

GAO

Testimony

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# FLU VACCINE

## Steps Are Needed to Better Prepare for Possible Future Shortages

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G A O

Accountability \* Integrity \* Reliability

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Chairman Craig, Ranking Member Breaux, and Senator Wyden:

I am pleased to be here today to discuss problems that occurred last fall with shortages of influenza vaccine and report on some steps that could help better prepare for possible future shortages.

Until the 2000-01 flu season, the production and distribution of flu vaccine generally occurred without major difficulties. Last year, however, things were different. You and other Members of Congress heard complaints from many of your constituents who wanted but could not get flu shots. You also heard from physicians and public health departments that could not provide shots to high-risk patients in their medical offices and clinics because they had not received vaccine they had ordered many months in advance, or because they were being asked to pay much higher prices for vaccine in order to get it right away. And at the same time, there were reports that providers in other locations, even grocery stores and restaurants, were offering flu shots to everyone—including younger, healthier people who were not at high risk. There were concerns that the delay, disruption, and confusion may have prevented some high-risk individuals from getting vaccinated at all.

Along with 28 other Members of Congress, you asked us to examine issues relating to the delays in production, distribution, and pricing of the 2000-01 flu vaccine. My remarks today will present the highlights of our recently released report on those issues.<sup>1</sup> Specifically, I will focus on the following:

- What circumstances contributed to the production delay, and what effects did the delay have on the prices paid for vaccine?
- How effectively do current distribution channels ensure that high-risk populations receive vaccine on a priority basis?
- What approaches are federal agencies taking to better prepare for possible future disruptions of influenza vaccine supply?

In brief, we found that manufacturing difficulties during the 2000-01 flu season resulted in an overall delay of about 6 to 8 weeks in shipping vaccine to most customers, which created an initial shortage and temporary price spikes. Manufacturing difficulties could occur in the future and again illustrate the fragility of current methods to produce a

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<sup>1</sup>See *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People* (GAO-01-624, May 15, 2001).

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new vaccine every year. Compounding the problem is that when the supply of vaccine is short, there is no system to ensure that high-risk people have priority for receiving flu shots. In considering how to better prepare for possible future shortages, it is important to recognize that the purchase, distribution, and administration of flu vaccine are mainly private-sector responsibilities. Consequently, federal actions to help mitigate any adverse effects of vaccine delays or shortages need to rely to a great extent on collaboration between the public and private sectors. Besides focusing on improving distribution of influenza vaccine, it may also be beneficial to consider how to increase immunization rates against pneumococcal pneumonia, which is one of the primary causes of deaths and hospitalizations associated with influenza.

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## Background

Annual vaccination is the primary method for preventing influenza, which is associated with serious illness, hospitalizations, and even deaths among people at high risk for complications of the disease, such as pneumonia. Senior citizens are particularly at risk, as are individuals with chronic medical conditions. The Centers for Disease Control and Prevention (CDC) estimates that influenza epidemics contribute to approximately 20,000 deaths and 110,000 hospitalizations in the United States each year. Here in Oregon, and throughout the nation, influenza and pneumonia rank as the fifth leading cause of death among persons 65 years of age and older.

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. 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. Only three manufacturers—two in the United States and one in the United

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Kingdom—produced the vaccine used in the United States during the 2000-01 flu season.<sup>2</sup>

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 shots at physicians' offices, public health clinics, nursing homes, and less traditional locations such as workplaces and various retail outlets. CDC has recommended October through mid-November as the best time to receive a flu shot because the flu season generally peaks from December through early March. However, if flu activity peaks late, as it has in 10 of the past 19 years, vaccination in January or later can still be beneficial.

To address our study questions, we interviewed officials from the Department of Health and Human Services (HHS), including CDC, FDA, and the Health Care Financing Administration (HCFA), as well as flu vaccine manufacturers, distributors, physician associations, flu shot providers, and others. We surveyed 58 physician group practices nationwide to learn about their experiences and interviewed health department officials in all 50 states.

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## Manufacturing Problems Caused Temporary Shortages and Spikes in Price

Although the eventual supply of vaccine in the 2000-01 flu season was about the same as the previous year's—about 78 million doses—production delays of about 6 to 8 weeks limited the amount that was available during the peak vaccination period. During the period when supply was limited and demand was higher, providers who wanted to purchase vaccine from distributors with available supplies often faced rapidly escalating prices. By December, as vaccine supply increased and demand dropped, prices declined.

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## Most Vaccine Was Not Ready During Period of Peak Demand

Last fall, fewer than 28 million doses were available by the end of October, compared with more than 70 million doses available by that date in 1999. Two main factors contributed to last year's delay. The first was that two manufacturers had unanticipated problems growing one of the two new influenza strains introduced into the vaccine for the 2000-01 flu season.

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<sup>2</sup>The two manufacturers with facilities in the United States were Wyeth-Ayerst Pharmaceuticals, Inc., and Aventis Pasteur, Inc. The manufacturer with facilities in the United Kingdom was Medeva Pharma, Ltd.

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Because manufacturers must produce a vaccine that includes all three strains selected for the year, delivery was delayed until sufficient quantities of this difficult strain could be produced. The second factor was that two of the four manufacturers producing vaccine the previous season shut down parts of their facilities because of FDA concerns about compliance with good manufacturing practices, including issues related to safety and quality control. One of these manufacturers reopened its facilities and eventually shipped its vaccine, although much later than usual. The other, which had been expected to produce 12 to 14 million doses, announced in September 2000 that it would cease production altogether and, as a result, supplied no vaccine.

These vaccine production and compliance problems did not affect every manufacturer to the same degree. Consequently, when a purchaser received vaccine depended to some extent on which manufacturer's vaccine it had ordered. Purchasers that contracted only with the late-shipping manufacturers were in particular difficulty. For example, health departments and other public entities in 36 states, including Oregon, banded together under a group purchasing contract and ordered nearly 2.6 million doses from the manufacturer that, as it turned out, experienced the greatest delays from production difficulties. Some of these public entities, which ordered vaccine for high-risk people in nursing homes or clinics, did not receive most of their vaccine until December, according to state health officials.

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### Limited Availability During Peak Demand Created Temporary Price Spikes

Because supply was limited during the usual vaccination period, distributors and others who had supplies of the vaccine had the ability—and the economic incentive—to sell their supplies to the highest bidders rather than filling lower-priced orders they had already received. Most of the physician groups and state health departments we contacted reported that they waited for delivery of their original lower-priced orders, which often arrived in several partial shipments from October through December or later.

Those who purchased vaccine in the fall found themselves paying much higher prices. For example, one physicians' practice in our survey 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

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expensive orders were delivered immediately, before any vaccine had been received from the original April order.

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### When More Vaccine Became Available, Demand Had Already Dropped

Demand for influenza vaccine dropped as additional vaccine became available after the prime period for vaccinations had passed. In all, roughly one-third of the total distribution was delivered in December or later. Part of this additional supply resulted from actions taken by CDC in September, when it appeared there could be a shortfall in production. At that point, CDC contracted with one of the manufacturers to extend production into late December for 9 million additional doses.<sup>3</sup> Despite efforts by CDC and others to encourage people to seek flu shots later in the season, providers still reported a drop in demand in December. The unusually light flu season also probably contributed to the lack of interest. Had a flu epidemic hit in the fall or early winter, the demand for influenza vaccine would likely have remained high.

As a result of the waning demand, manufacturers and distributors reported having more vaccine than they could sell. Manufacturers reported shipping about 9 percent less than in 1999, and more than 7 million of the 9 million additional doses produced under the CDC contract were never shipped at all. In addition, some physicians' offices, employee health clinics, and other organizations that administered flu shots reported having unused doses in December and later.

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### Distribution of Vaccine Does Not Ensure Priority to High-Risk Individuals

In a typical year, there is enough vaccine available in the fall to give a flu shot to anyone who wants one. However, when the supply is not sufficient, there is no mechanism currently in place to establish priorities and distribute flu vaccine first to high-risk individuals. Indeed last year, mass immunizations in nonmedical settings, normally undertaken to promote vaccinations, created considerable controversy as healthy persons received vaccine in advance of those at high risk. In addition, manufacturers and distributors that tried to prioritize their vaccine shipments encountered difficulties doing so.

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<sup>3</sup>The manufacturer began accepting orders under this contract in early November and began shipping vaccine from these orders in mid-December 2000. Prices were \$2.99 per dose for public purchasers and \$5 per dose for the private sector.

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## Availability of Vaccine for Mass Immunization Campaigns Created Controversy

Flu shots are 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 shots through mass immunization campaigns in nonmedical settings, where organizations, such as visiting nurse agencies under contract, administer the vaccine. The widespread availability of flu shots may help increase immunization rates overall, but it generally does not lend itself to targeting vaccine to high-priority groups.

The timing of some of the mass immunization campaigns last fall generated a great deal of controversy. 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. Examples of these situations include the following:

- A radio station in Colorado sponsored a flu shot and a beer for \$10 at a local restaurant and bar—at the same time that the public health department and the community health center did not have enough vaccine.
- One grocery store chain in Minnesota participated in a promotion offering a discounted flu shot for anyone who brought in three soup can labels.
- Flu shots were available for purchase to all fans attending a professional football game.

CDC took some steps to try to manage the anticipated vaccine delay by issuing recommendations for vaccinating high-risk individuals first. In July 2000, CDC recommended that mass immunization campaigns, such as those open to the public or to employee groups, be delayed until early to mid-November.<sup>4</sup> CDC issued more explicit voluntary guidelines in October 2000, which stated that vaccination efforts should be focused on persons aged 65 and older, pregnant women, those with chronic health conditions that place them at high risk, and health care workers.<sup>5</sup> The October guidelines also stated that while efforts should be made to increase

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<sup>4</sup>See CDC, "Delayed Supply of Influenza Vaccine and Adjunct ACIP Influenza Vaccine Recommendations for the 2000-01 Influenza Season," *Morbidity and Mortality Weekly Report*, Vol. 49, No. 27 (July 14, 2000), pp. 619-622.

<sup>5</sup>See CDC, "Updated Recommendations from the Advisory Committee on Immunization Practices in Response to Delays in Supply of Influenza Vaccine for the 2000-01 Season," *Morbidity and Mortality Weekly Report*, Vol. 49, No. 39 (Oct. 6, 2000), pp. 888-892.

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participation in mass immunization campaigns by high-risk persons and their household contacts, other persons should not be turned away.

Some organizations that conducted mass immunizations said they generally did not screen individuals who came for flu shots in terms of their risk levels. Some said they tried to target high-risk individuals and provided information on who was at high risk, but they let each person decide whether to receive a shot. Their perspective was that the burden lies with the individual to determine his or her own level of risk, not with the provider. Moreover, they said that the convenience locations provide an important option for high-risk individuals as well as others. Health care providers in both traditional and nontraditional settings told us that it is difficult to turn someone away when he or she requests a flu shot.

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### Manufacturers and Distributors Reported Difficulty Determining How to Get Vaccine to High-Risk Individuals

The manufacturers and distributors we interviewed reported that it was difficult to determine which of their purchasers should receive priority vaccine deliveries in response to CDC's recommendations to vaccinate high-risk individuals first. They did not have plans in place to prioritize deliveries to target vaccine to high-risk individuals because there generally had been enough vaccine in previous years and thus there had been little practical need for this type of prioritization. When they did try to identify purchasers serving high-risk individuals, the manufacturers and distributors often found they lacked sufficient information about their customers to make such decisions, and they also were aware that all types of vaccine providers were likely to serve at least some high-risk individuals.

As a result, manufacturers reported using various approaches in distributing their vaccine, including making partial shipments to all purchasers as a way to help ensure that more high-risk persons could be vaccinated. Others made efforts to ship vaccine first to nursing homes, where they could be identified, and to physicians' offices. All of the manufacturers and distributors we talked to said that once they distributed the vaccine it would be up to the purchasers and health care providers to target the available vaccine to high-risk groups.

Immunization statistics are not yet available to show how successful these ad hoc distribution strategies may have been in reaching high-risk groups, but there may be cause for concern. Some state health officials reported that nursing homes often purchase their flu vaccine from local pharmacies, and some distributors considered pharmacies to be lower priority for deliveries. In addition, many physicians reported that they felt



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they did not receive priority for vaccine delivery, even though nearly two-thirds of seniors—one of the largest high-risk groups—generally get their flu shots in medical offices. The experience of the 58 physicians' practices we surveyed seemed consistent with this reported lack of priority: as a group, they received their shipments at about the same delayed rate that vaccine was generally available on the market.

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## Additional Actions Needed to Prepare for Future Vaccine Delays and Shortages

Ensuring an adequate and timely supply of vaccine, already a difficult task given the complex manufacturing process, has become even more difficult as the number of manufacturers has decreased. Now, a production delay or shortfall experienced by even one of the three remaining manufacturers can significantly affect overall vaccine availability. Looking back, we are fortunate that the 2000-01 flu season arrived late and was less severe than normal because we lacked the vaccine last October and November to prepare for it. Had the flu hit early with normal or greater severity, the consequences could have been serious for the millions of Americans who were unable to get their flu shots on time.

This raises the question of what more can be done to better prepare for possible vaccine delays and shortages in the future. We need to recognize that flu vaccine production and distribution are private-sector responsibilities, and as such options are somewhat limited. HHS has no authority to directly control flu vaccine production and distribution, beyond FDA's role in regulating good manufacturing practices and CDC's role in encouraging appropriate public health actions.<sup>6</sup>

Working within these constraints, HHS undertook several initiatives in response to the problems experienced during the 2000-01 flu season. For example, the National Institutes of Health, working with FDA and CDC, conducted a clinical trial on the feasibility of using smaller doses of vaccine for healthy adults. If smaller doses offer acceptable levels of protection, this would be one way to stretch limited vaccine supplies. Final results from this work are expected in fall 2001. In addition, for the upcoming flu season CDC and its advisory committee extended the optimal period for getting a flu shot until the end of November, to encourage more people to get shots later in the season. HHS is also

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<sup>6</sup>Under the Federal Food Drug and Cosmetic Act, FDA 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. Wholesale distributors are excluded from the definition of health care entities.

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working to complete a plan for a national response to a severe worldwide influenza outbreak, called a pandemic. While the plan itself would likely be applied only in cases of public health emergencies, we believe that the advance preparations by manufacturers, distributors, physicians, and public health officials to implement the plan could provide a foundation to assist in dealing with less severe problems, such as those experienced last year.<sup>7</sup>

We believe it would be helpful for HHS agencies to take additional actions in three areas.<sup>8</sup> Progress in these areas could prove valuable in managing future flu vaccine disruptions and targeting vaccine to high-risk individuals. First, because vaccine production and distribution are private-sector responsibilities, CDC needs to work with a wide range of private entities to prepare for potential problems in the future. CDC can take an ongoing leadership role in organizing and supporting efforts to bring together all interested parties to formulate voluntary guidelines for vaccine distribution in the event of a future vaccine delay or shortage. In March 2001, CDC co-sponsored a meeting with the American Medical Association that brought together public health officials, vaccine manufacturers, distributors, physicians, and other providers to discuss flu vaccine distribution, including ways to target vaccine to high-risk groups in the event of a future supply disruption. This meeting was a good first step, and continued efforts should be made to achieve consensus among the public- and private-sector entities involved in vaccine production, distribution, and administration.

The experience of the 2000-01 flu season showed how difficult it is to change established behavior regarding when to be vaccinated. For this reason, we believe CDC can concentrate greater efforts on education and outreach to members of the public and providers focused on the value of being immunized later in the winter. CDC issued guidelines to this effect, posted similar information on a Web site, and conducted a media campaign in select cities, but it appears those efforts had limited impact on changing behavior. CDC could maximize the results of future efforts by assessing its past efforts to identify the most effective means of influencing behavior. Those means should be used to educate flu vaccine

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<sup>7</sup>See *Influenza Pandemic: Plan Needed for Federal and State Response* (GAO-01-4, Oct. 27, 2000).

<sup>8</sup>See [GAO-01-624 for formal recommendations to HHS](#).

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providers and the general public well before the start of the traditional fall vaccination period.

Finally, while vaccination against pneumococcal disease is not a substitute for the annual flu shot, it can provide protection against a major complication of the flu if vaccine is not available. One pneumococcal vaccination can provide long-term protection, with immunity lasting 5 to 10 years. Available data indicate that only about half of seniors have been vaccinated, however, and the rate is much lower for high-risk people under age 65. HCFA has ongoing activities directed toward increasing both pneumococcal and influenza vaccination rates for adults aged 65 and older in the Medicare program. At the same time, CDC supports state activities for both childhood and adult immunization, although little of that funding goes to adult immunization programs. Collaboration between HCFA and CDC in pneumococcal and influenza vaccination programs for adults could maximize the use of federal resources in this area. For example, CDC could focus on increasing these immunizations in the high-risk non-Medicare population, which would complement HCFA's ongoing activities to improve immunization rates in the Medicare population.

HHS responded to our first two recommendations by citing related actions that are under way. For example, HHS told us that CDC is also working with interested parties, including state health departments, to develop contingency plans for vaccine distribution and has started to assess the relative success of its various outreach and educational efforts last season. In response to our third recommendation, HHS commented that CDC supports efforts to use pneumococcal vaccine more widely.

This concludes my statement. I would be happy to answer any questions you may have.

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## GAO Contacts and Staff Acknowledgments

For more regarding this testimony, please contact Janet Heinrich, Director, Health Care—Public Health Issues, at (202) 512-7119, or Frank Pasquier, Assistant Director, at (206) 287-4861. Other individuals who made contributions to this statement include Lacinda Ayers, George Bogart, Ellen M. Smith, Stan Stenersen, and Kim Yamane.