

Testimony

Before the Special Committee on Aging, U.S. Senate

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INFECTIOUS DISEASE PREPAREDNESS

Federal Challenges in Responding to Influenza Outbreaks

Statement of Janet Heinrich Director, Health Care—Public Health Issues





Highlights of GAO-04-1100T, a testimony before the Special Committee on Aging, U.S. Senate

Why GAO Did This Study

Influenza is associated with an average of 36,000 deaths and more than 200,000 hospitalizations each year in the United States. Persons aged 65 and older are involved in more than 9 of 10 deaths and 1 of 2 hospitalizations related to influenza. The best way to prevent influenza is to be vaccinated each fall. In the 2000-01 flu season, and again in the 2003-04 flu season, this country experienced periods when the demand for flu vaccine exceeded the supply, and there is concern about the availability of vaccines for this and future flu seasons.

There is also concern about the prospect of a worldwide influenza epidemic, or pandemic, which many experts believe to be inevitable. Three influenza pandemics occurred in the twentieth century. Experts estimate that the next pandemic could kill up to 207,000 people in the United States and cause major social disruption. Public health experts have raised concerns about the ability of the nation's public health system to respond to an influenza pandemic.

GAO was asked to discuss issues related to supply, demand, and distribution of vaccine for a regular flu season and assess the federal plan to respond to an influenza pandemic. GAO based this testimony on products it has issued since October 2000, as well as work it conducted to update key information.

www.gao.gov/cgi-bin/getrpt?GAO-04-1100T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

INFECTIOUS DISEASE PREPAREDNESS

Federal Challenges in Responding to Influenza Outbreaks

What GAO Found

Challenges persist in ensuring an adequate and timely flu vaccine supply. The number of producers remains limited, and the potential for manufacturing problems such as those experienced in recent years is still present. If a manufacturer's production is affected, those providers who ordered vaccine from that manufacturer could experience shortages, while providers who received supplies from another manufacturer might have all the vaccine they need. This potential for imbalance is what creates situations in which some providers might not have enough vaccine for persons at highest risk, while other providers might have enough supply to hold mass-immunization clinics even for persons at lower risk for flu-related complications. To help limit the potential for such situations, the Centers for Disease Control and Prevention (CDC) and others have taken such steps as adding flu vaccine to federal stockpiles and more aggressively monitoring the projected supply of vaccine. However, there is no system in place to ensure that seniors and others at high risk for complications receive flu vaccinations first when vaccine is in short supply.

The Department of Health and Human Services' (HHS) draft "Pandemic Influenza Preparedness and Response Plan" provides a blueprint for the government's role but leaves some important decisions about the government's response unresolved. In addition to describing the federal role, responsibilities, and actions in collaboration with the states in responding to an influenza pandemic, the plan also provides planning guidance to state and local health departments and the health care system. The draft plan is comprehensive in scope, but it leaves decisions about the purchase, distribution, and administration of vaccines open for public comment and for the states to decide individually. In addition, the draft plan does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic. Difficulties encountered during the annual flu season in the purchase, distribution, and administration of flu vaccine highlight the importance of resolving these issues for pandemic preparedness.

Officials from CDC provided technical comments on this testimony that GAO incorporated as appropriate.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you discuss issues regarding the annual production and distribution of flu vaccine and preparedness for a worldwide influenza epidemic—known as a pandemic. Each year, influenza viruses cause outbreaks in the United States and elsewhere in the world. Influenza is associated with an average of 36,000 deaths and more than 200,000 hospitalizations each year in the United States. Persons aged 65 and older are involved in more than 9 of every 10 deaths and 1 of every 2 hospitalizations related to influenza. The best way to prevent influenza is to be vaccinated each fall. In the 2000-01 flu season, and again in last year's flu season, this country experienced periods when the demand for flu vaccine exceeded the supply, and there is concern about the availability of vaccines for this and future flu seasons.

There has also been increased concern about the prospect of an influenza pandemic, which many experts believe to be inevitable. Pandemic influenza, which arises periodically, but unpredictably, from a major genetic change in the virus, results in a strain that can cause worldwide disease and death. Three influenza pandemics occurred in the twentieth century. The worst occurred in 1918 (Spanish flu)and killed more than 20 million people worldwide and about 675,000 people in the United States. The pandemics of 1957 (Asian flu) and 1968 (Hong Kong flu) caused fewer fatalities—70,000 and 34,000, respectively, in the United States. Some experts believe that the next pandemic could be spawned by the recurring avian flu in Asia. They estimate that the pandemic could kill up to 207,000 people in the United States and cause major social disruption. Public health experts have raised concerns about the ability of the nation's public health system to detect and respond to emerging infectious disease threats such as pandemic influenza.²

You have asked us to provide our perspective on flu vaccine availability and preparedness for this year's flu season and an influenza pandemic. In this testimony, I will (1) discuss issues related to supply, demand, and

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¹Department of Health and Human Services, "HHS Orders Avian Flu Vaccine as Preventive Measure," http://www.os.dhhs.gov/news/pres/2004pres/20040921a.html (downloaded Sept. 26, 2004).

²See 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).

distribution of vaccine for a regular flu season and (2) assess the federal plan to respond to an influenza pandemic.

My remarks are based on reports and testimony we have issued since October 2000,³ as well as work conducted to update key information. Our prior work on flu vaccine included interviews with and analysis of information provided by Department of Health and Human Services (HHS) officials, vaccine manufacturers, medical distributors and their trade associations, companies that provide flu shots at retail outlets and work sites, physician and other professional associations, and other purchasers. We also surveyed physician group practices and interviewed health department officials in all 50 states about their experiences in the 2000-01 flu season. In September 2004 we updated this work with information on the 2003-04 flu season, Centers for Disease Control and Prevention (CDC) activities, including its responses to our prior recommendations for prevention and control of influenza, and the status of this year's flu vaccine. To learn about pandemic planning efforts, we interviewed HHS officials in the National Vaccine Program Office and reviewed HHS's August 2004 draft "Pandemic Influenza Preparedness and Response Plan." We conducted all of our work in accordance with generally accepted government auditing standards.

In summary, challenges persist in ensuring an adequate and timely flu vaccine supply. The number of producers remains limited, and the potential for manufacturing problems such as those experienced in recent years is still present. If a manufacturer's production is affected, those providers who ordered vaccine from that manufacturer could experience shortages, while providers who received supplies from another manufacturer might have all the vaccine they need. This potential for imbalance is what creates situations in which some providers might not have enough vaccine for persons at highest risk, while other providers might have enough supply to hold mass-immunization clinics even for persons at lower risk for flu-related complications. To help limit the potential for such situations, CDC and others have taken such steps as adding flu vaccine to federal stockpiles and more aggressively monitoring the projected supply of vaccine. However, there is no system in place to ensure that seniors and others at high risk for complications receive flu vaccinations first when vaccine is in short supply.

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³See "Related Products," at the end of this testimony, for a list of our earlier work related to flu vaccine and influenza pandemic planning.

HHS's draft "Pandemic Influenza Preparedness and Response Plan" provides a blueprint for the government's role but leaves some important decisions about the government's response unresolved. In addition to describing the federal role, responsibilities, and actions in collaboration with the states in responding to an influenza pandemic, the plan also provides planning guidance to state and local health departments and the health care system. The draft plan is comprehensive in scope, but it leaves decisions about the purchase, distribution, and administration of vaccines open for public comment and for the states to decide individually. In addition, the draft plan does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic. Difficulties encountered during the annual flu season with the purchase, distribution, and administration of flu vaccine highlight the importance of resolving these issues for pandemic preparedness.

Background

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

For the 2004-05 flu season, CDC is recommending that about 185 million Americans in these at-risk populations and other target groups receive the vaccine, which is the primary method for preventing influenza. Flu vaccine is generally widely available in a variety of settings, ranging from the usual physicians' offices, clinics, and hospitals to retail outlets such as drugstores and grocery stores, workplaces, and other convenience locations. Millions of individuals receive flu vaccinations through mass immunization campaigns in nonmedical settings, where organizations such as visiting nurse agencies under contract administer the vaccine.⁴ It takes

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⁴Data collected by states through the CDC Behavioral Risk Factor Surveillance System during 2002 indicate that among persons aged 18 years or older reporting receipt of flu vaccine, about two-thirds reported getting their last flu vaccination at a health care facility, such as a doctor's office, health center or health department, while about one-third reported getting vaccinated at a workplace, community center, store, or other location.

about 2 weeks after vaccination for antibodies to develop in the body and provide protection against influenza virus infection. CDC recommends October through November as the best time to get vaccinated because the flu season often starts in late November to December and peaks between late December and early March. However, if influenza activity peaks late, vaccination in December or later can still be beneficial.

Producing the influenza vaccine is a complex process that involves growing viruses in millions of fertilized chicken eggs. This process, which requires several steps, generally takes at least 6 to 8 months from January through August each year, so vaccine manufacturers must predict demand and decide on the number of doses to produce well before the onset of the flu season. Each year's vaccine is made up of three different strains of influenza viruses, and, typically, each year one or two of the strains is changed to better protect against the strains that are likely to be circulating during the coming flu season. The Food and Drug Administration (FDA) and its advisory committee decide which strains to include based on CDC surveillance data, and FDA also licenses and regulates the manufacturers that produce the vaccine.

In a typical year, manufacturers make flu vaccine available before the optimal fall season for administering flu vaccine. Currently, two manufacturers—one in the United States and one in the United Kingdom—produce over 95 percent of the vaccine used in the United States. According to CDC officials, for the 2002-03 flu season, manufacturers produced about 95 million doses of vaccine, of which about 83 million doses were used and 12 million doses went unused. Production for the 2003-04 flu season was based on the previous year's demand and was about 87 million doses. For the 2004-05 season, CDC estimates that about 100 million doses will be available.

Currently, flu vaccine production and distribution are largely privatesector responsibilities. Like other pharmaceutical products, flu vaccine is sold to thousands of purchasers by manufacturers, numerous medical supply distributors, and other resellers such as pharmacies. These purchasers provide flu vaccinations at physicians' offices, public health clinics, nursing homes, and less traditional locations such as workplaces

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⁵A third U.S. manufacturer produces a flu vaccine that is given by nasal spray and is only approved for healthy persons aged 5 through 49 years. According to CDC, this manufacturer is likely to supply about 1.5 million doses in the 2004-05 season.

and various retail outlets. Most 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.

HHS also has a role in planning to prepare for and respond to an influenza pandemic. Planning is key to being prepared for and mitigating the negative effects of the next influenza pandemic, including major illness, death, economic loss, and social disruption. A national pandemic influenza plan was first developed in 1978 and was revised in 1983. In 1993, efforts to revise the national plan were initiated, and these efforts picked up momentum in the late 1990s. In August 2004, HHS released a draft plan for comment entitled, "Pandemic Influenza Preparedness and Response Plan."

To foster state and local pandemic planning and preparedness, CDC first issued draft interim planning guidance to states in 1997 and posted guidance on its Web site for state and local health departments in 2001. Since that time, states have been preparing pandemic response plans, and many are integrating these plans with existing state plans to respond to public health emergencies such as natural disasters and bioterrorist attacks.

Challenges Exist in Ensuring an Adequate and Timely Flu Vaccine Supply

Ensuring an adequate and timely supply of vaccine is a difficult task. It has become even more difficult because there are few manufacturers. Problems at one or more manufacturers can significantly upset the traditional fall delivery of influenza vaccine. These problems, in turn, can create variability in who has ready access to the vaccine.

Matching flu vaccine supply and demand is a challenge because the available supply and demand for vaccine can vary from month to month and year to year. For example,

• In 2000-01, when a substantial proportion of flu vaccine was distributed much later than usual due to manufacturing difficulties, temporary shortages in the prime period for vaccinations were followed by decreased demand as additional vaccine became available later in the year. Despite efforts by CDC and others to encourage people to seek flu vaccinations later in the season, providers still reported a drop in demand in December. The light flu season in 2000-01, which had relatively low influenza mortality, probably also contributed to the lack of interest. As a result of the waning demand that year, manufacturers and distributors reported having more vaccine than they could sell. In addition, some physicians'

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offices, employee health clinics, and other organizations that administered flu shots reported having unused doses in December and later.

For the 2003-04 flu season, shortages of vaccine have been attributed to an
earlier than expected and more severe flu season and to higher than
normal demand, likely resulting from media coverage of pediatric deaths
associated with influenza. According to CDC officials, this increased
demand occurred in a year in which manufacturers had produced about
the same number of doses as in the previous season and that supply was
not adequate to meet the demand.

If production problems delay the availability of vaccine in a given year, the timing for an individual provider to obtain flu vaccine may depend on which manufacturer's vaccine it ordered. This happened in the 2000-01 season, and it could happen again. This year, one of the two major manufacturers recently announced a delay in its shipments of vaccine. On August 26, 2004, one manufacturer announced that release of its flu vaccine would be delayed because of production problems related to sterility of a small number of doses at its manufacturing facility. The company stated that it expected to deliver between 46 million and 48 million doses to the U.S. market beginning in October, and CDC issued a notice on September 24, 2004, stating that some delays might occur for customers receiving this manufacturer's vaccine. Those customers may receive their vaccine later than those who ordered from the other manufacturer, which reported sending its vaccine on schedule beginning in August and September. As a result, one provider could hold vaccination clinics in early October that would be available to anyone who wants a flu shot, while another provider would not yet have any vaccine for its highrisk patients.

Shortages of flu vaccine can result in temporary spikes in the price of vaccine. When vaccine supply is limited relative to public demand for flu shots, distributors and others who have supplies of the vaccine have the ability—and the economic incentive—to sell their supplies to the highest bidders rather than filling lower-priced orders they had already received. When there was a delay and temporary shortage of vaccine in 2000, those who purchased vaccine that fall—because their earlier orders had been cancelled, reduced, or delayed, or because they simply ordered later—found themselves paying much higher prices. For example, one physician's practice ordered flu vaccine from a supplier in April 2000 at \$2.87 per dose. When none of that vaccine had arrived by November 1, the practice placed three smaller orders in November with a different supplier at the escalating prices of \$8.80, \$10.80, and \$12.80 per dose. On December 1, the

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practice ordered more vaccine from a third supplier at \$10.80 per dose. The four more expensive orders were delivered immediately, before any vaccine had been received from the original April order.

Our work has also found that there is no mechanism in place to ensure distribution of flu vaccine to high-risk individuals before others when the vaccine is in short supply. When the supply was not sufficient in the fall of 2000, focusing distribution on high-risk individuals was difficult because all types of providers served at least some high-risk individuals. Some physicians and public health officials were upset when their local grocery stores, for example, were offering flu shots to everyone when they, the health care providers, were unable to obtain vaccine for their high-risk patients. Many physicians reported that they felt they did not receive priority for vaccine delivery, even though about two-thirds of seniors—one of the largest high-risk groups—generally get their flu shots in medical offices. In our follow-up work, we found no indication that the situation would be different if there was a shortage today.

This raises the question of what more can be done to better prepare for possible vaccine delays and shortages in the future. Because flu vaccine production and distribution largely are private-sector responsibilities, options are somewhat limited. While CDC can recommend and encourage providers to immunize high-risk patients first, it does not have control over the distribution of vaccine, other than the small amount that is distributed through public health departments.

Although HHS has limited authority to directly control flu vaccine production and distribution,⁷ it undertook several initiatives following the 2000-01 flu season. More specifically, CDC has taken actions that may

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⁶Data collected by states through the CDC Behavioral Risk Factor Surveillance System during 2002 indicated that among persons aged 65 years or older reporting receipt of influenza vaccine, about 58 percent reported receiving their last influenza vaccination at physicians' offices and health maintenance organizations; followed by clinics or health centers (12 percent); stores (8 percent); community centers (6 percent); health departments (6 percent); other locations (5 percent); hospitals (4 percent); and workplaces (2 percent). Percentages do not add to 100 due to rounding.

⁷Under the Federal Food Drug and Cosmetic Act, FDA ensures compliance with good manufacturing practice 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. This authority would not extend to resale of the vaccine for emergency medical reasons. The term health care entity does not include wholesale distributors. CDC has a role in encouraging appropriate public health actions.

encourage manufacturers to supply more vaccine because the action could lead to increased or more stable demand for flu vaccines. Actions taken by CDC and its advisory committee include the following:

- Extending the optimal period for getting a flu vaccination until the end of November, to encourage more people to get vaccinations later in the season.
- Expanding the target population to include children aged 6 through 23 months and all persons who take care of children aged 0 to 23 months.
- Including the flu vaccine in the Vaccines for Children (VFC) stockpile to help improve flu vaccine supply. For 2004, CDC has contracted for a stockpile of approximately 4.5 million doses of flu vaccine through its VFC authority.
- Beginning an annual assessment of the projected vaccine supply, and
 making a determination if vaccination should proceed for all persons or if
 a tiered approach should be used, targeting limited vaccine supplies to
 seniors and other high-risk individuals first.

For both last season and the upcoming flu season, CDC announced that it did not envision any need for a tiered approach. For the 2004-05 flu season, CDC issued a notice on September 24 recommending that vaccination proceed for all recommended persons as soon as vaccine is available.

HHS's Draft Pandemic
Influenza Plan
Defines Roles and
Responsibilities but
Leaves Some
Important Issues
Unresolved

HHS's draft pandemic influenza plan describes federal roles and responsibilities in responding to an influenza pandemic and provides planning guidance to state and local health departments and the health care system. Although the draft plan is comprehensive in scope, it leaves some important decisions about the purchase, distribution, and administration of vaccines unresolved. In addition, the draft plan does not make recommendations for how population groups should be prioritized to receive vaccines in a pandemic. Consequently, states are left to make their own decisions, potentially compromising the timing and adequacy of a response to an influenza pandemic.

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Draft Plan Defines Roles and Responsibilities

HHS's draft pandemic influenza 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 federal, state, and local levels, including both the public and the private sectors. Pandemic influenza response activities are outlined by the different phases of a pandemic. The draft plan also provides technical background information on preparedness and response activities such as vaccine development and production.

The draft plan acknowledges that states and local areas have important roles in the national response to a pandemic. To facilitate the state and local response, the draft plan provides guidance for state and local health departments and the health care system. The draft plan states that planning for an influenza pandemic will build on HHS-supported efforts to prepare for other public health emergencies such as infectious disease outbreaks, bioterrorist events, or natural disasters, and provides important guidance on areas specific to an influenza pandemic, including disease surveillance, delivery of vaccine and other medications, and communication. According to the Council of State and Territorial Epidemiologists, currently 11 states have pandemic influenza plans. Six of these states have final plans, and five states have draft plans.

According to the draft plan, federal agencies are taking steps to ensure and expand influenza vaccine production capacity; increase influenza vaccination use; stockpile influenza medications; enhance U.S. and global disease detection and surveillance infrastructures; expand influenza-related research; support public health planning and laboratory capacity; and improve health care system readiness at the community level. Although most of these activities have not been targeted specifically to pandemic planning, according to HHS officials, spending in these areas will help prepare for the next influenza pandemic. The draft plan also encourages states to allocate funding from the CDC Bioterrorism

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⁸HHS describes five phases of a pandemic. In phase 1, there is an outbreak in one country, confirmation of efficient person-to-person transmission, and serious morbidity and mortality. In phase 2, there are regional outbreaks with global disease spread. Phase 3 is the end of the first pandemic wave; phase 4 refers to a second seasonal wave. In phase 5, the pandemic ends as population immunity has increased.

⁹California, Florida, Indiana, Maryland, Minnesota, and New Jersey have final plans, and Massachusetts, New Hampshire, South Carolina, Tennessee, and Texas have draft plans.

Cooperative Agreement and 2004 Immunization Continuation Grants for pandemic preparedness planning.¹⁰

Draft Plan Leaves Many Important Issues Unresolved, Making It Difficult for States to Plan

Although HHS's draft pandemic influenza plan is comprehensive in scope, it leaves many important decisions about the purchase, distribution, and administration of vaccines unresolved. These decisions include determining the public- versus the private-sector roles in the purchase and distribution of 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. As we have stated previously, until these key decisions are made, states will find it difficult to plan, and the timeliness and adequacy of response efforts may be compromised.

The draft plan does not establish a definitive federal role in the purchasing and distribution of vaccine. 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. Currently, approximately 85 percent of the influenza vaccine produced for annual outbreaks is purchased by the private sector, and a majority of the annual vaccinations are also delivered by the private sector. HHS states in the draft plan that such a distribution method may not be optimal in a pandemic.

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. 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. States also approach annual vaccine procurement and distribution differently. Approximately half the states handle procurement and distribution of the 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.

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¹⁰Under the CDC's Public Health Preparedness and Response for Bioterrorism Program, all 50 states, the District of Columbia, the country's largest municipalities, and territories receive funding to complete specific activities designed to build public health and health care capacities.

In 2003 we reported that state officials were concerned that there were no national recommendations for how population groups should be prioritized to receive vaccines. Identifying priority populations from among high-risk groups and essential health care and emergency personnel is likely to be a controversial issue. The draft plan does not identify priority groups, but HHS indicates that it has separately developed an initial list of suggested priority groups and is soliciting public comment on this list. The draft pandemic plan instructs the states to prioritize the persons receiving the initial doses of vaccine and indicates that as information about the severity of the virus becomes available, recommendations will be formulated at the national level. Prioritization will be an iterative process and will be tied to vaccine availability and the progression of the pandemic. While recognizing that this is an iterative process, state officials have consistently told us that a lack of detailed guidance makes it difficult for states to plan for the use of limited supplies of vaccine.

Concluding Observations

Ensuring an adequate and timely supply of vaccine to protect seniors and others from influenza and flu-related complications continues to be challenging. Only two manufacturers currently produce flu vaccine for seniors and others at high risk for flu-related complications, and manufacturing problems experienced in recent years illustrate the fragility of the current methods of production. Despite efforts by CDC and others, there remains no system to ensure that persons at high risk for complications receive flu vaccine first when vaccine is in short supply.

These influenza vaccine supply and distribution problems may become especially acute in a pandemic. We acknowledge the need for flexibility in planning because many aspects of an influenza pandemic cannot be known in advance. However, the absence of more detail in HHS's draft plan creates uncertainty for the states regarding how to plan for the use of limited supplies of vaccine. Until decisions are made about vaccine purchase, distribution, and administration, and priority populations are designated, states will not be able to develop strategies consistent with federal priorities.

Agency Comments

Officials from CDC provided technical comments that we incorporated as appropriate.

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Mr. Chairman, this concludes my statement. I would be happy to answer any questions you or other Members of the Committee may have.

Contact and Staff Acknowledgments

For further information about this testimony, please contact Janet Heinrich at (202) 512-7119. Gigi Barsoum, Anne Dievler, Martin Gahart, Jennifer Major, Roseanne Price, and Kim Yamane also made key contributions to this statement.

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Related GAO Products

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.

Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain. GAO-03-654T, Washington, D.C.: April 9, 2003.

Flu Vaccine: Steps Are Needed to Better Prepare for Possible Future Shortages. GAO-01-786T, Washington, D.C.: May 30, 2001.

Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People. GAO-01-624, Washington, D.C.: May 15, 2001.

Influenza Pandemic: Plan Needed for Federal and State Response. GAO-01-4, Washington, D.C.: October 27, 2000.

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