



**Testimony before the  
Committee on Oversight and  
Government Reform  
United States House of Representatives**

**Responding to the 2009-2010 Influenza  
Season**

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Chairman Towns, Ranking Member Issa, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. I am Dr. Tom Frieden, Director, Centers for Disease Control and Prevention (CDC). As the former Commissioner of the New York City Department of Health and Mental Hygiene, and an infectious disease doctor by training, I am pleased to have been asked to work under the leadership of Secretary Sebelius to ensure that the Administration is implementing a comprehensive plan to address H1N1 throughout this fall and winter. CDC and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned this spring, as well as on preparedness for pandemic influenza during the past several years. 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 the ongoing influenza pandemic.

Since the initial spring emergence of 2009-H1N1 influenza, the virus has triggered a pandemic and has become the dominant strain of influenza in the southern hemisphere during its winter season. The virus has not changed to become more deadly. The viruses characterized at CDC and the other World Health Organization (WHO) Collaborating Centers have shown very little genetic variation with no acquisition of genetic markers known to be associated with increased virulence in other strains. Viruses collected worldwide have been very similar both genetically and antigenically.

In the United States, we saw unusual levels of influenza activity over the summer, and have seen early increases in 2009-H1N1 influenza activity in many states beginning in late August, and expect this to continue to spread across the United States during the coming weeks. We anticipate that even more communities may be affected than during this past spring and summer. In addition, seasonal influenza viruses could cause illness this fall and winter. Influenza is unpredictable, and only time will tell how long the current wave of infection with the H1N1 continues, whether there is another wave, whether the virus becomes more deadly and whether seasonal influenza causes widespread illness this winter.

### **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 should be done when the flu impacts our communities, schools, businesses, or homes this fall. Given that influenza is already circulating in the United States, 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. Each individual can take actions to prevent respiratory infections. At the current level of disease in the community, we emphasize three personal actions: (1) When sick, stay home and don't go to school, work, or public places. It is very important for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, the mall or other places children and teenagers gather. If a child becomes sick with the flu, CDC

recommends keeping the child at home for at least 24 hours after there is no longer a fever or signs of a fever (without the need for fever-reducing medicine). (2) Cover the nose and mouth with a tissue when coughing or sneezing (or a shirt sleeve or elbow if no tissue is available) (3) Wash hands frequently, especially after coughing or sneezing. Use soap and water when possible or alcohol-based hand sanitizer otherwise. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory viruses.

CDC has issued guidance for schools, child care settings, colleges and universities, and large and small businesses. The guidance contains information about strategies to prevent the spread of flu, especially important in the remaining time before large scale vaccination with 2009-H1N1 vaccine can begin. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. CDC also has issued guidance for healthcare providers about appropriate use of antiviral medications to treat patients who are at highest risk of complications from influenza. 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. In this rapidly changing situation, it is essential that the American people are fully engaged so they can be part of the response. CDC will continue to conduct weekly and, when necessary, more frequent briefings that will be available at [flu.gov](http://flu.gov) and other media to get critical information to the American people.

## **Vaccination Campaign**

The federal government is taking strong, proactive steps to control the spread of the 2009-H1N1 virus, including preparing for a voluntary national vaccination campaign starting in October.

With unprecedented speed, we have completed key steps in the vaccine development process: we have characterized the virus, identified a candidate vaccine strain, through our HHS partners expedited manufacturing, and performed clinical trials. The speed of this vaccine development was possible due to the investments made by the Congress over the past five years in advancing research and development and building infrastructure. Two types of vaccine will be available: vaccine made from inactivated virus for injection (flu shot) and a live attenuated virus vaccine administered by nasal spray. Some vaccine manufacturers will be producing 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

The vaccines are being manufactured by the same companies using the same methods used for the production of the seasonal flu vaccines administered every year. Dr. Fauci will describe in more detail the results from clinical trials which are very encouraging and have allowed us to move forward rapidly. Continued characterization of circulating strains of 2009-H1N1 suggests the vaccines being produced should be an excellent match with the circulating virus at this time, and are expected to be highly effective if the virus doesn't change. One of the major determinants in effectiveness of influenza vaccines is how closely the strains used to create the vaccine match the strains being transmitted and causing illness in our communities. The

circulating strains of 2009 H1N1 virus have not undergone major mutations and match the vaccine strains very closely. Therefore, we have every reason at this time to expect that the vaccine will produce good antibody responses and provide protection against H1N1 illness.

Adverse events from the 2009 H1N1 vaccine in the clinical trials are similar to those seen with seasonal flu vaccine—mainly, mild pain, tenderness, redness, or swelling at the injection site. No severe adverse events have been identified in the clinical trials, but we will remain alert for the possibility of rare, severe adverse events. Ensuring a vaccine that is safe as well as effective is our top priority. CDC and the Food and Drug Administration (FDA) have been working with other agencies to establish and enhance surveillance systems to detect as rapidly as possible any unexpected adverse events among persons who are vaccinated and to adjust the vaccination program to minimize risks and maximize benefits from vaccination. Two primary systems that will be used are the Vaccine Adverse Events Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations with more than nine million members designed to determine whether any reported adverse events are occurring among vaccinated persons more than among unvaccinated persons.

Our goal is to make vaccine available to every American who wishes to be vaccinated, beginning with population groups at greatest risk. The federal government has been working in close partnership with states, territories, tribes, and local communities as well as with the private sector to help distribute and administer the new H1N1 vaccine. Thanks to support from Congress, the

federal government has made a significant investment in states and hospitals to support planning and preparation efforts.

We expect initial shipping of 2009-H1N1 vaccines from our central distributor to sites where it will be administered to begin as early as the end of this week. During these initial days of the program, vaccine will be available in limited quantities. However, vaccine production is continuing and the amount of vaccine becoming available will increase throughout the fall, and we expect sufficient quantities to be available for all who want to be vaccinated through the end of the year. Vaccine production is a complex and demanding process with many variables—CDC is working with other agencies and with the manufacturers to provide as much vaccine as possible as soon as possible. Projections for the amount of vaccine available at any given time during the fall may change as more information on the production process becomes available from the manufacturers. This is a challenging process; because we want to speed the delivery of vaccine as quickly as it becomes available, we need to depart from the traditional process of warehousing and distribution of a more complete inventory.

The 2009-H1N1 vaccine will be distributed to providers and state and local health departments in a manner similar to how federally purchased vaccine are distributed in the Vaccines for Children program. The amount of vaccine allocated to each state is based on the total population of that state. This system follows state-developed plans for delivery to up to roughly 90,000 locations, and is designed to provide maximal flexibility to meet the differing needs in various parts of the country. States will have vaccine delivered directly to clinics and other sites of vaccine administration and some will also receive, repackage, and redistribute some of the shipments

according to local needs. The number of doses shipped will be reported to the CDC daily, and states have been asked to report the number of doses administered to the CDC weekly. The planning for this vaccine campaign has been informed by experience working with States and localities through the Vaccines for Children program. We have been able to provide significant new resources to States and localities to facilitate their ability to rapidly deliver vaccine as it becomes available and we were fortunate to be able to take advantage of preliminary findings from a recent HHS Inspector General report on preparedness for vaccine and antiviral distribution as we worked with States on their final vaccine planning.

The vaccine, which was purchased with Federal funding, will be available free of charge to the American people, but some private providers may charge an administration fee or bill the administration fee to a third party payer. Administration of vaccine in public settings will be free of charge and we have been working with public agencies and the insurance industry to insure that no American goes unvaccinated because of lack of insurance and inability to pay administration fees.

The virus has not changed compared with the spring in terms of the illness that it causes or who is most likely to become ill. This virus is infecting more young people, including children and younger adults than is typical for seasonal influenza; and pregnant women are more severely affected with H1N1 flu than the general population. CDC's Advisory Committee on Immunization Practices (ACIP) recommended providing initial doses of the 2009-H1N1 vaccine to five groups—totally approximately 159 million people. CDC endorsed these recommendations. These groups are:



- people ages 25 through 64 years who are at higher risk for complications from 2009 H1N1 infection because of chronic health disorders like asthma and diabetes or compromised immune systems.
- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel, and
- persons between the ages of 6 months through 24 years of age.

However, an effective vaccine against 2009-H1N1 does not mean that we can become complacent about other control measures. We need to remind all Americans about the things they should be doing right now: stay home if you're sick, cover your cough or sneeze, and wash your hands often. Flu.gov has good tips for what you need to do to avoid getting the flu as well as information about both the 2009-H1N1 vaccine, as well as the seasonal flu vaccine. 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. It is estimated that about 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all people 50 years of age and over, all adults with certain chronic medical conditions, as well as infants and children. More than 60 million doses of seasonal flu vaccine had been distributed as of last week.

### **Closing Remarks**

CDC is working hard to limit the impact of the pandemic and we are committed to keeping the public and the Congress fully informed about the situation and our response. We are

collaborating 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. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge. Our nation's current preparedness is a direct result of the investments and support of the Congress over recent years as well as in recent months, effective planning and action by Federal agencies, and the hard work of state and local officials across the country. While we must remain vigilant, 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.

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.