

May 2001

# FLU VACCINE

## Supply Problems Heighten Need to Ensure Access for High-Risk People



GAO

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## **Abbreviations**

ACIP Advisory Committee on Immunization Practices  
CDC Centers for Disease Control and Prevention  
FDA Food and Drug Administration  
HCFA Health Care Financing Administration  
HHS Department of Health and Human Services  
NVPO National Vaccine Program Office  
PRO Peer Review Organization



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United States General Accounting Office  
Washington, DC 20548

May 15, 2001

### Congressional Requesters

Each year, influenza contributes to approximately 20,000 deaths and 110,000 hospitalizations in the United States. Influenza itself may not be the reason for death or hospitalization, but it weakens the body's defenses against other diseases, such as pneumonia. Those individuals aged 65 years or older, people with chronic medical conditions, and pregnant women are at particular risk for medical complications. Annual vaccinations, commonly known as flu shots, are currently the best defense for these high-risk populations. About one in every three adults in the United States receives a flu shot, according to 1999 survey data. Of these, the Centers for Disease Control and Prevention (CDC) estimates that about half are at high risk for medical complications from influenza.

Until the 2000-01 flu season, production and distribution of flu vaccine generally occurred without major difficulties. The fall of 2000, however, produced many stories about delays in obtaining flu vaccine. News media reported instances in which medical providers were unable to get vaccine for patients at high risk for hospitalization or death from complications resulting from the flu, while other providers had enough vaccine to give shots even to younger, healthier people at lower risk for medical complications. The media also reported stories in which vaccine was apparently available for providers willing to pay considerably higher prices, while providers that had ordered vaccine at lower prices were still waiting to receive their orders. You asked us to examine these issues. Our review focused on the following questions:

- What circumstances contributed to the 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 is the federal government doing to better prepare for possible disruptions of influenza vaccine supply?

In response to your request, we reviewed relevant documents and interviewed officials from three agencies within the Department of Health and Human Services (HHS): CDC, Food and Drug Administration (FDA), and Health Care Financing Administration (HCFA). In addition, we interviewed officials from HHS' National Vaccine Program Office (NVPO). We also interviewed and obtained documents from all vaccine

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manufacturers, two trade associations for medical supply distributors, as well as several distributors, companies that provide flu shots at retail outlets and work sites, physician and other professional associations, and other purchasers. Because physicians are the main source of flu shots for the elderly (who comprise about half of the high-risk population), we surveyed 58 physician group practices to determine how readily they were able to obtain vaccine and the prices they paid for the 2000-01 season. The groups we selected included a diverse array of primary care groups nationwide, but they were not a statistically representative sample that can be generalized to all physician groups.<sup>1</sup> We also interviewed officials of health departments in all 50 states about their vaccine purchase and distribution activities. We conducted this work from November 2000 through April 2001 in accordance with generally accepted government auditing standards.

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## Results in Brief

For the 2000-01 flu season, manufacturing difficulties resulted in an overall delay of about 6-8 weeks in shipping vaccine to most customers, creating an initial shortage and a temporary price spike. Manufacturing difficulties illustrate the fragility of the system to produce a new flu vaccine each year on a timely basis. Manufacturers experienced problems growing a new viral strain. At the same time, two of the four manufacturers halted production—one permanently—to address safety and quality control concerns. While the roughly 78 million doses eventually produced were about the same amount produced in the previous year, the delay resulted in a shortage of vaccine during October and November when people normally receive their flu shot. Many purchasers who had placed orders received only partial shipments—and in some cases, no vaccine at all—by this period of high demand. During the shortage period, providers who wanted to purchase vaccine often faced rapidly escalating prices from distributors with an available supply. For example, orders placed by physicians in our sample during the peak vaccination months of October and November cost an average of \$7 per dose, compared with less than \$3 per dose for orders that had been placed before the end of June 2000. State health officials and providers who had placed orders early often waited for

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<sup>1</sup>We selected physician practices that were members of the Medical Group Management Association. Association members represent 7,000 to 8,000 physician group practices nationwide that include an estimated 38 percent of office-based physicians who practice in the United States. Because primary care practices routinely order flu vaccine, we randomly selected from those group practices that were coded in the association's membership database as family practice and internal medicine specialties.

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delivery of their lower-priced vaccine from manufacturers and distributors until late November or December. By December, when roughly one-third of the vaccine became available, vaccine prices declined. However, because the usual time for vaccination had passed and flu outbreaks were relatively mild, demand for vaccine had also subsided and about 10 percent of vaccine eventually produced—or more than 7 million doses—went unsold.

Currently, there is no system to ensure that high-risk people have priority when the supply of vaccine is short. In a typical year, enough vaccine is available in the fall to meet total demand, both from high-risk individuals and from others who simply want to avoid the flu. When the supply became short in the fall of 2000, however, there was no mechanism to target vaccine to those who needed it most. For example, while more elderly people tend to receive flu shots in physicians' offices than at any other location, our survey of physician practices found that on the whole these physicians received their shipments at about the same delayed rate that vaccine was generally available on the market. Efforts to target scarce vaccine are complicated because all types of purchasers serve at least some high-risk people. When shortages developed, manufacturers and distributors had limited ability to identify and give priority to those providers serving more high-risk individuals.

HHS has several initiatives underway to help mitigate the adverse effects of future influenza vaccine shortages and delays. For example, CDC revised its guidelines to extend the recommended timeframe for receiving immunizations, and is helping bring together manufacturers, distributors, providers, and others in the private and public sectors to explore ways to improve distribution to high-risk individuals. The success of these initiatives relies to a great extent on the cooperation of the many organizations involved because the federal government has no direct control over how influenza vaccine is purchased and distributed by the private sector and state and local governments. This cooperation could be fostered by HHS' completion of its national plan to distribute scarce vaccine during severe influenza epidemics—called pandemics. A related step that could help mitigate the adverse effects of influenza during a shortage of flu vaccine is to increase immunization rates against pneumococcal pneumonia, one of the primary causes of deaths and hospitalizations associated with influenza. HHS has initiated activities to improve these immunization rates, but it has a long way to go to meet the immunization goals it has set for the year 2010.

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We are making recommendations to the Secretary of HHS to better prepare for possible future disruptions to the influenza vaccine supply. In commenting on a draft of this report, HHS identified ongoing or planned actions related to two of our recommendations, and in response to our third recommendation commented that CDC supports efforts to use pneumococcal vaccine more widely.

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## Background

Vaccination is the primary method for preventing influenza and its more severe complications. Flu vaccine is produced and administered annually to provide protection against particular influenza strains expected to be prevalent that year. When the match between the vaccine and the circulating viruses is close, vaccination may prevent illness in about 70-90 percent of healthy people aged 64 or younger. It is somewhat less effective for the elderly and those with certain chronic diseases but, according to CDC, it can still prevent secondary complications and reduce the risk for influenza-related hospitalization and death.<sup>2</sup> CDC estimates that during the average flu season, for every 1 million elderly persons that are vaccinated approximately 1,300 hospitalizations and 900 deaths are prevented. Information on which groups are at highest risk for medical complications associated with influenza and recommendations on who should receive a flu shot are issued by CDC's Advisory Committee on Immunization Practices (ACIP).<sup>3</sup>

Because the flu season generally peaks between December and early March, and because immunity takes about 2 weeks to establish, most medical providers administer vaccinations between October and mid-November. CDC's ACIP recommended this period as the best time to receive a flu shot. However, if flu activity peaks in February or March, as it has in 10 of the past 19 years, vaccination in January or later can still be beneficial.

Producing the 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 between January and 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

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<sup>2</sup>Limited studies have shown influenza vaccine may be about 30 to 70 percent effective in reducing hospitalization among the noninstitutionalized elderly population.

<sup>3</sup>See app. I for additional information on the recommendations for the 2000-01 flu season.

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changed to better protect against the strains that are likely to be circulating during the next flu season. FDA decides which strains to include and also licenses and regulates the manufacturers that produce the vaccine.<sup>4</sup> Three manufacturers—two in the United States and one in the United Kingdom—produced the vaccine used during the 2000-01 flu season.<sup>5</sup>

Much like other pharmaceutical products, flu vaccine is sold to thousands of purchasers by manufacturers, numerous medical supply distributors, and other resellers such as pharmacies. Purchasers then administer flu shots in medical offices, public health clinics, nursing homes and pharmacies, as well as in less traditional settings such as grocery stores and other retail outlets, senior centers, and places of employment. For the 1999-2000 flu season, about 77 million doses of vaccine were distributed nationwide.<sup>6</sup> CDC estimates that about half of the vaccine was administered to people with high-risk conditions and to health care workers, and the balance was administered to healthy people younger than 65 years.

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## Manufacturing Problems Caused Temporary Shortages and Spikes in Price

Overall, manufacturing problems led to vaccine production and distribution delays of about 6-8 weeks in 2000-01. Although the eventual supply was about the same as the previous year's, the delay limited the amount of vaccine available during October and early November, the period when most people normally receive their flu shot. While the effect of the delay and initial shortage in terms of the number of high-risk persons vaccinated will not be known for some time, other effects can be observed, particularly in terms of the price of the vaccine. Providers who decided to purchase vaccine from those distributors who had it available during the October and November period of limited supply and higher demand often found prices that were several times higher than expected. Many providers who decided to wait for their orders placed earlier eventually received them, and at the lower prices they had initially

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<sup>4</sup>FDA decides which strains to include in the annual influenza vaccine based on the recommendations of its Vaccines and Related Biological Products Advisory Committee.

<sup>5</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.

<sup>6</sup>About 3 million doses were returned to manufacturers at the end of the season, for a net distribution of 74 million doses.

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contracted for. 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

For the 2000-01 flu season, manufacturers collectively took about 6-8 weeks longer than normally expected to produce and distribute all of the flu vaccine. This delay meant that the bulk of the vaccine was not ready for market during the period of October and early November that CDC recommended as the best time to receive flu shots. This is also the time when most practitioners are used to administering the vaccine and when most people are used to receiving it. In 1999, more than 70 million doses of vaccine were available by the end of October; in 2000, fewer than 28 million doses were available by that date.

Two main factors contributed to the delay. The first was that two manufacturers had unanticipated problems growing one of the two new influenza strains introduced into the vaccine for 2000-01. 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 that produced vaccine the previous season shut down part of their manufacturing facilities because of FDA concerns about compliance with good manufacturing practices. One manufacturer temporarily closed on its own initiative to make facility improvements and address quality control issues raised during an FDA inspection; the other was ordered by FDA to cease production until certain actions were taken to address a number of concerns, including issues related to safety and quality control. The former reopened its facilities but the other manufacturer, which had been expected to produce 12-14 million doses for the 2000-01 flu season, announced in September 2000 that it would cease production altogether and, as a result, supplied no vaccine for 2000-01.

These problems did not affect every manufacturer to the same degree. In particular, the manufacturer that produced the smallest volume of vaccine did not experience production problems or delays in shipping its vaccine. By the end of October, this manufacturer had distributed nearly 85 percent of its vaccine, while the two other manufacturers had shipped only about 40 percent and less than 15 percent, respectively. Purchasers who ordered their vaccine from the manufacturer with no major production problems were far more likely to receive their vaccine on time. For example, the state of Alabama ordered vaccine directly from all three manufacturers before July 2000 at a similar price per dose. As table 1 shows, the state received its shipments at markedly different times, reflecting how soon

each manufacturer was able to get its vaccine to market. Purchasers that contracted only with the late-shipping manufacturers were in particular difficulty. For example, health departments and other public entities in 36 states banded together under a group purchasing contract and ordered nearly 2.6 million doses from the manufacturer that ended up having the greatest delays from production difficulties.<sup>7</sup> 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.

**Table 1: Flu Vaccine Orders Placed in 2000 by the State of Alabama**

Manufacturer	Manufacturer's rank to market	Dates orders placed	Number of vaccine doses ordered	Price per dose	Date when at least 75% of order received
Manufacturer #1	First	May 3/ June 23	50,000	\$2.49	October 3
Manufacturer #2	Second	May 1	40,000	\$2.37	October 25
Manufacturer #3	Third	May 1/ June 23	35,030	\$2.37	December 20

Source: Manufacturers' rank based on data provided by influenza vaccine manufacturers. Alabama's specific order information based on data from the state of Alabama's Department of Public Health.

The 2000-01 experience illustrates the fragility of the vaccine supply. Because influenza virus strains take a certain period of time to grow, the process cannot be accelerated to make up for lost time. When manufacturers found that one strain for the vaccine was harder to produce than expected, they adjusted their procedures to achieve acceptable yields, but it still took months to produce.<sup>8</sup> Because only three manufacturers remain, the difficulties associated with vaccine production, and the need to formulate a new vaccine involving one or more new strains each year, the future vaccine supply is uncertain. Problems at one or more manufacturers can significantly upset the traditional fall delivery of influenza vaccine.

<sup>7</sup>These included nearly 1,000 orders from state health departments, city and county health departments, and other public institutions such as hospitals, universities, and prisons.

<sup>8</sup>While each manufacturer produces the same three strains as the others for the annual influenza vaccine, each manufacturer has its own production processes. As a result, one manufacturer's experience in producing a particular strain can differ from another manufacturer's experience with the same strain.

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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 bidder during this time rather than filling lower-priced orders they had already received. According to distributors, and purchasers, a vaccine order’s price, quantity, and delivery might not be guaranteed. When no guarantee or meaningful penalty applies, orders can be cancelled or cut and deliveries can be delayed when vaccine is in short supply.<sup>9</sup>

Because of the production delays, many purchasers found themselves with little or no vaccine when the peak time came for vaccinations. Many of these purchasers had ordered vaccine months earlier at agreed-upon prices, with delivery scheduled for early fall. While some orders were cancelled outright or cut substantially, many purchasers were told that the vaccine was still being produced and that their full order would be delayed but delivered as soon as possible. This left many purchasers with a choice: they could take a risk and wait for the vaccine they had ordered, or they could try to find vaccine immediately to better ensure that patients were vaccinated before the flu season struck. Most of the physician groups and state health departments that we contacted reported that they waited for delivery of their early orders.<sup>10</sup> For example, of the 53 physician group practices we surveyed that ordered vaccine before the end of June 2000, 34 groups waited for delivery of these original orders.<sup>11</sup>

Those who purchased vaccine in the fall—because they did not want to wait for their early orders to be delivered later, had orders canceled or reduced, or just ordered later—found themselves paying much higher prices. The following examples illustrate the higher prices paid to make up for reduced orders or delayed delivery:

- The state of Hawaii initially ordered 12,000 doses of vaccine from one distributor in June at \$2.80 per dose. When the distributor cut the order

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<sup>9</sup>Alternatively, if meaningful guarantees or penalties are in place, manufacturers and distributors may have less flexibility to redirect vaccine in the event of a shortage.

<sup>10</sup>Some state health officials, such as those in New York and Delaware, also ordered additional vaccine to counter the potential effects of availability problems.

<sup>11</sup>The 34 physician groups placed 36 orders before the end of June 2000 that resulted in shipments. They waited until November 2000 or later to receive the first shipments for most of these orders.

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by one-third, the state purchased vaccine from another distributor in September at a price between \$5.00 and \$6.00 per dose.

- One physician practice ordered flu vaccine from a supplier in April 2000 at \$2.87 per dose. When it received none of that vaccine 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. By the first of December, 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.

The data we collected from 58 physician group practices around the country provide another indication of how prices spiked during the period of high demand in October and November. Overall, the price paid by these practices averaged \$3.71 per dose. However, as table 2 shows, the average price paid for orders placed by these practices in October and November was about \$7 per dose, compared with about \$3 per dose for advance orders placed in June or before.

**Table 2: Prices Paid for Influenza Vaccine by Physician Groups Surveyed by GAO**

<b>Date order was placed</b>	<b>Range of price per dose</b>	<b>Average price per dose</b>
June 2000 and earlier	\$1.90 to \$6.35	\$2.90
July through September 2000	\$2.27 to \$4.90	\$4.01
October and November 2000	\$2.50 to \$12.80	\$6.98
December 2000 and later	\$1.50 to \$10.80	\$3.48

Note: The 58 physician group practices we surveyed purchased a total of 89,245 doses of flu vaccine during the 2000-01 season. This table is based on prices the groups paid for nearly 77,000 doses of vaccine received in multidose vials. (The groups received a total of 77,240 doses of vaccine in vials, but 350 doses were provided at no cost by a state health department and for 200 doses the price was not known.) The physician groups also received 12,005 doses of vaccine in prefilled syringes, which are excluded from this table because vaccine in prefilled syringes costs roughly double the price per dose of vaccine sold in vials.

While some vaccine was available to those willing to pay a higher price in October and November, some purchasers trying to buy vaccine reported that they were unable to find vaccine from any supplier at any price during that time. For example, one large health maintenance organization told us that when delivery of its early order was delayed, it could not find any source with the large number of doses it needed and ended up waiting until November and December for delivery of more than a million doses it had ordered in the spring.

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

Vaccine prices came down as a large quantity of vaccine was delivered in December, after the prime period for flu vaccinations had passed. Vaccine became increasingly available in December and manufacturers and distributors delivered the orders or parts of orders that had been postponed. In addition, recognizing the potential shortfall in production, CDC contracted in September 2000 with one manufacturer to extend production into late December for 9 million additional doses.<sup>12</sup> Providers buying vaccine in December could do so at prices similar to those in place during the spring and summer. Among the physician groups we contacted, none of which ordered under the CDC contract, the price for orders placed in December or later averaged about \$3.50 per dose—somewhat above the average price paid through June, but about half of the average price of orders placed in October and November.

Although vaccine was plentiful by December, fewer people were seeking flu shots at that time. According to manufacturers and several large distributors, demand for influenza vaccine typically drops by November and it is difficult to sell vaccine after Thanksgiving. Despite efforts by CDC and other public health officials to encourage people to obtain flu shots later in the 2000-01 season, providers and other purchasers still reported a drop in demand for flu shots in December 2000.

A reason people did not continue to seek flu shots in December and later may have been that the 2000-01 flu season was unusually light. Data collected by CDC's surveillance system showed relatively low influenza activity and mortality. While mortality due to influenza and pneumonia—one indicator of the severity of a flu season—had surpassed CDC's influenza epidemic thresholds every year since 1991, it had not done so by April of the 2000-01 season.<sup>13</sup> Had a flu epidemic hit in the fall or early winter, the demand for influenza vaccine may have increased substantially.

As a result of the waning demand, manufacturers and distributors reported having more vaccine than they could sell. Manufacturers reported shipping about 70 million doses, or about 9 percent less than the previous year. More than 7 million additional doses produced under the CDC contract

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<sup>12</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-sector purchasers and \$5.00 per dose for private-sector purchasers.

<sup>13</sup>CDC monitors influenza activity through May of each year.

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were never shipped at all because of lack of demand. None of the physician practices that we contacted had ordered from the CDC contract, mainly because they were waiting for earlier orders to arrive or they had already received some or all of their vaccine. In addition, some physicians' offices, employee health clinics, and other organizations that administered flu shots reported having unused doses in December and later. For example, the state of Oklahoma reported having more than 75,000 unused doses of vaccine.

While it is difficult to determine if any of these events will affect the price of vaccine in the future, prices for early orders for the upcoming 2001-02 flu season have increased substantially over prior years' prices. Physician practices, state public health departments, and other purchasers reported that their suppliers are quoting prices of \$4 to \$5 per dose, or about 50 to 100 percent higher than the early order prices for the 2000-01 season. Citing expenses associated with expanding the production capacity and the costs of maintaining a modern and compliant facility, one manufacturer notified customers of a significant price increase for 2001-02.

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

There is no mechanism currently in place to distribute flu vaccine to high-risk individuals before others. In a typical year, there is enough vaccine available in the fall to give a flu shot to anyone who wants one. 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 people. Lacking information to identify which orders should be filled first to serve the population most in need, manufacturers and distributors who did attempt to target higher-risk persons used a variety of approaches to distribute the limited vaccine. According to public health officials and providers, there was confusion in many communities as some providers were able to administer flu shots to anyone requesting one, while at the same time, other providers had no vaccine for even their highest-risk patients.

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## Influenza Vaccine Is Distributed Through Multiple Channels

Like other pharmaceutical products, influenza vaccine is distributed largely through multiple channels in the private sector that have evolved to meet the specific needs of different types of purchasers. Those selling and delivering vaccine include the manufacturers themselves, distributors of general medical supplies and pharmaceuticals, and other types of resellers such as pharmacies. According to data from the manufacturers, about half

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of all flu vaccine is purchased by providers directly from manufacturers and roughly half is purchased through distributors and resellers.

As a general practice, manufacturers said they pre-sell almost all of their planned production volume by May or June of each year. Major distributors and other large volume purchasers, including state health departments, can obtain the most favorable prices by ordering directly from manufacturers during this early order period. The distributors and other resellers can then offer smaller purchasers such as physicians' offices the convenience and flexibility of buying flu vaccine along with their other medical supplies. Most experts we interviewed agreed that when the supply of vaccine is sufficient, reliance on these varied distribution channels allows for the successful delivery of a large volume of influenza vaccine in time for the annual fall vaccination period.

Providers of flu vaccine also represent a diverse group. The annual influenza vaccine is widely available as a convenience item outside the usual medical settings of physicians' offices, clinics, and hospitals. Millions of individuals, including those who are not at high risk, receive flu shots where they work or in retail outlets such as drugstores and grocery stores. Some of these providers order their own flu vaccine from a manufacturer or distributor, others participate in different types of purchasing groups, and others contract with organizations such as visiting nurse agencies to come in and administer the vaccine.

The widespread availability of flu shots at both traditional medical settings and at convenience locations where people shop, work, and play may contribute to increased immunization rates. HHS survey data show that between 1989 and 1999, influenza immunization rates more than doubled for individuals aged 65 and older (see table 3). During that same period, however, immunization rates increased more than five-fold for the 18-49 year age group, which includes individuals who are likely to be at lower risk and to receive flu shots in nonclinical settings.

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**Table 3: Percentage of Population Receiving Influenza Vaccination**

Age group	Percent vaccinated		
	1989	1995	1999
18-49 years	3.4	13.1	18.8
50-64 years	10.6	27.0	35.8
65 years and older	30.4	58.2	66.9

Sources: CDC's 1989 and 1995 National Health Interview Surveys and 1999 Behavioral Risk Factor Surveillance System data.

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## Availability of Vaccine for Mass Immunization Campaigns Created Controversy

While access to flu shots in a wide range of settings is an established mass immunization strategy, some physicians and public health officials view it as less than ideal for targeting high-risk individuals. Because of the expected delay or possible shortage of vaccine for the 2000-01 season, CDC and ACIP recommended in July 2000 that mass immunization campaigns be delayed until early to mid-November.<sup>14</sup> CDC issued updated 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 who care for them. Regarding mass immunization campaigns, these updated guidelines stated that while efforts should be made to increase participation by high-risk persons and their household contacts, other persons should not be turned away.<sup>15</sup>

Although some vaccination campaigns open to both high-risk and lower-risk individuals were delayed as recommended by CDC, many private physicians and public health departments raised concerns that they did not have vaccine to serve their high-risk patients at the time these campaigns were underway. The following are a few examples of promotional campaigns held across the nation that created controversy:

- One radio station sponsored a promotional event where a flu shot and a beer were available at a local restaurant and bar for \$10 to whoever wanted one.
- One grocery store chain offered a discounted flu shot for anyone bringing in three soup can labels.
- Flu shots were available for purchase at a professional football stadium to all fans attending the game.

We interviewed several retail outlets and employers and the companies they contract with to conduct mass immunization clinics. While some reported that they disseminated information on who was at high risk and stressed the need for priority vaccination among high-risk groups, they generally did not screen flu shot recipients for risk. The perspective of

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<sup>14</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>15</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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these companies 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, because physicians' offices would have difficulty vaccinating all high-risk individuals during the optimal time period of October through mid-November. Other organizations held flu clinics open to lower-risk individuals in the early fall before realizing the extent of the vaccine supply problems.

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

Because there generally has been enough vaccine to meet demand in recent years, there was little practical need for the fragmented distribution process to develop the capability to determine which purchasers might merit priority deliveries based on serving high-risk individuals. When the supply of vaccine was delayed in the fall of 2000, 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 the ACIP's July and October 2000 recommendations to vaccinate high-risk groups first. Although some types of providers are more likely than others to serve high-risk individuals, it is likely that all types of providers serve at least some high-risk individuals. CDC and ACIP did not provide guidance about how to implement priority deliveries, and manufacturers and some distributors reported that they often did not have enough information about their customer base to make such decisions. As a result, they reported using various approaches in distributing their vaccine.<sup>16</sup>

- One manufacturer reported that it initially followed its usual policies of distributing vaccine on the basis of initial order date—that is, orders were filled on a first in, first out basis—and honoring contracts with specific delivery dates. According to the manufacturer, a few contracts in which purchasers paid a premium price for an early delivery date received priority in distribution. However, less than halfway through its season's distribution, this company notified customers at the end of October that it changed its policy in order to make partial shipments to all purchasers as a way of ensuring more equitable treatment for all.

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<sup>16</sup>In addition to their specific approaches to distributing vaccine, two manufacturers also sent letters notifying customers of the delays in distribution and the recommendations by CDC and ACIP for the 2000-01 flu season.

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- One manufacturer reported that it first shipped vaccine to nursing home customers (where such customers could be identified) and then made partial shipments to other customers.
  - One manufacturer sold all of its vaccine in the United States through one distributor. That distributor, which also sold vaccine from the other manufacturers, told us that it attempted to give priority to orders from physicians and then orders from state and local governments.

Other distributors we contacted also used varied approaches to distribute vaccine in 2000. For example, officials from one large medical supply distributor said that after a manufacturer cut its order substantially, the distributor gave priority to the medical practices that ordered early. The distributor reported that it cancelled all orders from resellers and pharmacies, cancelled all orders that came in after June 21, and reduced all orders from medical practices that came in before June 21 by an equal percentage. Another medical supply distributor said it did not sell vaccine to any providers that were not regular customers until it had filled the early orders of its regular customers. Officials from the Health Industry Distributors Association, a national trade association representing medical products distributors, said that distributors are limited in their ability to target certain types of people because they can only target distribution by type of provider, such as physicians' offices, nursing homes, or hospitals. 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.

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### Attempts to Target High-Risk Groups Were Complicated by the Variety of Distribution Channels

The success of these various approaches to reach high-risk groups was limited by the wide variety of paths the vaccine takes from the manufacturers to the providers who administer the flu shots. For example, although one manufacturer shipped available vaccine to the nursing homes it could identify in its customer base as first priority, this did not ensure that all nursing homes received vaccine for their high-risk patients on a priority basis. State health officials reported that nursing homes often purchase their flu vaccine from local pharmacies or rely on public health officials to provide the vaccine. In those cases, how quickly nursing homes received vaccine for their high-risk residents depended on the practices along the distribution chain—in some cases involving the practices of manufacturers, distributors, pharmacies, and public health providers.

Physicians also reported that they did not receive priority, even though nearly two-thirds of the elderly who had flu shots in 1998-99 received them in medical offices.<sup>17</sup> The American Medical Association and other physicians told us that in some communities vaccine was available at retail outlets and other sources before physicians' offices. The 58 physician group practices we surveyed, which received nearly 90,000 doses from manufacturers, distributors, and other resellers reported receiving their vaccine at about the same time or slightly later than when manufacturers shipped more than 70 million doses (see table 4). Thus as a group these physician practices appeared to experience no priority in vaccine distribution.

**Table 4: Percentage of Influenza Vaccine Shipped by Manufacturers Compared With Percentage Received by Surveyed Physician Groups, by Month, 2000-01 Flu Season**

	Month shipped/received			
	September 2000 and earlier	October 2000	November 2000	December 2000 and later
Vaccine shipped by manufacturers	20	19	29	31
Vaccine received from all sources by surveyed physician groups	20	18	25	38

Note: Percentages may not total 100 percent because of rounding. Table does not include over 7 million unsold and unshipped doses retained by manufacturers. Vaccine received by physician groups includes vaccine in vials and prefilled syringes from all sources.

Source: Vaccine shipped by manufacturers based on data provided by influenza vaccine manufacturers. Vaccine received by physician groups based on data from GAO's survey of 58 physician group practices.

<sup>17</sup>Data collected by states through the CDC Behavioral Risk Factor Surveillance System during 1999 indicated that among persons aged 65 years or older reporting receipt of influenza vaccine in the past 12 months, about 63 percent reported receiving their last influenza vaccination at physicians' offices and health maintenance organizations; followed by other types of clinics (9 percent); senior, recreation, or community centers (7 percent); health departments (6 percent); hospitals (6 percent); stores (5 percent); workplaces (1 percent); and other locations (2 percent).

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## HHS Has Initiatives Under Way to Prepare for Future Vaccine Delays and Shortages

While HHS has no direct control over how influenza vaccine is purchased and distributed by the private sector and local governments during the annual influenza season, it has several initiatives under way to help mitigate the adverse effects of any future shortages and delays.<sup>18</sup> Success of these various efforts, however, relies on collaboration between the public and private sectors. Completion of HHS' national plan to respond to an influenza pandemic could help foster this type of collaboration and provide a foundation to deal with vaccine shortages or delays in non-pandemic years. In the meantime, increasing immunization rates against pneumococcal pneumonia, which can follow the flu, may help reduce influenza-related illness and death.

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## Several Initiatives Undertaken in Response to the 2000-01 Flu Season

In response to the production and distribution problems experienced with flu vaccine for the 2000-01 flu season, HHS has undertaken several initiatives. As shown in table 5, these initiatives include (1) conducting clinical trials on the feasibility of using smaller doses of vaccine for healthy 18- to 49-year-olds, (2) working with public and private sector entities involved in vaccine distribution to explore ways of better targeting vaccine to high-risk groups, (3) recommending state and local health department actions to prepare for a vaccine delay or shortage, and (4) revising guidelines to expand the recommended timing of influenza immunizations.

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<sup>18</sup>Under the Federal Food, Drug and Cosmetic Act, FDA has only 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 does not apply to wholesale distributors, who are excluded from the definition of health care entities.

**Table 5: HHS Initiatives in Response to the 2000-01 Flu Season**

<b>Initiative</b>	<b>How this would help</b>	<b>Status</b>
The National Institutes of Health, working with FDA and CDC, conducted a clinical trial to evaluate the immune responses in healthy adults aged 18-49 years who received a half-dose of vaccine.	Reducing the dosage of vaccine given to healthy adults may be an acceptable strategy to increase the number of doses available in the event of shortages.	Preliminary results that were disseminated in October 2000 indicated that a half-dose of one manufacturer's vaccine appears to offer an acceptable level of protection for healthy adults aged 18-49 years. Final results are due in the fall of 2001.
Discussion among private- and public-sector entities involved in vaccine distribution regarding options to improve distribution of influenza vaccine when in short supply.	Private- and public-sector entities involved with vaccine distribution could agree to consistent strategies and approaches to direct vaccine to high-risk groups in times of delay or shortage.	On March 27, 2001, CDC and the American Medical Association cosponsored a meeting with representatives from physician groups, manufacturers, distributors, and public health officials to discuss the problems experienced in 2000-01 and distribution of flu vaccine in the event of a future shortage.
Recommending state and local government actions and requesting that states develop draft contingency plans to maximize influenza vaccination in the event of a delay or shortage of vaccine.	State and local health officials could work with private- and public-sector entities involved in providing vaccine to develop strategies and approaches to direct vaccine to high-risk groups if a vaccine delay or shortfall occurred.	CDC has recommended actions for state and local health departments. These include developing contingency plans to address delays in distribution or shortages of vaccine if they occur and collaborating with other groups or coalitions involved in adult immunization efforts. CDC requested that states provide draft plans before June 2001.
Revising guidelines on timing of influenza vaccination to extend the optimal time for vaccination after mid-November.	Extending the demand past mid-November could help during temporary shortages. Most flu seasons do not peak until late December through early March and vaccine can be an effective intervention if given 2 weeks before exposure.	CDC's ACIP issued revised guidelines for the 2001-02 flu season on April 20, 2001. These guidelines extend the optimal time for vaccination through the end of November.

Success of these initiatives relies to a great extent on the willingness of manufacturers, distributors, private physicians, other vaccine providers, and the public to cooperate. For example, if manufacturers requested and FDA approved the use of half-doses of vaccine for certain healthy adults while full-doses of vaccine were given to high-risk adults, implementation strategies may have to address provider concerns about any associated administrative burden. And if distribution guidelines are agreed upon and implemented, vaccine sellers may have to sacrifice the additional revenue of selling to those willing to pay higher prices regardless of relative need.

The importance of collaboration between the public and private sector to develop and implement initiatives to address flu vaccine shortages at the state and local level was highlighted by state public health officials we interviewed. States where public- and private-sector entities collaborated

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early to deal with the delay in vaccine shipments reported some success in targeting high-risk people for vaccination. For example:

- Before the fall 2000 vaccination period, health officials in Utah had partnered with Medicare's local Peer Review Organization (PRO) and a private managed care organization and others to form an Adult Immunization Coalition.<sup>19</sup> This coalition had already identified the number and location of high-risk people living in the state and worked to target vaccine first to these locations.
- New Mexico health officials participated in a consortium with public and private providers that purchased about 90 percent of vaccine in the state. After nursing home residents were vaccinated, this consortium implemented a three-tiered vaccination strategy. This strategy first targeted the elderly, people with chronic disease and health care workers. Next it targeted household members or close contacts of the first group. Finally, it targeted vaccine to everyone else.

CDC officials acknowledge that outreach and educational efforts are needed to change the behavior of both providers and the public to recognize the benefit of flu shots administered after mid-November. For the 2000-01 flu season, CDC undertook several outreach and educational efforts, including issuing guidelines and notices in its *Morbidity and Mortality Weekly Report*, posting information on a CDC web site, and conducting a media campaign in selected cities. However, the relative effectiveness of these various efforts remains unknown.<sup>20</sup>

In addition, CDC has planned various projects to evaluate the impact of the delay of flu vaccine availability on immunization rates and the vaccination practices of providers for the 2000-01 season. For example, CDC is surveying providers about the risk level of the people they vaccinated, providers' responses to the delays in obtaining vaccine, and the methods they used to target vaccinations.

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<sup>19</sup>PROs promote quality of care improvements for Medicare beneficiaries in every state.

<sup>20</sup>One example of the difficulties of outreach to provider groups is that fewer than half of the 58 physician group practices we contacted had heard about the CDC contract that made available 9 million doses in December.

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## Pandemic Response Plan Is Still Incomplete

HHS has been working since 1993 to develop a national response plan that would outline actions to be taken to address vaccine delays or shortages during an influenza pandemic.<sup>21</sup> While such a plan is expected to be used only in cases of public health emergencies, advance preparation by manufacturers, distributors, physicians, and public health officials to respond to a pandemic could provide a foundation to deal with some of the problems experienced during the 2000-01 flu season. For example, while some manufacturers and distributors tried various methods to target vaccine first to people who were at high risk for complications, they were often unable to identify these populations. The development of a methodology to identify and target various population groups under the pandemic plan could be a useful tool in this regard. In addition, pandemic planning activities could build collaborative relationships among affected parties that could be useful in dealing with vaccine shortages in non-pandemic years. As we reported in October 2000, HHS has not completed a national pandemic response plan that would, among other things, address how to deal with shortages of vaccine.<sup>22</sup> While HHS has set a completion date of June 2001 for the body of the plan, it has not set specific dates for completing the detailed appendixes needed to implement the plan should vaccine be delayed or in short supply.

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## Increased Pneumococcal Immunizations Could Mitigate the Impact of an Influenza Vaccine Shortage

Another ongoing HHS effort that could mitigate the impact of an influenza vaccine shortage is to increase adult immunization rates against pneumococcal disease, which causes a type of pneumonia that frequently follows influenza.<sup>23</sup> The population most at risk for pneumococcal pneumonia includes the elderly and those with chronic illnesses—the same groups at high-risk for complications or death following infection with influenza. Because pneumococcal vaccine provides immunity for at least 5 to 10 years, it can provide some protection against one of the serious complications associated with influenza if the annual influenza vaccine is unavailable.

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<sup>21</sup>Occasionally, worldwide influenza epidemics—called pandemics—cause exceptionally high levels of illness and mortality in the population. The worst flu pandemic occurred in 1918 and killed half a million U.S. citizens. More recent pandemics occurring in 1957 and 1968 were responsible for 70,000 and 34,000 U.S. deaths, respectively.

<sup>22</sup>See *Influenza Pandemic: Plan Needed for Federal and State Response* (GAO-01-4, Oct. 2000).

<sup>23</sup>CDC officials generally attribute about one-third of the 20,000 flu-related deaths each year to influenza-related pneumonia, and most of these deaths are attributed to a type of bacterial pneumonia that may be prevented with the pneumococcal vaccine.

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Although pneumococcal vaccine provides added protection against a major influenza-related illness, widespread use among the high-risk population remains relatively low. HHS has set its goal for 2010 to achieve 90 percent immunization against pneumococcal disease among the elderly and 60 percent among other high-risk adults.<sup>24</sup> Available data show that only 54 percent of the elderly and 13 percent of younger high-risk adults have been vaccinated against pneumococcal disease.<sup>25</sup> For the population 65 years and older, HCFA, which administers the Medicare program, has activities directed toward increasing both pneumococcal and influenza vaccination rates. For example, HCFA has contracted with its 53 PROs to work within communities to raise immunization rates. The extent that state immunization rates for pneumococcal vaccine and influenza vaccine improve over time is a factor that HCFA will consider in evaluating PRO performance.

CDC also supports efforts to increase adult immunizations, such as influenza and pneumococcal immunizations, for people aged 65 and older and others with medical conditions placing them at high risk for influenza and pneumococcal pneumonia. In 2001, CDC awarded \$159 million for Preventive Health Services Immunization grants to support state infrastructures for childhood and adult immunization. However, because CDC considers activities to support childhood immunization a priority for these grants, only 5 of the 64 grantees targeted more than 10 percent of grant funds to support adult immunization efforts.

While HCFA and CDC have taken some steps to coordinate many of their adult immunization activities, including efforts to increase pneumococcal immunization, their performance goals may differ. For example, in their fiscal year 2001 performance plans, HCFA set a target of vaccinating 55 percent of those 65 years and older against pneumococcal disease, while CDC set a more ambitious target of 63 percent.

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<sup>24</sup>For the year 2000, HHS had set a target of 60 percent immunization against pneumococcal disease among noninstitutionalized people aged 65 and older.

<sup>25</sup>The estimated rate for those aged 65 and older is based on preliminary data from CDC's 1999 Behavioral Risk Factor Surveillance System. The estimated rate for the high-risk population aged 18-64 years is based on 1998 baseline data from CDC's National Health Interview Survey, as reported in Department of Health and Human Services, "Immunization and Infectious Diseases," *Healthy People 2010*, Second Edition, November 2000.

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## Conclusions

The circumstances that led to the delay and early shortage of flu vaccine during the 2000-01 flu season could repeat themselves in the future. Ensuring an adequate and timely supply of vaccine, already a difficult task given the current 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 impact overall vaccine availability. The effects of production delays in 2000-01 were exacerbated by the expectation of providers and the public that flu shots should be received by Thanksgiving or not at all, even though a flu shot after this time would provide a reasonable level of protection in most years. In the event of a future delay or shortage, determining the most effective means of changing this traditional behavior will be beneficial.

The purchase, distribution, and administration of flu vaccine are mainly private-sector responsibilities. Consequently, HHS' actions to help mitigate any adverse effects of vaccine delays or shortages need to rely to a great extent on collaboration with private-sector participants. By completing its own planning efforts for dealing with these issues during a pandemic, as we previously recommended, HHS would provide a foundation for building collaboration among suppliers and purchasers of flu vaccine that could help improve the vaccine distribution process. The March 2001 meeting with public health officials, vaccine manufacturers, distributors, physicians, and others is a potentially useful first step towards developing voluntary guidelines for distribution in the event of a future delay or shortage, but more work is needed before consensus is achieved. Success is contingent on consensus and continued commitment by all parties.

In addition, to maximize results federal and state agencies need to fully coordinate their pneumococcal vaccination efforts to set and achieve common goals. While pneumococcal vaccination is not a substitute for the annual flu shot, it can provide protection against a major complication of influenza if the flu vaccine is not available. In the event that future shortages of influenza vaccine cannot be avoided, coordination among HCFA, CDC, and state programs designed to increase pneumococcal immunizations now may contribute to lowering future hospitalization and death rates due to influenza-related pneumonia.

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## Recommendations for Executive Action

We recommend that the Secretary of HHS take the following actions:

- To prepare for potential delays or shortages in flu vaccine, instruct the Director of CDC to assess the relative success of its past outreach and

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education efforts and identify those means that are most effective in changing behavior to meet public health priorities. When appropriate, these means should be used as the primary method to educate flu vaccine providers and the general public well before the start of the traditional fall vaccination period.

- To improve response to future vaccine delays or shortages, instruct the Director of CDC to continue to take a leadership role in organizing and supporting efforts to bring together all stakeholders to formulate voluntary guidelines for vaccine distribution. Specifically, in formulating guidelines for getting vaccine to high-risk individuals first in times of need, work with stakeholders to pursue the feasibility of steps that showed promise in the 2000-01 flu season.
- To maximize use of federal resources, instruct the Director of CDC to work to complement HCFA's ongoing activities to improve pneumococcal immunization rates among the Medicare population and focus CDC's funded efforts on increasing pneumococcal immunization in the high-risk non-Medicare population.

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## Agency Comments

We provided a draft of this report to HHS for review. In its written comments (see app. II), HHS identified actions that it had initiated or planned to undertake related to two of our recommendations. For example, HHS stated that CDC had efforts underway to assess the relative success of the outreach and educational efforts for the 2000-01 flu season, and that it was working with stakeholders to try to develop contingency plans for vaccine distribution in the event of future supply problems. Regarding our third recommendation, HHS stated that pneumococcal immunization could be part of a broader plan for the government to reduce the overall impact of influenza in case of vaccine supply problems.

HHS also commented that our draft report overstated HHS' authority to exercise greater control over vaccine purchase and distribution in the event of a public health emergency such as an influenza pandemic. We have revised the report language to better reflect our point, which was not about the extent of HHS' authority to respond to a pandemic, but rather about using pandemic planning activities to better prepare for vaccine shortages in non-pandemic years as well. HHS also provided technical comments, which we incorporated where appropriate.

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We are sending copies of this report to the Honorable Tommy G. Thompson, Secretary of HHS; the Honorable Jeffrey P. Koplan, Director of CDC; the Honorable Bernard A. Schwetz, Acting Principal Deputy Commissioner of FDA; Michael McMullan, Acting Deputy Administrator of

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HCFA; Martin G. Myers, Director of NVPO; and others who are interested. We will also make copies available to others on request.

If you or your staffs have any questions, please contact me at (202) 512-7119. An additional GAO contact and the names of other staff who made major contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Janet Heinrich". The signature is written in a cursive, flowing style.

Janet Heinrich  
Director, Health Care—Public Health Issues

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*List of Requesters*

The Honorable Tim Johnson  
The Honorable Ron Wyden  
United States Senate

The Honorable Sherrod Brown  
The Honorable Lois Capps  
The Honorable Gary A. Condit  
The Honorable Joseph Crowley  
The Honorable Peter A. DeFazio  
The Honorable Lloyd Doggett  
The Honorable Jo Ann Emerson  
The Honorable Bob Filner  
The Honorable Martin Frost  
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The Honorable Thomas C. Sawyer  
The Honorable Janice D. Schakowsky  
The Honorable Christopher H. Smith  
The Honorable Fortney Pete Stark  
The Honorable Mike Thompson  
The Honorable Tom Udall  
The Honorable Henry A. Waxman  
The Honorable Anthony D. Weiner  
House of Representatives

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# Appendix I: CDC Advisory Committee Recommendations on Target Groups for Influenza Vaccination, 2000-01

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For the 2000-01 flu season, the CDC Advisory Committee on Immunization Practices (ACIP) issued guidance in April 2000 that strongly recommended influenza vaccination for those persons who—because of age or underlying medical condition—are at increased risk for complications of influenza. For the first time, the committee lowered the age for universal vaccination from 65 years to 50 years of age, adding an estimated 28 to 31 million persons to the target population. The reason for this expansion was to increase vaccination rates among persons aged 50-64 with high-risk conditions, since age-based strategies have been more successful than strategies based on medical condition. The committee also recommended that health-care workers and other individuals in close contact with persons in high-risk groups should be vaccinated to decrease the risk of transmitting influenza to persons at high risk.

Because of expected delays or possible shortages of influenza vaccine for the 2000-01 flu season, the committee issued adjunct recommendations on July 14, 2000. In addition to recommending that mass immunization campaigns be delayed, these adjunct recommendations said that (1) vaccination of high-risk individuals should proceed with available vaccine, (2) provider-specific contingency plans should be developed for possible vaccine shortages, and (3) vaccine administered after mid-November can still provide substantial benefits.

Updated recommendations were issued on October 6, 2000, stating that a shortage had been averted but distribution would be delayed. These updated recommendations placed highest priority on those persons aged 65 and older, pregnant women and those persons with chronic health conditions that placed them at high risk, and health care workers who care for them. Table 6 shows the target groups for influenza immunization from these updated recommendations. The update also recommended that mass vaccination campaigns should be scheduled later in the season and that these campaigns should try to enhance coverage among those at greatest risk for complications of influenza and their household contacts. However, the recommendations stated that other persons should not be turned away. The updated recommendations also emphasized that special efforts should be made in December and later to vaccinate persons aged 50-64 and that vaccination efforts for all groups should continue into December and later when vaccine was available.

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**Appendix I: CDC Advisory Committee  
Recommendations on Target Groups for  
Influenza Vaccination, 2000-01**

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**Table 6: Updated ACIP Recommendations on Target Groups for Influenza Immunization, 2000-01**

<b>Target group</b>	<b>Estimated population</b>
All persons aged 65 and older	35 million
Persons under age 65 with chronic underlying medical conditions	33-39 million
Residents of nursing homes and other chronic-care facilities	2 million
Pregnant women (in 2nd or 3rd trimester during the flu season)	2 million
Health care workers	7-8 million
Close contacts of those at high risk	40-60 million

Note: Categories are not mutually exclusive.

Source: 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; CDC, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, Vol. 49, No. RR-3 (April 14, 2000), pp. 1-38; and National Immunization Program, CDC, unpublished data, 2000.

# Appendix II: Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 8 2001

Ms. Janet Heinrich  
Director, Health Care--Public  
Health Issues  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft report, "Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Michael Mangano".

Michael F. Mangano  
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

**Comments of the Department of Health and Human Services  
on the General Accounting Office Draft Report,  
“Flu Vaccine: Supply Problems Heighten Need to Ensure Access  
for High-Risk People”**

The Department of Health and Human Services thanks the General Accounting Office (GAO) for providing the opportunity to review their draft report. In addition to the responses to the recommendations, we have a number of more general comments regarding the draft report.

General Comments

As GAO acknowledges, the purchase, distribution, and administration of flu vaccine are mainly private-sector responsibilities. The vast majority of vaccine flows directly from the manufacturers through distributors to private providers for distribution to the general public. The Department can recommend and encourage providers to immunize high-risk patients first, but does not have any control over the distribution of vaccine, other than the small amount which is distributed through public health departments.<sup>1</sup> As this is a key issue, the Department believes that the following sentence should be placed prominently in the “Results in Brief” section: “The purchase, distribution, and administration of flu vaccine are mainly private sector responsibilities.”

The Department agrees with GAO’s analysis that, despite being a private sector program, substantial efforts have been made by the Department to address future influenza immunization concerns. As GAO notes, the Department’s Centers for Disease Control and Prevention (CDC) is working proactively with the FDA, manufacturers, distributors, State and local health departments and other key partners. We have requested that States develop and submit written plans to CDC for dealing with any influenza vaccine delays or shortfalls in the 2001-02 season. In addition, CDC has developed a comprehensive communications and public information strategy using findings from recent focus groups and other experiences of the 2000-01 season.

High-risk African American and Hispanic American populations required special emphasis last fall not only because disparities exist, but because this was an important element of increasing coverage among those at highest risk (for example, people 65 and older). It seems appropriate to emphasize that this is an important and needed element when there are delays or shortages in the availability of influenza vaccine.

We believe that GAO has overstated the Department’s authority regarding control over vaccine purchase and distribution in the event of an influenza pandemic (see footnote 15). We suggest the following change to the third sentence of the first paragraph on page 19: “Currently, HHS is reviewing its authority to purchase and distribute vaccine in the event of an influenza pandemic.”

<sup>1</sup> Under the Federal Food, Drug, and Cosmetic Act, the Department’s Food and Drug Administration (FDA) does have limited authority to regulate the resale of prescription drugs, including influenza vaccine, which have been purchased by a public or private hospital or other health care entity.

GAO Recommendation

We recommend that the Secretary of HHS take the following actions:

To prepare for potential delays or shortages in flu vaccine, instruct the Director of CDC to assess the relative success of its past outreach and education efforts and identify those means that are most effective in changing behavior to meet public health priorities. When appropriate, these means should be used as the primary method to educate flu vaccine providers and the general public well before the start of the traditional fall vaccination period.

Department Comment

The CDC is working on assessing the relative success of last fall's (2000-01 season) outreach and education efforts. The CDC will continue their research and evaluation efforts to identify the most effective means of changing behavior to meet public health priorities.

GAO Recommendation

To improve response to future vaccine delays or shortages, instruct the Director of CDC to continue to take a leadership role in organizing and supporting efforts to bring together all stakeholders to formulate voluntary guidelines for vaccine distribution. Specifically, in formulating guidelines for getting vaccine to high-risk individuals first in times of need, work with stakeholders to pursue the feasibility of steps that showed promise in the 2000-01 flu season.

Department Comment

The CDC has made substantial progress in working with stakeholders in the development of contingency plans, including obtaining agreement from a manufacturer to voluntarily redistribute some amount of their vaccine to high-risk customers of a manufacturer that does not produce vaccine, if that should occur. In addition, CDC has provided guidance to States for the development of contingency plans which the States have been asked to prepare and submit to CDC by the end of May. The CDC will hold a workshop at their National Immunization Conference to focus on these plans.

GAO Recommendation

To maximize use of federal resources, instruct the Director of CDC to work to complement HCFA's ongoing activities to improve pneumococcal immunization rates among the Medicare population and focus CDC's funded efforts on increasing pneumococcal immunization in the high-risk non-Medicare population.

Department Comment

The CDC supports the efforts to use pneumococcal vaccine more widely. However, it is more important to have influenza vaccine available as a preventive tool for pneumococcal disease than vice versa. The vaccine has been shown to have separate and additive effects in some studies. Pneumococcal immunization could be one part of a broader plan for the Government to find ways to reduce the overall impact of influenza in case of influenza vaccine supply problems. In addition, GAO should recognize that while needing improvements, pneumococcal immunization rates for persons 65 or older have significantly increased over recent years, from 29 percent in 1993 to 54 percent in 1999, according to the Behavioral Risk Factor Surveillance Survey. The CDC will continue efforts to reach the Healthy People 2010 goal of 90 percent.

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

Frank C. Pasquier, (206) 287-4861

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## Staff Acknowledgments

Other major contributors to this report were Lacinda Ayers, George Bogart, Ellen M. Smith, Stan Stenersen, and Kim Yamane.

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