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**Testimony**  
**Before the Subcommittee on Oversight and**  
**Investigations**  
**Committee on Energy and Commerce**  
**United States House of Representatives**

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**US Influenza Vaccine Supply and**  
**Preparations for the Upcoming**  
**Influenza Season**

*Statement of*

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Mr. Chairman and members of the Committee, I am pleased to be here today to update you on the Centers for Disease Control and Prevention's (CDC) efforts to address the influenza vaccine supply status and our planning for the 2005-06 influenza season. We faced unprecedented challenges during the 2004-2005 influenza season. Due to tremendous collaboration among our public health and private sector partners, our collective ability to modify and enhance our response strategy as circumstances changed, and the cooperation of the public, I am pleased to report that we have been successful in our effort to promote and protect the public's health. We learned valuable lessons from the 2004-2005 influenza season that are enhancing our planning efforts for the upcoming influenza season.

Vaccination is the primary strategy for protecting people who are at greatest risk of serious complications and death from influenza. In the face of this season's influenza vaccine supply shortage, CDC, state and local public health officials, vaccine manufacturers and distributors initiated extraordinary partnership activities to address this public health challenge. For example, sanofi pasteur (formerly Aventis Pasteur) provided access to vaccine distribution information to aid in the allocation of the available vaccine supply to those people most in need this season. State and local public health officials also worked closely with CDC to ensure equitable distribution of vaccine to those areas with the greatest need. And we must not forget the important service of immunization providers on the front lines in doctors' offices, health clinics, grocery stores, and pharmacies.

working to prioritize, deliver, and administer vaccine so that it reaches high-risk individuals. Together, we found new and effective ways to address the sudden, late emergence of a substantial influenza vaccine shortage that had never before occurred.

Despite the challenges presented by the unexpected shortage of influenza vaccine, CDC immediately responded by changing recommendations to focus vaccine efforts and then began monitoring the results of those changes. State specific flu vaccination data for adults and children were rapidly collected and reported on an ongoing basis from November 2004 through February 2005. CDC's Behavioral Risk Factor Surveillance System reported that 62.7 percent of Americans 65 years of age and older reported being vaccinated for influenza between September 2004 and January 2005. This coverage is comparable to the percentage of older Americans vaccinated in previous years without supply shortages. So, many at-risk older Americans were vaccinated as a result of effective work of state and local health departments and the cooperation of younger, healthier Americans who "stepped aside" to allow the older and more vulnerable populations to receive vaccine. In addition, through January of 2005, 48.4 percent of young children (between 6 and 23 months of age) were vaccinated. This marked the highest vaccination coverage rate in response to a first-time recommendation of a new vaccine for children.

## **PREPARATIONS FOR THE 2005-06 INFLUENZA SEASON**

As we prepare for the 2005-2006 influenza season, we are incorporating into the planning process successful strategies used this past year. For example, our budget request reflects the need to strengthen the influenza vaccine supply. Another example is the inclusion of our state and local public health partners and the vaccine manufacturers in the planning process for the next influenza season. Another partnership is the National Influenza Summit, which is cosponsored by the American Medical Association (AMA) and CDC and has been meeting annually since 2001. The Summit brings together stakeholders to discuss issues of concern regarding the annual influenza season, including vaccine supply. Additionally, throughout the year Summit partners continue to collaborate to address barriers to increased influenza vaccinations. This year the Summit will be held May 10-11 in Chicago.

The best strategy for influenza prevention and control both during annual outbreaks and during a pandemic is vaccination. However, the vaccine manufacturing system in the United States is fragile. Currently, there are only three influenza vaccine manufacturers producing vaccines for the US market, and only one of those manufacturers produces its vaccine entirely in the United States.

Anticipating and planning for the next influenza season is an enormous and complex challenge, involving numerous public health and private sector entities. The production of influenza vaccine is a lengthy and complicated process. Six to

nine months before the influenza season begins, manufacturers must predict demand and decide the amount of the vaccine to produce. Moreover, the onset of the influenza season, its severity and duration, as well as the potential public demand for vaccine are highly unpredictable from year to year.

CDC has already begun its planning efforts for the 2005-06 influenza season in anticipation of continued challenges in meeting the nation's vaccine supply needs. We have established a planning team that meets almost weekly. The team consists of staff from across CDC, as well representatives from state and local public health agencies with input from the National Vaccine Program Office and the Food and Drug Administration.

To date, CDC has:

- Developed possible scenarios for vaccine supply for the coming season, including the possible disruption of production among the current influenza vaccine manufacturers for the U.S. market, the re-entry of Chiron into the market, and the entry of additional influenza vaccine manufacturers into the U.S. market;
- Worked with the Advisory Committee on Immunization Practices (ACIP) to develop more refined vaccination priority plans that can be used should there be another critical vaccine shortage;

- Met with U.S.-licensed and other vaccine manufacturers to discuss their plans for the next season, including production estimates, and distribution strategies and anticipated time lines for vaccine availability; and
- Worked with sanofi pasteur and other prospective manufacturers and distributors so that, during the prebooking process, customers indicate both the total amount of vaccine they need, assuming an adequate supply, and the number of doses needed to vaccinate high priority groups in the event of supply limitations.

In addition, CDC is:

- Pursuing a vaccine contracting strategy that addresses routine influenza vaccine purchase and stockpile purchase. We recently signed contracts for 3.5 million doses maximum of sanofi pasteur thimerosal-free vaccine, three million doses maximum of sanofi pasteur multi-dose vials and one million doses of MedImmune's FluMist. The stockpile doses are being negotiated now that we have the contracts. The bulk purchase solicitation is pending.
- Monitoring antigen-sparing studies designed to determine if reduced vaccine dosages can provide sufficient immunity against influenza, thereby allowing for the protection of more persons with fewer doses of vaccine.
- Developing infection control strategies to prevent the spread of influenza.
- Drafting a written plan highlighting key activities that state and local public health agencies should consider to prepare for the upcoming season. This plan is currently being reviewed by our partners, and we hope to have it

finalized before the end of summer 2005. This will be complemented with a list of key activities CDC will undertake.

- Preparing communication strategies with appropriate messages to respond to the fluctuations in supply and demand anticipated throughout the season.
- Developing and implementing a plan to evaluate the season.

These comprehensive planning efforts are intended to support the achievement of important public health objectives, including increasing the domestic production of influenza vaccine, increasing demand for vaccine among persons indicated for annual influenza vaccination, and increasing vaccination coverage, particularly among persons in high-risk groups, so that we can protect and improve the public's health.

## **CONCLUSION**

Influenza is a serious public health threat, taking the lives of about 36,000 Americans each year and hospitalizing on average more than 200,000 each year. For this reason, it is imperative that we continue to refine and improve our capacity to meet any challenges that arise in terms of vaccine supply, seasonal severity, or other unusual circumstances. We are applying the lessons learned from the challenging experiences of the 2004-05 influenza season for this upcoming season and have established a mechanism to continue to improve and learn in an effort to assure our nation's citizens are protected from this disease.

Thank you for focusing attention on this important public health issue and for the opportunity to provide an update on our current efforts. CDC is committed to protecting and promoting health for all Americans, preventing disease and disability through public health research and public outreach, and supporting important public health interventions, including vaccination. We appreciate your interest in this issue and your support of CDC's efforts to protect the public's health.

I will be happy to answer any questions.