



**Testimony
Before the Committee on Homeland
Security
United States House of Representatives**

**2009-H1N1 Influenza:
HHS Preparedness and Response Efforts**

Statement of
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Good afternoon Chairman Thompson, Ranking Member King, and Members of the Committee. I am Bill Corr, Deputy Secretary at the U.S. Department of Health and Human Services (HHS). I am pleased to have this opportunity to update the Committee on HHS' activities related to the 2009-H1N1 influenza outbreak. Several HHS agencies, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), play key roles in our preparations for and response to pandemic influenza.

We appreciate the quick action of Congress in recently providing \$1.85 billion in immediately available resources and an additional \$5.8 billion contingency emergency appropriation for pandemic influenza preparedness and response, of which we have notified you that we plan to immediately access \$1.825 billion. The Congress has provided sufficient flexibility within the appropriation for HHS to target its responses and resources as the situation evolves. Immediate activities will include providing funding to states for important planning necessary if a 2009-H1N1 immunization program is implemented this fall; funding to hospitals for preparation activities given a likely surge in patients during the flu season; purchasing additional vaccines, syringes and needles; and providing support for monitoring, diagnostics and public health response capabilities.

Mr. Chairman, we at the Department are proud of what we've done so far to protect the American people. While the headlines and 24-hour news updates may have quieted down, this virus has not gone away, and we have not let up. In concert with our partners at the Department of Homeland Security and throughout the administration, we are doing everything possible to monitor and respond to this virus.

It has been our goal to build the national infrastructure necessary to mount a scalable and flexible response to a novel influenza virus. This has included developing pre-pandemic vaccines for viruses with pandemic potential; federal and state stockpiling of key medical countermeasures, such as antiviral drugs; and conducting exercises to practice accessing and distributing materiel from the stockpiles.

With the strong support of Congress, and working with governors, mayors, tribes, state and local health departments, the medical community, and our private sector partners, the administration has been actively building on the preparations that have been underway for several years for an anticipated influenza pandemic to ensure the nation is ready for the H1N1 virus scenarios that may develop over the next few months. From the outset, we have said that medical science will lead the way, and we are preparing action plans based on the best scientific information available.

I want to be clear: the Department's efforts are not about raising alarms or stoking fears. They are about being prepared. This is a serious virus capable of causing severe disease and death, and it is essential that we have a clear and coordinated strategy to combat it.

With that in mind, HHS is currently working with the White House and our Federal interagency partners to focus and galvanize our efforts around a National Framework for 2009-H1N1 Influenza Preparedness and Response that is based on four pillars: surveillance, mitigation, immunization and communication.

Surveillance entails learning as much as we can about whether and how the virus is changing and spreading in the rest of the world, so that we have a clearer idea of how the virus will present in the U.S. during the fall flu season. Mitigation means encouraging people to do basic things at work, at home, in schools, and in their neighborhoods to help stop the spread of the virus; managing a potential surge in demands on our medical infrastructure; and providing appropriate medical countermeasures to infection. Immunization involves laying the groundwork for a potentially large-scale campaign to distribute an H1N1 vaccine and prioritize its use. And communication means providing clear and accurate information to state and local governments and to the public, which is essential during an outbreak.

Each of the efforts I will describe this morning fits into this framework.

Since the first 2009-H1N1 influenza patient in the United States was confirmed by laboratory testing at CDC on April 15, 2009, the virus has reached every state in the U.S. . On April 26, 2009 HHS issued a nationwide Public Health Emergency Declaration and declared that the emergency justified emergency use of several products. On that and the following day FDA issued four Emergency Use Authorizations (EUAs) in response to requests by CDC. An EUA allows the use of an unapproved product or use of an approved product for an unapproved use in an emergency declared as justifying such use. These authorizations allowed for the emergency use of certain antiviral medications, in vitro diagnostic devices, and respiratory protection products. A fifth EUA for a diagnostic panel for laboratory screening followed.

As of July 24, 2009 CDC reported 43,771 confirmed and probable cases in the U.S., with 5,011 hospitalizations and 302 deaths. However, most cases are not tested and confirmed and CDC estimates that there have been more than 1 million cases of novel H1N1 flu in the United States to date. Since the exact number of persons ill with 2009-H1N1 flu is likely to be much higher than individual case counts indicate, Friday, July 24, 2009, was the last day that CDC is providing individual confirmed and probable cases of novel H1N1 influenza. CDC will continue to report the total number of hospitalizations and deaths each week, and to use its traditional surveillance systems to track the progress of the novel H1N1 flu outbreak. These systems work to determine when and where flu activity is occurring, track flu-related illness, determine what flu viruses are circulating, detect changes in flu viruses and measure the impact of flu on hospitalizations and deaths in the U.S. The World Health Organization (WHO) reported 94,512 confirmed cases on July 6, 2009. For similar reasons, earlier in July the World Health Organization announced that it would stop issuing its global tables showing the numbers of confirmed novel H1N1 flu cases for all countries.

This virus usually causes a self-limited disease that gets better without treatment, but it can also cause severe illness and even death. Infants, children, and those with underlying health conditions appear to be most vulnerable to severe disease.

CDC staff worldwide are collaborating with WHO, the Pan American Health Organization (PAHO) and ministries of health to study characteristics of the 2009-H1N1 virus, including: the severity and transmissibility of H1N1 illness; population-based rates of mild and severe illness; risk factors for severe disease; impact on the healthcare infrastructure; and rates of transmission in households and communities in the Southern Hemisphere. These activities will better prepare the nation and other Northern Hemisphere countries when we enter flu season in the fall.

To date, we have observed rapid early season increase in flu cases in the Southern Hemisphere, evidence of increased burden on health care systems and extended school closures in several locations. We also are working aggressively to monitor for evidence of changes in the 2009-H1N1 virus itself, whether the virus is becoming more virulent or transmittable.

Efforts are underway to develop a vaccine against this new virus. NIH plans to invest more than \$200 million in influenza research, including research on the 2009-H1N1, this fiscal year. Over the years, NIH has built a substantial infrastructure of research centers, intramural and NIH-supported extramural laboratories, highly trained personnel, and clinical research networks to rapidly conduct research on new pandemic viruses, such as 2009-H1N1 influenza. This established infrastructure enabled intramural researchers on the NIH campus, researchers at medical centers throughout the country in pre-existing NIH research networks, such as the Centers of Excellence in Influenza Research and Surveillance (CEIRS) and Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), as well as industry partners and individual NIH grantees to act quickly to study the 2009-H1N1 influenza virus. In addition, NIH has been working with the biotechnology and pharmaceutical industries to speed development of new influenza vaccines, diagnostic tools and anti-influenza drugs.

On May 22, 2009 HHS Secretary Sebelius announced that \$1.1 billion of funds previously appropriated for such purposes would be used for vaccine development and manufacturing. This includes resources for the clinical trials that are being carried out through NIH and through the manufacturers in collaboration with the FDA, CDC and ASPR. On July 13, Secretary Sebelius announced that the department will commit an additional \$884 million to secure additional ingredients, including antigens and adjuvants, needed to manufacture the H1N1 vaccines. The Biomedical Advanced Research and Development Authority (BARDA) within ASPR has contracted with five vaccine manufacturers for the purchase of these bulk vaccine components. In addition to clinical trials conducted by the manufacturers, NIH will use its longstanding vaccine clinical trials infrastructure, notably the network of Vaccine and Treatment Evaluation Units, to conduct clinical studies to confirm safety and determine the optimal dose needed to induce a protective immune response. The five manufacturers who already produce U.S.-licensed seasonal vaccine are also conducting their own 2009-H1N1

influenza vaccine trials under contract with HHS. These studies are just beginning to get under way and will be carried out over the next several months. We anticipate that limited quantities of a vaccine may be available by mid-October.

NIH and its industry partners have been developing several other kinds of influenza vaccines, for example, DNA vaccines, in which harmless influenza genetic sequences are injected directly into a person to stimulate an immune response against the proteins coded for by these genetic sequences. Studies are underway to evaluate how well these candidate antiviral drugs block the 2009-H1N1 influenza strain and to screen other compounds for activity against the virus. However, because these “next-generation” vaccines will require additional safety and efficacy testing before they can be deployed, they are unlikely to reach the public before the vaccines that are currently being produced.

Today a special meeting of CDC’s Advisory Committee on Immunization Practices (ACIP) will take place in Atlanta to follow up on issues related to planning for a 2009-H1N1 immunization campaign should it become necessary. Meeting topics include 2009 H1N1 epidemiology in the U.S. and internationally; implementation planning; vaccine development and formulations; communications; and ACIP Workgroup recommendations on age/risk groups recommended for vaccination.

To help communities prepare for an increase in 2009-H1N1 influenza cases in the fall, HHS, the Department of Homeland Security, the Department of Education and the White House held the H1N1 Influenza Preparedness Summit at NIH on July 9, 2009 for federal, state, local, and tribal officials to build on and tailor states’ existing pandemic plans, share lessons learned and best practices, and discuss preparedness priorities.

At the summit, Secretary Sebelius announced the availability of \$350 million in supplemental funding. These funds will be available to state, local and territorial health departments to bolster their response activities to the 2009 H1N1 influenza pandemic, including: addressing planning gaps; preparing for a potential mass vaccination campaign; meeting the information needs of the public, health, and educational professionals to support their decision-making; implementing strategies to reduce people’s exposure to the 2009 H1N1 virus; supporting laboratory testing; preparing hospitals and the healthcare community; and improving influenza surveillance and investigations.

At the summit we sent a strong message to our State, tribal, and local partners that they must be ready to begin an immunization program by mid-October, when the first licensed vaccine is anticipated to be available. Before an immunization campaign begins, we will review what we know about the vaccine, its safety and efficacy, as well as the status of the pandemic to determine if an immunization program should proceed.

Vaccines are not the only tools we have in our response armamentarium. Other 2009-H1N1 response efforts include the use of antiviral drugs and mitigation efforts, such as social distancing.

The 2009-H1N1 influenza virus is currently sensitive to the antiviral drugs oseltamivir (Tamiflu®) and zanamivir (Relenza®). (Although cases of resistance to oseltamivir have been detected in some 2009 H1N1 virus isolates, they are currently rare.) When it became apparent that 2009 H1N1 was spreading within the United States, HHS released 25 percent of the states' pro rata share of antiviral drugs and personal protective equipment. to help the states prepare to respond to the outbreak. Thirteen million regimens of antiviral drugs have been purchased and are scheduled to be delivered to replenish the CDC's Strategic National Stockpile (SNS) by the end of September 2009. An additional 400,000 regimens of antiviral drugs from the SNS were delivered to Mexico in response to an official request for assistance in combating the 2009 H1N1 influenza outbreak. Additionally, HHS recently announced plans to provide 420,000 treatment courses of oseltamivir to PAHO to fight the 2009 H1N1 virus in Latin America and the Caribbean.

CDC and other HHS agencies continue to educate the public on ways to prevent infection, including frequent hand washing, staying home from school or work if ill, and coughing and sneezing into your elbow instead of your hands.

School guidance is an area of particular concern because children are one of the groups at greatest risk of illness with this particular strain of influenza and are transmitting the virus at high rates. HHS is working with federal, state, local, and tribal partners to develop a comprehensive public health guidance package to inform decisions about a range of interventions applicable to school settings. Our goal, if possible, is to keep schools open and safe for students, faculty and staff, but we will also advise communities to be prepared for the possibility of school closures, particularly if the virus were to change or become more severe. It will include decision-making guidance about how to choose combinations of interventions most applicable to the local situation and acceptable to the community.

HHS is also working with federal, state, local, and tribal partners to develop a more general set of community-based interventions applicable in a wide range of settings. HHS will develop tools and materials to make the recommendations specific to various settings, and is establishing a technical assistance cadre to provide one-on-one consulting.

To assist in preparing communities for increased healthcare demand, HHS is increasing the level of engagement with healthcare providers by convening stakeholder meetings to develop guidance and/or tools; providing tools and templates for local community planners; facilitating or supporting the development of clinical and triage protocols; and providing other technical assistance to partners and federal agencies.

Additionally, HHS will continue to evaluate community mitigation guidelines. As the outbreak progresses, we will continue to assess all guidelines to ensure that they are appropriately based upon the available science.

Please be assured that we will continue to communicate with you. We will tell you what we know when we know it, and we will also inform you when we don't know. To that end, we continue to work with our state, local, territorial and tribal partners to best prepare our communities to respond effectively to the formidable public health and medical challenge that 2009-H1N1 influenza presents to us all.

I would like to conclude by making two important points. First, we are all in this together. While the steps the Department and other agencies have taken will help engage the American people and ensure they are prepared, it's important for every family, business and school to prepare its own household and business plan and think through the steps they will take if a family member, co-worker, or student contracts the H1N1 flu. This is a responsibility that we all share as parents, neighbors, co-workers and community members.

The second point is that, while the H1N1 pandemic presents a tremendous challenge, it has also brought a valuable opportunity that has helped us accelerate our work to improve the entire public health system; raise awareness about the basic steps people can take to stop the spread of germs and disease and the value of seasonal flu vaccine; and identify the strengths and weaknesses in our prevention and preparedness systems. The application of these lessons will be invaluable.

We have made tremendous progress over the years in preparing for a flu pandemic. Congress has provided strong leadership and support for these efforts. We look forward to working with you to continue the progress we have made to ensure that our nation is prepared for any public health threat.

I would be happy to answer any questions.