pandemic preparedness began in 2004, with H5N1 vaccine (23 million doses). In 2005 and 2006, the first six contracts for cell-based vaccines were initiated with two manufacturers at a cost of $1.3 billion. In 2007, two manufacturers were contracted for work on adjuvants, which are vaccine-boosting compounds ($137.5 million). Throughout, clinical studies have been supported by ASPR/BARDA and the National Institutes of Health/ National Institute on Allergy and Infectious Diseases (NIH/NIAID).

These initial activities to prepare for H5N1 provided valuable lessons that have informed our efforts to respond to the current 2009 H1N1 outbreak. For example, we learned that coordination between ASPR/BARDA and NIH/NIAID was necessary to learn about the immunogenic properties of the virus and to conduct clinical trials. Working with our industry partners, we learned that, just as for seasonal influenza vaccines, one dose of the H1N1 vaccine induces a response that is likely to be protective in adults and older children. We also learned that vaccine distribution through Points of Distribution (POD) should not be the only option. Instead, we need to develop our planning and contractual relationships to allow for flexible distribution--in this case, through a third-party--to 150,000 State-specified locations.

Antiviral Stockpiling

Under the *HHS Pandemic Influenza Plan*, HHS was required to:

- Establish national influenza antiviral drug stockpiles to treat 25 percent of the U.S. population during a pandemic, plus an immediate readiness cache of 6 million treatment courses for containment at pandemic onset;
- Support the advanced development of new and promising influenza antiviral drugs toward U.S. approval; and
- Boost U.S.-based production of antiviral drugs.

To accomplish these mandates, ASPR awarded contracts in 2004-2007 totaling more than $924 million to establish and coordinate the federal and State pandemic stockpiles of antiviral drugs. We procured 50 million treatment courses for storage in the Strategic National Stockpile (SNS) by the end of 2007, completing the federal contribution to the antiviral goal. Additionally, using funding provided by Congress, ASPR subsidized States in their purchase of 22 million treatment courses of antivirals towards the 31 million treatment course goal for State stockpiles.

To support antiviral development and manufacturing ramp-up activities, BARDA awarded a contract in 2007 for $102.7 million for advanced development and

domestic industrialization of a new influenza antiviral drug. Beginning in 2008, BARDA also solicited and awarded additional contracts for new and combination influenza antiviral drugs. These efforts directly benefited pediatric and critically ill populations.

We know that antiviral resistance is a threat. So our acquisition strategy for additional antivirals needed to be flexible. A lesson learned from the 2009 H1N1 outbreak is that rare cases of H1N1 have been Tamiflu resistant. As a result, ASPR has increased efforts to stockpile an alternative antiviral, Relenza. We also know from this outbreak that children are disproportionately affected by 2009 H1N1 influenza, leading us to procure more pediatric courses of antivirals.

Another challenge presented by 2009 H1N1 influenza is the treatment of critically ill individuals, who potentially may require an intravenous antiviral formulation that requires an Emergency Use Authorization (EUA) from the FDA. Since January 2007, HHS has supported the advanced development of a new antiviral drug, Peramivir, which may be administered intravenously to hospitalized influenza patients. On October 23, an Emergency Use Authorization was authorized by the FDA for the utilization of Peramivir to treat critically ill patients with H1N1 virus infections. In addition, the emergency use of intravenous formulations of two other antiviral drugs, approved already for other indications, is under evaluation.

Situational Awareness

Situational awareness is an essential component of any incident response. During the 2009 H1N1 influenza response, HHS worked very closely with the Department of Homeland Security (DHS) to develop a National Situation Report (SitRep) which is then inserted into the Homeland Security Information Network (HSIN). Working cooperatively, DHS and HHS have modified the SitRep to accurately reflect public health and medical issues. HHS has also been working with DHS to enable State and local public health officials to gain access to the HSIN so they can maintain their situational awareness.

Private Sector Collaboration

HHS has engaged many private sector partners in a series of problem-solving dialogues related to the vaccine dispensing program The Association of State and Territorial Health Officials (ASTHO) worked with ASPR to convene a series of meetings with America's Health Insurance Plans (AHIP), individual insurers, American Pharmacists Association, retail pharmacy chains, American Medical Association (AMA), National Vaccine Safety Program, and other State and federal partners. The private sector demonstrated a firm commitment to working through complex issues of vaccine administration, billing processes, and other policy issues that would facilitate a successful vaccine campaign with the goal of

providing easy access to the 2009 H1N1 influenza vaccine for every person in the United States who wants it.

Many issues related to vaccine administration, including billing and payment issues, were raised and partnerships with the HHS Centers for Medicare & Medicaid Services and the AMA yielded the development of specific vaccine codes, and unique vaccine administration codes for both Medicare recipients and the privately insured. In addition, the health insurers and pharmacies agreed upon a set of principles for billing practices and payment procedures and developed associated draft templates to support State vaccine program consistency.

International Assistance

There is broad international recognition that the 2009 H1N1 pandemic is a global health challenge. Millions of people around the world have been affected, thousands have died and the virus continues to spread across international borders. Recognizing that 2009 H1N1 infection, like most diseases, knows no borders and that the health of the American people is inseparable from the health of people around the world, President Obama committed to make 10 percent of the US 2009 H1N1 vaccine supply available to other countries through the World Health Organization (WHO). Vaccine will be donated on a rolling basis, as it becomes available, in order to assist countries that will not otherwise have direct access to the vaccine. We are taking this action in concert with international partners: Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, Japan, Germany, and the United Kingdom.

On October 5, we met with the Governments of Mexico and Canada to review current 2009 H1N1 efforts and decided to re-institute the North American Plan for Avian and Pandemic Influenza Coordinating Body to ensure continued international coordination in the areas of human health, animal health, border issues and emergency management.

CONCLUSION

I want to assure the Subcommittee that the Administration is taking the public health challenges of 2009 H1N1 seriously and is implementing a comprehensive strategy to monitor and address this influenza outbreak throughout this fall and winter. HHS continues to work in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring.

Working together with governors, mayors, tribal leaders, state and local health departments, the medical community, and our private sector partners, the federal government has been actively implementing a vaccination program and

continues to revise and refine our pandemic influenza plans and activities based on new data and information.

It is important to reiterate that our current level of preparedness and subsequent ability to respond is a direct result of the investments and support of Congress; the hard work of State, local, tribal, and territorial public health officials; and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities.

Our Nation's investment in public health infrastructure, particularly at the state and local levels, remains a critical challenge that has real life consequences in peoples' lives. Today, these consequences are impacting our communities, our schools, our workplace and our homes.

Investments in science and the public health infrastructure will enable us to better prepare and respond to threats, such as 2009 H1N1, that arise in the future. For instance, the President's 2010 budget includes funding for advanced development of antiviral drugs and invests in new vaccine technology. These investments are critical to building the resilience needed to better prepare for a flu pandemic or other public health emergency before it occurs. Moreover, these investments require our continuing attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency.

Building resilience makes us more secure from a number of public health emergencies – from the current 2009 H1N1 pandemic, to chemical, biological, radiological, or nuclear threats and natural disasters.

Our experience with 2009 H1N1, and the lessons we have learned, demonstrate a need to examine new paradigms for leveraging the public health infrastructure to facilitate proper preparedness, recovery and response to future disasters.

Thank you for your time and interest. I am happy to answer any questions.