Testimony before the
Committee on Energy and Commerce
United States House of Representatives

Preparing for the 2009-2010 Influenza Season

Kathleen Sebelius
Secretary,
U.S. Department of Health and Human Services

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Chairman Waxman, Ranking Member Barton, Chairman Emeritus Dingell, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. I want to assure the Committee that the Administration is taking these challenges seriously, and has mounted an aggressive plan to address H1N1 throughout this fall and winter. HHS has a leading role because this is a health event, and we are working 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 preparing for possible H1N1 virus outbreak scenarios that may develop over the next few months.

Since the initial spring outbreak of 2009 H1N1 influenza, the virus has triggered a worldwide pandemic, and has been the dominant flu strain in the southern hemisphere during its winter flu season. The evidence to date shows that the virus has not changed to become more deadly. Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably in summer camps. More recently, we have seen an increase in 2009 H1N1 influenza activity in several states and expect this to continue across the United States during the coming months. As fall begins, we anticipate that even more communities may be affected than those that saw cases this past spring and summer. In addition, communities may be more severely affected, reflecting wider transmission and causing potentially greater impact. Seasonal influenza viruses may cause illness concurrently with 2009 H1N1 this fall and winter 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. It is also difficult to predict the severity of the disease that we will see in the coming months from either 2009 H1N1 or seasonal influenza. Influenza is an unpredictable disease and we know that things will change and we will learn more throughout the fall.

Shared Responsibility and Science-Based Guidance

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

CDC has provided specific recommendations for what individuals, communities, clinicians, and other professionals can do. Individuals can take actions to prevent respiratory infections. We emphasize frequent hand-washing as an effective way to reduce transmission of disease. It is very important for sick individuals to stay at home, and for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, or other places children gather. Similarly, sick individuals should not get on an airplane or any public transport. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory illnesses.

We have issued new guidance from the CDC on flu.gov for schools, child care settings, colleges and universities, and large and small businesses that also includes strategies for preventing the spread of flu, especially in the early fall when the 2009 H1N1 vaccine will not yet be ready. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. The CDC also has issued guidance for healthcare providers about appropriate use of anti-viral drugs to treat patients who are at highest risk from complications from the seasonal and 2009 H1N1 flu. Additional work is being done on critical guidelines to address infection control and worker safety in healthcare settings.

Our recommendations and action plans are based on the best scientific information available to help our nation respond aggressively and effectively to the 2009 H1N1 virus. We are working to ensure that Americans are informed and consistently updated with information in clear language. This is a dynamic situation, but it is essential that the American people are fully engaged so they can be part of the response. The federal government, particularly the CDC, will be conducting weekly and, when necessary, daily briefings that will be available at flu.gov to get critical information out to the American people.

Vaccination Campaign

The federal government is also preparing for a voluntary national vaccination campaign for the 2009 H1N1 virus starting in October. With unprecedented speed, we have completed key steps in the vaccine development process -- we have characterized the virus, identified a candidate strain, expedited manufacturing, and performed clinical trials. The speed of this vaccine development was possible due to the investments made through ASPR/BARDA over the past six

years in advanced research and development and infrastructure building. One-hundred ninety-five (195) million doses of H1N1 vaccine have been purchased from five manufacturers by the U.S. government. Two types of vaccine will be available: vaccine made from killed virus for injection (flu shot) and vaccine with live, weakened virus administered by nasal spray.

The vaccines are being manufactured by the same methods used for the production of the seasonal flu vaccines administered every year. NIH is conducting a series of clinical trials on the vaccine to determine the safety and number of doses needed to induce a protective immune response. Trials in healthy adults and the elderly began in the first week of August. Complete immune response data from the first trials—those studying two doses in healthy adults—are expected in late October. Preliminary data indicate that the vaccines are safe and that a single 15-microgram dose induces what is likely to be a protective immune response in healthy adults between the ages of 18 and 64. For adults aged 65 and over, the preliminary data indicate that the immune response to the 2009 H1N1 influenza vaccine is somewhat less robust, as is the case with seasonal influenza vaccine. Trials in children began in mid-August, and trials in pregnant women have just begun. Our expectation is that vaccine will be a good match for the virus currently circulating in the United States based on intensive monitoring of the virus.

We are coordinating this 2009 H1N1 vaccination campaign with the seasonal influenza vaccination campaign, and are working hard with state and local authorities and the clinical community to address the challenges this presents.

From what we know as of today, 2009 H1N1 virus preferentially affects a population different from that affected by seasonal flu. In particular, this virus is infecting more young people including children, younger adults and pregnant women. Typically these groups, particularly young children and pregnant women, are at greater risk of serious complications from any influenza, including the 2009 H1N1. CDC's Advisory Committee on Immunization Practices (ACIP) recommended on July 29 providing initial doses of the new H1N1 vaccine to five groups—approximately 159 million people. CDC endorsed these recommendations. These groups are:

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

The H1N1 virus is particularly dangerous to healthy women who are pregnant. Not only has this virus caused greater numbers of pregnant women to be hospitalized, it has also been fatal in a higher percentage of this population than in other affected groups.

The federal government will be working in partnership with states, territories, tribes, and local communities as well as the private sector to help distribute and administer the new H1N1

vaccine. Thanks to support from Congress, the federal government has allocated $1.444 billion for states and hospitals to support planning and preparation efforts.

The large scale 2009 H1N1 vaccine program will begin mid-October with small amounts of vaccine becoming available the first full week in October. The vaccine itself will be available free of charge to the American people, but some public and private providers may charge an administration fee. It will be distributed to providers and state health departments in a manner similar to how federally purchased vaccines are distributed in the Vaccines For Children program. The CDC and states will work with a contractor to get vaccine to where it needs to go. The number of doses shipped will be reported to the CDC daily, and the number of doses administered will be reported to the CDC weekly.

The fact that vaccine won't begin distribution until October makes preventing the spread of flu even more critical. Again, we need to remind all Americans about the things they should be doing right now: washing hands, staying home if you're sick, and taking the necessary precautions to stay healthy and avoid getting sick. Flu.gov has good tips for what you need to do to avoid getting the flu.

While the 2009 H1N1 flu virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by the seasonal flu viruses. More than 36,000 people die each year from complications associated with the flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all infants, children, and people at greater risk for influenza complications. Seasonal flu vaccine already is becoming available in many places.

It is not too early to get a seasonal flu shot as soon as it is available. The protection you get from the vaccine will not wear off before the flu season is over.

Closing Remarks

At HHS, we are simultaneously working hard to understand and control this outbreak while also keeping the public and the Congress fully informed about the situation and our response. We are working in close collaboration with our federal partners as well as with other organizations with unique expertise that helps us provide guidance for multiple sectors of our economy and society. It is important to recognize that there have been enormous efforts in the United States and abroad to prepare for this kind of an outbreak and a pandemic. Our nation's current preparedness is a direct result of the investments and support of the Congress and the hard work of state and local officials across the country. While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our nation’s history have we been more prepared to face this kind of challenge.

But the government cannot solve this alone and, as I have noted, all of us must take constructive steps. Taking all of those reasonable measures will help us mitigate how many people actually get sick in our country.

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