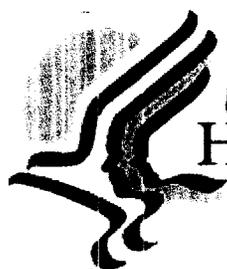


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United States Department of
Health and Human Services

Testimony

Statement by

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on

Protecting the Pubic's Health: CDC Influenza Preparedness Efforts

before the

The Committee on Government Reform

United States House of Representatives

February 12, 2004

Good Morning, Mr. Chairman, Members of the Committee. Thank you for inviting me here today to provide information regarding the current influenza season and the country's preparedness for a major public health threat. Assuring the Nation's preparedness has been one of Secretary Tommy Thompson's greatest priorities.

Introduction

As you are aware, this influenza season presented several challenges for the nation's public health system. The season began and peaked earlier than in most years; there was substantial media coverage, particularly of disease and death among children, creating the perception that the season was more severe than prior years and demand for trivalent inactivated influenza vaccine exceeded the amount that had been produced by the market. There were other complications this season, as well, revolving around reports of a more severe season than usual being caused by an H3N2 strain of influenza, which is often associated with more severe influenza seasons, and surveillance data showing that the predominant virus circulating was different from the corresponding strain contained in the vaccine. I will outline what the Centers for Disease Control and Prevention (CDC) did to respond to this situation and provide information on the current state of preparedness for a larger scale event. The timing of this hearing is opportune, as CDC is very concerned about the recent widespread outbreaks of avian influenza in poultry flocks spanning many countries in Asia and the associated human illnesses and deaths reported from Thailand and Vietnam.

The situation of limited availability of influenza vaccine this year arose from the unusual combination of: (1) an early onset of relatively severe influenza which led to a surge in demand for the vaccine at the end of the traditional vaccination season; and, (2) production of the same number of doses of trivalent inactivated influenza used in prior years which was not adequate to meet the surge in demand that occurred this past influenza season. The surge in the demand for vaccine was also sparked by the reporting of substantial numbers of pediatric cases of influenza, including severe or unusual complications and deaths, noted in several states. At this point, it is unclear whether influenza is impacting children more severely than in other years or if a heightened awareness of severe influenza disease in children has led to increased testing and reporting of pediatric cases. The overall influenza morbidity reported from surveillance this influenza season is similar to what has been seen in other years where an H3N2 influenza strain predominated.

While our experience this influenza season has heightened national interest in influenza disease and its prevention, CDC has long recognized the impact of this disease on our population and its importance as a cause of illness, hospitalization, and death. CDC scientist's estimate that an average of 36,000 people die from influenza-related complications each year in the United States. At a meeting of the National Vaccine Advisory Committee (NVAC) last week, Dr. Christina Beato, Acting Assistant Secretary for Health, called on the committee to work with CDC and other Department of Health and Human Services (DHHS) agencies to review the entire influenza vaccination system and make recommendations on how we can improve our prevention efforts. We welcome this charge and will work with NVAC to provide a preliminary report to the Assistant Secretary in June. The Department has, however, already begun important new vaccine development activities, which I will describe later in this testimony.

Vaccinating individuals who are at greatest risk of serious complications from influenza is the primary strategy for preventing severe complications from the disease, including associated deaths. Our communications to the public urging them to get vaccinated as the most effective means of prevention has helped yield the strong consumer demand for influenza vaccine this year, exceeded the demand seen in previous influenza seasons. Some healthcare providers used all of their supplies of influenza vaccine. In past years, supply has generally been sufficient to meet demand. Typically, almost all influenza vaccination is completed by late November. This year, however, a surge in demand began in late November continuing into the month of December. At a time when influenza vaccination clinics are typically winding down, people were still seeking vaccination.

Communications 2003-2004 Influenza Season

Each year, CDC works with the Advisory Committee on Immunization Practices (ACIP) to review and update influenza vaccination recommendations. These annual recommendations are published before each influenza season so that providers can become familiar with these recommendations and have time to implement any recommended changes. Prior to the influenza season CDC conducted its annual national public-education campaign to promote the benefits of influenza vaccine and the most current influenza vaccination recommendations. Partnerships with health departments, medical societies, social service organizations and the private sector were important elements in the influenza communication efforts. Based on formative research, printed materials were developed in both English and Spanish and made available on the website. A national media campaign, consisting of press conferences, teleconferences, new releases (video, audio and print) was launched in September.

As I have stated, the influenza season started early this year. In October, CDC received reports about several laboratory-confirmed school outbreaks in Texas. Preliminary analysis of the Texas isolates at CDC showed that some were different from the strain contained in the vaccine for the current year. CDC increased its efforts to analyze the viruses circulating in the United States as quickly as possible and to educate our partners and the public about this season's vaccine and the need for timely vaccination. A series of CDC Health Updates, Morbidity and Mortality Weekly Reports (MMWR) and additional guidelines for infection control and use of influenza antiviral drugs were disseminated by CDC to keep health care providers and states informed of important information as the season progressed.

Production of influenza vaccines is a complex process that requires many steps, including selection of suitable vaccine viruses, growth of these viruses in eggs, and testing to ensure safety and purity of the vaccine. Recommendations about which strains should go into the vaccines for the United States are based on year-round surveillance and are typically made in February for vaccine that will be used in the following season. The A/Fujian strain was identified late in January 2003. At that time, it seemed possible that this strain might predominate during the coming influenza season, but it was too early to be certain. In addition, there was no isolate that had been grown exclusively in eggs. Currently all influenza viruses used in vaccine production are grown only in eggs or avian cell culture.

U.S. health authorities postponed their recommendation about which A (H3N2) strain should be included in the vaccine for a full month (until March) while more viruses were tested and while attempts were made to grow an egg isolate of the A/Fujian virus that could be used in vaccine production. A suitable isolate could not be grown in time and waiting longer likely would have jeopardized the supply of influenza vaccine for the 2003-04 season. Because of these considerations, in March it was recommended that the influenza vaccine for the 2003-04 influenza season include an A/Panama strain, which is related to the A/Fujian strain. This chain of events is a

reminder of the fragility of a time-consuming vaccine production process that is reliant upon eggs. The Department is undertaking efforts to move toward the development of a modern, cell culture influenza vaccine, for which production can be scaled up more rapidly than the traditional egg-based vaccine.

Childhood influenza has been of concern to CDC for the past several years and was highlighted this year in the media. A CDC study showed that children less than two years of age were at a similar risk for hospitalization due to influenza complications as older age groups for which vaccine is recommended. The ACIP voted in October 2003 to recommend routine use of influenza vaccine for children 6-23 months of age, beginning in the 2004-2005 influenza season. Previously, influenza vaccine had been encouraged for this age group but no formal recommendation had been made. CDC also has been closely following reports from Japan about influenza-related pediatric encephalopathy cases and has increased our own efforts to report and characterize severe disease in the pediatric populations. This season CDC sent additional requests to all state health departments to report cases of influenza related deaths in the pediatric populations. Discussions are underway with state and national partners about the feasibility of making the reporting of influenza deaths in pediatric populations nationally notifiable. CDC continues to analyze pediatric mortality data collected this year. The attention that this topic has received is timely in that it underscores the severe impact influenza has on pediatric populations, particularly for children with chronic medical conditions.

As the season progressed and widespread disease was reported in virtually every State, CDC activated its Emergency Operations Center (EOC) on December 5, 2003. This enabled CDC to respond to the multiple issues surrounding vaccine supplies, to enhance efforts to document morbidity and mortality caused by influenza, and to develop additional guidelines for the prevention or treatment of influenza. A focus was placed on providing frequent, up-to-date guidance to state public health partners, health care professionals and the general public about how and where to obtain vaccine and how to prevent and control influenza.

Vaccine Supply 2003-2004 Influenza Season

The situation of limited availability of influenza vaccine this year arose from the unusual combination of an early onset of severe influenza outbreaks leading to a surge in demand for the vaccine later than usual in the influenza season and production of the same doses of the influenza vaccine used in previous years which was not adequate to meet the surge in demand. Addressing issues associated with the increased demand for influenza vaccine this season was a major focus of CDC actions.

U.S. licensed influenza vaccine is produced by three manufacturers--two making inactivated vaccine and one making a live attenuated vaccine delivered by nasal spray. All vaccine is produced, and the vast majority distributed, by the private sector. Because of the time required to manufacture vaccine and the need to obtain adequate supplies of embryonated eggs in which influenza virus is grown for vaccine production, manufacturers must predict demand and decide on the number of vaccine doses to produce approximately 6 to 9 months before onset of the influenza season. For the 2002-2003 influenza season, manufacturers produced approximately 95 million doses of influenza vaccine of which about 83 millions doses were used; and the remaining 12 million doses that were produced went unused. Production of vaccine for this year was based on last year's demand--manufacturers produced about 83 million doses of the inactivated vaccine, as well as about 4 million doses of the new live vaccine, FluMist, for a total of about 87 million vaccine doses.

CDC vaccine recommendations are made through a deliberative process involving advice and guidance from the ACIP. The ACIP issues recommendations regarding influenza vaccination, including which groups of individuals are at highest risk for developing complications from influenza, and optimal time frames for administering vaccine. If vaccine manufacturers delay production, or if there is a shortage of influenza vaccine, CDC can take steps to minimize the effects.

Actions Taken By CDC 2003-2004 Influenza Season

CDC took aggressive steps to communicate issues regarding influenza to all possible audiences. As a first step, the CDC influenza website was completely reorganized. A single site with all influenza related information made information easier to find. A series of updates targeted at all audiences were prepared and posted to inform providers and the public of the latest information on vaccine availability, guidelines for the prevention and

control of influenza and answers to the many questions that arose as the influenza season progressed. A proactive campaign to keep health care providers and states informed as the season progressed was also mounted through the dissemination of a series of CDC Health Updates and MMWRs reports beginning October 20, 2003. These publications provided updates on U.S. influenza activity and addressed issues such as the importance of timely vaccination, with priority placed on vaccinating persons at high risk for complications from influenza, including children 6-23 months of age; interim guidelines on the use of antiviral medications for prophylaxis and treatment; and, the request for reporting of severe pediatric cases through state public health departments.

Actions taken by CDC in response to the demand for influenza vaccine this season include the following:

- CDC worked with the vaccine manufacturers, distributors, health care providers, and state and local public health departments to redistribute vaccine wherever possible from areas with vaccine excess to those with the greatest need.
- CDC also explored every opportunity to obtain additional doses of influenza vaccine. In December and January, we were able, through the contracting process to obtain 463,000 doses of adult influenza vaccine, and 213,000 of the pediatric doses. Additionally, 49,000 doses of FluMist were donated by the manufacturer and more than 40,000 doses of inactivated vaccine were received from the Department of Veterans' Affairs. The principal consideration in allocating these additional doses was to distribute them in a fair and equitable manner to reach as many high-risk individuals as possible.
- CDC encouraged states to develop plans to help manage and direct vaccine supplies in their jurisdictions.
- The CDC Emergency Operations Center was activated.
- Special calls were held with National Influenza Vaccine Summit participants and with partners. The National Influenza Vaccine Summit, co-chaired by the American Medical Association and CDC, consists of organizations dedicated to improving influenza control.
- Several studies were begun at CDC to obtain rapid assessments of the effectiveness of this year's vaccine. Work on these studies is ongoing. It is difficult to implement these studies in the middle of the influenza season and we need to develop a routine system for real time measurement of how well influenza vaccines are protecting our citizens.
- The National Vaccine Program Office (NVPO) in the Department of Health and Human Services has responsibility for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities. As such, they are completing a pandemic influenza preparedness and response plan that will include approaches for improving annual influenza disease control, including vaccine production, distribution, and administration.

Preparedness for Communicable Disease Outbreaks Including Influenza

This year's influenza season and the threat of an influenza pandemic, exemplified by the current situation with avian and human deaths in Asia caused by H5N1 viruses, highlight the importance of improving the nation's preparedness to respond to disease outbreaks such as influenza. Much work has been done to improve the public health infrastructure during recent public health emergencies. Our current and evolving efforts include: (1) expanding our capacity to conduct surveillance for influenza to try to identify new strains of influenza more rapidly so that they can be incorporated in vaccines; (2) conducting research that leads to the development of better vaccines and vaccine candidates for use during annual influenza outbreaks and in a pandemic; (3) improving the nation's vaccine supply to meet demand and eventually cover the 185 million American for whom influenza vaccine is recommended; (4) improving the infrastructure needed to deliver vaccines; (5) developing

stockpiles of antiviral drugs and other medications and items that will be in short supply during a pandemic; (6) developing communications strategies and materials; (7) improving coordination with and planning by our state, local and private sector partners; and, (8) We also need to assure that more of our health care providers receive influenza vaccine. According to the National Health Interview Survey for Health Care Workers, only 36 percent to 41 percent of health care providers receive influenza vaccine annually.

In a time when U.S. and international health are inextricably linked, the fulfillment of CDC's domestic mission – to protect the health of the US population – requires increased global awareness and collaborations with global partners. Beginning in FY 2004, CDC is investing in a Global Disease Detection initiative, which will facilitate the faster recognition of infectious disease outbreaks globally, improved ability to control and prevent outbreaks, and enhanced capability to detect emerging microbial threats. By expanding international surveillance network and filling gaps in key areas of the world, we will gain greater access to circulating influenza viruses from other parts of the world. By increasing the international partners who regularly share influenza virus isolates through the World Health Organization (WHO) surveillance network, we will increase our ability to detect new variants earlier, and thus be in a better position to make vaccine decisions. At the same time we will have the added benefit of detecting new viruses with pandemic potential and for other infectious diseases. The surveillance network created for influenza played a key role in detecting and characterizing the spread of SARS. Enhancements also are needed for domestic surveillance. These include improving the ability of state public health laboratories to detect and subtype influenza viruses, expanding the sentinel provider surveillance system, and developing a new system of reporting for hospitalizations associated with influenza. This hospital-based information is crucial for understanding the impact of influenza on both people and the health care systems that treat them.

There are several ways by which prevention of influenza by vaccination can be improved. More information needs to be collected about the effectiveness of influenza vaccines to determine the impact of vaccine in various populations for whom vaccine is recommended in reducing the burden of influenza and to help in evaluating whether the present strategy which is focused on vaccination of person at high risk of influenza is the most effective way to reduce the burden of this disease. For example, more vaccination of healthy younger people may lead to indirect protection of high risk persons, by reducing the likelihood that such persons will be exposed to the virus. Additionally, research is needed to better understand the immune response to influenza vaccines--particularly among high risk groups such as the elderly--and to improve influenza vaccines so that they are more effective in preventing disease and death. This research is underway. Finally, there are several approaches that can be pursued to expand influenza vaccine supply and availability at the time of a pandemic.

DHHS is currently beginning work on long-range strategies to improve influenza vaccine supply in the future. The current egg-based system used to produce licensed influenza vaccines – despite being reliable for more than 40 years – can be improved. Limitations of the current system include: 1) a lengthy manufacturing process; 2) the need to select which virus strains will be in the vaccine at least six months in advance of the influenza season; 3) the need to produce nearly 90 million doses of a new influenza vaccine each year; and 4) the requirement of hundreds of millions of fertilized chicken eggs to manufacture the vaccine. The current production techniques to make influenza vaccine cannot be scaled up rapidly to provide additional doses of vaccine in a bad influenza season or in the event of an influenza pandemic. In the 2003-2004 season, the national demand for vaccine was higher than the 87 million doses that were produced for the United States. In the event of an influenza pandemic, the demand for vaccine could spike to between 280 million and 575 million doses, with no more than four or five months for manufacturing – and it would have to be made in the U.S. to ensure its availability. DHHS is encouraging the development and U.S. licensure of influenza vaccines produced using new technology, including the development of cell-based vaccines. Given that industry generally produces enough annual influenza vaccine to meet demand under the current egg-based production methods, they would not get a return on the investment that would be needed to switch to a cell culture method of production. Resources have been made available in the FY 2004 budget, and requested in the FY 2005 budget, for this activity. We are very grateful that \$40 million dollars was allocated for the pediatric influenza vaccine stockpile in the recently passed budget. Additionally, the President's fiscal year 2004 budget request included \$100 million for pandemic preparedness and Congress appropriated \$50 million. The President's fiscal year 2005 request again includes \$100 million for pandemic preparedness.

As part of CDC planning efforts, we also have been evaluating approaches with vaccine manufacturers for increasing annual vaccine production. One important stimulus to increased production is increased demand and annual vaccine use. Through our educational efforts for providers and the public, we are stimulating increased vaccination. To achieve our Healthy People 2010 targets of vaccinating 90 percent of adults 65 years and older

and 60 percent of high-risk adults ages 18 to 64, we will need to increase these efforts and to address other barriers to vaccination. CDC participates on international workgroups to develop guidance for the production and licensing of vaccines using new technology such as reverse genetics and participates internationally in efforts to look at global vaccine supply issues.

CDC has been working with the private sector, state and local health officials and provider organizations in the development of contingency plans and is taking steps to help ensure that high-risk patients are vaccinated in the event of a delay or shortage. Several activities are underway and are planned to anticipate and deal with potential problems.

- CDC has continued its collaboration with the Centers for Medicare and Medicaid Services (CMS) to encourage and promote "standing orders" to improve influenza and pneumococcal vaccination levels in nursing homes throughout the country. A standing order enables nursing homes to provide these vaccinations to nursing home residents without an individual prescription. In 2002, CDC and CMS completed a three year program to promote standing orders for Medicare patients in nursing homes. Initial data showed that standing orders are both more effective and more cost-effective than other methods for increasing immunization rates in increasing immunization coverage against influenza and pneumococcal diseases among nursing home residents.
- In addition, Medicare increased its reimbursement rates to health care providers to deliver vaccine to their patients. The Medicare reimbursement rate for administration of flu vaccine increased from an average of \$3.98 in 2002 to \$7.72 in 2003 – an increase of 94 percent. The reimbursement rate for the vaccine product also increased, from \$8.02 to \$9.95.
- CDC and the American Medical Association hosted a National Influenza Vaccine Summit for the past three years with manufacturers, selected distributors, trade organizations, provider organizations and public health officials to learn more about private sector production and distribution challenges and to address contingency planning.
- In July 2001, CDC implemented the DHHS Racial and Ethnic Adult Disparities in Immunization Initiative (READII) in five demonstration sites to improve influenza and pneumococcal vaccination rates for African-Americans and Hispanics 65 years of age and older. This initiative is being implemented with the support of the CMS, HRSA, the Administration on Aging, the Agency for Healthcare Research and Quality (AHRQ), and other federal agencies.
- CDC, beginning in 2001, requested that states develop contingency plans in the event of an influenza vaccine shortage and provided written guidelines to assist them in planning. In March of 2003, 15 states had complete or draft plans and 34 states were preparing their plans. We will get an updated status on this next month.
- CDC is evaluating strategies to improve influenza vaccine supply in the future. The recent addition of the \$40 million for the VFC program to stockpile the vaccine will help us in these efforts. DHHS is completing a pandemic influenza preparedness and response plan that will include approaches for improving influenza surveillance, expanding vaccine research, and improving annual influenza disease control, through vaccine production, distribution, and administration.
- Each year, CDC encourages those for whom vaccine is recommended to receive influenza vaccines, and we will continue these efforts in the future.

Influenza antiviral drugs can have an important impact on morbidity and mortality from influenza disease and would have a role in the event of a pandemic. Studies show these drugs are 70 to 90 percent effective in preventing influenza when begun as chemoprophylaxis before exposure to influenza virus. Additionally, one class of drugs has been shown to decrease hospitalizations and lower respiratory complications such as pneumonia and bronchitis when used as treatment. In an influenza pandemic, use of antiviral drugs may be particularly important early in the response to protect and prevent transmission by persons who perform critical functions

such as first responders, including health care workers, and those responsible for public safety. This season CDC acquired, with the strong support of Secretary Thompson, several hundred thousand treatment courses of one antiviral drug as part of the Strategic National Stockpile. A range of issues including the ability of the manufacturers to supply large amounts of drug quickly, currently are being explored. Antiviral drug resistance is a concern in that it can render the more widely available and lower cost antiviral medications ineffective, as was demonstrated for the strain of avian influenza causing deaths in Vietnam and Thailand. Even more ideal than an antiviral stockpile, however, is an effective influenza vaccine.

While we are addressing the issues of surveillance, vaccine supply, and antiviral drug stockpiles at the national level and these efforts will provide the ability to respond to an influenza pandemic, actually implementing that response is the job of the state and local health departments and the health care system. Federal funding, guidelines, and technical assistance are available to support planning efforts at state and local levels. CDC also is developing tabletop and field exercises to practice those plans.

Conclusion

Mr. Chairman, our surveillance data are showing that although the influenza season arrived earlier than usual this year, the morbidity and mortality caused by influenza this year was on par with other recent years when influenza A(H3N2) viruses predominated, though unprecedented media attention helped to increase consumer demand for vaccine late in the influenza season. Normally, we have millions of doses that go unsold and get discarded. This year is unprecedented in that interest in influenza vaccination remained strong into December and all doses of inactivated influenza vaccine were sold. CDC, and its partners, took steps to make the situation better by working with the private and public sectors to obtain vaccine and assist with redistribution. The challenges caused by this year's consumer demand for vaccine highlight the urgent need to improve the Nation's capacity to prepare for a catastrophic event of a much larger nature, as can occur in an influenza pandemic.

To address the challenges we face, we need to be able to respond to an unusually bad influenza season, or an influenza pandemic, more rapidly than current vaccine production methods allow. In addition, we need to enhance our surveillance activities so we can detect virus variants earlier so they can be incorporated into our vaccine. We must continue and strengthen our promotional efforts to educate the public about the importance of routine influenza immunization to create the demand to vaccinate high-risk individuals, alleviate surges in demand, and develop a consistent market so manufacturers can better gauge vaccine supply. The recent recommendations to vaccinate all 6-23 month old children and their household contacts will help reduce the terrible burden of pediatric morbidity and mortality. The \$40 million made available in FY 2004 and FY 2005 to develop an influenza vaccine stockpile through our VFC program will help us respond to sudden unanticipated surges in demand. And our continuing collaboration with state and local health care providers, in both the public and private sectors will help to focus on preparedness efforts.

DHHS is completing a pandemic influenza preparedness and response plan that will include approaches for: improving surveillance; targeting research to improve influenza vaccines and promote the use of new vaccine production technology; and, provide surge production capacity establishing mechanisms to work with manufacturers to ensure adequate annual vaccine production; and improving coordination with public and private partners. Together we will continue to work to improve our Nation's ability to plan and prepare for a pandemic.

Thank you again for holding this hearing on such an important public health issue. I would be happy to respond to any questions you may have.

Appendix I

The initial recommendations made by the ACIP for the prevention and control of influenza for the 2003-2004 season were reported in CDC's April 25, 2003, Morbidity and Mortality Weekly Report (MMWR) (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5208a1.htm>).

The ACIP recommends the following individuals get vaccinated against influenza:

- persons 50 years and older;
- residents of nursing homes and other long-term care facilities;
- adults and children 6 months of age and older with chronic heart or lung conditions;
- adults and children 6 months of age and older who need regular medical care or had to be in a hospital because of metabolic diseases, chronic kidney disease, or a weakened immune system;
- children and teenagers 6 months to 18 years who are on long-term aspirin therapy;
- women who will be more than 3 months pregnant during the influenza season; and
- healthy children 6-23 months of age (to begin in 2004-2005 according to October 2003 recommendation of ACIP, implemented this year).

In addition, the ACIP recommends the following groups get vaccinated to prevent spread to individuals at high risk of complications from influenza:

- doctors, nurses, and other employees in hospitals and doctors' offices, including emergency response workers;
- employees of nursing homes and long-term care facilities who have contact with patients or residents;
- employees of assisted living and other residences for people in high-risk groups;
- people who provide home care to those in high-risk groups; and
- household members of people in high-risk groups

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