Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss issues regarding the nation's preparedness to respond to a worldwide influenza epidemic, or influenza pandemic.[1] The emergence of new diseases such as severe acute respiratory syndrome (SARS) has raised concerns about our ability to respond to other infectious disease outbreaks such as an influenza pandemic,[2] which many experts believe to be inevitable. Vaccine shortages and distribution problems during the 2004-2005 influenza season add to these concerns.

Influenza pandemics arise periodically but unpredictably from a major genetic change in the virus that results in a new strain.[3] Some experts believe that the next pandemic could be spawned by the recurring avian influenza in Asia. As of May 19, 2005, 97 people, mostly young and otherwise healthy, have been confirmed by the World Health Organization (WHO) to have been infected with avian influenza since 2003, and 53 of them have died. Recent studies suggest that avian influenza strains are increasingly capable of causing severe disease in humans and suggest that these strains have become endemic in some wild birds. If these avian influenza strains directly infect humans and acquire the ability to be readily transmitted between people, a pandemic could occur.

While the severity of the next pandemic cannot be predicted, modeling studies suggest that its effect in the United States could be severe. The Centers for Disease Control and Prevention (CDC) estimates that if a "medium-level" influenza pandemic were to occur in the United States, in the absence of any control measures (e.g., vaccination and drugs), it could cause 89,000 to 207,000 deaths, 314,000 to 734,000 hospitalizations, 18 million to 42

[1]An influenza pandemic is defined by the emergence of a novel influenza virus, to which much or all of the population is susceptible, that is readily transmitted person-to-person and causes outbreaks in multiple countries.

[2]See GAO, *SARS Outbreak: Improvements to Public Health Capacity Are Needed for Responding to Bioterrorism and Emerging Infectious Diseases*, GAO-03-769T (Washington, D.C.: May 7, 2003).

[3]Influenza pandemics can have successive "waves" of disease and last for up to 3 years. Three pandemics occurred in the 20th century: the "Spanish flu" of 1918, which killed 500,000 people in the United States; the "Asian flu" of 1957, which caused 70,000 deaths in the United States; and the "Hong Kong flu" of 1968, which caused 34,000 deaths in the United States.

million outpatient visits, and another 20 million to 47 million cases of the illness.[4] From 15 percent to 35 percent of the U.S. population could be affected by an influenza pandemic, with associated costs ranging from $71 billion to $167 billion.

You asked us to provide our perspective on the nation's ability to conduct disease surveillance[5] for an influenza pandemic, as well as the public health system's preparedness for an influenza pandemic. In this testimony, I will discuss (1) surveillance systems in place to identify and monitor an influenza pandemic and (2) challenges in preparedness and response to an influenza pandemic.

My testimony today is based largely on our 2004 report on disease surveillance[6] as well as reports and testimony on influenza outbreaks, influenza vaccine supply, pandemic planning, and the SARS outbreak that we have issued since October 2000[7] and work we have conducted to update key information. Our prior work on disease surveillance and influenza pandemics included analysis of information provided by multiple federal departments and agencies, including the Department of Health and Human Services (HHS)—specifically from CDC and the Food and Drug Administration (FDA)—and the Departments of Agriculture, Defense, and Homeland Security, as well as interviews with officials of those departments and agencies. We also interviewed public health department officials from 11 states,[8] vaccine manufacturers, and vaccine distributors and surveyed physician group practices. To learn about pandemic planning efforts, we

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[4]See CDC, *Fact Sheet*, *Information about Influenza Pandemics*, 3, www.cdc.gov/flu, downloaded May 12, 2005.

[5]Disease surveillance is the process of reporting, collecting, analyzing, and exchanging information related to cases of infectious diseases.

[6]See GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: Sept. 30, 2004).

[7]See "Related GAO Products" at the end of this testimony for a list of our earlier work related to emerging infectious diseases and influenza pandemic planning.

[8]These states—California, Colorado, Indiana, Louisiana, Minnesota, New York, Pennsylvania, Tennessee, Texas, Washington, and Wisconsin—were selected based on their participation in CDC's Emerging Infections Program, each state's most recent infectious disease outbreak, and their geographic location.

interviewed HHS officials in the National Vaccine Program Office and reviewed HHS's August 2004 draft "Pandemic Influenza Preparedness and Response Plan." Our prior work on the SARS outbreak included analysis of information provided by U.S. agencies, WHO, and Asian governments, as well as interviews with officials from those entities. We also conducted fieldwork on SARS in Beijing; Hong Kong; Guangdong Province, China; and Taipei, Taiwan. In May 2005, we updated our information to include issues that arose during the 2004-2005 influenza season and to verify the current status of HHS efforts on surveillance, planning, and preparedness activities. We conducted all of our work in accordance with generally accepted government auditing standards.

In summary, federal public health officials plan to rely on the nation's existing influenza surveillance system and enhancements to identify an influenza pandemic. CDC currently collaborates with multiple public health partners, including WHO, to obtain data that provide national and international pictures of influenza activity. Federal public health officials and health care organizations have undertaken several initiatives that are intended to enhance influenza surveillance capabilities. While some of these initiatives are focused more generally on increasing preparedness for bioterrorism and other emerging infectious disease health threats, others were undertaken in preparation for an influenza pandemic. For example, in response to concerns over the past few years about the potential for avian influenza to become the next influenza pandemic, CDC implemented an initiative in cooperation with WHO to improve influenza surveillance in Asia. CDC has also implemented initiatives to improve the communications systems it uses to collect and disseminate surveillance information. In addition, CDC, USDA, and FDA have made efforts to enhance their coordination of surveillance efforts for diseases that arise in animals and can be transferred to humans, such as SARS and certain strains of influenza with the potential to become pandemic.

While public health officials have undertaken several initiatives to enhance influenza surveillance capabilities, challenges remain with regard to other aspects of preparedness for and response to an influenza pandemic. In particular, HHS has not finalized planning for an influenza pandemic. In 2000, we recommended that HHS complete the national

plan for responding to an influenza pandemic, but the plan has been in draft format since August 2004. Absent a completed federal plan, key questions about the federal role in the purchase, distribution, and administration of vaccines and antiviral drugs during a pandemic remain unanswered. Other challenges with regard to preparedness for and response to an influenza pandemic exist across the public and private sectors, including challenges in ensuring an adequate and timely influenza vaccine and antiviral supply; addressing regulatory, privacy, and procedural issues surrounding measures to control the spread of disease, for example, across national borders; and resolving issues related to an insufficient hospital and health workforce capacity for responding to a large-scale outbreak such as an influenza pandemic.

BACKGROUND

To be prepared for major public health threats such as an influenza pandemic, public health agencies need several basic capabilities, including disease surveillance systems. Specifically, to detect cases of pandemic influenza, especially before they develop into widespread outbreaks, local, state, and federal public health officials as well as international organizations collect, analyze, and share information related to cases of the disease. When effective, surveillance can facilitate timely action to control outbreaks and promote informed allocation of resources to meet changing disease conditions.

Influenza

Influenza is more severe than some other viral respiratory infections, such as the common cold. Most people who get influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. People aged 65 and older, people of any age with chronic medical conditions, children younger than 2 years, and pregnant women are more likely than other people to develop severe complications from influenza. Influenza and pneumonia rank as the fifth leading cause of death among persons aged 65 and older.

Influenza viruses undergo minor but continuous genetic changes from year to year. Almost every year, an influenza virus causes acute respiratory disease in epidemic proportions somewhere in the world. Vaccination is the primary method for preventing

influenza and its more severe complications. Influenza vaccine is produced and administered annually to provide protection against particular influenza strains expected to be prevalent that year. Influenza vaccine takes several months to produce. Deciding which viral strains to include in the annual influenza vaccine depends on data collected from domestic and international surveillance systems that identify prevalent strains and characterize their effect on human health. FDA decides which strains to include in the vaccine and also licenses and regulates the manufacturers that produce the vaccine.[9] HHS has limited authority, however, to directly control influenza vaccine production and distribution.[10]

FDA has approved four antiviral medications (amantadine, rimantadine, oseltamivir, and zanamivir) for prevention and treatment of influenza. However, influenza virus strains can become resistant to one or more of these drugs, and so they may not always be effective.

Disease Surveillance and Response

In the United States, responsibility for disease surveillance is shared—involving health care providers; more than 3,000 local health departments, including county, city, and tribal health departments; 59 state and territorial health departments; more than 180,000 public and private laboratories; and public health officials from multiple federal departments and agencies.

States, through the use of their state and local health departments, have principal responsibility for protecting the public's health and therefore take the lead in conducting disease surveillance and supporting response efforts. According to the Institute of

[9]FDA decides which strains to include in the annual influenza vaccine based on the recommendations of its Vaccines and Related Biological Products Advisory Committee.

[10]Under the Federal, Food, Drug and Cosmetic Act, FDA ensures compliance with good manufacturing practices and has limited authority to regulate the resale of prescription drugs, including influenza vaccine, that have been purchased by health care entities, such as public or private hospitals. The term "health care entity" does not include wholesale distributors. This authority would not extend to resale of the vaccine for emergency medical reasons. CDC also has a role in encouraging appropriate public health actions.

Medicine (IOM), most states require health care providers to report any unusual illnesses or deaths—especially those for which a cause cannot be readily established—to their local and/or state health department.[11] Generally, local health departments are responsible for conducting initial investigations into reports of infectious diseases. Laboratory personnel test clinical and environmental samples for possible exposures and identification of illnesses. Epidemiologists in health departments use disease surveillance systems to detect clusters of suspicious symptoms or diseases in order to facilitate early detection and treatment. Local and state health departments monitor disease trends. Local health departments are also responsible for sharing information they obtain from providers or other sources with their state departments of health. State health departments are responsible for collecting surveillance information—which they share on a voluntary basis with CDC and others—from across their state and for coordinating investigations and response efforts. Public health officials provide needed information to the clinical community and the public.

At the federal level, several departments and agencies are involved in disease surveillance and response. For example,

- HHS has primary responsibility for coordinating the nation's response to public health emergencies. As part of its mission, the department has a role in planning to prepare for and respond to an influenza pandemic. One action the department has taken is the development of a draft national pandemic influenza plan, titled "Pandemic Influenza Preparedness and Response Plan."

- CDC is charged with protecting the nation's public health by directing efforts to prevent and control diseases and responding to public health emergencies. It has primary responsibility for conducting national disease surveillance and

[11]The requirement to report clinically anomalous symptoms is particularly important for the detection of emerging infectious diseases, many of which may be unfamiliar to health care providers.

developing epidemiological and laboratory tools to enhance disease surveillance. CDC also provides an array of technical and financial support for state infectious disease surveillance efforts. In addition, CDC participates in international disease and laboratory surveillance sponsored by WHO.

- FDA is responsible for ensuring that new vaccines and drugs are safe and effective and for conducting research on diagnostic tools and treatment of disease outbreaks. The agency also regulates and licenses vaccines and antiviral agents through the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research, respectively. FDA also develops influenza viral reference strains and reagents and makes them available to manufacturers for vaccine development and evaluation.

- The Department of Defense (DOD) contributes to global disease surveillance, training, research, and response to emerging infectious disease threats. DOD maintains the DOD Influenza Surveillance Program, a laboratory-based surveillance program. DOD maintains multiple sites throughout the world that serve as sentinels for disease outbreaks, where it collects and analyzes viral specimens.

- The Department of Agriculture (USDA) is responsible for protecting and improving the health and marketability of animals and animal products by preventing, controlling, and eliminating animal diseases. USDA undertakes disease surveillance and response activities to protect U.S. livestock, ensure the safety of international trade, and contribute to the national zoonotic disease[12] surveillance effort.

The United States is a member of WHO, which is responsible for coordinating international disease surveillance and response efforts. An agency of the United Nations, WHO administers the International Health Regulations, which outline WHO's role and

[12]Zoonotic diseases are those diseases that are transmitted from animals to humans.

the responsibility of member countries and regions in preventing the global spread of infectious diseases. WHO also helps marshal resources from its members to control outbreaks within individual countries or regions. In addition, WHO works with national governments to improve their surveillance capacities through—for example—assessing and redesigning national surveillance strategies, offering training in epidemiologic and laboratory techniques, and emphasizing more efficient communication systems.

EXISTING INFLUENZA SURVEILLANCE SYSTEM AND ENHANCEMENTS WOULD BE USED TO IDENTIFY AN INFLUENZA PANDEMIC

Surveillance is a key component in planning for an influenza pandemic, and federal public health officials plan to rely on the nation's existing annual influenza surveillance system and enhancements to identify an influenza pandemic. Federal public health officials have undertaken several initiatives that are intended to enhance influenza surveillance capabilities. These initiatives have been undertaken both through programs specific to influenza as well as through programs focused more generally on increasing preparedness for bioterrorism and other emerging infectious disease health threats. Federal officials have implemented and expanded syndromic surveillance systems[13] in order to detect outbreaks more quickly, but there are concerns that these systems are costly to run and still largely untested. Federal officials have also implemented initiatives designed to improve public health communications and have undertaken initiatives intended to improve the coordination of zoonotic surveillance efforts.

Systems Are in Place to Routinely Monitor for Influenza

Current U.S. surveillance for identifying annual influenza outbreaks as well as an influenza pandemic involves multiple public health partners at all levels of government and relies on several data sources. At the federal level, CDC's Influenza Branch leads the

[13]Many syndromic surveillance systems currently in use in the United States were developed in response to the September 11, 2001, attacks on the World Trade Center and Pentagon and to the anthrax outbreaks that occurred shortly afterwards. The fundamental objective of syndromic surveillance is to identify illness clusters early, before diagnoses are confirmed and reported to public health agencies.

national influenza surveillance effort, monitoring disease and viral trends using data submitted each week from October through May. These surveillance data are collected at the local and state levels and voluntarily submitted to CDC. Data submitted on influenza activity in the United States include data from more than 120 laboratories and 2,000 health care providers and mortality reports from 122 cities. In addition, influenza data are collected from all 50 state health departments and the health departments in the District of Columbia and New York City. CDC also receives data that are specifically focused on influenza in pediatric patients. When the data are used collectively, they provide a national picture of influenza activity. Specifically, they allow CDC to (1) identify when and where influenza activity is occurring, (2) determine what strains of the influenza virus are in circulation, (3) detect changes in the influenza virus, (4) monitor flu-related illnesses, and (5) measure the impact influenza is having on deaths in the United States.

DOD also plays a role in national and international influenza surveillance. Specifically, DOD's Influenza Surveillance Program, under the direction of the Air Force, collects viral specimens from its active duty personnel and their dependents at military facilities around the world. DOD's program also sends specimens to CDC for further analysis and contributes to the determination of which viral strains FDA includes in the nation's annual influenza vaccine. Internationally, DOD provides viral specimens to WHO and assists in identifying emerging influenza strains.

In countries throughout the world, infectious disease surveillance is a national responsibility, but WHO assists its members' efforts through its Global Influenza Surveillance Network. WHO's Network is composed of 112 institutions, called National Influenza Centres, from 83 countries. Collectively, these Centres monitor influenza activity and annually gather more than 175,000 viral specimens for analysis from patients with influenza-like illnesses throughout the world. Selected influenza isolates—an estimated 2,000 viruses—may also be sent to one of four WHO Collaborating Centres[14]

[14]A WHO Collaborating Centre is a national institution designated by WHO to form part of an international collaborative network that contributes to implementing WHO's program priorities and to strengthening institutional capacity in countries and regions. Collaborating Centre activities include collection and dissemination of information, education and training, and participation in collaborative research

for further, more specific genetic analysis. The additional analysis conducted by the WHO Collaborating Centers is used for the annual WHO recommendations on which strains to include in the influenza vaccine for the northern and southern hemispheres. In addition to making recommendations on the components of the influenza vaccine, this Global Influenza Surveillance Network also serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential.

Federal Agencies Have Undertaken Initiatives to Enhance Influenza Surveillance

CDC has undertaken several initiatives that are intended to enhance influenza surveillance capabilities in preparation for an influenza pandemic. CDC works with its international partners to improve global surveillance for influenza. For example, CDC participates in international disease and laboratory surveillance sponsored by WHO. Also, when concerns were raised over recent influenza seasons that the avian influenza A (H5N1) could become the next influenza pandemic, CDC led a variety of efforts with its international partners to plan for and address threats of increased influenza activity worldwide. For example, CDC worked collaboratively with WHO to conduct investigations of avian influenza A in Vietnam and to provide laboratory testing. CDC also provided training assistance and has implemented an initiative to improve influenza surveillance in Asia.

CDC also supports several domestic initiatives to improve surveillance capabilities for influenza. For example, CDC supports enhanced influenza surveillance activities through its Epidemiology and Laboratory Capacity (ELC) Grants. Established in 1997, this program provides funding to state and local influenza programs. Grants have steadily increased from the first awards in 1997, when less than $100,000 was provided to five states through August 2004, with funding totaling more than $2 million being given to about 47 states or major metropolitan areas. States and cities receiving ELC-influenza funding are encouraged to achieve three highlighted influenza epidemiology and

developed under WHO's leadership. The four Collaborating Centres that are part of WHO's Global Influenza Surveillance Network are located in the United States, Australia, Japan, and the United Kingdom.

laboratory surveillance capacities: sentinel physician surveillance, viral isolation and subtyping, and year-round surveillance. Each state targets funding to meet one or more of these three priorities and uses funding for support of improvements that include the assignment or hiring of an influenza coordinator, recruitment of sentinel physicians to collect influenza specimens and report influenza-like illness to the state, laboratory infrastructure enhancements to increase influenza testing capabilities for viral isolation and subtyping, and expansion of influenza surveillance activities to year-round.

In an effort to enhance the ability to detect infectious disease outbreaks, particularly in their early stages, federal funding has supported state efforts to implement numerous syndromic surveillance systems. These systems collect information on syndromes from a variety of sources. For example, the National Retail Data Monitor (NRDM) collects data from retail sources instead of hospitals. As of February 2004, NRDM collected sales data from about 19,000 stores, including pharmacies, in order to monitor sales patterns in such items as over-the-counter influenza medications for signs of a developing infectious disease outbreak.

CDC is taking steps to enhance its two public health communications systems, the Health Alert Network (HAN)[15] and the Epidemic Information Exchange (Epi-X),[16] which are used in disease surveillance and response efforts. For example, CDC is working to increase the number of HAN participants who receive assistance with their communication capacities. In addition, following reports of human deaths from avian influenza A in Vietnam in August 2004, CDC issued a HAN message reiterating criteria for domestic surveillance, diagnostic evaluation, and infection control precautions. CDC also issued detailed laboratory testing procedures for avian influenza through HAN.

[15]The Health Alert Network (HAN) is an early-warning and response system operated by CDC that is designed to ensure that state and local health departments as well as other federal agencies and departments have timely access to emerging health information.

[16]The Epidemic Information Exchange (Epi-X) is a secure, Web-based communication system operating in all 50 states. CDC uses this system primarily to share information relevant to disease outbreaks with state and local public health officials and with other federal officials. Epi-X also serves as a forum for routine professional discussions and nonemergency inquiries.

Similarly, CDC has expanded Epi-X by giving officials at other federal agencies and departments, such as DOD, the ability to use the system. CDC is also adding users to Epi-X from local health departments, giving access to CDC staff in other countries, and making the system available to Field Epidemiology Training Programs (FETP) located in 21 countries.[17] Finally, CDC is facilitating Epi-X's interface with other data sources by allowing users to access the Global Public Health Intelligence Network (GPHIN), the system that searches Web-based media for information on infectious disease outbreaks worldwide.

In addition to the efforts to enhance communication systems, federal public health officials also have enhanced federal coordination for zoonotic disease surveillance and expanded training programs. According to CDC, nearly 70 percent of emerging infectious disease episodes during the past 10 years have been zoonotic diseases. Moreover, recent outbreaks of human disease caused by avian influenza strains in Asia and Europe highlight the potential for new strains to be introduced into the population. Surveillance for zoonotic diseases requires collaboration between animal and human disease specialists. CDC, USDA, and FDA have made efforts to enhance their coordination of zoonotic disease surveillance. For example, CDC and UDSA are working with two national laboratory associations to add veterinary diagnostic laboratories to the Laboratory Response Network (LRN).[18] As of May 2004, 10 veterinary laboratories had

[17]In selected foreign locations, CDC operates international training programs, such as FETP. Through FETP, each year CDC trains approximately 50 to 60 physicians and social scientists in applied public health, integrating disease surveillance, applied research, prevention, and control activities. Graduates of the FETP program serve in their native country and provide links between CDC and their respective ministries of health. CDC officials said that trainees from its international programs have frequently provided important information on disease outbreaks.

[18]To strengthen the nation's capacity to rapidly detect biological and chemical agents that could be used as a terrorist weapon, CDC, in partnership with the Federal Bureau of Investigation and the Association of Public Health Laboratories, created LRN in 1999. According to CDC, LRN leverages the resources of 126 laboratories to maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies. The network includes federal, state and local public health, military, and international laboratories, as well as laboratories that specialize in food, environmental, and veterinary testing. LRN laboratories have been used in several public health emergencies. For example, in 2001, a Florida LRN laboratory discovered the presence of *Bacillus anthracis*, the pathogen that causes anthrax, in a clinical specimen it tested.

been added to LRN, and CDC officials told us that they had plans to add more veterinary laboratories in the future. In addition, CDC officials told us the agency has appointed a staff person whose responsibility, in part, is to assist in finding ways to enhance zoonotic disease coordination efforts among federal agencies and departments and with other organizations. This person is helping CDC develop a working group of officials from CDC, USDA, and FDA to coordinate zoonotic disease surveillance.[19] According to CDC officials, the goal of this working group is to explore ways to link existing surveillance systems to better coordinate and integrate surveillance for wildlife, domestic animal, and human diseases. CDC officials also said that the agency is exploring the feasibility of a pilot project to demonstrate this proposed integrated zoonotic disease surveillance system. In addition, USDA officials told us that they hired 23 wildlife biologists in fall 2003 to coordinate disease surveillance, monitoring, and management activities among USDA, CDC, states, and other federal agencies. While each of these initiatives is intended to enhance the surveillance of zoonotic diseases, each is still in the planning stage or the very early stages of implementation.

USDA also conducts influenza surveillance in domestic animals. Coordination with USDA is important because a pandemic strain is likely to arise from genetic mixing of animal and human influenza viruses. Recent outbreaks in domestic poultry in Asia and Europe associated with cases of human disease highlight the importance of coordinating surveillance activities. Surveillance for influenza viruses in poultry in the United States has increased substantially since the outbreak of highly pathogenic avian influenza (HPAI) in Pennsylvania and surrounding states in 1983 and 1984. However, individual states are generally responsible for the development and implementation of surveillance programs that are consistent with the size and complexity of the resident poultry industry.

[19]This working group was created in response to a congressional mandate that the Secretary of Health and Human Services, through FDA and CDC, and USDA, coordinate the surveillance of zoonotic diseases. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §313, 116 Stat. 594, 674 (2002).

DESPITE EFFORTS BY FEDERAL OFFICIALS, CHALLENGES REMAIN REGARDING PREPAREDNESS FOR AND RESPONSE TO AN INFLUENZA PANDEMIC

Challenges regarding the nation's preparedness for and response to an influenza pandemic remain. Specifically, our prior work has found that although CDC participated in an interagency working group that developed the U.S. plan for pandemic preparedness that was posted for public comment in August 2004, as of May 23, 2005, the plan had not been finalized. Further, we found that the draft plan does not address certain critical issues, including how vaccine for an influenza pandemic will be purchased, distributed, and administered; how population groups will be prioritized for vaccination; what quarantine authorities or travel restrictions may need to be invoked; and how federal resources should be deployed. At the state level, we found that most hospitals across the country lack the capacity to respond to large-scale infectious disease outbreaks.

HHS's Pandemic Influenza Plan Remains in Draft and Leaves Many Important Issues Unresolved

In August 2004, HHS released its national pandemic influenza plan for comment. The draft "Pandemic Influenza Preparedness and Response Plan" describes HHS's role in coordinating a national response to an influenza pandemic and provides guidance and tools to promote pandemic preparedness planning and coordination at the federal, state, and local levels, including both the public and the private sectors. However, as of May 23, 2005, this document remained in draft form. Further, although the plan is comprehensive in scope, it leaves many important decisions unresolved about the purchase, distribution, and administration of vaccines. For example, some decisions yet to be made include determining the public- versus private-sector roles in the purchase and distribution of pandemic influenza vaccines; the division of responsibility between the federal government and the states for vaccine distribution; and how population groups will be prioritized and targeted to receive limited supplies of vaccines. Until these key decisions

are made, public health officials at all levels may find it difficult to plan for an influenza pandemic, and the timeliness and adequacy of response efforts may be compromised.

The draft plan does not establish a definitive federal role in the purchase and distribution of vaccines during an influenza pandemic. Instead, HHS provides options for vaccine purchase and distribution that include public-sector purchase and distribution of all pandemic influenza vaccine; a mixed public-private system where public-sector supply may be targeted to specific priority groups; and maintenance of the current largely private system. In its draft plan, HHS does not recommend a specific alternative.

Furthermore, the draft plan delegates to the states responsibility for distribution of vaccine. The lack of a clearly defined federal role in distribution complicates pandemic planning for the states. Furthermore, among the current state pandemic influenza plans, there is no consistency in terms of their procurement and distribution of vaccine and the relative role of the federal government. Approximately half of the states handle procurement and distribution of the annual influenza vaccine through the state health agency. The remainder either operate through a third-party contractor for distribution to providers or use a combination of these two approaches.

Challenges Persist in Ensuring an Adequate and Timely Influenza Vaccine Supply

Challenges persist in ensuring an adequate and timely influenza vaccine supply. The number of producers remains limited, and the potential for manufacturing problems such as those experienced during the 2004-2005 influenza season is still present. When one manufacturer's production is affected, providers who order vaccine from that manufacturer can experience shortages, while providers who receive supplies from another manufacturer may have all the vaccine they need. The allocation plan CDC developed for this past season's shortage was dependent upon voluntary compliance by the private sector and individuals to forgo vaccination. Most annual influenza vaccine distribution and administration are accomplished within the private sector, with relatively small amounts of vaccine purchased and distributed by CDC or by state and

local health departments. In the United States, 85 percent of vaccine doses are purchased by the private sector, such as private physicians and pharmacies. HHS has not yet determined how influenza vaccine will be distributed and administered during an influenza pandemic.

There are many issues surrounding the production of influenza vaccine, which will only become exacerbated during an influenza pandemic. Vaccines, which are considered the first line of defense to prevent or reduce influenza-related illness and death, may be unavailable or in short supply. Producing the vaccine is a complex process that involves growing viruses in millions of fertilized chicken eggs. Experience has shown that the vaccine production cycle takes at least 6 to 8 months after a virus strain has been identified, and vaccines for some influenza strains have been difficult to mass-produce, causing further delay. The lengthy process for developing a vaccine may mean that a vaccine would not be available during the initial stages of a pandemic.

Vaccine shortages during the 2004-2005 influenza season have highlighted the fragility of the influenza vaccine market and the need for its expansion and stabilization. Currently only two manufacturers are licensed to sell their vaccine in the United States.[20] Maintaining an influenza vaccine supply is critically important for protecting the public's health and improving our preparedness for an influenza pandemic. As a result, according to CDC officials, the agency plans to alleviate the impact of next year's influenza season by taking aggressive steps to ensure an expanded influenza supply to protect the nation. To this end, the agency's fiscal year 2006 budget request includes an increase of $30 million for CDC to enter into guaranteed purchase contracts with vaccine manufacturers to ensure the production of bulk monovalent influenza vaccine. If supplies fall short, this bulk product can be turned into a finished trivalent influenza vaccine product for annual distribution. If supplies are sufficient, the bulk vaccine can be held until the following year's influenza season and developed into vaccines if the circulating strains remain the same. In addition, according to CDC, this guarantee will help to expand the influenza

[20]During the 2004-2005 influenza season, the license for a third manufacturer was suspended by British regulatory authorities due to safety concerns with the vaccine.

market by providing an incentive to manufacturers to expand capacity and possibly encourage additional manufacturers to enter the market. In addition, the fiscal year 2006 budget request includes an increase of $20 million to support influenza vaccine purchase activities.

Even if sufficient quantities of the vaccine are produced in time, vaccines against various strains differ in their ability to produce the immune response necessary to provide effective protection against the disease. Studies show that it is uncertain how effective a vaccine will be in preventing or controlling the spread of a pandemic influenza virus.

Challenges Persist in Ensuring an Adequate Supply of Antiviral Drugs

Early in an influenza pandemic, especially before a vaccine is available or during a period of limited vaccine supply, use of antiviral drugs may have a significant effect. Specifically, antiviral drugs can help prevent or mitigate the number of influenza-related deaths until an influenza vaccine becomes available. They can be used against all strains of pandemic influenza and have immediate availability as both a prophylactic to prevent illness and as a treatment if administered within 48 hours of the onset of symptoms. According to HHS, analysis is ongoing to define optimal antiviral use strategies, potential health impacts, and cost-effectiveness of antiviral drugs in the setting of a pandemic.

The United States has a limited supply of influenza antiviral medications stored for an influenza pandemic. HHS officials expect the amount produced will be below demand during a pandemic. This assumption, supported by drug manufacturers, is based on the fact that current production levels of antiviral drugs are set in response to current demand, whereas demand in a pandemic is expected to increase significantly if vaccines are unavailable. In addition, the production of antiviral medications cannot be rapidly expanded and involves a long production process—at least 6 to 9 months. Moreover, sometimes influenza virus strains can become resistant to one or more of the four approved influenza antiviral drugs, and thus the drugs may not always work. For example, the influenza A (H5N1) viruses identified in human patients in Asia in 2004 and 2005 have been resistant to two of the four antiviral drugs, amantadine and rimantadine.

Implementation of Control Measures to Prevent Spread of Pandemic Influenza Present Difficulties

Another challenge in responding to an influenza pandemic involves implementing certain control measures to prevent the spread of the disease. These control measures—case identification and contact tracing, transmission control, and exposure management—are well-established and have proved effective in both health care and community settings.[21] Federal attempts to limit the spread of SARS into the United States by advising passengers who traveled to infected countries faced multiple obstacles. For example, due to airline concerns over authority and privacy, as well as procedural constraints, CDC was unable to obtain passenger contact information it needed to trace travelers. Although HHS has statutory authority to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States,[22] HHS regulations implementing the statute do not specifically provide for HHS to obtain passenger manifests or other passenger contact information from airlines and shipping companies for disease outbreak control purposes.[23]

Most Hospitals Lack the Capacity to Respond to Large-Scale Infectious Disease Outbreaks

A challenge identified during the SARS outbreak that may also affect response efforts during an influenza pandemic is lack of sufficient hospital and workforce capacity. This lack could be exacerbated during an influenza pandemic, compared to other natural

[21]In the United States, the Healthcare Infection Control Practices Advisory Committee, a federal advisory committee made up of 14 infection control experts, develops recommendations and guidelines regarding general infectious disease control measures for CDC. Expert recommendations include (1) case identification and contact tracing, which involves defining what symptoms, laboratory results, and medical histories constitute a positive case in a patient and tracing and tracking individuals who may have been exposed to these patients; (2) transmission control, which involves controlling the transmission of disease-producing microorganisms through use of proper hand hygiene and personal protective equipment, such as masks, gowns, and gloves; and (3) exposure management, which involves separating infected and noninfected individuals.

[22] Section 361 of the Public Health Service Act, 42 U.S.C. § 264.

[23] See 42 C.F.R pts 70 and 71; 21 C.F.R. pts 1240 and 1250.

disasters, such as a tornado or hurricane, or an intentional release of a bioterrorist agent, because it is likely that a pandemic would result in both widespread and sustained effects.

Public health officials we spoke with said a large-scale outbreak, such as an influenza pandemic, could strain the available capacity of hospitals by requiring the use of entire hospital sections (along with their staff) to be used as isolation facilities. As we have reported earlier, most states lack "surge capacity," that is, the capacity to respond to the large influx of patients that could occur during a large public health emergency.[24] For example, few states reported that they had the capacity to evaluate, diagnose, and treat 500 or more patients involved in a single incident. In addition, few states reported having the capacity to rapidly establish clinics to immunize or provide treatment to large numbers of patients. Moreover, a shortage in workforce could increase during an influenza pandemic because higher disease rates could result in high rates of absenteeism among health care workers who are likely to be at increased risk of exposure and illness.

CONCLUDING OBSERVATIONS

There are a number of systems in place to identify influenza outbreaks abroad, to alert us to a pandemic, and these systems generally appear to be working well. HHS has taken important steps to enhance surveillance and to fund initiatives for preparedness and response, including steps to increase the vaccine supply.

However, important challenges remain in our preparedness to respond, should an influenza pandemic occur in the United States. The steps HHS is taking to address vaccine production capacity and stockpiling of antiviral drugs may not be in place in time to fill the current gaps in preparedness should an influenza pandemic occur in the next several years. As we learned in the 2004-2005 influenza season, problems affecting

[24]See GAO, *Public Health Preparedness: Response Capacity Improving, but Much Remains to be Accomplished*, GAO-04-458T (Washington, D.C.: Feb. 12, 2004).

even a single manufacturer can produce major shortages. Once a pandemic influenza strain is identified, a vaccine will take many months to produce, and our current stockpile of antiviral drugs is insufficient to meet the likely demand. Pandemic influenza would have major impacts on the ability of communities to respond, businesses to function, and public safety to be maintained when communities across the country are simultaneously impacted and hospital capacity is overwhelmed.

Since 2000, we have been urging the department to complete its pandemic plan. A draft plan was issued in August 2004, with a 60-day period for public comment, but as of this week, the plan had not been finalized. It is important for the federal government and the states to work through issues such as how vaccine will be purchased, distributed, and administered, how population groups will be prioritized for vaccination, what quarantine authorities or travel restrictions may need to be invoked, and how federal resources should be deployed before we are in a time of crisis.

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Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

Contact and Staff Acknowledgments

For further information about this testimony, please contact Marcia Crosse at (202) 512-7119. Gloria E. Taylor, Gay Hee Lee, Elizabeth T. Morrison, and Roseanne Price made key contributions to this statement.

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