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the Subcommittee on Oversight and
Investigations, Committee on Energy and
Commerce, House of Representatives

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FLU VACCINE

Recent Supply Shortages
Underscore Ongoing
Challenges

Statement of Janet Heinrich
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Highlights of [GAO-05-177T](#), a testimony before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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 who are aged 65 and older, people with chronic medical conditions, children younger than 2 years, and pregnant women are more likely to get severe complications from influenza than other people. The best way to prevent influenza is to be vaccinated each fall.

In early October 2004, one major manufacturer of flu vaccine for the United States announced that its facility's license had been temporarily suspended and it would not be releasing any vaccine for the 2004-2005 flu season. Because this manufacturer was expected to produce roughly one-half of the U.S. flu vaccine supply, the shortage resulting from its announcement has led to concern about the availability of flu vaccine, especially to those at high risk for flu-related complications.

GAO was asked to discuss issues related to the supply, demand, and distribution of vaccine for this flu season in the context of the current shortage. GAO based this testimony on products we have issued since May 2001, as well as work we conducted to update key information.

www.gao.gov/cgi-bin/getrpt?GAO-05-177T.

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.

FLU VACCINE

Recent Supply Shortages Underscore Ongoing Challenges

What GAO Found

The current vaccine shortage demonstrates the challenges to ensuring an adequate and timely flu vaccine supply. Only three manufacturers produce flu vaccine for the U.S. market, and the potential for future manufacturing problems such as those experienced both this year and to a lesser degree in previous years is still present. When shortages occur, their effect can be exacerbated by the existing distribution system. Under this system, health providers and vaccine distributors generally order a particular manufacturer's vaccine and have limited recourse, even for meeting the needs of high-risk persons, if that manufacturer's production is adversely affected. By contrast, providers who purchased vaccine from a different manufacturer might receive more of their order and be able to vaccinate their high-risk patients.

The current situation also reflects another concern: the nation lacks a systematic approach for ensuring that seniors and others at high risk for flu-related complications receive flu vaccine when it is in short supply. Once this year's shortage became apparent, the Centers for Disease Control and Prevention (CDC) took a number of steps to influence distribution patterns to help providers get some vaccine for their high-risk patients. These steps are still playing themselves out, and it will take more time to assess how well they will work. Problems have not been totally averted, however, as there have been media reports of long lines to obtain limited doses of vaccine and of high-risk individuals unable to find a flu vaccination in a timely fashion.

We shared the facts contained in this statement with CDC officials. They informed us they had no comments.

Messrs. Chairmen and Members of the Subcommittees:

Thank you for the opportunity to be here today as you discuss the nation's response to problems with the supply and distribution of influenza vaccine. This year's loss of roughly half of the country's supply of flu vaccine highlighted what has become a growing problem—the fragility of the vaccine production and distribution system. We have been monitoring this issue for a number of years, and we are starting new work for the House Committee on Government Reform to analyze this year's situation in greater detail. My testimony today focuses on (1) the challenges in ensuring adequate supply to meet demand for vaccine and (2) the mechanisms in place to target high-risk populations when, as happened this year, a vaccine shortage occurs.

My remarks are based on reports and testimony we have issued since May 2001¹ as well as work conducted to update key information. Our prior work on flu vaccine included analysis of information provided by and interviews with Department of Health and Human Services (HHS) officials, vaccine manufacturers, medical distributors and their trade associations, companies that provide flu vaccinations 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 2000-2001 flu season. In September and November 2004 we updated this work with analysis of information provided by Centers for Disease Control and Prevention (CDC) officials, one major manufacturer, and other sources. We obtained information on (1) the available doses and demand for the 2002-2003 and 2003-2004 flu seasons, (2) the status of this year's flu vaccine, and (3) CDC activities, including actions taken following the announcement that one major manufacturer could not supply any vaccine for the U.S. market this year. We conducted all of our work in accordance with generally accepted government auditing standards.

In summary, the current situation demonstrates the challenges of ensuring an adequate and timely flu vaccine supply. Only three manufacturers produce flu vaccine for the U.S. market, and the potential for future manufacturing problems such as those experienced both this year and to a lesser degree in previous years is still present. When shortages occur, their

¹See "Related GAO Products," at the end of this testimony, for a list of our earlier work related to flu vaccine.

effect can be exacerbated by the existing distribution system. Under this system, health providers and vaccine distributors generally order a particular manufacturer's vaccine and have limited recourse, even for meeting the needs of high-risk persons, if that manufacturer's production is adversely affected. By contrast, providers who purchased vaccine from a different manufacturer might receive more of their order and be able to vaccinate their high-risk patients.

The current situation also reflects another concern: the nation lacks a systematic approach for ensuring that seniors and others at high risk for flu-related complications receive flu vaccine when it is in short supply. Once this year's shortage became apparent, CDC took a number of steps to influence distribution patterns to help providers get some vaccine for their high-risk patients. These steps are still playing themselves out, and it will take more time to assess how well they will work. Problems have not been totally averted, however, as there have been media reports of long lines to obtain limited doses of vaccine and of high-risk individuals unable to find a flu vaccination in a timely fashion.

Background

Influenza is associated with an average of more than 200,000 hospitalizations and 36,000 deaths each year in the United States. Most people who get the flu recover completely in 1 to 2 weeks, but some develop serious and 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.²

For the 2004-2005 flu season, CDC initially recommended in May 2004 that about 185 million Americans—about 85 million in high-risk groups and over 100 million in other target groups—receive the vaccine, which is the primary method for preventing influenza. Groups at high-risk for flu-related complications included people aged 65 years or older; residents of nursing homes and other chronic-care facilities; people with chronic conditions such as asthma and diabetes; children and adolescents aged 6 months to 18 years who are receiving long-term aspirin therapy;

²Influenza and pneumonia rank as the fifth leading cause of death among persons aged 65 and older. Persons aged 65 and older are involved in more than 1 of 2 hospitalizations and 9 of 10 deaths related to influenza.

pregnant women; and children aged 6 to 23 months. Other target groups identified in the May 2004 recommendations included persons aged 50 to 64 years and people who can transmit influenza to those at high-risk, such as health care workers, employees of nursing homes, chronic-care facilities, and assisted living facilities, and household contacts of and those who provide home care to high-risk individuals.³ Not everyone in these high-risk and target groups, however, receives a vaccination each year. For example, based on the 2002 National Health Interview Survey and other sources, CDC estimates that only about 44 percent of individuals at high-risk and about 20 percent of individuals in the other target groups were vaccinated.

It takes 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 sufficient quantities of 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 for distribution in the United States.

In a typical year, manufacturers make flu vaccine available before the optimal fall season for administering flu vaccine. For the 2003-2004 flu season, two manufacturers—one with production facilities in the United

³See HHS, Centers for Disease Control and Prevention, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 53 (2004). CDC also recommended a vaccination for anyone who wanted one.

States and one with production facilities in the United Kingdom—produced about 95 percent of the vaccine for the United States. A 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. This nasal spray vaccine is not recommended for individuals at high risk for flu-related complications. According to CDC, this manufacturer produced about 4 million doses of the nasal spray vaccine for the 2003-2004 season.

Flu vaccine production and distribution are largely private-sector 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 at nonmedical locations such as workplaces and various retail outlets. Millions of individuals receive flu vaccinations through mass immunization campaigns in these nonmedical settings, where organizations such as visiting nurse agencies under contract administer the vaccine.⁴ In a typical year, 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.

For the 2004-2005 season, CDC had estimated that about 100 million doses of flu vaccine would be available for distribution through this network. On August 26, 2004, one major manufacturer announced a small quantity of its flu vaccine did not meet sterility specifications and that distribution of its vaccine would be delayed until after further tests were completed. On October 5, 2004, this manufacturer announced that the regulatory body in the United Kingdom, the Medicines and Healthcare Products Regulatory Agency (MHRA), had temporarily suspended the company's license to manufacture flu vaccine in its facility in Liverpool, England. The manufacturer stated that this action prevented the company from releasing any vaccine for the 2004-2005 flu season—effectively reducing the anticipated U.S. supply by nearly half. This sudden disruption of the supply set off the chain of events the nation has experienced in the past

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.

6 weeks, and has focused national attention on the flu vaccine supply and distribution system.

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. As we are witnessing this year, 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, as the following examples illustrate.

- In 2000-2001, when a substantial proportion of flu vaccine was distributed much later than usual due to manufacturing difficulties, temporary shortages during 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 2000-2001, 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' offices, employee health clinics, and other organizations that administered flu vaccinations reported having unused doses in December and later.
- For the 2002-2003 flu season, according to CDC officials, vaccine manufacturers produced about 95 million doses of vaccine, of which about 83 million doses were used and about 12 million doses went unused.
- For the 2003-2004 flu season, shortages of vaccine were 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 used in the previous season—about 87 million doses total—and that supply was not adequate to meet the demand.

If production problems delay or disrupt 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

2000-2001 season, and there are reports of similar problems this season after one manufacturer that had previously stated it expected to supply 46 million to 48 million doses announced that it would not deliver any flu vaccine to the U.S. market. Those who ordered from this manufacturer did not receive their expected vaccine—a different situation 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 have held vaccination clinics in early October that would be available to anyone who wanted a flu vaccination, while another provider may not yet have had any vaccine for its high-risk 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 vaccinations, 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 the lower priced orders they had already received. When there was a delay causing a temporary shortage of vaccine in 2000, those who purchased vaccine that fall—because their earlier orders had been canceled, reduced, or delayed, or because they simply ordered later—found they paid 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 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.

With the severely reduced vaccine supply this year, opportunities exist for vendors who have vaccine to significantly inflate the price of available supplies. CDC is collecting information on allegations of such price increases and is providing information to respective state attorneys general. To date, CDC officials report receiving and forwarding over 100 reports of alleged price gouging that they received from 33 states.

Following the 2000-2001 flu season, HHS undertook several initiatives to address supply and demand of flu vaccine and to protect high-risk individuals from flu-related complications when vaccine is in short supply. Actions taken include the following:

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- 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.
 - Including the flu vaccine in the Vaccines for Children (VFC) stockpile to help improve flu vaccine supply. For the 2004-2005 flu season, CDC had originally contracted for a stockpile of approximately 4.5 million doses of flu vaccine through its VFC authority—of which 2 million doses were ordered from the manufacturer whose license was temporarily suspended and therefore will not be available. CDC officials said the remaining 2.5 million doses intended for the stockpile will be apportioned as they become available.
 - Taking steps to identify additional sources of influenza vaccine from foreign manufacturers that, once approved for safe use, could help increase the flu vaccine supply in the United States.

Challenges Persist in Targeting Flu Vaccine to High-Risk Individuals

Our work has also found continuing obstacles to delivering flu vaccine to high-risk individuals in a time of short supply. During the fall 2000 vaccine shortage, for example, targeting limited doses to high-risk individuals was problematic 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 were offering flu vaccinations 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 vaccinations in medical offices.

For the 2004-2005 flu season, despite early indications that one manufacturer was having production difficulties, CDC published guidance in September 2004 stating that it did not envision any need for tiered vaccination recommendations or prioritization of vaccine for those at higher risk of flu-related complications. Following the suspension of one manufacturer's license and the announcement it would not supply any vaccine to the U.S. market this season, CDC revised its recommendations and took steps to mitigate the vaccine shortage.

Although HHS has limited authority to control flu vaccine distribution,⁵ upon learning that nearly half of the nation's expected flu vaccine supply was in jeopardy, it took steps to help direct the available vaccine to help providers get some vaccine for their high-risk patients. In particular, CDC officials have worked with the remaining major manufacturer, as well as state and local health departments, to assess needs, prioritize customers, and make plans to distribute the remaining vaccine.

CDC also convened its Advisory Committee on Immunization Practices (ACIP) to reassess and revise the recommended vaccination priorities for the flu season.⁶ The revised priority groups for the 2004-2005 flu vaccine include the estimated 85 million people in high-risk groups, but they do not include many of the other target groups. In addition to high-risk individuals, the revised priority groups include an estimated 7 million health care workers and an estimated 6 million household contacts of children aged 6 months or younger, for a total population of about 98 million in the revised priority groups.

While CDC can recommend and encourage providers to immunize high-risk patients first, it does not have direct control over the distribution of vaccine (other than the generally small amount that is distributed through public health departments); thus, CDC cannot ensure that its priorities will be implemented. As these actions play out, more time is needed to gauge the success of CDC's efforts to mitigate the current flu vaccine shortage.

Despite the efforts by CDC and others, many high-risk individuals appear to be experiencing problems getting a flu vaccination. Media across the country are reporting that some seniors are waiting hours for flu vaccinations and others are so frustrated they are traveling to Canada or Mexico to get vaccinated. There are other media reports of anxious seniors unable to get vaccinated in a timely fashion. How many high-risk individuals ultimately get vaccinated against influenza this season remains

⁵Under 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.

⁶See HHS, Centers for Disease Control and Prevention, "Interim Influenza Vaccination Recommendations, 2004-2005 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53 (2004).

to be seen. We are beginning new work to analyze this year's vaccine shortage and the federal response.

Concluding Observations

Ensuring an adequate and timely supply of vaccine to protect high-risk individuals from influenza and flu-related complications remains a challenge. The limited number of manufacturers and the manufacturing problems experienced in recent years illustrate the fragility of vaccine production. The abrupt loss of nearly half of the nation's vaccine supply has further highlighted the potential inequities that can result from the current vaccine distribution system. Under this system, some providers can be left with little immediate recourse for meeting the needs of those most at risk. CDC is responding by working with the remaining major flu vaccine manufacturer and states and local public health agencies to better target high-risk populations. Nonetheless, with this flu season, there are reports of long lines, people crossing international boundaries to obtain their flu vaccinations, and anxious seniors unable to obtain a vaccination on a timely basis. Whatever the outcome of this flu season, ensuring that vaccine can be made available as expeditiously as possible to those who need it most in times of shortage remains a challenge.

Agency Comments

We shared the facts contained in this statement with CDC officials. They informed us they had no comments.

This concludes my statement. I would be happy to answer any questions the Chairmen or other Members of the Subcommittees may have.

Contact and Staff Acknowledgments

For further information about this testimony, please contact Janet Heinrich at (202) 512-7119. Jennifer Major, Terry Saiki, Stan Stenersen, and Kim Yamane also made key contributions to this statement.

Related GAO Products

Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks. [GAO-04-1100T](#), Washington, D.C.: September 28, 2004.

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.

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