S. HRG. 107–97

THE VACCINE VACUUM: WHAT CAN BE DONE TO PROTECT SENIORS?

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

PORTLAND, OR

MAY 30, 2001

Serial No. 107–7

Printed for the use of the Special Committee on Aging

U.S. GOVERNMENT PRINTING OFFICE

74–367 PS WASHINGTON : 2001

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC. 20402

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THE VACCINE VACUUM: WHAT CAN BE DONE TO PROTECT SENIORS?

WEDNESDAY, MAY 30, 2001

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Portland, OR

The committee met, pursuant to notice, at 9:30 a.m., in the Metro Regional Building, 600 N.E. Grand Avenue, Portland, OR, Hon. Ron Wyden, presiding.

OPENING STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. The Senate Special Committee on Aging will come to order, and it is a pleasure to be home and have a chance to examine some critically important issues to senior citizens in our communities this morning. I especially want to express my gratitude to Senator Larry Craig and Senator Breaux. The Senate Aging Committee has always worked in an intensity bipartisan way on the critical issues involving this country's senior citizens. I'm very pleased that two good friends of mine, Larry Craig and John Breaux, constitute the leadership of our Select Committee on Aging. We are very fortunate to have their staffs represented here today, which is yet an indication that Senator Craig and Senator Breaux are especially concerned about this issue. I want to express my appreciation to the Committee and to Senator Craig and Senator Breaux for their leadership.

I want to begin with an announcement this morning. Today, I was able to talk with the Secretary of Health and Human Services, Tommy Thompson, and we discussed the flu shortage issue and the problems that we have experienced in this country. He shares my view that it is time to put in place a system that really works for senior citizens and communities across this country.

Fortunately, it was possible to dodge the bullet last winter due to a variety of circumstances that we will discuss this morning, but that is not always going to be the case. It is unacceptable, in my view, that a dose of vaccine becomes a rare privilege in this country and that there would be a hit and miss system where many vulnerable people simply end up going without this essential healthcare services.

So, this morning, I asked Secretary Thompson to create within the next 60 days, a plan to insure that we do not have a shortage this winter or in the days ahead. The Federal Government has been studying this issue for long enough. The Federal Government has been examining this kind of question now for more than a decade. I asked Secretary Thompson to bring together industry, par-

ticularly the manufacturers and distributors, State health specialists, consumer groups, work with the bipartisan leadership of the Senate Aging Committee, Senator Craig, and Senator Breaux, and to put in place a plan to insure that there will not be shortages of this critical needed health service in the future.

The Secretary, to his credit, agreed to my request. So, what will happen now within 60 days, we will have an effort underway to insure that we do not have these shortages in the future. It will be a bipartisan effort working under the auspices of the Secretary, but with Senator Craig and Senator Breaux and other interested senators involving health specialists at the State level, consumer groups. We are going to get a system in place so we do not have to have our seniors and our communities and families at risk this winter. We will not have to have a hit and miss system that leaves vulnerable people behind and uncertain about where to turn to get assistance.

I want to make sure that it is understood that I think that Secretary Thompson moving so quickly deserves great credit, and it is certainly a statement on the part of the Secretary and the administration that they want to work with the Congress and not repeat the problems of last winter. I am very appreciative of the Secretary's response.

Suffice it to say, last year, this country was lucky. It was a light year for the flu. Had there been a true epidemic, it is my view that there would have been real tragedies across this country. The flu vaccine is absolutely basic to protecting the health of seniors and other high risk patients, and it is critical that access be assured to this vaccine. In a sense, last year's shortage was more than a wake-up call. It was a real alarm bell making it clear that now is the time to get serious about this issue. That is why Secretary Thompson's willingness this morning to turn this problem around over the next 60 days is welcome.

We are going to examine this morning, a number of issues, the congressional watchdog office, the General Accounting Office at the request of a number of us in the Congress particularly, including myself, have put together an excellent set of recommendations going to be discussing what the Federal Government's role should be in distributing flu vaccines to seniors and other high risk patients.

Suffice it to say, given the Secretary's agreement with me this morning and with his willingness to work with the bipartisan leadership of the Aging Committee, I am particularly hopeful that our witnesses will give us suggestions of what they would like to see in this plan that is going to be designed over the next 60 days to deal with this issue.

Given the openness and responsiveness of the Secretary—put a special kind of focus on trying to get those ideas and suggestions.

Finally, I want to thank the good folks at Metro. We may have Mr. Bragden and others here, but they are allowing us to use this beautiful facility for this morning's hearing, and we appreciate that. And why don't we go now to our witnesses beginning with Mary Keene of Portland?

STATEMENT OF MARY KEENE, PORTLAND, OR

Ms. KEENE. Good morning.

Senator WYDEN. Ms. Keene, welcome. And we'll put your complete statement into the hearing record in its entirety, and you just speak in any way that you feel comfortable. And we sure appreciate your coming and anxious to hear from you.

Ms. KEENE. It is an honor to be here. I would like to thank——

Senator WYDEN. Why don't you pull that microphone down just a little bit? Perfect.

Ms. KEENE. There?

Senator WYDEN. Perfect.

Ms. KEENE. It's fine?

Senator WYDEN. You are doing better than perfect.

Ms. KEENE. Good morning again. I would like to thank Chairman Craig and Senator Wyden for inviting me to give my testimony this morning in front of the U.S. Special Committee on Aging.

My name is Mary Keene. I am 67 years old. I am currently living in Portland, OR as a retired senior citizen. I also spend my days volunteering at Loaves and Fishes serving meals to the elderly. My experience with receiving a flu shot this past flu season was frustrating, and it left me without a flu shot in 2000.

This past September, I planned to attend an annual Loaves and Fishes Flu Shot Fair. Because of the vaccine shortage, the doctors who were participating canceled a prearrangement event because he ran out of the flu vaccine. That meant I and many other senior citizens were left without this important vaccine. Since I had a doctor's appointment for my annual physical checkup in December, I believed I could get a vaccination then. Unfortunately, my doctor's receptionist told me I could not have a flu shot because I was not in high risk category. I believe that I was in a high risk population because I am a senior citizen.

After visiting the doctors, I decided to stop by the local Fred Meyer's, a grocery store that was also sponsoring a flu shot fair. I stood in line for 40 minutes. When I reached the front of the line, the vaccine was completely out. I also went to another grocery store chain, Safeway, a couple of days later, and they ran out as well. Because of my early experience, I gave up on getting a flu shot altogether.

Senator, I do not want to gamble with my health in the future. I was fortunate this past year that I was not sick with the flu, but I did get sick. I hate to think of all the senior citizens like me who were unable to get a flu shot and did get sick. I hope that you do something to help ensure that I receive a flu shot this coming year. Taking the necessary preventing measures like the flu vaccine is important to me and other seniors like myself.

Thank you, Senator Wyden and Committee staff for looking into this issue. Mary Keene, senior citizen.

[The prepared statement of Ms. Keene follows:]

May 30, 2001

Good Morning!

I would like to thank Chairman Craig, and Senator Wyden for inviting me to give my testimony this morning in front of the U. S. Special Committee on Aging.

My name is Mary Keene, I am 67 years old. I am currently living in Portland, Oregon as a retired senior citizen. I also spend my days volunteering at Loaves & Fishes serving meals to the elderly.

My experience with receiving a flu-shot this past flu season was frustrating and it left me without a flu shot in 2000. This past September I planned to attend the annual Loaves & Fishes flu shot fair. Because of the vaccine shortages, the doctor who was participating cancelled a prearranged event because he ran out of the flu vaccine. That meant I, and many other senior citizens were left without this important vaccine.

Since I had a doctor's appointment for my annual physical checkup in December, I believed I could get a vaccination then. Unfortunately, my doctor's receptionist told me I could not have a flu shot because I was **not** in the high risk category. I believed that I was in a high risk population because I am a senior citizen.

After visiting the doctor, I decided to stop by the local Fred Meyer, a grocery store that was also sponsoring a flu shot fair. I stood in line for forty minutes. When I reached the front of the line, the vaccine was completely out. I also went to another grocery store chain, Safeway, a couple of days later and they ran out as well. Because of my earlier experiences, I gave up on getting a flu shot altogether.

Senator, I do not want to gamble with my health in the future. I was fortunate this past year that I was not sick from the flu. I hate to think of all the senior citizens like me who weren't able to get a flu shot and did get sick.

I hope that you can do something to help ensure that I receive a flu shot this coming year. Taking the necessary preventive measures like the flu vaccine is important to me and other seniors like myself.

Thank you Senator Wyden and committee staff for looking into this issue.

Mary Keene, Senior Citizen

Senator WYDEN. Well, thank you very much for an excellent statement. I gather from what you said is that what happened last year was you and other senior citizens basically had to traipse all over town—you went to your doctors' office, you went to grocery stores, you went to various programs trying to find the flu vaccine. In a lot of instances even after traipsing all over town, you couldn't figure out how to get it, and at some point, everybody just gives up in frustration. Is that a fair account of what happened?

Ms. KEENE. Yes.

Senator WYDEN. Your sense is that a lot of seniors had the same sort of experience? You started with your doctor's office; is that right? The first visit you made was to your doctor's office?

Ms. KEENE. Right. Yes, sir.

Senator WYDEN. Your doctor essentially didn't know where else to turn, I mean, given the fact that the doctor ran out? What did he say you ought to do?

Ms. KEENE. My doctor?

Senator WYDEN. Yes.

Ms. KEENE. She went to her receptionist, like I said in my testimony, and the receptionist said that I could not really have it because they were keeping whatever vaccine they had left for the higher risk patients.

Senator WYDEN. I see. So, they actually had some vaccine there?

Ms. KEENE. Yes.

Senator WYDEN. And your physician, in effect, said, You know, Mary, we would like to be able to help you, but we have got to hang on to it for higher risk people. And then she said—at least the physician and the receptionist—they said, "Sorry. You are going to have to go somewhere else." Ms. Keene. Well, they didn't put it that I would have to go somewhere else. I just proceeded to try to get it somewhere else.

Senator WYDEN. I guess what I was looking for—I mean, it just seems to me that the chain of distribution with respect to flu vaccine breaks down at every single stage of the process.

Ms. KEENE. Right.

Senator WYDEN. There you are. You want it from your doctor. And I'm sure your doctor was a good person. She would have liked to have given it to you, but she had to reserve it for other people. So the next thing you did is ask yourself "Well, can they give me a place where I can get it?" And apparently, they couldn't do that. Then, you went to one grocery store, and they weren't able to give it to you. And then by your testimony, which is very good, you went to another grocery store, and they couldn't give it to you. So, it was like here in our hometown, the whole distribution system seems to have broken down; is that right?

Ms. KEENE. Right.

Senator WYDEN. OK. Well, I guess the only other question is, how did you learn about the system at the outset? Did you get information from senior programs and the like, or did you just say to yourself, "I know I ought to go to my doctor's office on my own." How did you first learn about the availability of——

Ms. KEENE. Flu shots?

Senator WYDEN. Yes.

Ms. KEENE. We had an activity coordinator who arranged for we seniors at the center to get the shot. She prearranged with a doctor who was supposed to come in, and he ran out of—she said—she came in and told us one day that he would not be here. He had to cancel because he didn't come in.

Senator WYDEN. Well, this is very helpful because what you have said now is the breakdown with respect to your access to the physicians was both at the senior center where you thought somebody was going to come, and then that person couldn't get the vaccine and it also was a problem in the doctor's office because they said, "Mary, we can't give it to you because we have to save it for higher risk individuals." This is exactly what we're going to try to correct in the next 60 days because I just don't think folks like yourself who are active members of our community and volunteering in senior programs should be subject to this kind of treatment. You ought to be able to go to one place and be able to get access to a vaccination and that would be that. That may be too logical for the Federal Government at this point, but we're going to sure try to change it. And the Democrats and the Republicans are going to work together, and we are going to get it done.

Ms. KEENE. Thank you.

Senator WYDEN. Anything else you would like to add?

Ms. KEENE. Not that I know of.

Senator WYDEN. All right.

You said it very well.

Ms. KEENE. I believe I said everything that needed to be said.

Senator WYDEN. And you said it very well, and I thank you for coming.

Ms. KEENE. Thank you very much. Thank you, staff.

Senator WYDEN. OK. Our next panel, Janet Heinrich with the General Accounting Office, John Sattenspiel, M.D., Salem, OR, Stephen Allred, GetAFluShot.com, Clackamas, OR.

Welcome to all of you. And Janet, always good to see you and know about the fine work that you all do there at the GAO and welcome to Oregon. Why don't we begin with you, and we'll put your prepared statement into the record. And if you would summarize your principle views, that would be great.

Ms. HEINRICH. Thank you.

STATEMENT OF JANET HEINRICH, DIRECTOR, HEALTH CARE-PUBLIC HEALTH ISSUES, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Ms. HEINRICH. Thank you, Senator Wyden. I am pleased to be here today to discuss problems from a national perspective that occurred last fall with shortages of influenza vaccine. These problems could repeat themselves in the future. I'm here to report on some steps that could help better prepare for future shortages.

You asked us to examine reasons for delays in production and distribution and pricing of the 2000/2001 flu vaccine. I will also address approaches Federal agencies could take to prepare for future disruptions in vaccine supply. My comments are highlights from a recently released report on the flu vaccine and supply problems.

In Oregon, as in the rest of the Nation, influenza and pneumonia rank as the fifth leading cause of death among persons 65 and

over. People are encouraged to obtain a flu shot each fall to protect against the disease. Producing the vaccine is a complex process that takes at least 6 to 8 months for manufacturers to produce. Each year's vaccine changes the strains of the virus to better protect against the expected varieties circulating that season.

Last fall, two manufacturers had unanticipated problems growing one of the two new strains introduced in the vaccine. Also, two of the four manufacturers producing vaccine, shut down parts of their facilities because of FDA concerns about good manufacturing practices. One of those did not reopen. Now, only three companies, two in the U.S. and one in the United Kingdom, produced the vaccine used in the United States. Because of these problems, only about 28 million doses were available by the end of October. Seventy-eight million were expected. Companies experienced problems in production to varying degrees. So, when a health care provider received vaccine depended on which manufacturer's vaccine it ordered. For example, health departments and other public entities in 36 States, including Oregon, banded together under a group purchasing contract and ordered about 2.6 million doses from the manufacturer, as it turns out, experienced the greatest delays from production difficulties. These entities then, these public organizations, did not receive most of their vaccine until mid to late December. Because supply was limited, distributors and others who had supplies of the vaccine had the ability and the economic incentive to sell their supplies to the highest bidder rather than filling lower priced orders that they had already received.

Those who purchased vaccine in the fall had to pay much higher prices. For example, a physician group ordered the vaccine at $2.87 per dose in April. When none arrived in November, the provider approached another distributor and purchased vaccine at the escalating prices of $8.80, $10.80 and ultimately, $12.80 per dose.

Demand for the vaccine dropped as additional vaccine became available after the expected flu season passed. Roughly, one-third of the total distribution was delivered in December or later. Because of the waning demand, manufacturers and distributors reported ultimately having more vaccine than they could sell. 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.

CDC took some steps to try to manage the anticipated vaccine delay by issuing recommendations for first vaccinating high risk groups such as persons age 65 and over and those with chronic health conditions. Several States took actions to ensure that high risk groups obtain flu shots. A few States have explicit requirements to offer the vaccine to nursing home residents, while others developed collaborative coalitions among provider groups. These efforts to target high risk groups were not always successful. The timing of some mass immunization campaigns upset physicians and public health officials because grocery stores were offering flu shots to anyone when they were unable to obtain vaccine for their high risk patients. Manufacturers and distributors told us that it was difficult to determine which of their customers should receive priority, nor did they have plans in place to prioritize deliveries. As

a result, they made partial shipments to all customers as one way to ensure that all providers had some vaccine. Others shipped vaccine only to nursing homes or first to nursing homes where those could be identified and to physicians offices.

We need to recognize that flu vaccine production and distribution are private sector responsibilities and that the Department of Health and Human Services has no authority to control flu vaccine production and distribution. Working within these constraints, we believe it would be helpful for the Health and Human Services agencies to take some additional actions. For example, CDC needs to continue to provide leadership in organizing and supporting efforts to bring together all interested parties to formulate voluntary guidelines for vaccine distribution in the event of another shortage.

CDC can concentrate greater efforts on education and outreach to members of the public and providers focusing on the value of being immunized past November.

Finally, while vaccine against pneumococcal disease is not a substitute for the annual flu shot, CDC and the Health Care Financing Administration should collaborate to increase vaccination rates for these diseases in adults 65 and over and for other high risk groups.

This concludes my remarks, Senator Wyden. And I am happy to answer any questions you may have.

[The prepared statement of Ms. Heinrich follows:]

United States General Accounting Office

GAO

Testimony

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

For Release on Delivery
Expected at 9:30 a.m. PDT
Wednesday, May 30, 2001

FLU VACCINE

Steps Are Needed to Better Prepare for Possible Future Shortages

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

GAO-01-786T

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.[1] 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?

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

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 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.

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 Kingdom—produced the vaccine used in the United States during the 2000-01 flu season.[2]

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.

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

[2]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.

from distributors with available supplies often faced rapidly escalating prices. By December, as vaccine supply increased and demand dropped, prices declined.

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. 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.

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

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.[3] Despite efforts by CDC and others to encourage people to seek flu shots later in the season, providers still

[3]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.

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.

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.

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.[4] 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.[5] The October guidelines also stated that while efforts should be made to increase 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

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[4]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.
[5]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.

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.

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 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.

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.[6]

[6]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.

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 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.[7]

We believe it would be helpful for HHS agencies to take additional actions in three areas.[8] 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.

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

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 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

[8]See GAO-01-624 for formal recommendations to HHS.

United States General Accounting Office

GAO

Report to Congressional Requesters

May 2001

FLU VACCINE

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

GAO

Accountability * Integrity * Reliability

GAO-01-624

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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

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

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.[1] 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.

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

[1]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.

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.

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.

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.[2] 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).[3]

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

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

[3]See app. I for additional information on the recommendations for the 2000-01 flu season.

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.[4] Three manufacturers—two in the United States and one in the United Kingdom—produced the vaccine used during the 2000-01 flu season.[5]

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.[6] 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.

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

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

[5]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.

[6]About 3 million doses were returned to manufacturers at the end of the season, for a net distribution of 74 million doses.

contracted for. By December, as vaccine supply increased and demand dropped, prices declined.

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.[7] 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.[8] 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.

[7]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.

[8]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.

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.[9]

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.[10] 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.[11]

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

[9]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.

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

[11]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.

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

Date order was placed	Range of price per dose	Average price per dose
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.

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.[12] 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.[13] 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

[12]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.

[13]CDC monitors influenza activity through May of each year.

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.

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.

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

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.

Table 3: Percentage of Population Receiving Influenza Vaccination

	Percent vaccinated		
Age group	**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.

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.[14] 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.[15]

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

[14]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.

[15]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.

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.

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.[16]

- 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.

[16]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.

- 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.

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.[17] 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	
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.

[17]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).

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.[18] 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.

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.

[18]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

Initiative	How this would help	Status
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

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.[19] 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.[20]

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.

[19]PROs promote quality of care improvements for Medicare beneficiaries in every state.

[20]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.

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.[21] 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.[22] 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.

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.[23] 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.

[21]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.

[22]See *Influenza Pandemic: Plan Needed for Federal and State Response* (GAO-01-4, Oct. 2000).

[23]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.

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.[24] Available data show that only 54 percent of the elderly and 13 percent of younger high-risk adults have been vaccinated against pneumococcal disease.[25] 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.

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

[25]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.

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.

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

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.

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.

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

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.

Janet Heinrich
Director, Health Care---Public Health Issues

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
The Honorable Charles A. Gonzalez
The Honorable Dennis J. Kucinich
The Honorable Sander M. Levin
The Honorable Frank A. LoBiondo
The Honorable Nita M. Lowey
The Honorable James H. Maloney
The Honorable James P. McGovern
The Honorable Patsy T. Mink
The Honorable Earl Pomeroy
The Honorable Lucille Roybal-Allard
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

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

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.

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

Target group	Estimated population
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,

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.[1] 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."

[1] 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.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Frank C. Pasquier, (206) 287-4861

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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Senator WYDEN. Thank you. Thank you very much. And as always, we really appreciate your good work at GAO. I'll have some questions in a moment.

Dr. Sattenspiel.

STATEMENT OF JOHN SATTENSPIEL, M.D., SALEM, OR

Dr. SATTENSPIEL. Thank you. My name is John Sattenspiel. I am a family physician, and I am here on behalf of the Oregon Medical Association and the Oregon Academy of Family Physicians.

I would like to thank you for asking me to appear before this body, and I appreciate the opportunity to share with you my perspective on the matter of influenza vaccine availability during the 2000/2001 flu season.

By way of background, I am in a four-physician family practice group. We are located in Salem, OR. During the fall and early winter of 2000/2001, our practice was responsible for the primary care of approximately 9,000 patients. The number in my statement is actually an error. It's about 18 percent where high risk over age 65, and probably another 5 percent or so with other high risk conditions.

Prior to the start of the immunization season, sometime around February of the year 2000, we placed an order for our usual quantity of vaccine with our local distributor at a quoted price of $3.95 per dose. In early October, we learned that our distributor would not be able to provide us with any vaccine whatsoever. Fortunately, we were able to round up vaccine from a national distributor and were able to obtain about two-thirds of the vaccine that we needed at a price of $4.67 per dose.

Due to the limited quantity of the vaccine that we received, we initially restricted the use of the vaccine to members of high risk groups and our office staff. This situation then lasted until around mid-December when we received enough additional vaccine to then offer immunization to all of our patients who desired it.

We are very fortunate because this year's flu season was extremely mild, and in the end, we did have adequate supply of vaccine. Perhaps the most difficult aspect of the shortage from my perspective was the confusion and the uncertainty among my staff and the public about how best to deal with the situation.

Early in the season, many of my high risk patients were quite nervous about being able to receive their vaccinations. Many of the media reports that they had seen made it seem as if only a very fortunate few would have access to the vaccine. It took some doing for my office staff to reassure them that we were prioritizing our use of the supply that we had and that our supply would be sufficient to allow us to vaccinate them at the appropriate time.

I would like to come back to that, if I could. Later in the season, some of my more public-minded patients called for advice when their employers offered immunization to their employees, most of whom were in low-risk groups. Because it rapidly became clear that the shortage was more apparent than real and especially in light of the mild flu season, we were then able to advise them to accept the vaccine, if desired.

I recently attended the OAFP's Annual Scientific Assembly. During that organization's Congress of Members, a resolution address-

ing broader issues of vaccine and pharmaceutical shortages was debated. In the course of that debate, I polled some of my colleagues about their experiences with vaccine supply issues. I received only one reply, and that was from a physician in solo practice in Newberg who reported that his supplier too had canceled his order due to lack of supply. He was able to obtain a supply from another distributor, but again at a much higher price. He reported that when he looked into the matter, the only answer as to why his original order had been canceled, and he was only able to obtain it at a higher price was that the initial supply had been snapped up by large commercial organizations that were using vaccines for marketing purposes. This was the only report, however, that I heard of that nature, and I have no corroboration of its facts.

In summary then, this year the matter seems to have been a temporary glitch in the vaccine distribution system that was fortunately resolved relatively quickly, and more fortunately occurred in the context of a very mild influenza season. My major concern is that this episode clearly uncovered that our system of allocated vaccines will be woefully short of adequate in the circumstances where there is a genuine shortage of vaccine and/or a more severe influenza season. In the future, it will be important for the system to have some mechanisms in place to assure that those who are responsible for high risk patients will have access to limited vaccine supplies and that those who have vaccines to administer will take care to deliver it to the most appropriate patients.

[The prepared statement of Dr. Sattenspiel follows:]

Testimony before the Senate Special Committee on Aging

Wednesday, May 30, 2001

My name is John Sattenspiel, MD and I am a Family Physician, here on behalf of the Oregon Medical Association and the Oregon Academy of Family Physicians. I would like to thank you for asking me to appear before this body, I appreciate the opportunity to share my perspective on the matter of Influenza vaccine availability during the 2000-2001 flu season.

By way of background, I am in a 4-physician Family Practice group located in Salem Oregon. During the late fall and early winter 2000-2001 our practice was responsible for the primary care of about 9000 patients, 10-15% of whom are at high risk from influenza due to age or illness.

Prior to the start of the immunization season, sometime in February of 2000, we placed an order for our usual quantity of vaccine with our usual local distributor at a quoted price of $3.95/dose. It was in early October of 2000 that we learned that our distributor would be unable to provide us with any vaccine at all. We were fortunate in that we were able to obtain two-thirds of the vaccine we needed in a timely fashion from a national distributor, at $4.67/dose. Due to the limited quantity of vaccine we received, we initially limited our use of the vaccine to members of high-risk groups and our office staff. This situation lasted until around mid-December when we received enough additional vaccine of offer the immunization to all patients who desired it. Fortunately, this year's flu

season was extremely mild and in the end, our vaccine supply turned out to be adequate. Perhaps the most difficult aspect of the shortage from my perspective was the confusion and uncertainty among my staff and the public about how best to deal with the situation. Early in the season many of my high-risk patients were quite nervous about being able to receive their vaccinations, many of the media reports made it seem as if only a very fortunate few would have access to vaccine. It took some doing for my office staff to reassure them that we were prioritizing out use of the supply we had and that our supply was sufficient to allow us to vaccinate them at the appropriate time. Later in the season, some of my more public minded patients called for advice when their employers offered immunization to their employees, most of whom were in low-risk groups. Because it actually became rapidly apparent that the shortage was more apparent than real, especially in light of the mild flu season, we soon advised them to accept the vaccine if desired.

Recently I attended the OAFP Annual Scientific Assembly. During that organization's Congress of Members a resolution addressing the broader issue of vaccine and pharmaceutical shortages was debated. In the course of the debate I polled my colleagues about any of their experiences with the vaccine supply problem. I received only one reply from a Physician in solo practice in Newburg who reported that his supplier cancelled his order due to lack of supply. He was then able to obtain a supply from another distributor but at a much higher price. He reported that when he looked into why his original order had been cancelled and why the replacement price was so much higher,

the only answer he was given was that the initial available supply had been snapped up by large commercial organizations that were using the vaccine for marketing purposes. This was the only such report I heard and I have no corroboration of its facts.

In summary, then, this year the matter seems to have been a temporary glitch in the vaccine distribution system that was fortunately resolved relatively quickly and more fortunately occurred in the context of a very mild influenza season. My major concern is that this episode clearly uncovered that our system of allocating vaccines will be woefully short of adequate in the circumstances where there is a genuine shortage of vaccine and/or a more severe influenza season. In the future it will be important for the system to have some mechanisms in place to assure that those who are responsible for high risk patients will have access to limited vaccine supplies and that those who have vaccine to administer take care to deliver it to the most appropriate populations.

Respectfully Submitted,

John E Sattenspiel, MD

Senator WYDEN. Doctor, thank you.
Mr. Allred.

STATEMENT OF STEPHEN ALLRED, NURSE PRACTITIONER, OWNER AND GENERAL MANAGER OF GETAFLUSHOT.COM

Mr. ALLRED. I am Nurse Practitioner Steve Allred with GetAFluShot.com. Senator Wyden, I want to thank you for the opportunity to speak before this committee hearing on the flu vaccine shortage that occurred this past fall.

My company, GetAFluShot.com, received 50,000 doses of influenza vaccine from General Injectables and Vaccine the week of October 16. This represented our entire pre-book order with the company. GetAFluShot.com has a 9-year history of purchasing vaccine through this company. We paid the pre-book price that had been agreed to the previous spring.

I have made some revisions on the percentage changes from the original document to correct them. This price was 65 percent higher than we had paid the previous year for flu vaccine. In September, this company advised us that additional flu vaccine, if and when available, would be increased another 64 percent. We purchased no more vaccine through that company last season.

We did receive an additional 30,000 doses of flu vaccine in November and December from two other wholesalers who we had also pre-booked flu vaccine through them the previous spring. Both wholesalers honored their pre-book price which is similar to what we paid GIV.

In September and October, we were contacted by several other wholesalers previously unknown to us. These wholesalers offered immediate shipments of flu vaccine for prices ranging from $70 to $130 per ten-dose vial. As the committee is aware, these prices exceeded the Medicare reimbursement rate. Purchasing vaccine at these prices would have made it impossible for us to service Medicare recipients. We did not purchase any vaccine through them.

GetAFluShot.com is a mass provider of flu vaccinations having administered more than 66,000 flu shots in Oregon, Washington and Idaho this past season. As professional healthcare providers, we break down access barriers bringing adult immunizations to the people. GetAFluShot.com provides immunizations in senior centers, retirement facilities, adult foster homes, churches, grocery stores and the workplace.

One item that I would like to add to the statement, Senator, is that in most counties that we went to throughout Oregon and Washington, county health departments contacted us to be able to send their high risk patients to the clinics that we were operating in their county. Most of our services are provided in grocery stores. The major grocery chains that we work with include Thriftway, Sentry, Red Apple, Rosauers, Supervalu, and Zupan's. These grocery stores donate space to host flu shot clinics and receive no revenue from this community service. In fact, busy flu clinics disrupted regular activities and cost stores sales numerous times this past season. GetAFluShot.com made every effort to comply with the Center for Disease Control's recommendations to prioritize service to seniors and the medically needy. Copies of the guidelines were posted at clinic sites and distributed to those in lines. Our guide-

lines were also posted at our web site, GetAFluShot.com. We relied upon self-policing, what we found to be a very effective policy. It was regularly reported that people took themselves out of line, sometimes after being there for an hour, with some comments to the effect, "I can wait until next month for my shot."

Unfortunately, it was also observed that several people who were high risk but not elderly deferred their own flu shots, apparently out of confusion. GetAFluShot.com also deferred the majority of business vaccinations until the supply issues resolved. I am a strong believer in voluntary guidelines. A mandatory priority system would require us to obtain documentation from everyone not obviously over the age of 64. Many diabetics, asthmatics, and those with cardiac disease would be dissuaded from obtaining needed protection from the potentially deadly complications of influenza. Our staff, already working at capacity, would be further strained and perceived as adversarial rather than supportive.

The decision to honor the CDC guidelines was not without cost to our company. In a typical year, 25 percent of our flu shots are provided to Medicare recipients. During the shortage this past season, this increased to 42 percent Medicare's reimbursement rate is significantly lower than the retail price. Deferring employee vaccinations cost us contracts both last season and for seasons to come. We continued offering immunization clinics through mid-January. Unfortunately, many did not obtain flu shots once they were available. Our company finished this season with approximately 14,000 unused doses of flu vaccine. Without the limitations of the priority system that we voluntarily put into place, we could have easily administered all of those flu shots and more.

Our wholesalers are advising us of the probability of another 79 percent increase in the wholesale price of flu vaccine for the 2001/2002 season. This means that GetAFluShot.com and others will be paying up to three times the price paid for flu vaccine 2 years ago in 1999. We were forced to raise the price for flu shots this past year. The public understood, and there were few complaints. Medicare reimbursement rates also were increased retroactively, we were notified, in April to adjust to the increased wholesale cost. Medicare reimbursement rates will again need to be adjusted for this coming season.

Again, I appreciate the opportunity to speak before the committee, and I will gladly answer any questions, Senator Wyden.

[The prepared statement of Mr. Allred follows:]

The Honorable Senator Ron Wyden
United States Senate
Special Committee on Aging
Washington, D.C. 204510-6400

May 30, 2001

Dear Senator Wyden and Committee Members,

Thank you for the opportunity to testify before the Senate Special Committee on Aging (Committee)'s hearing on the flu vaccine shortage that occurred in the Fall of 2000.

My company, Get A Flu Shot.com, received 50,000 doses of influenza vaccine from General Injectables and Vaccines, Inc. (GIV) the week of October 16, 2000, before many others had received vaccine. This represented our entire pre-book order with GIV. Get A Flu Shot.com has a nine year history of purchasing vaccine through GIV. We paid our pre-book price that was agreed to the previous spring. This price was 61% higher than we had paid the previous year for flu vaccine. In September, GIV advised us that additional flu vaccine, if and when available, would be increased another 61%.We purchased no more flu vaccine from GIV, that season.

We received an additional 30,000 doses of flu vaccine in November and December from two other wholesalers, Besse Medical and National Specialty Services. We had also pre-booked flu vaccine through them the previous spring. Both wholesalers honored their pre-book price, which was similar to what we paid GIV.

In September and October, Get A Flu Shot.com was contacted by several other wholesalers, previously unknown to us. These wholesalers offered us immediate shipments of flu vaccine for prices ranging from $70 to $130 per 10 dose vial. As the committee is aware, these prices exceeded the Medicare reimbursement rate. Purchasing vaccine at these prices would have made it impossible for us to service Medicare recipients. We purchased no vaccine through these wholesalers.

Get A Flu Shot.com is a mass provider of flu vaccinations, administering more than 65,000 flu shots in Oregon, Washington and Idaho during the 2000-2001 season. As professional health care providers, we break down access barriers bringing adult immunizations to the people. Get A Flu Shot.com provides immunizations in senior centers, retirement facilities, adult foster homes, churches, grocery stores and the workplace.

Most of our services are provided in grocery stores. The major grocery stores we work with include Thriftway, Sentry, Red Apple, Rosauers, Supervalu, and Zupan's. These grocery stores donate space to host flu shot clinics and receive no revenue from this community service. In fact, busy flu clinics disrupted regular activities and cost stores sales numerous times this past season.

Get A Flu Shot.com made every effort to comply with the Center for Disease Control's recommendations to prioritize service to seniors and the medically needy. Copies of the guidelines were posted at clinic sites and were distributed to those in line. The guidelines were also posted at our website www.getaflushot.com. We relied upon self policing, a very effective policy. It was regularly reported that people took themselves out of line, with comments to the effect "I can wait until December for my shot."

Unfortunately, it was also reported that a number of people who were high risk, but not elderly, deferred their own flu shots. Get A Flu Shot.com also deferred the majority of business based vaccinations until the supply issue resolved.

I am a firm believer in voluntary guidelines. A mandatory priority system would require us to obtain documentation from everyone not obviously over the age of 64. Many diabetics, asthmatics and those with cardiac disease would be dissuaded from obtaining needed protection from the potentially deadly complications of influenza. Our staff, already working at capacity, would be further strained and perceived as adversarial rather than supportive health care providers.

The decision to honor the CDC guidelines was not without cost to our company. In a typical year, approximately 25% of our flu shots are provided to Medicare recipients. During the shortage this past season, this increased to 42%. Medicare's reimbursement rate is significantly lower than the retail price. Deferring employee vaccinations cost us contracts, both last season and for seasons to come. We continued offering immunization clinics through mid-January. Unfortunately, many did not obtain flu shots once they were readily available. Our company finished the season with approximately 14,000 unused doses of flu vaccine. Without the limitations of the priority system, we could easily have administered all of those flu shots and more.

Our wholesalers are advising us of the probability of another 56% increase in the wholesale price of flu vaccine for the 2001-2002 season. This means that Get A Flu Shot.com, and others, will be paying three times the price paid for flu vaccine in 1999. We were forced to raise the price for flu shots this past year. The public understood and there were few complaints. Medicare reimbursement rates also were increased retroactively to adjust to the increased wholesale costs. Medicare reimbursement rates will again need to be adjusted for this coming season.

Again, I appreciate the opportunity to speak before the committee and will gladly answer any questions.

Sincerely,

Stephen Allred
Nurse Practitioner
Owner and General Manager of GetA*FluShot*.com

Senator WYDEN. Well, thank you all. It's very helpful to have your testimony. And let me ask you a few questions.

The Oregon Medical Association, in a letter to me at the end of last year, described the current system for distributing flu vaccine as "chaotic" and "irrational." Would any of you three disagree with that assessment?

Ms. HEINRICH. I think one of the things that we have to remember, Senator Wyden, is that when we have enough vaccine, the system seems to be working quite well. We're able to—in a very short period of time—provide vaccine to a lot of people across this whole country. The problem is that when you have a shortage, and you have these multiple approaches for distribution, the system does appear to be chaotic, and in fact, we found that it really depended on which manufacturer and which manufacturer was working with which distributors was a key factor on when you would get your vaccine. So, in fact, some people really did have vaccine available relatively early in the season, not as early as usually, but they had it in October. But there were also existing contracts so that mass immunizers; as we heard, were able to obtain a limited supply of vaccine relatively early as well. What it meant is that there were many providers serving high risk groups that could not find easy access to the vaccine.

Senator WYDEN. I think I am going to record that as a "yes" answer to my question that it's chaotic and irrational with the important qualifier that you have made, which is that it applies when there is a shortage. I think it is fair to say that experts agree when you have got a boatload of vaccine available for all concerned, you can deal with pretty much any situation. Although we'll need to get to the price question that Mr. Allred mentioned in a moment. I appreciate your thoughtful answer.

Did you want to add anything?

Dr. SATTENSPIEL. I would simply echo those comments with the statement that I think, in large measure, the public health policy in regards to vaccine is very clear, and in most of our offices with apologies to Ms. Keene who had difficulty getting her vaccine when she was clearly high risk, most of our offices generally do a pretty good job of identifying high risk patients and prioritizing our use of our vaccine, but what happens in between the clear policy and the actual delivery in our offices is truly chaotic.

Senator WYDEN. Do you want to add anything to that, Mr. Allred?

Mr. ALLRED. The only comment to add is that it was an extremely chaotic season for us and for others.

Senator WYDEN. The one thing you all didn't get into is this matter of trying to turn this around in the next 60 days, because I feel very strongly that after all of this study and after all of these reports, we have got an opportunity now with the Secretary who said this morning and wants to work on a bipartisan basis with this committee that he wants to turn this around that this has festered long enough.

So, let us take a minute, and each one of you sort of pretend that you are sitting there with the Secretary, and Senator Craig, and Senator Breaux, and our committee, and health experts, and consumers and the like. Tell us what you want to see in that plan that

we are going to try to turn around quickly to prevent this from happening again.

Janet, why don't you start?

Ms. HEINRICH. Well, first of all, you do have to have a plan in place when there are shortages. And it does seem to me that, as we've said in our report, that if there was progress on the development of a plan for a influenza pandemic that would really pave the way for some of the agreements and the collaborative efforts that have to occur.

It's also terribly important that we learn from this past year and really understand what educational efforts worked as we tried to educate both the public, and the providers.

The other thing that I would stress is that whatever systems you put in place, we still have to depend on people at the State and local level to carry these activities out, and that means that you have to have collaboration. You have to have the knowledge of all the different players involved and that varies from State to State.

The other thing that I think would be very interesting for the group to focus on as they think about developing this plan is what I would call a natural experiment that occurred last year. We had many States doing many very effective interventions to make sure that the groups that are at risk did receive the vaccine, and I think there are a lot of valuable lessons there to be learned.

Senator WYDEN. So, I want to see if I can distill out as concretely as possible what you want to see in the plan. You want a public education component?

Ms. HEINRICH. Yes.

Senator WYDEN. You want a lead role for the States?

Ms. HEINRICH. Yes.

Senator WYDEN. Lead role for the States. What else?

Ms. HEINRICH. I think that at the Federal level that we have to have strong leadership, and it seems natural that that be the CDC in terms of being the group that says we understand that there is going to be a shortage, and this is the plan that we will follow. These are the guidelines that we have all agreed to.

Senator WYDEN. So you want to see CDC be the Federal agency to drive this effort to turn this around?

Now, I think it would also be helpful to know whether GAO thinks that the Department of Health and Human Services and CDC, of course, has enough authority under current law to put in place what needs to be done, or does the U.S. Congress need to pass varied and sundry additional laws?

Ms. HEINRICH. We have struggled with that issue as we've examined the current law. Our legal counsel, at the U.S. General Accounting Office in reviewing those laws, stated to us that there appeared to be adequate authority in a time of emergency. I guess, the issue is when does the Secretary decide that there is an emergency?

I think that what we heard from the Department of Health and Human Services and the Centers for Disease Control is that they wanted to review that authority much more carefully to make sure that they indeed had the authority that they would need to take an action to essentially manage the supply of a vaccine.

Senator WYDEN. One last question for all of you at GAO. Did it turn out in your inquiry that there were problems with contracts being broken with respect to vaccine? We're talking about manufacturers breaking contracts or distributors breaking contracts for physicians and other providers. Was that a problem in your inquiry? And, if so, how would you incorporate it into this 60-day effort to turn this around?

Ms. HEINRICH. What we found very interesting, Senator Wyden, is that there were contracts—it's hard to say that they were broken because there was flexibility on the side of the purchaser, the provider, as well as flexibility on the side of the person that was distributing the vaccine, be it the manufacturer or the distributor. And it was really quite amazing for us to find out that many providers, be they physician groups, public health agencies, were told rather precipitously that the vaccine that they had ordered early on would not be delivered, or they were told——

Senator WYDEN. Who told them that?

Ms. HEINRICH. The distributors, or they were told that there would be a significant cutback in the amount of vaccine that would be available to them, even though they had these early orders and early agreements.

In some cases we found that the distributors would come back and say, "But we can offer you 'X' percent of what you want at a higher rate." But it's hard to say that the contract was broken because there was no guarantee of delivery or price. Instead there was flexibility built in at both ends. For example, in some arrangements, if you don't use the vaccine as a provider, you can send it back.

Senator WYDEN. I think this is an important issue because clearly, you have got to have enough flexibility to deal with real world circumstances. But at the same time, if you are going to have any predictability in planning capability, you can't have people going off and sort of saying, "Fine, you know, we thought we were going to do this, but we have decided to do something else." So, I am going to examine that issue some more.

Anything else you want to see in the 60-day effort to turn this around?

Ms. HEINRICH. I don't think so at this time, but we'll certainly think about it and get back to you.

Senator WYDEN. OK. I'm going to hold the record open for each of the groups here today to give us their ideas and suggestions on what should go into this 60-day effort. I mean, if we are going to do this and do it effectively, we are going to have to move fast.

And the sense given that, you know, the time line and the prospect of the Congress going out for the summer and like, that is what it is going to take. Could you get us your recommendations for the 60-day effort within 2 weeks?

Ms. HEINRICH. Sure. We would be happy to do that.

Senator WYDEN. We will hold the record open. That will be transmitted to the Senators Craig and Breaux through the Aging Committee, which will be involved in this effort with Secretary Thompson.

Very good. All right. Mr. Sattenspiel.

Dr. SATTENSPIEL. Great. Thank you.

To finish up on the issue of contracts, in my office, we submit purchase orders, and I don't believe that they would really constitute the type of contract that could be necessarily considered broken. They simply were not filled.

Clearly, from the discussion, I think that the first thing that is absolutely crucial in terms of addressing the issue is to make sure that we have adequate supply of vaccine. As has already been testified to by the GAO, the system worked when the supply is adequate. And clearly that, to me, is going to be the No. 1 issue.

The thing that got to me is the issue and the confusion that was arranged in terms of timing. Influenza vaccine has become a marketing tool for some of our larger chains of pharmacies and other organizations, and as such, sometimes it seemed to us that there was almost a race, if you will, to see who can do influenza clinics first for their patients. And as the CDC, I am sure would be happy to testify, that's not appropriate. Vaccines should be given at the appropriate time based upon the disease that you are trying to treat.

With influenza, the ideal time probably is not before mid-October and can extend into late November, even December, depending upon when the flu season starts. But when we have companies that are beginning to advertise and promote flu clinics beginning in September, and then we start having news reports that talk about shortages so that people may not get their vaccine if they want it, I think that combination was very volatile and really did lead to at least some minor degrees of hysteria among my patients.

Senator WYDEN. So, you would like to see in this effort that we would undertake a process to ensure the information got out in a way that was fair to all parties and didn't produce this kind of, you know, semi-hysteria——

Dr. SATTENSPIEL. Absolutely.

Senator WYDEN [continuing.] About how you would you get it and would give some parties an advantage?

Dr. SATTENSPIEL. An effort to coordinate among those people who are providing public flu clinics, whether they are public organizations or private organizations or what have you, any effort that would coordinate their activities so that they are done according to an appropriate calendar as opposed to according to a marketing calendar would, in my mind, be very helpful.

And then finally, from a standpoint of myself, and my office, and my colleagues, I think making sure that the vaccine supplies that are available at times of shortage do have a clear and easy pathway into my office. I do a lot of flu vaccinations. I think my colleagues overall, while the public clinics play a very important role, I believe the majority of vaccination are still provided in private physician offices. So, any system that does not recognize that and does not ensure that we get adequate supplies into our offices is going to fail in the long run.

Senator WYDEN. Well, we'll keep this record open for 2 weeks, and I invite you and the Oregon Medical Association, and of course, the parent of all the State medical associations, the American Medical Association, to give us your ideas and suggestions. We would like it within 2 weeks so that we can move quickly.

Dr. SATTENSPIEL. Thank you.

Senator WYDEN. Mr. Allred.

Mr. ALLRED. Yes, Senator, I have several thoughts on some issues that could help turn around the problem. One of the things that has been suggested and discussed at some of the national immunization conferences is the question of who is licensed to manufacture vaccine.

As you are aware, we lost one manufacturer last year. We are now down to three. It is my understanding, I do not have direct knowledge—this is secondhand information, but it is my understanding that there are a number of pharmaceutical companies who would like to be licensed by the FDA to be able to produce flu vaccine rather than it being controlled by only three manufacturers in the country. I would like to see that system looked at to find out what the bottleneck is as to why other reputable pharmaceuticals are not able to get license to produce it. Let's increase the supply for everyone.

Senator WYDEN. That is a good suggestion, and we may not be able to have a perfect answer for that in 60 days, but we can sure get started looking into that. That is a very constructive suggestion.

Mr. ALLRED. Thank you, Senator. Another issue that I am concerned about is the rate Medicare reimbursement. It is my understanding that the reimbursement rate is set in the spring based upon what they anticipate the wholesale price to be. In fact, when we were giving vaccinations, as I said, 42 percent of our vaccinations are Medicare recipients last year, we were very concerned about the reimbursement rate which was previously set. We were told that there would be no adjustments. As I mentioned, there was retroactively. We went out and we vaccinated these people because, as healthcare providers, we know the priorities, who needed to receive it. It could be a matter of life and death with seniors. However, if the reimbursement rate is not adequate to cover the cost of providing the service, that is a serious detriment. I could see why some other organizations might have been attempted to not prioritize to seniors because of the low reimbursement rate.

Senator WYDEN. And you are saying that the Medicare reimbursement rate is a problem now even before that 79 percent potential increase that you have heard discussed kicks in?

Mr. ALLRED. Absolutely, Senator.

Senator WYDEN. Well, we will definitely follow-up on that, as well. We have the good fortune of having Senators Craig and Breaux being influential Members of the Senate Finance Committee which deals with these issues. So, we are well positioned to look into that one as well.

Mr. ALLRED. Thank you, Senator.

Senator WYDEN. It has been an excellent panel. Anything you would like to add further? All right, we will excuse you at this time.

Senator WYDEN. Our next panel consists of Dr. Keiji Fukuda, M.D., National Center for Infectious Diseases, CDC; Sanford Kaufman, Director of Public Policy at Aventis Pasteur; Matthew J. Rowan, President and CEO of the Health Industry Distributors Association; Steven Skoronski, President and CEO of the Associated

Medical Products in Indianapolis, IN; and Grant Higginson, M.D., MPH, State of Oregon Health Officer, Portland, OR.

Gentlemen, we welcome you. It's going to be a long panel. If you can, try to keep your prepared remarks to about a half an hour or, excuse me, about 5 minutes or thereabouts so we will have plenty of time for questions.

I would like to ask you, as I have with our other panel members, I would like you to put a special focus on this matter that Secretary Thompson and I talked about this morning. I think we had a very exciting opportunity extended to us by the Secretary to have a chance to, through his offices working with the Aging Committee on a bipartisan basis, to mobilize over the next 60 days to turn this around. So, I know that constitutes some revisions you may have to make in your prepared remarks. We are going to make them a part of the record in their entirety. If you would, put a special focus on your ideas and suggestions on what could be done here over the next 60 days to mobilize and prevent this problem from happening again.

Dr. Fukuda, welcome. I had a chance to work with the Centers for Disease Control in a number of instances over the years. I think you know I wrote the fertility clinic statute that you all administer very well. And we welcome you and appreciate the good work that you do.

STATEMENT OF KEIJI FUKUDA, M.D., CHIEF, EPIDEMIOLOGY AND SURVEILLANCE SECTION, INFLUENZA BRANCH, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ATLANTA, GA

Dr. FUKUDA. Thank you. Good morning, Senator Wyden. I am Dr. Keiji Fukuda from the Centers for Disease Control and Prevention.

Influenza is a major public health problem in the United States which disproportionately harms the elderly and chronically ill. Influenza vaccine is the best tool to protect people from this disease. In an average influenza season, vaccination of each one million persons over the age of 65 years will prevent approximately 900 deaths and 1,300 hospitalizations.

In 2000/2001, influenza vaccine delay was severe and unusual. In other seasons, the system for providing and distributing influenza vaccine has successfully met the country's vast influenza vaccine needs, and in recent years, has provided between 70 to 80 million vaccine doses annually.

Influenza vaccine is produced and distributed primarily in the private sector. CDC recommends use of the vaccine through a deliberative process involving guidance from the Advisory Committee on Immunization Practices, ACIP. Each year, ACIP issues recommendations identifying which groups of individuals are at highest risk for developing complications from flu, and optimal timeframes for administering vaccine. The viral strains in the vaccine are updated annually based on information collected through a global public health surveillance system and through the closely coordinated work conducted by the Food and Drug Administration, CDC, and other public health organizations.

The manufacturers then produce very large amounts of influenza vaccine and work with distributors to get the supplies to providers within very tight timeframes. The complexity, fragility, scope, and time pressures make the production and distribution of influenza vaccine a unique product.

When difficulties in growing or processing the vaccine strains or other manufacturing issues delay vaccine distribution, CDC can take steps to minimize the effects, but cannot solve the entire problem.

Last year, it became clear by June that flu vaccine delays and shortages were possible. CDC undertook a number of activities such as mounting an education and media campaign which encouraged people at high risk of complications to seek a flu shot early and which encouraged healthy people 50 to 64 years to seek flu shots in December or later. As insurance against the possibility of a severe shortage, CDC contracted with one manufacturer to extend their production period and produce up to nine million additional doses of flu vaccine. Despite these initiatives, many persons, including those at high risk and providers experienced serious delays in obtaining vaccine.

This year, three manufacturers will produce influenza vaccine for the U.S., and they have estimated that up to 84 million vaccine doses may be available. However, these estimates are subject to change and not until much later this year will it be possible to know with certainty how much or when vaccine may be available.

In general, CDC agrees with the GAO report and concurs that the purchase, distribution and administration of flu vaccine are mainly private sector responsibilities. Substantial efforts have been made by the Department to address future influenza immunization concerns. CDC continues to take a leadership role in supporting efforts to address flu vaccination and is working proactively with the FDA and other key public and private sector partners to help ensure that high risk patients are vaccinated in the event of a vaccine delay or shortage.

In March 2001, CDC and the American Medical Association hosted a meeting with manufacturers, distributors, trade and provider organizations, and public health officials to discuss the need for contingency plans and to learn more about vaccine production and distribution challenges.

CDC has asked States to develop contingency plans and has provided written guidelines that assist them in planning. CDC has sent letters to the healthcare provider organizations serving high risk populations, including nursing homes and specialty physicians and is working with the Health Care Financing Administration to remind providers participating in Medicare reimbursement plans to order vaccine now and to immunize high risk patients at the earliest possible time.

ACIP has extended the optimal influenza vaccination period to the end of November. Mr. Chairman, it was an unusual year for flu vaccination. CDC and its partners undertook steps to minimize the effect of the delays, but we must anticipate that future supply problems could occur again and could be more severe. Long-term solutions are needed including increased routine collaborations be-

tween State and local health officials and private sector vaccine distributors and providers.

CDC will continue to work closely with its public and private sector partners and will provide more information about the flu vaccine supply as the season progresses.

Thank you again for your interest in this important public health problem. I will be happy to respond to any questions you may have.

[The prepared statement of Dr. Fukuda follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

TESTIMONY OF

KEIJI FUKUDA, MD

CHIEF, EPIDEMIOLOGY AND SURVEILLANCE SECTION

INFLUENZA BRANCH

DIVISION OF VIRAL AND RICKETTSIAL DISEASES

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SPECIAL COMMITTEE ON AGING

U.S. SENATE

MAY 30, 2001

Good morning, Mr. Chairman. I am Dr. Keiji Fukuda from the Centers for Disease Control and Prevention (CDC). I'm happy to be here today to provide information regarding last year's influenza vaccine delays and efforts underway to help mitigate similar potential problems in the future.

Introduction

Influenza vaccine is the best tool to prevent severe illness and death related to influenza among the elderly and chronically ill in the United States. As the Nation's prevention agency, CDC's overriding public health concern is to prevent hospitalizations and deaths, especially among high risk persons. Influenza causes, on average, approximately 20,000 excess deaths and approximately 110,000 hospitalizations per year. For each 1 million persons over the age of 65 vaccinated in an average influenza season, approximately 900 deaths and 1,300 hospitalizations are prevented.

The 2000-2001 vaccine delay was severe and unusual. In other seasons, the system for providing and distributing influenza vaccine has successfully met vast flu vaccine needs and in recent years has provided between 70-80 million vaccine doses annually.

Influenza vaccine is produced and primarily distributed in the private sector. CDC vaccine recommendations are made through a deliberative process involving advice and guidance from the Advisory Committee on Immunization Practices (ACIP). Although ACIP issues recommendations regarding influenza vaccination, including which groups of individuals are at

highest risk for developing complications from influenza, and optimal time frames for administering vaccine, influenza vaccine is produced entirely by the private sector, and the distribution of the vaccine is primarily through the private sector. Because of this, if vaccine manufacturers have delayed production, or there is a shortage, of flu vaccine, CDC can take steps to minimize the effects, but cannot solve the entire problem.

Flu Vaccine Production in 2000-2001

Each year, manufacturers produce a new influenza vaccine, based upon the selection of viral strains that are most likely to circulate for the upcoming influenza season. This is done to produce the most effective vaccine possible each year. A relatively short window exists between the time when viral strains are selected and the time when manufacturers develop and produce vaccine for each season. Delays can occur due to difficulties in growing or processing the vaccine strains or due to other manufacturing issues, and these delays in turn can affect vaccine distribution.

By June 2000, it became clear from discussions between influenza vaccine manufacturers and federal public health officials that there was a possibility of delays or shortages in influenza vaccine shipments for the 2000-2001 influenza season. This possibility of delay or shortage was due to a combination of factors, including difficulty by some manufacturers in growing and processing one of the virus strains used in vaccine, and good manufacturing practice issues with two companies. Ultimately, a significant delay in the availability of influenza vaccine occurred, resulting in concerns regarding the distribution and pricing system of influenza vaccine. One of

the four manufacturers withdrew from the market and did not distribute any vaccine.

CDC Actions

To deal with the delays and potential shortfall, CDC undertook a number of activities. CDC contracted with one manufacturer to extend their production period and produce up to 9 million additional doses of additional influenza vaccine. This decision was made to protect the nation against severe shortage. The additional vaccine was available in December 2000, and, as a result, the final supply of influenza vaccine approximated what was distributed in the previous year; however, a substantial amount of vaccine reached providers much later than usual, creating functional shortages for some providers. In addition to CDC's contracting for the production of additional influenza vaccine, CDC: 1) recommended that vaccine be administered to high-risk individuals first, 2) provided an internet-based system to facilitate the exchange and redistribution of vaccine, 3) conducted promotional campaigns to encourage vaccination of high risk persons, 4) communicated with health care providers and partners to keep them informed of events, and 5) encouraged states to develop plans to help manage and direct vaccine supplies in their jurisdictions.

CDC's influenza education and media campaign encouraged people at high risk of complications from influenza to seek a flu shot; the campaign also encouraged healthy people 50-64 to seek flu shots in December and early January. The campaign was based on discussions with a total of 26 focus groups that were held around the country with African Americans, Spanish-speaking Hispanics, and Caucasians. The groups were used to determine and test key messages. Both

English-language and Spanish-language versions of the campaign materials were made available, including television, radio public service announcements, and one-page flyers.

These initiatives were undertaken to help mitigate the effect of vaccine delays. But, as previously indicated, influenza vaccine is produced by the private sector and is also largely distributed there. The Federal government does not control the private production and distribution system. Therefore, despite our best efforts, some patients (including those at high risk) and providers experienced delays in obtaining vaccine, resulting in uneven distribution. The degree of delay experienced by individual providers varied greatly, depending on the vaccine manufacturer, distributor, and when vaccine was ordered.

The GAO Report entitled, "Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People," looked at these issues. In general, CDC agrees with the GAO report and continues to take a leadership role in supporting efforts to address influenza vaccination. As GAO acknowledges, the purchase, distribution, and administration of influenza vaccine are mainly private-sector responsibilities. Substantial efforts have been made by the Department to address future influenza immunization concerns. CDC is working proactively with the Food and Drug Administration, manufacturers, distributors, State and local health departments and other key partners to better prepare for the upcoming flu season.

The Upcoming Flu Season: What We Expect

Three manufacturers are currently producing influenza vaccine for the U.S. population. Each has provided an estimate of vaccine production for the upcoming year. Based upon the manufacturers' estimates, the total possible vaccine available in the 2001-2002 influenza season may be up to 84 million doses. In a usual year, approximately 70-80 million doses of vaccine are distributed. However, it's important to note that the manufacturers' estimates are subject to change, and it is not possible to know for certain how much vaccine may be available, or when it may be available, until much later this year.

Because influenza vaccine is newly produced for each influenza season, numerous factors may affect the manufacturers' vaccine production and distribution. If some manufacturers are delayed in getting their vaccine to the providers, there will be uneven distribution of the vaccine, with providers who ordered from some manufacturers receiving vaccine later than providers who ordered from other manufacturers. Further, providers who order late may receive vaccine late. Providers who order from third party distributors will be dependent upon which manufacturer is supplying that distributor.

CDC Plans

CDC has been working with the private sector, state and local health officials and provider organizations in the development of contingency plans and is taking steps to help ensure that high-risk patients are vaccinated in the event of a delay or shortage. Several activities are underway and are planned to anticipate and deal with potential problems.

1) CDC and the American Medical Association hosted a meeting on March 27, 2001 with manufacturers, selected distributors, trade organizations, provider organizations and public health officials to discuss the need for contingency plans and to learn more about the private sector production and distribution challenges.

2) CDC has requested that states develop contingency plans in the event of an influenza vaccine shortage and has provided written guidelines to assist them in planning. CDC requested that states submit their draft contingency plans by June 2001. CDC will hold a workshop at the National Immunization Conference this week to share planning efforts and best practices so that plans can be finalized by August of this year. CDC will also share state plans as they become available.

3) CDC also plans to send letters to health care provider organizations serving high-risk populations, including nursing homes, specialty physicians, and will work with Health Care Financing Adminstration (HCFA) to notify providers who participate in Medicare reimbursement plans, reminding them to order vaccine now and to immunize high-risk individuals at the earliest possible time.

4) One manufacturer has indicated it plans to fill approximately 25% of each customer's order in September. If, after that, a vaccine shortage or delay is expected, they will work with CDC to reallocate some amount of their remaining vaccine to their customers who serve high-risk patients, as well as to the high-risk customers of any non-producing manufacturer.

5) The ACIP influenza recommendations were revised this year to extend the optimal vaccination period for high-risk individuals to the end of November (see Appendix I). Health care providers should continue to offer vaccine to unvaccinated persons after November and throughout the influenza season even after influenza has been documented in the community. Influenza activity peaked during January in 5 of the last 19 years and in February or later in 10 of the last 19 years. Therefore, immunizations should continue even after November because they can still confer significant benefit in the great majority of influenza seasons. ACIP recommendations also suggest that persons planning substantial organized vaccination campaigns consider scheduling these events after mid-October, to minimize cancellations if vaccine delivery is delayed.

The new ACIP recommendations also encourage physicians to strongly consider administering pneumococcal and influenza vaccines at the same time to persons who had not previously received the pneumococcal vaccine. The target groups for these vaccines overlap considerably, and disease caused by pneumococcus and other types of bacteria can be a major complication of influenza. Pneumococcal vaccination has some value in protecting against complications of influenza, but is not a substitute for flu vaccine for several reasons: 1) pneumococcal vaccine does not protect against influenza; 2) many influenza complications resulting in hospitalization are not related to pneumococcal disease; and 3) the pneumococcal vaccine may only protect against the 10 to 25 percent of cases of pneumococcal bloodstream infections (bacteremia).

For the long term, it is important to increase collaboration between State and local health

officials and private sector vaccine distributors and providers on a routine basis. These collaborative relationships would be critical in redirecting vaccine, if necessary, during a shortage or delay in availability.

Conclusion

Mr. Chairman, it was an unusual year for flu vaccination. There were problems throughout the country caused by the supply and distribution of vaccine. CDC, and its partners, took steps to make the situation better and minimize the effects of the delays. Fortunately, the 2000-2001 season was unusually mild, which probably diminished demand for the influenza vaccine. We must anticipate that future seasons may be more severe, emphasizing the need to establish long-term solutions. CDC and its public and private sector partners will continue to work closely together to target vaccination to high risk individuals first to minimize the adverse impact of delays. As the season progresses and more information is available regarding influenza vaccine supply, CDC will provide updates at its website at www.cdc.gov.

Thank you again for your interest in this important public health issue. I would be happy to respond to any questions you may have.

Appendix I

CDC has published the Advisory Committee on Immunization Practices' (ACIP) recommendations, "Prevention and Control of Influenza" in the April 20, 2001 Morbidity and Mortality Weekly Report. (The MMWR can be found at www.cdc.gov).

The ACIP recommends vaccination for the following people who are at high risk for complications from influenza:

- persons aged $\geq$ 65 years;
- residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
- adults and children who have required medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppresion caused by medications or by human immunodeficiency virus);
- children and teenagers (aged 6 months to 18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for developing Reye syndrome after influenza infection; and
- women who will be in the second or third trimester of pregnancy during the influenza season.

In addition to these groups of individuals at high risk of complications from influenza, vaccination is also recommended for all persons aged 50 - 64 years because the prevalence of individuals with high-risk conditions in this age group is elevated, and for health-care workers and others in close contact with persons at high risk, including household members because they can easily pass infection onto high risk persons.

Senator WYDEN. I will have some, you can be sure of that.

Mr. Kaufman, welcome.

STATEMENT OF SANFORD KAUFMAN, DIRECTOR OF PUBLIC POLICY, AVENTIS PASTEUR, SWIFTWATER, PA

Mr. KAUFMAN. Thank you, Senator Wyden. My name is Sanford Kaufman. I am Director for Public Policy for Aventis Pasteur.

Aventis Pasteur is one of the major vaccine manufacturers in this country, and influenza vaccine is part of our portfolio. And we appreciate greatly the opportunity to speak here today. As you requested, my comments will be limited to lessons learned from last year, our view on recommendations for improving the current system, as well as, some recommendations and steps we are putting into place for the upcoming year, as well as, comments on the GAO Report.

The current public private distribution system delivers most vaccine orders to customers within a period of 24 to 48 hours. This system relies on direct shipments from manufacturers and a national network of wholesalers and distributors.

The current state-of-the-art U.S. private sector influenza distribution network exhibits unparalleled time-tested efficiency, reliability, safety, and cost-effectiveness. The existing infrastructure provides optimal flexibility for the most expeditious delivery of vaccine to thousands of healthcare providers. As was mentioned, about 80 percent of U.S. influenza doses are distributed to private sector healthcare providers with less than 20 percent being distributed by Federal, State and local government. Private sector providers include physicians offices, HMOs, food stores, chain drug stores, mass merchandisers, independent pharmacies, hospitals, and integrated health systems.

It's very important to note that the manufacturer, distributors, and government agencies involved cannot completely control how the end-user ultimately utilizes vaccine supplies. Compliance with CDC recommendations must rely on broad cooperation and extensive and persistent educational efforts by medical professional societies, State and local health departments, healthcare providers, and the general public.

In an effort to ease any potential influenza supply problems during the 2001/2002 influenza season, Aventis Pasteur announced on February 13, 2001, that effective in 2001, our company will begin shipping vaccines after Labor Day. Second, all public and private sector customers will receive a partial shipment of approximately 25 percent of their orders, which should be adequate to immunize their high risk patients. This will assure all of our customers have at least some product early on and avoid a situation where some channels of distribution have vaccines and others do not. To the extent that these shipments may not be adequate for the provider's high risk population, they can contact our company to obtain additional quantities which we provide on a case-by-case basis. The balance of all other customer orders will be shipped thereafter between October and November as additional vaccine lots are manufactured and released by the FDA.

Third, our company will implement a "no return" policy to prevent providers and distributors from hoarding supplies or hedging the market.

Finally, Aventis Pasteur will offer no guarantees or penalties for designated shipping dates, thereby eliminating any preferential treatment for one customer over another.

Additional lessons learned include the fact that the timing of market demand was not consistent with the CDC's optimal time to immunize. We are very pleased that government is making significant efforts to extend the immunization season through November.

We believe that one of the biggest lessons learned is that there is a critical role for government in mounting extensive professional education efforts during any vaccine delay or shortage. It is extremely important to emphasize that the only practical approach for addressing noncompliance is a greatly expanded educational effort by governmental and healthcare professional organizations. We are very pleased this effort is being undertaken and is being endorsed by all members of the vaccine enterprise.

Finally, regarding the GAO Report, I would like to first commend the investigators from the GAO for conducting a most thorough investigation in a most professional manner. Aventis Pasteur believes that the recommendations provided in the GAO Report are appropriate and should serve to assist in any future vaccine delay or shortage. As mentioned earlier, we wholeheartedly support the assessment and refinement of outreach efforts to make them more effective in meeting the challenge of educating the public and providers regarding the appropriate prioritization of patients. Aventis Pasteur also welcomes the opportunity to take part in any ongoing effort to bring all stakeholders together in order to formulate and refine voluntary guidelines for vaccine distribution, especially as related to getting this vaccine to high risk individuals first.

I'll be pleased to answer any questions.

[The prepared statement of Mr. Kaufman follows:]

Aventis Pasteur

Senator Wyden:

My name is Sanford Kaufman and I am Director of Public Policy for Aventis Pasteur. Aventis Pasteur is a major vaccine manufacturer whose portfolio includes influenza vaccine. We greatly appreciate the opportunity to testify today and to provide our perspective on some very important issues.

My comments today, as you requested, will be limited to the lessons learned from last year and our views on the recommendations to improve the current system of distribution as well as some comments about the recent U.S. General Accounting Office report on the 2000 flu season.

The current private-sector distribution system delivers most vaccine orders to customers within 24-48 hours. This system relies on both direct shipments from manufacturers and a national network of wholesalers and distributors. The current state-of-the-art U.S. private-sector influenza distribution network exhibits unparalleled time-tested efficacy, reliability, safety and cost-effectiveness. The existing infrastructure provides optimal flexibility for the most expeditious delivery of vaccine to the thousands of healthcare providers who administer them.

About 80% of U.S. influenza doses are distributed to private sector healthcare providers with less than 20% distributed to federal, state and local governmental entities in the public sector. Private sector providers include physician offices, HMOs, food stores, chain drugstores, mass merchandisers, independent pharmacies, hospitals, and integrated health systems.

It is important to note that the manufacturer, distributor and government agencies involved cannot completely control how the end-user ultimately utilizes vaccine supplies. Compliance with CDC recommendations must rely on broad cooperation and extensive and persistent educational efforts by medical/professional societies, state and local health departments, healthcare providers and the general public.

Aventis Pasteur

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Additional lessons learned include the fact that the timing of market demand was not consistent with the CDC's optimal time to immunize. We are very pleased that government is making significant efforts to extend the influenza immunization season through November.

We believe one of the biggest lessons learned is that there is a critical role for the government in mounting an extensive, professional education effort during any vaccine delay or shortage. It is extremely important to emphasize that the only practical approach for addressing non-compliance is a greatly expanded educational effort by governmental and healthcare professional organizations. We are very pleased that this effort is being undertaken and is being endorsed by all members of the vaccine enterprise.

Aventis Pasteur

Finally, regarding the GAO report, I would first like to commend the investigators from the GAO for conducting a most thorough investigation in a most professional manner. Aventis Pasteur believes that the recommendations provided in the GAO report are appropriate and should serve to assist in any future vaccine delay or shortage. As mentioned earlier, we wholeheartedly support the assessment and refinement of outreach efforts to make them more effective in meeting the challenge of educating the public and providers regarding the appropriate prioritization of patients. Aventis Pasteur also welcomes the opportunity to take part in any on-going effort to bring all stakeholders together in order to formulate and refine voluntary guidelines for vaccine distribution, especially as related to getting this vaccine to high-risk individuals first.

Thank you.

Senator WYDEN. Thank you.
Mr. Rowan.

STATEMENT OF MATTHEW J. ROWAN, PRESIDENT AND CEO, HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION, ALEXANDRIA, VA

Mr. ROWAN. Good morning, Senator Wyden. My name is Matthew Rowan, and I am the President and CEO of the Health Industry Distributors Association. I appreciate the opportunity this morning to appear before your committee to discuss the causes of the vaccine delays that occurred during this past flu season, and I also look forward to informing you of the steps the industry is taking to collaboratively develop contingency plans with providers and the Centers for Disease Control and Prevention, the CDC, to deal with any future supply disruption.

In most years, flu vaccine was forecast, manufactured and distributed to providers at pre-book prices and administered to millions of patients. To properly serve the public, the flu vaccine system requires each entity in the production and supply chain to be accurate and timely. It is important to note that manufacturers directly deliver 50 percent of flu vaccine to providers. Distributors account for the remaining 50 percent. In most seasons, in excess of 70 million patients are inoculated over the span of just a few months. Only after the 2000/2001 flu season could we fully understand the weaknesses in this producer to patient supply chain. The breakdown started early with the delayed CDC forecast. This was followed by production problems and subsequent confusion in the supply chain about how to get vaccine to the high risk populations that the CDC singled out for priority treatment.

During the last flu season, the vaccine supply was hampered at every critical juncture. I can report to you three conclusions based on HIDA members actual experience during the past flu season. First, vaccine suppliers, whether they are manufacturers or distributors, were left to guess which of their customers served high risk populations. The CDC recommendations gave doctors and providers precise direction on which patients should receive treatment priority. However, the same direction confused distributors. Distributors tracked delivery information to healthcare facilities. They do not typically maintain clinical information on provider's patient make-up. Distributors can only guess at the mix of patients treated by a particular healthcare facility they supply. While some information may be deduced from the name on the address, once the product is delivered, the provider determines each individual patient's risk status.

Distributors report being unsure if CDC was recommending supplying nursing homes first or physicians offices, which dispense the largest quantity of flu vaccine. Among physician offices, it was unclear which specialties were likely to treat high risk patients. Also, in some areas of the country, patients might get vaccinated at a clinic or hospital, while in other places, they go to physician offices. People also get shots at convenient, nonclinical settings such as chain stores, community centers, libraries, schools, and at their work site. Distributors have no control or role in these settings.

Second, the vast majority of distributors behaved ethically in response to the delays.

In the 2000/2001 flu season, how much vaccine a provider received and when it was received depended entirely on the entity with which he or she booked their initial pre-order. The general Accounting Office Report clearly documents that manufacturers and distributors pursued different strategies to comply with the CDC recommendation. According to the GAO Report, some suppliers, both manufacturers and distributors, chose to supply based on the initial order date and honoring contracts with special delivery dates. Others chose to partially supply their customers based on the amount of vaccine they were able to obtain from manufacturers cutting the supply by equal proportions to all customers. Many filled orders with their existing customers first before supplying new customers who did not pre-book their orders. Still others gave priority to either physician offices or nursing facilities. These separate supply strategies were the result of the confusion in the supply chain. In some cases, supply strategies were also altered mid-season.

This confusion is the most likely explanation of the often quoted example of a physician who was unable to receive his supply vaccine order only to find a flu clinic at a shopping mall or other convenient location was fully supplied. A long-term customer relationship is critical to a distributor's financial performance. Most distributors would not engage in price gouging simply because it's bad for business. They know that is a sound business strategy to sell vaccines to their long term customers who pre-book their orders for vaccines year after year. These are the same customers who are likely to purchase other medical supplies throughout the year and provide a steady flow of orders. Giving up a steady customer for a one-time profit is a losing business strategy for a distributor. Despite this, many distributors reported damaged customer relationships due to their inability to supply flu vaccine.

We know of numerous instances where HIDA members turned down higher priced offers for vaccines from potential new customers. These offers were denied because distributors wanted to serve their existing customers or simply did not have the vaccine to supply.

Third, HIDA members lost millions of dollars in contracted sales because there was no vaccine for them to distribute during the height of the inoculation season. Our members have described to us numerous instances where they were unable to fulfill existing contracts or pre-booked orders for vaccines because they did not have the product available. This seems to have been most pronounced for members who serve the physician market.

Distribution is a low profit margin business. HIDA members average a pre-tax profit of just 1.8 percent in 1999, which is the most recent year we have figures for. This number reflects the industry's high investment cost relative to revenue and profit. An average-sized HIDA member distributor generates gross revenues of $5 million dollars per year in total sales of medical products. One of our members in this size category reported losing $250,000 in pre-contracted vaccine orders that he could not supply. This loss rep-

resents 5 percent of his annual sales that would be very difficult for him to recover.

HIDA has concluded that the supply system is fundamentally sound but needs greater communication and contingency planning. We oppose suggestions that the CDC or State government should take over distribution. In fact, some States looked into this option in the mid–1990's and concluded that the distribution system is a good and efficient one and should not be tampered with. HIDA believes that the government, through the CDC, can better serve the vaccine distribution system by advising distributors on where priority distribution should occur and to whom and by encouraging more manufacturers to enter the vaccine production market.

In addition, CDC education and communication to the general public about the expanded inoculation season and locations for high risk patient inoculation are important priorities.

Based on the experiences from last year, HIDA recommends the following steps be taken: first, the CDC lead and support effort among various groups that are involved in distributing and administering vaccines. This is the heart of our recommendations to GAO. In fact, HIDA recently met with officials from the CDC's National Immunization Program to discuss establishing procedures that clearly define and communicate which providers should have priority in receiving vaccines should there be another delay; second, guidance on treatment and supply priorities driven by physician recommendations should be developed and communicated by CDC. Distributors particularly need guidance that is based on provider category, physician specialty, or facility type. Instructions such as first treat high risk patients who are seen by primary care physicians, that is internal medicine, family practice, general practice, or who reside in nursing homes would give suppliers guidance they can confidently act upon.

Third, the CDC forecast must be released on schedule so that time is built into the system for any manufacturing delays that cannot always be predicted.

Fourth, the Department of Health and Human Services must reexamine reimbursement levels for flu shots. We need to attract more manufacturers to vaccine production. We simply cannot expect the two or three manufacturers who still produce flu vaccines to consistently meet the rising demand for a product that health conscious consumers want at the same time regardless of their actual risk.

Short of a major scientific advance in vaccine production, additional manufacturing capacity is the only way to improve production numbers. This will improve the system's ability to respond to forecast changes or any unexpected manufacturing delays.

Suppliers are in the business of supporting physicians and nurses in what they do best: Providing patient care. In the upcoming flu season, distribution will play a much less significant role in delivering flu vaccines. Major domestic manufacturers appear to be pursuing a direct-to-customer approach that bypasses distributors, who in the past, delivered approximately 50 percent of the flu vaccine supply. Early reports are that prices will be double those of last year. It remains to be seen how this new "no distribution approach" will impact healthcare providers and their access to the flu

vaccines they need to administer to the millions of patients they serve.

Thank you again for inviting me to testify before your committee.

[The prepared statement of Mr. Rowan follows:]

TESTIMONY OF MATTHEW J. ROWAN
PRESIDENT AND CEO
HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
SENATE SPECIAL COMMITTEE ON AGING
FIELD HEARING—PORTLAND, OREGON
MAY 30, 2001

GOOD MORNING SENATOR WYDEN. MY NAME IS MATTHEW ROWAN. I AM THE PRESIDENT AND CEO OF THE HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION.

I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE YOUR COMMITTEE TO DISCUSS THE CAUSES OF THE VACCINE DELAYS THAT OCCURRED DURING THIS PAST FLU SEASON. I ALSO LOOK FORWARD TO INFORMING YOU OF STEPS THE INDUSTRY IS TAKING TO COLLABORATIVELY DEVELOP CONTINGENCY PLANS WITH PROVIDERS AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) TO DEAL WITH ANY FUTURE SUPPLY DISRUPTION.

IN MOST YEARS, FLU VACCINE IS FORECASTED, MANUFACTURED AND DISTRIBUTED TO PROVIDERS AT PRE-BOOKED PRICES, AND ADMINISTERED TO MILLIONS OF PATIENTS. TO PROPERLY SERVE THE PUBLIC, THE FLU VACCINE SYSTEM REQUIRES EACH ENTITY IN THE PRODUCTION AND SUPPLY CHAIN TO BE ACCURATE AND TIMELY. IT IS IMPORTANT TO NOTE THAT MANUFACTURERS DIRECTLY DELIVER 50 PERCENT OF FLU VACCINE TO PROVIDERS. DISTRIBUTORS ACCOUNT FOR THE OTHER 50 PERCENT OF VACCINE DISTRIBUTION. IN MOST SEASONS, IN EXCESS OF 70 MILLION PATIENTS ARE INOCULATED OVER THE SPAN OF SEVERAL MONTHS. ONLY

AFTER THE 2000-2001 FLU SEASON CAN WE FULLY UNDERSTAND THE WEAKNESSES IN THIS PRODUCER-TO-PATIENT SUPPLY CHAIN.

THE BREAKDOWNS STARTED EARLY, WITH A DELAYED CDC FORECAST. THIS WAS FOLLOWED BY PRODUCTION PROBLEMS AND SUBSEQUENT CONFUSION IN THE SUPPLY CHAIN ABOUT HOW TO GET VACCINE TO THE HIGH-RISK POPULATIONS THAT THE CDC SINGLED OUT FOR PRIORITY TREATMENT. DURING THE LAST FLU SEASON, THE VACCINE SUPPLY WAS HAMPERED AT EVERY CRITICAL JUNCTURE.

I CAN REPORT TO YOU THREE CONCLUSIONS BASED ON HIDA MEMBERS ACTUAL EXPERIENCE DURING THIS PAST FLU SEASON.

FIRST, VACCINE SUPPLIERS, WHETHER MANUFACTURER OR DISTRIBUTOR, WERE LEFT TO GUESS WHICH OF THEIR CUSTOMERS SERVE HIGH-RISK POPULATIONS. THE CDC RECOMMENDATIONS GAVE DOCTORS PRECISE DIRECTION ON WHICH PATIENTS SHOULD RECEIVE TREATMENT PRIORITY.

HOWEVER, THIS SAME DIRECTION CONFUSED DISTRIBUTORS. DISTRIBUTORS TRACK DELIVERY INFORMATION TO HEALTHCARE FACILITIES. THEY DO NOT TYPICALLY MAINTAIN CLINICAL INFORMATION ON PROVIDERS' PATIENT MAKE-UP. DISTRIBUTORS CAN ONLY GUESS AT THE MIX OF PATIENTS TREATED BY A PARTICULAR HEATLHCARE FACILITY THEY SUPPLY. WHILE SOME INFORMATION CAN BE DEDUCED FROM THE NAME ON THE ADDRESS, ONCE THE PRODUCT IS DELIVERED, THE PROVIDER DETERMINES EACH INDIVIDUAL PATIENT'S RISK STATUS.

DISTRIBUTORS REPORT BEING UNSURE IF CDC WAS RECOMMENDING SUPPLYING NURSING HOMES FIRST, OR PHYSICIAN OFFICES, WHICH DISPENSE THE LARGEST QUANTITY OF FLU VACCINE. AMONG PHYSICIAN OFFICES, IT WAS UNCLEAR WHICH SPECIALTIES WERE LIKELY TO TREAT HIGH-RISK PATIENTS.

ALSO, IN SOME AREAS OF THE COUNTRY, PATIENTS MIGHT GET VACCINATED AT A CLINIC OR HOSPITAL, WHILE IN OTHER PLACES, THEY GO TO PHYSICIAN OFFICES. PEOPLE ALSO GET SHOTS AT CONVENIENT, NONCLINICAL SETTINGS, SUCH AS CHAIN STORES, COMMUNITY CENTERS, LIBRARIES, SCHOOLS, AND AT THEIR WORK SITE. DISTRIBUTORS HAVE NO CONTROL OR ROLE IN THESE SETTINGS.

SECOND, THE VAST MAJORITY OF DISTRIBUTORS BEHAVED ETHICALLY IN RESPONSE TO THE DELAYS.

OUR BELIEF IS THAT MUCH OF WHAT IS PERCEIVED TO BE PRICE-BASED FAVORITISM IN SUPPLY IS A RESULT OF THE CONFUSION OVER HOW TO BEST SERVE CUSTOMERS.

IN THE 2000-2001 FLU SEASON, HOW MUCH VACCINE A PROVIDER RECEIVED AND WHEN IT WAS RECEIVED DEPENDED ENTIRELY ON THE ENTITY WITH WHICH HE OR SHE BOOKED A PRE-ORDER. THE GENERAL ACCOUNTING OFFICE REPORT CLEARLY DOCUMENTS THAT MANUFACTURERS AND DISTRIBUTORS PURSUED DIFFERENT STRATEGIES TO COMPLY WITH THE CDC RECOMMENDATIONS. ACCORDING TO THE GAO REPORT, SOME SUPPLIERS

(BOTH MANUFACTURERS AND DISTRIBUTORS) CHOSE TO SUPPLY BASED ON THE INITIAL ORDER DATE AND HONORING CONTRACTS WITH SPECIAL DELIVERY DATES. OTHERS CHOSE TO PARTIALLY SUPPLY THEIR CUSTOMERS BASED ON THE AMOUNT OF VACCINE THEY WERE ABLE TO OBTAIN FROM MANUFACTURERS, CUTTING THE SUPPLY BY EQUAL PROPORTIONS TO ALL CUSTOMERS. MANY FILLED ORDERS WITH THEIR EXISTING CUSTOMERS FIRST BEFORE SUPPLYING NEW CUSTOMERS WHO DID NOT PRE-BOOK THEIR ORDER EARLIER IN THE YEAR. STILL OTHERS GAVE PRIORITY TO EITHER PHYSICIAN OFFICES OR NURSING FACILITIES. THESE SEPARATE SUPPLY STRATEGIES WERE THE RESULT OF CONFUSION IN THE SUPPLY CHAIN. IN SOME CASES, SUPPLY STRATEGIES WERE ALTERED MID-STREAM.

THIS CONFUSION IS THE MOST LIKELY EXPLANATION OF THE OFTEN-QUOTED EXAMPLE OF A PHYSICIAN WHO WAS UNABLE TO RECEIVE A VACCINE ORDER ONLY TO FIND A FLU CLINIC AT A LOCAL SHOPPING MALL WAS FULLY SUPPLIED.

A LONG TERM CUSTOMER RELATIONSHIP IS CRITICAL TO A DISTRIBUTOR'S FINANCIAL PERFORMANCE. MOST DISTRIBUTORS WOULD NOT ENGAGE IN PRICE GOUGING SIMPLY BECAUSE ITS BAD FOR BUSINESS. THEY KNOW THAT IT IS A SOUND BUSINESS STRATEGY TO SELL VACCINES TO THEIR LONG TERM CUSTOMERS WHO PRE-BOOK THEIR ORDERS FOR VACCINES EVERY YEAR. THESE ARE THE SAME CUSTOMERS WHO ARE LIKELY TO PURCHASE OTHER MEDICAL SUPPLIES THROUGHOUT THE YEAR AND PROVIDE A STEADY FLOW OF ORDERS. GIVING UP A STEADY CUSTOMER FOR A ONE-TIME PROFIT IS A LOSING BUSINESS STRATEGY FOR A DISTRUBUTOR. DESPITE THIS, MANY

DISTRIBUTORS REPORT DAMAGED CUSTOMER RELATIONSHIPS DUE TO THEIR INABILITY TO SUPPLY FLU VACCINE.

WE KNOW OF NUMEROUS INSTANCES WHERE HIDA MEMBERS TURNED DOWN HIGHER-PRICED OFFERS FOR VACCINES FROM POTENTIAL NEW CUSTOMERS. THESE OFFERS WERE DENIED BECAUSE DISTRBUTORS WANTED TO SERVE THEIR EXISTING CUSTOMERS OR SIMPLY DID NOT HAVE THE VACCINE TO DISTRIBUTE.

THIRD, HIDA MEMBERS LOST MILLIONS OF DOLLARS IN CONTRACTED SALES BECAUSE THERE WAS NO VACCINE PRODUCT FOR THEM TO DISTRIBUTE DURING THE HEIGHT OF THE INOCULATION SEASON. OUR MEMBERS HAVE DESCRIBED TO US NUMEROUS INSTANCES WHERE THEY WERE UNABLE TO FULFILL EXISTING CONTRACTS FOR VACCINES BECAUSE THEY DID NOT HAVE THE PRODUCT AVAILABLE. THIS SEEMS TO HAVE BEEN MOST PRONOUNCED FOR MEMBERS WHO SERVE THE PHYSICIAN MARKET.

DISTRIBUTION IS A LOW PROFIT MARGIN BUSINESS. HIDA MEMBERS AVERAGED A PRE-TAX PROFIT OF JUST 1.8% IN 1999, THE LAST YEAR FOR WHICH STATISTICS ARE AVAILABLE. THIS NUMBER REFLECTS THE INDUSTRY'S HIGH INVESTMENT COSTS RELATIVE TO REVENUE AND PROFIT.

AN AVERAGE-SIZED HIDA MEMBER GENERATES GROSS REVENUES OF 5 MILLION DOLLARS PER YEAR IN TOTAL SALES OF MEDICAL PRODUCTS. ONE OF OUR MEMBERS IN THIS SIZE CATEGORY REPORTED LOSING $250,000 IN PRE-CONTRACTED VACCINE ORDERS THAT HE COULD NOT SUPPLY. THIS

LOSS REPRESENTS FIVE PERCENT OF HIS ANNUAL SALES THAT WILL BE VERY DIFFICULT FOR HIM TO RECOVER.

HIDA HAS CONCLUDED THAT THE SUPPLY SYTEM IS FUNDAMENTALLY SOUND, BUT NEEDS GREATER COMMUNICATION AND CONTINGENCY PLANNING. WE OPPOSE SUGGESTIONS THAT THE CDC OR STATE GOVERNMENTS SHOULD TAKE OVER DISTRIBUTION. IN FACT, SOME STATES LOOKED INTO THIS OPTION IN THE MID-1990S AND CONCLUDED THAT THE DISTRIBUTION SYSTEM IS A GOOD AND EFFICIENT ONE THAT SHOULD NOT BE TAMPERED WITH. HIDA BELIEVES THAT THE GOVERNMENT, THROUGH THE CDC, CAN BETTER SERVE THE VACCINE DISTRIBUTION SYSTEM BY ADVISING DISTRIBUTORS ON WHERE PRIORITY DISTRIBUTION SHOULD OCCUR AND TO WHOM, AND BY ENCOURAGING MORE MANUFACTURERS TO ENTER THE VACCINE PRODUCTION MARKET. IN ADDITION, CDC EDUCATION AND COMMUNICATION TO THE GENERAL PUBLIC ABOUT THE EXPANDED INOCULATION SEASON AND LOCATIONS FOR HIGH RISK PATIENT INOCULATION ARE IMPORTANT PRIORITIES.

BASED ON THE EXPERIENCES FROM LAST YEAR, HIDA RECOMMENDS THE FOLLOWING STEPS BE TAKEN:

(1) THE CDC LEAD AND SUPPORT EFFORTS AMONG VARIOUS GROUPS THAT ARE INVOLVED IN DISTRIBUTING AND ADMINISTERING VACCINES. THIS IS THE HEART OF OUR RECOMMENDATIONS TO GAO. IN FACT, HIDA RECENTLY MET WITH OFFICIALS FROM THE CDC'S NATIONAL IMMUNIZATION PROGRAM TO DISCUSS ESTABLISHING PROCEDURES THAT CLEARLY DEFINE AND

COMMUNICATE WHICH PROVIDERS SHOULD HAVE PRIORITY IN RECEIVING VACCINES, SHOULD THERE BE ANOTHER DELAY IN GETTING PRODUCTS TO MARKETS.

(2) GUIDANCE ON TREATMENT AND SUPPLY PRIORITIES DRIVEN BY PHYSICIANS' RECOMMENDATIONS SHOULD BE DEVELOPED AND COMMUNICATED BY CDC. DISTRIBUTORS PARTICULARLY NEED GUIDANCE THAT IS BASED ON PROVIDER CATEGORY, PHYSICIAN SPECIALTY, OR FACILITY TYPE. AN INSTRUCTION SUCH AS "FIRST TREAT HIGH RISK PATIENTS WHO ARE SEEN BY PRIMARY CARE PHYSICIANS (INTERNAL MEDICINE, FAMILY PRACTICE, GENERAL PRACTICE) OR WHO RESIDE IN NURSING HOMES" WOULD GIVE SUPPLIERS GUIDANCE THEY CAN CONFIDENTLY ACT UPON.

(3) THE CDC FORECAST MUST BE RELEASED ON SCHEDULE SO TIME IS BUILT INTO THE SYSTEM FOR MANUFACTURING DELAYS THAT CANNOT ALWAYS BE PREDICTED.

(4) THE DEPARTMENT OF HEALTH AND HUMAN SERVICES MUST RE-EXAMINE REIMBURSEMENT LEVELS FOR FLU SHOTS. WE NEED TO ATTRACT MORE MANUFACTURERS TO VACCINE PRODUCTION. WE SIMPLY CANNOT EXPECT THE TWO OR THREE MANUFACTURERS WHO STILL PRODUCE FLU VACCINES TO CONSISTENTLY MEET THE RISING DEMAND FOR A PRODUCT THAT HEALTH CONSCIOUS CONSUMERS WANT AT THE SAME TIME, REGARDLESS OF THEIR ACTUAL RISK.

SHORT OF A MAJOR SCIENTIFIC ADVANCE IN VACCINE PRODUCTION, ADDITIONAL MANUFACTURING CAPACITY IS THE ONLY WAY TO IMPROVE PRODUCTION NUMBERS. THIS WILL ALSO IMPROVE THE SYSTEM'S ABILITY TO RESPOND TO FORECAST CHANGES OR UNEXPECTED MANUFACTURING DELAYS.

SUPPLIERS ARE IN THE BUSINESS OF SUPPORTING PHYSICIANS AND NURSES AT WHAT THEY DO BEST: PROVIDING PATIENT CARE. IN THE UPCOMING FLU SEASON, DISTRIBUTION WILL PLAY A MUCH LESS SIGNIFICANT ROLE IN DELIVERING FLU VACCINES. MAJOR DOMESTIC MANUFACTURERS APPEAR TO BE PURSUING A DIRECT-TO-CUSTOMER APPROACH THAT BYPASSES DISTRIBUTORS, WHO IN THE PAST DELIVERED APPROXIMATELY 50 PERCENT OF THE FLU VACCINE SUPPLY. EARLY REPORTS ARE THAT PRICES WILL BE DOUBLE THOSE OF LAST YEAR. IT REMAINS TO BE SEEN HOW THIS NEW, "NO-DISTRIBUTION" APPROACH WILL IMPACT HEALTHCARE PROVIDERS AND THEIR ACCESS TO THE FLU VACCINES THEY NEED TO ADMINISTER TO THE MILLIONS OF PATIENTS THEY SERVE.

THANK YOU AGAIN FOR INVITING ME TO TESTIFY BEFORE THE COMMITTEE.

Senator WYDEN. Thank you. Anything you would like to add, Mr. Skoronski.

STATEMENT OF STEVE SKORONSKI, PRESIDENT AND CEO, ASSOCIATED MEDICAL PRODUCTS, INDIANAPOLIS, IN

Mr. SKORONSKI. No. I believe Matt's testimony covered the specifics to this particular issue. My testimony dealt more with the broader and general issues in medical practice distribution. I suspect the written testimony will probably cover what you are looking for there.

[The prepared statement of Mr. Skoronski follows:]

TESTIMONY OF STEVE SKORONSKI
PRESIDENT/CEO, ASSOCIATED MEDICAL PRODUCTS
SENATE SPECIAL COMMITTEE ON AGING
FIELD HEARING—PORTLAND, OREGON
MAY 30, 2001

GOOD MORNING SENATOR WYDEN, AND THANK YOU FOR INVITING ME TO TESTIFY THIS MORNING TO PROVIDE INFORMATION ABOUT HOW THE MEDICAL PRODUCT DISTRIBUTION SYSTEM WORKS.

MY NAME IS STEVE SKORONSKI, AND I AM THE PRESIDENT AND CEO OF ASSOCIATED MEDICAL PRODUCTS IN INDIANAPOLIS, INDIANA. ASSOCIATED MEDICAL PRODUCTS IS A FULL SERVICE MEDICAL PRODUCTS DISTRIBUTION FIRM. IN ADDITION TO PROVIDING RESPIRATORY AND INFUSION THERAPY SERVICES TO THE HOME CARE AND LONG TERM CARE MARKETS, WE ALSO LEASE MEDICAL EQUIPMENT AND OFFER THIRD-PARTY BILLING SERVICES.

I AM ALSO THE CHAIRMAN OF THE HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION (HIDA), A NATIONAL TRADE ASSOCIATION BASED IN ALEXANDRIA, VIRGINIA THAT REPRESENTS MEDICAL PRODUCTS DISTRIBUTORS. OUR 220 MEMBER COMPANIES SERVE THE NATION'S HOSPITAL, IMAGING, LONG TERM CARE, AND PHYSICIAN AND ALTERNATE CARE MARKETS. THEY DISTRIBUTE ITEMS THAT RANGE FROM LATEX GLOVES TO EXAM TABLES TO WOUND CARE PRODUCTS. MANY ALSO DISTRIBUTE FLU VACCINES, PRIMARILY TO NURSING FACILITIES AND PHYSICIAN OFFICES.

DISTRIBUTION IS AN IMPORTANT FORCE IN THE ECONOMY. IN 1999, SALES OF ALL WHOLESALE DISTRIBUTORS REACHED 2.7 TRILLION DOLLARS.

DISTRIBUTION CONTRIBUTED 7 PERCENT OF U.S. NATIONAL INCOME IN 1999 AND ACCOUNTS FOR ABOUT ONE IN EVERY 20 JOBS IN THE UNITED STATES. DISTRIBUTION OCCURS IN NEARLY EVERY SEGMENT OF OUR ECONOMY. THE PRODUCTS YOU BUY IN A GROCERY STORE HAVE BEEN DELIVERED BY A DISTRIBUTOR. THE BOOKS AT BARNES AND NOBLE ARE PURCHASED FROM A DISTRIBUTOR. FOOD SERVED IN A RESTAURANT IS DELIVERED BY DISTRIBUTORS.

DISTRIBUTORS SELL PRODUCTS TO RETAILERS, MERCHANTS, CONTRACTORS, INDUSTRIAL INSTITUTIONS, AND COMMERCIAL USERS BUT DO NOT SELL IN SIGNIFICANT AMOUNTS TO HOUSEHOLD CONSUMERS. THE INDUSTRY INCLUDES COMPANIES THAT DISTRIBUTE BOTH DURABLE AND NONDURABLE GOODS. DISTRIBUTORS EXIST LARGELY BECAUSE OF THE VALUE THEY ADD IN SALES, MARKETING, AND PHYSICAL DISTRIBUTION OF PRODUCTS. ONE REASON THAT DISTRIBUTORS HAVE INCREASED THEIR SHARE OF TOTAL SALES IS THAT THEY PERFORM THESE FUNCTIONS MORE EFFECTIVELY AND EFFICIENTLY THAN EITHER MANUFACTURERS OR CUSTOMERS. DISTRIBUTORS OFFER FLEXIBLE, FAST RESPONSE TO CUSTOMER NEEDS, CONSISTENCY OF SERVICE, AND A LOCAL PRESENCE.

IN TERMS OF LOCALE, THERE ARE APPROXIMATELY 25 HIDA MEMBERS IN OREGON WHO REPRESENT FOUR OF THE LARGEST MEDICAL PRODUCT DISTRIBUTORS IN THE UNITED STATES: OWENS & MINOR, PSS/WORLD MEDICAL, MCKESSON HBOC, AND ALLEGIANCE HEALTHCARE. IN ADDITION, THERE ARE APPROXIMATELY 40 SMALLER MEDICAL PRODUCTS DISTRIBUTORS THROUGHOUT THE STATE, MOSTLY IN PORTLAND BUT ALSO IN

SALEM, HOME TO PRAXAIR, A MEDICAL GAS SUPPLIER; CLACKAMAS, WHERE MOBILE LABORATORY PRODUCTS OPERATES; LAKE OSWEGO, WHERE MPM PRODUCTS SUPPLIES X-RAY PARTS; AND HILLSBORO, HOME TO FOREST MEDICAL PRODUCTS. OTHERS ARE IN SMALL TOWNS SUCH AS HOOD RIVER, HOME TO CASCADE DENTAL PRODUCTS, AND KEIZER, WHERE STAR 21 HEALTHCARE PRODUCTS CONDUCTS BUSINESS. IN ADDITION TO SUPPLYING OREGON'S HOSPITALS, NURSING FACILITIES, AND PHYSICIAN OFFICES, THESE DISTRIBUTORS ARE ALSO EMPLOYERS AND CONSUMERS OF OTHER PRODUCTS NECESSARY FOR CONDUCTING BUSINESS.

MEDICAL PRODUCTS DISTRIBUTORS PROVIDE THE PROCESS AND INFRASTRUCTURE THROUGH WHICH MOST MEDICAL SUPPLIES AND EQUIPMENT, INCLUDING FLU VACCINES, FLOW TO THE FINAL USERS IN ALL HEALTHCARE SETTINGS. THIS REQUIRES DISTRIBUTORS TO SUPPLY THE RIGHT PRODUCTS, IN THE PROPER AMOUNTS, TO THE RIGHT PLACES, AT THE RIGHT TIME, AND IN EXCELLENT CONDITION. DOING THIS REQUIRES DECISION-MAKING AT EVERY JUNCTURE, FROM PLACING AN ORDER TO WAREHOUSING THE PRODUCT TO DELIVERY. A TYPICAL PRODUCER-TO-PATIENT DISTRIBUTION CHAIN MAY BE STORED, HANDLED, AND TRANSPORTED AS MUCH AS 15 TIMES BEFORE IT IS ACTUALLY CONSUMED BY A PATIENT.

MEDICAL PRODUCTS DISTRIBUTORS PROVIDE SEVERAL KEY SERVICES THAT SUPPORT AND MAINTAIN A HEALTHY SUPPLY CHAIN. THEY INCLUDE TAKING ORDERS FROM CUSTOMERS AND HELPING THEM DEFINE THEIR NEEDS; PLACING ORDERS WITH MANUFACTURERS IN A TIMELY FASHION; PROVIDING

DELIVERY AND TRANSPORTATION SERVICES; RECEIVING AND HANDLING PRODUCTS; STORAGE; PACKAGING; FINANCIAL TRANSACTIONS AND ORDER PROCESSING; BILLING; CREDIT MANAGEMENT; AND PROCESSING RETURNS AND OTHER CUSTOMER SERVICES. THESE FUNCTIONS ARE ALL INTERRELATED AND HELP SUPPORT EFFICIENT BUSINESS PRACTICES FOR BOTH DISTRIBUTORS AND THE PROVIDERS THEY SERVE.

WHILE EVERY DISTRIBUTION SCENARIO IS UNIQUE, I CAN OFFER AN OUTLINE OF HOW DISTRIBUTION GENERALLY WORKS:

DISTRIBUTORS PROVIDE PRE-SALES SERVICES, SUCH AS PROVIDING CUSTOMER EDUCATION AND TRAINING ON HOW TO USE THE PRODUCT, AND ESTABLISHING SALES AGREEMENTS, TERMS, AND DEFINING CUSTOMER SERVICE NEEDS.

DISTRIBUTORS ALSO PROVIDE ORDERING SERVICES, INCLUDING ORDER ENTRY, PROCESSING, MANAGEMENT, CHECKING INVENTORY, SCHEDULING AND DELIVERY—MUCH OF THIS IS NOW PERFORMED ELECTRONICALLY.

DISTRIBUTORS PROVIDE DELIVERY SERVICES, SUCH AS HANDLING AND SHIPPING, WAREHOUSING, AND BREAKING BULK INTO SMALLER PACKAGES.

POST-SALES SERVICES OFFERED BY DISTRIBUTORS INCLUDES ACCOUNTING AND INVENTORY MANAGEMENT. IN ADDITION, CUSTOMER SERVICE IS A KEY ELEMENT WOVEN THROUGHOUT THIS PROCESS. DISTRIBUTORS PROVIDE

TRAINING, TECHNICAL ASSISTANCE, AND EVEN FINANCING SO THAT CUSTOMERS MAXIMIZE THE UTILITY OF THE PRODUCTS THEY PURCHASE.

IN ADDITION, MANY MEDICAL DISTRIBUTORS MANAGE BILLING AND COLLECTION SERVICES FOR HOSPITALS, NURSING FACILITIES, SUBACUTE CARE FACILITIES, AND HOME HEALTHCARE SERVICES—ANYWHERE THAT MEDICAL EQUIPMENT IS NEEDED. OTHERS PROVIDE VALUE-ADDED SERVICES SUCH AS EQUIPMENT RENTAL, ASSEMBLY, REPAIR, AND MAINTENANCE; PRODUCT IN-SERVICE TRAINING; AND INSTALLATION.

SO YOU CAN SEE THAT DISTRIBUTION INVOLVES MORE THAN SIMPLY GETTING PRODUCTS FROM ONE POINT TO ANOTHER.

DISTRIBUTORS HAVE DEVELOPED INNOVATIVE METHODS TO CONSOLIDATE AND STREAMLINE ORDERS FROM CUSTOMERS AND TRANSLATE THEM INTO ORDERS TO MANUFACTURERS. THEY HAVE INVESTED SUBSTANTIAL CAPITAL IN ORDER PROCESSING TECHNOLOGIES THAT HELP THEM MAINTAIN AN EFFICIENT AND COST-EFFECTIVE SUPPLY CHAIN. THESE KINDS OF PRACTICES ALLOW DISTRIBUTORS TO SAVE THE OVERALL HEALTHCARE SYSTEM ABOUT $50 BILLION EACH YEAR, PRIMARILY BY REDUCING THE OVERALL NUMBER OF TRANSACTIONS TO CUSTOMERS.

FOR EXAMPLE, ONE STUDY FOUND THAT WITHOUT DISTRIBUTORS, THERE WOULD BE 1.3 BILLION ANNUAL TRANSACTIONS BETWEEN MANUFACTURERS AND PHARMACIES, ASSUMING ONE ORDER PER MONTH FROM PHARMACIES.

WITH DISTRIBUTORS, THIS NUMBER SHRINKS TO 43.8 MILLION TRANSACTIONS, ASSUMING FIVE ORDERS PER WEEK.

HERE ARE SOME OTHER EXAMPLES OF HOW DISTRIBUTORS PROVIDE A UNIQUE VALUE TO THE SUPPLY CHAIN BY REDUCING ACTUAL CUSTOMER COSTS:

- DISTRIBUTORS HAVE INVESTED HEAVILY IN PAPERLESS TRANSACTIONS, ALSO KNOWN AS ELECTRONIC DATA INTERCHANGE OR EDI, WHICH REDUCES HANDLING COSTS, MAXIMIZES FILL RATES, AND MINIMIZES EXCESS INVENTORY.

- DISTRIBUTORS PROVIDE ASSET MANAGEMENT PROGRAMS, SUCH AS CONSIGNMENT, STOCKLESS, AND JUST-IN-TIME INNOVATIONS, TO HELP MEDICAL FACILITIES CONVERT INVENTORY ASSETS TO CASH. ASSET MANAGEMENT HELPS MEDICAL FACILITIES ENSURE THAT HEALTHCARE PROFESSIONALS DO NOT HAVE TO SPEND VALUABLE TIME PROCESSING SUPPLIES AND PAPERWORK, BUT CAN FOCUS ON PATIENT CARE.

- MANY HIDA MEMBERS PROVIDE MEDICARE SERVICES AND PRODUCTS TO MEDICARE BENEFICIARIES WHO RESIDE IN SKILLED NURSING FACILITIES AND NEED INTENSIVE SERVICES THAT MANY FACILITIES DO NOT PROVIDE IN-HOUSE, SUCH AS PARENTERAL AND ENTERAL FEEDING AND SPECIALIZED WOUND CARE. IN ADDITION TO PROVIDING MEDICAL EQUIPMENT, THESE DISTRIBUTORS IMPLEMENT PHYSICIANS' INSTRUCTIONS, TRAIN STAFF IN USING SPECIALTY EQUIPMENT, AND

ASSIST FACILITY ADMINISTRATORS IN NEGOTIATING THE MAZE OF MEDICARE BILLING AND DOCUMENTATION. MANY ACTUALLY BILL FOR PART B MEDICARE SERVICES DIRECTLY, THUS RELIEVING NURSING HOME ADMINISTRATORS FROM ONE OF THE MOST COMPLEX MEDICARE BILLING TASKS. FULL REALIZATION OF THESE SERVICES CAN HELP FACILTIIES ACHIEVE SIGNIFICANT COST SAVINGS, AS WELL AS IMPROVED PATIENT CARE.

- DISTRIBUTORS ASSUME THE FINANCIAL BURDEN AND RISK OF HOLDING LARGE INVENTORIES. DISTRIBUTORS ABSORB MUCH OF THESE COSTS ON BEHALF OF THEIR CUSTOMERS.

- DISTRIBUTORS PROVIDE COST-SAVINGS FOR CUSTOMERS IN TERMS OF RENTING OR PURCHASING STORAGE SPACE, PAYING TAXES ON INVENTORY, PURCHASING INSURANCE, AND ASSUMING THE RISK FOR DAMAGES.

- DISTRIBUTORS PERFORM REAL-TIME PRODUCT STORAGE TRACKING AND DELIVER PRODUCTS TO CUSTOMERS WHEN THEY NEED THEM, AND IN THE PROPER QUANTITIES, EVEN ON SHORT, SAME-DAY NOTICE. BECAUSE DISTRIBUTORS ARE LOCATED CLOSE TO THEIR CUSTOMERS, THEY ARE SENSITIVE TO CUSTOMER NEEDS AND CAN PROVIDE A LEVEL OF PRODUCT AVAILABILITY THAT MANUFACTURERS RARELY ACHIEVE.

- DISTRIBUTORS ASSUME TRANSPORTATION COSTS AS PRODUCTS MOVE FROM ONE FACILITY TO ANOTHER. THIS SAVES MONEY FOR BOTH MANUFACTURERS AND PROVIDERS WHO WORK ALONE, AND HELPS KEEP OVERALL MEDICAL PRODUCT COSTS IN CHECK.

- DISTRIBUTORS HAVE DEVELOPED SOPHISTICATED RECEIVING SCHEDULES THAT ENABLE THEM TO SCHEDULE DATES AND TIMES FOR INBOUND SHIPMENTS THAT ALLOW THEM TO COORDINATE INSPECTION AND STORAGE TASKS.

- FINALLY, DISTRIBUTORS PROVIDE EXCELLENT CUSTOMER SERVICE BY PROVIDING A SINGLE POINT OF CONTACT FOR EACH PURCHASER. PROVIDERS KNOW THAT THEY CAN TURN TO A KNOWLEDGEABLE SALES REP WHO IS ABLE TO FOCUS ON AND UNDERSTAND THEIR EQUIPMENT AND SERVICE NEEDS.

I HOPE THIS PROVIDES YOU WITH A CLEAR PICTURE ABOUT MEDICAL PRODUCTS DISTRIBUTION. THANK YOU AGAIN FOR INVITING HIDA TO TESTIFY AT THIS HEARING.

Senator WYDEN. Well, extra points for brevity and candor, and I appreciate it.

We will have some questions here in a moment.

Dr. Higginson, welcome.

STATEMENT OF GRANT HIGGINSON, M.D., MPH, STATE OF OREGON HEALTH OFFICER, PORTLAND, OR

Dr. HIGGINSON. Thank you, Senator Wyden. For the record, my name is Dr. Grant Higginson. I am the State Health Officer, and the acting Administrator for the Oregon Health Division Department of Human Services, which is the State's public health agency. I am also here today representing ASTHO, the State and Territorial Health Officials. And once again, thank you for the opportunity to let me testify.

I am going to dispense with the background information I provided in the testimony. I think that's been adequately covered. I would like to get right into what the health division's role is in coordinating flu vaccine programs. And as you have already heard, by and large, the influenza vaccine is primarily purchased, distributed and administrated through the private sector.

The Oregon Health Division does have a role though, in efforts around immunization for adult populations. We have one adult immunization coordinator, and what she does is work with local health departments, other local groups to try to ensure that there is a coordinated effort at the local level to make sure that adults are getting appropriately immunized.

In addition to that one coordinator, we also publish an article in our Communicable Disease Summary Newsletter which is sent to all healthcare providers which encourages them and urges them to vaccinate the appropriate populations. We also issue a press release every year, which again deals with the influenza season and appropriate recommendations for who should be immunized.

Last year, as you have heard, was an unusual year when the Health Division was informed of expected delays in the influenza vaccine, we learned about that in June and we immediately started notifying and working with providers.

On September 15, we issued our first press release of this season detailing the guidelines for vaccine recommendations and notifying the public about the expected delay in vaccine distribution.

On September 26, we actually came out with contingency guidelines, and what they did was identify the high risk groups for priority vaccination and urged collaboration among providers and county health departments to share vaccine to ensure that vaccine was available to high risk populations.

Long-term care facilities were also notified of the delays by their affiliated organizations. On November 9, we then sent another memo to all county health departments regarding the vaccine supply, distribution delays and how to order additional vaccines from a new CDC contract that they had with Aventis. In late November, we actually purchased over 1,500 doses of flu vaccine from the Oregon Health Sciences University. We then surveyed our county health departments to see who was in the most need for those immunizations, and we then distributed them, who in turn distributed those to people serving high risk populations.

In December, we also received an additional 700 doses from the Public Employees Benefit Board, another 130 doses from the University of Portland, and they were similarly distributed to most needy populations through county health departments. I would also like to note that a number of health systems and hospitals at the local level also voluntarily distributed vaccines through local health departments to needy population.

We also, in December, surveyed each county about the availability of vaccine in their communities and encouraged them to make information available through a 1–800 number on where people could get that vaccination.

Then, our final press release of last flu season was on December 13 where we announced that flu season had officially arrived in Oregon and stated that vaccine supplies were now near normal.

As you have heard from a number of other people, there were problems that were experienced here in Oregon as were experienced around the country. Many private providers and county health departments simply had no vaccine available during October and November when most people should have got vaccinated, similar to what GAO has found, we did hear anecdotes that vaccines were being inappropriately administered in some grocery stores and other places where clinics were provided. We did follow-up on some such reports. A number of people were administering to appropriate populations; some were not. Most of those people did appropriately respond to our recommendations when we talked to them.

Unfortunately, as you have heard, by the time vaccine supplies arrived, many of the providers had already had their clinics scheduled. New clinics for immunizations were not scheduled. And so, a lot of vaccine was left on the shelf.

And so from what I have presented, Oregon's Health Division's role during the 2000 vaccine season of flu vaccine season really was one of information broker. We issued recommendations, prioritized vaccination of high risk patients. However, I should note here that while we made those recommendations, we did not have any authority to enforce those recommendations. We won't know how well we've done with last season or how poorly we have done until we get this year's Behavioral Risk Factors Survey results in. That is something that we will share with you when that data is available.

And as other people have said, I think we were very lucky that we did have a mild to moderate flu season last year.

The current private system, in general, as a number of people have said, usually does work well. I have been here in Oregon now for 14 flu seasons. This is the first year we have had a situation like we did last year.

It's important to keep in mind though that because the vaccines have not been an issue in the past that we do need to continue to encourage most people to be vaccinated. It is important that not only the high risk people be vaccinated, but that most people be vaccinated as well to curb this disease, if possible. However, we have seen that while the current system works fine in most circumstances, there are going to be times when shortage of delays can have substantial detrimental effects on providing vaccine to the most vulnerable populations. Inadequate vaccine availability could

have led to significant increases in morbidity and mortality in Oregon if we had seen the peak of the influenza season come earlier or have seen a more virulent strain of the disease.

So, we do have a number of recommendations that I would like to get on the record, and I do appreciate the opportunity to have a couple of more weeks to get you more. And I will get that information to ASTHO, as well as, to our people in our program.

The first recommendation is that we think that CDC and the FDA need to work with vaccine manufacturers so that we get the earliest possible indications of expected vaccine. Availability for us to plan for the season and any potential shortages is a very important thing.

Second, CDC should work with manufacturers and large distributors to ensure that in a situation of delayed or shortage of vaccine, that those customers who are most likely to vaccinate high risk persons would be served first, and from our perspective, this should include public clinics, physician practices, and nursing homes. It is unclear to me right now whether or not that should be totally voluntary or whether or not there should be some mandates. At the State level, we think that it is important that State health agencies at least consider gaining the authority to direct the distribution and administration of vaccine during times of shortage or delays. This is something that we actually have been working with our legislature on during this session.

There is a House Bill, House Bill 3339 which I have attached to my testimony that actually would give the State Health Officer the authority to implement a vaccine education and prioritization plan. It would allow the State Health Officer to develop these guidelines for the distribution and administration of vaccine, and it would also grant us authority to mobilize public and private health resources to help with that distribution and administration. It would also give us some teeth in that it would allow us the ability to impose $500 civil penalty fines for people who knowingly failed to adhere to those guidelines.

A fourth recommendation is, we think that Federal, State and the local public health agencies should promote persistently the value of vaccination, and that's not only just the general public education, but vaccination later in the season. If we do have delays, it is important that people know that they can get vaccinated in December, and if the peak is in January or February like we had this year, that that still would do a lot of good.

NIH should be supported in completing their studies of the half dose of influenza vaccine in healthy persons. It is actually shown by NIH that that can be an effective preventive measure as a way to stretch existing supplies of vaccine.

Another recommendation is that we think that Federal, State, and local public health agencies could more actively support efforts to reduce mortality and morbidity during the influenza season by increasing the rates of vaccination against pneumococcus. This is something again that you have heard from a number of people, and I won't dwell any longer on that.

What people haven't, I think, specifically said, but I do believe is inherent in a lot of recommendations is that more Federal funding is needed. I think that both at the Federal level, and from our

perspective at the State level, to deal with adult immunizations. We have an extensive immunization program for childhood vaccinations. In fact, we have 35 staff positions that are working on childhood immunizations. They do things such as provide public education, work with local communities to coordinate those efforts. While we have 35 people for childhood immunization, we only have one person involved in adult immunizations. And we think that this is really a disproportionate amount of funding and that more funding should be provided to provide those same kind of levels of service in planning, coordination, public education for the adult population as well.

Then, just one final thought is that I think that thought should be given at the national level to set standards for adult immunizations. We need to make sure that providers and insurers are using effective measures in protecting people against influenza and pneumococcus.

And with that, I will close and be happy to answer any questions.

[The prepared statement of Dr. Higginson follows:]

Oregon

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May 30, 2001

TO: U.S. Senate Special Committee of Aging

FROM: Grant Higginson, MD, MPH
Acting Administrator, State Health Officer
Department of Human Services, Health Division

SUBJECT: ADULT IMMUNIZATION & FLU VACCINE SHORTAGE

Influenza is a major, recurrent public-health problem. Influenza is not merely a common cold; rather, it is a severe viral respiratory infection, often complicated by pneumonia, that each year kills an estimated 20,000 persons nationwide. At highest risk are the elderly and those with chronic diseases or immunocompromising conditions. For this reason, it is important that we vaccinate as many of these persons as possible against influenza every year. Among persons over 65 years of age, the vaccine is about 80% effective in preventing death from influenza.

Oregon Health Division role in coordinating flu vaccination programs

In Oregon, influenza vaccine is primarily purchased, distributed and administered in the private sector. Oregon Health Division efforts to vaccinate against influenza are led by our Adult Immunization Coordinator. This Coordinator provides local providers and county health departments influenza vaccine and surveillance information. Additionally, the Coordinator meets regularly with the Oregon Adult Immunization Coalition, which includes representatives of managed-care plans, the Oregon Medical Peer Review Organization, and other dedicated members of the community to strategize about ways to raise rates of adult immunization against influenza and pneumococcal disease. We publish an annual article in our *CD Summary* newsletter, which is sent to all licensed physicians, nurse practitioners, and physician assistants in the state, reviewing high-risk groups and urging vaccination. We issue a press release each influenza season highlighting the importance of preventing influenza and the need for vaccination, especially of high-risk groups.

When the Oregon Health Division was informed of the expected delay in influenza vaccine distribution last June, we notified immunization providers statewide and began to develop contingency guidelines. On September 15, we issued our first press release of the season, detailing changes in the vaccine recommendations, and notifying the public about the expected delay in vaccine distribution. The contingency guidelines were disseminated on September 26; they identified high-risk groups for priority vaccination, and urged collaboration among providers and county health departments to share vaccine so as to ensure vaccination of high-risk persons. Long-term-care facilities were notified of the delays by their affiliated organizations. We shared our contingency plans with the Southwest Washington Health District, so that the approach would be similar throughout the Portland Metro area.

On November 9, we sent another memo to all county health departments regarding the vaccine supply, distribution delays, and how to order additional vaccine from the new CDC contract with Aventis. In late November, we purchased 1,600 doses of flu vaccine from OHSU; we then surveyed our county health departments and distributed the vaccine to those in greatest need, to be administered exclusively to high-risk persons. In December, we received an additional 700 doses from the Public Employees Benefit Board and 130 doses from the University of Portland; these were similarly distributed to counties with greatest need. Notably, a number of local hospitals and health systems also made vaccine available to county health departments experiencing need. We again surveyed each county about the availability of vaccine in their communities and urged them to make information on flu vaccination clinics available through SafeNet — which maintains an 1-800 number and web site with information on immunization clinics throughout Oregon.

On December 13, we issued a second press release, announcing the arrival of influenza in Oregon and stating that vaccine supplies were now near normal.

Problems experienced in Oregon during the delay in vaccine distribution

During this past flu season, Oregon experienced difficulties that were probably seen in every state. Many private providers and county health departments had no

vaccine available during October and November, when vaccination clinics are usually held. Similar to what GAO investigators found, we heard anecdotes about vaccinations being administered in grocery stores without regard to high-risk status. We did follow up on such reports; some were, indeed, administering vaccine to low-risk person, while in other cases we learned that the clinics were, indeed, adhering to our recommendations when vaccine was in short supply. Unfortunately, by the time adequate supplies of vaccine arrived, many providers had already held their planned vaccination clinics; they didn't schedule new ones, and so vaccine was left on the shelf.

The Oregon Health Division's role during the year 2000 vaccine delay was primarily that of an information broker. We issued recommendations to prioritize vaccination of high-risk persons. However, we did not have the authority to enforce such recommendations.

We won't know how well we did dealing with the vaccine delay until the results of this year's Behavioral Risk Factor Survey are available to show our actual vaccination rates. Data regarding the severity of this influenza season in Oregon are, at best, sketchy; but overall, it seems, fortunately, to have been a mild-to-average year. As measured by viruses isolated by the Oregon State Public Health Laboratory, the season peaked at the end of January. The peak was well after adequate vaccine supplies had arrived in the state.

The current private distribution system and the needs of high-risk patients

In general, the current private distribution system for influenza vaccine meets the needs of high-risk patients fairly well. It is important to keep in mind that because shortages of vaccine have not been an issue in the past, we have tried to encourage vaccination of as many Oregonians as possible against influenza. Indeed, data from other studies indicate that vaccination of healthy school children is an effective means of preventing influenza in others who may be at higher risk. Long term, we would rather encourage increased production of influenza vaccine to vaccinate larger numbers of persons than to discourage the vaccination of low-risk persons. However, this past flu season has shown that while the current systems works fine

in most circumstances, shortages and delays can have substantial detrimental effects on providing vaccine for the most vulnerable populations. Inadequate vaccine availability could have led to significant increases in morbidity and mortality in Oregon if we'd seen an earlier peak of influenza cases or a more virulent strain.

Recommendations for the future

I believe federal and state governments could help mitigate the effects of vaccine shortage or delays through several avenues. They include:

- CDC and FDA need to work with vaccine manufacturers so that we get the earliest possible indications of expected vaccine availability.
- CDC should work with manufacturers and large distributors to ensure that, in a situation of delayed distribution or shortage of influenza vaccine, those customers most likely to vaccinate high-risk persons would be served first. These would include public clinics, physician practices, and nursing homes.
- State public health agencies should consider gaining authority to direct distribution and administration of vaccine during times of shortage or delay. We have been working with the Oregon Legislative Assembly on House Bill 3339 (attached) to give the State Health Officer the authority to implement a Vaccine Education and Prioritization Plan. This plan would include guidelines on the distribution and administration of vaccine and other medications, and would grant authority both to mobilize public and private health resources to assist in vaccine distribution and administration, and to impose $500 fines for failure to adhere to the guidelines.
- Federal, state and local public health agencies should promote, persistently, the value of vaccination even later in the season. The optimal time for vaccination is generally October, but lost on many people is the fact that the season usually peaks in January or February: so there is a lot of benefit to be gained even if you don't get vaccinated until December or January.
- NIH should be supported in completing their studies of ½ doses of influenza vaccine in healthy persons. If the reduced dose is found to be effective, we would be able to immunize more of our citizens and prevent more illness.
- Federal, state and local public health agencies could more actively support

efforts to reduce mortality during influenza season by increasing rates of vaccination against the pneumococcus. The "pneumococcus" is a bacterium that causes pneumonia, bloodstream infection, meningitis, and other infections. It is probably the main cause of pneumonia among adults, and it often is a secondary infection associated with influenza. Many deaths could be prevented with widespread vaccination of adults with pneumococcal vaccine; nevertheless, according to a survey conducted during the year 2000, only 63% of Oregonians over 65 had received the pneumococcal vaccine.

- More federal funding is needed at the state level for adult immunizations in general. Even during recent years when vaccine was in ample supply, about 30% of Oregonians over 65 years of age went unvaccinated against influenza. And unlike childhood immunizations, where section 317 of the Public Health Act and the Vaccines for Children program fund extensive efforts at the state level to educate, and to identify and remove barriers to immunization, we have almost no federal funding for adult immunizations. We have 35 positions dedicated to childhood immunization, while funding for adult immunization is limited to a single FTE. This funding is not commensurate with the morbidity and mortality caused by vaccine-preventable diseases in adults. Because vaccine purchasing and distribution, health-care markets, and barriers to immunization are different in every state, it is important that states be allowed flexibility to administer funds in the most effective way for their needs.
- Thought should be given at the national level to standards for adult immunization. We need to measure the effectiveness of providers and insurers at least in part by the degree to which their patients are protected by influenza and pneumococcal vaccines and other preventive modalities. This is particularly important for the Medicare population.

Influenza is a classic example of a disease where an ounce of prevention is worth a pound of cure. We in public health look forward to working with you on this issue.

71st OREGON LEGISLATIVE ASSEMBLY–2001 Regular Session

A-Engrossed
House Bill 3339

Ordered by the House May 17
Including House Amendments dated May 17

Sponsored by Representative KRUSE

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

[*Authorizes State Health Officer to declare vaccine shortage emergency or vaccine shortage crisis in certain circumstances. Authorizes Health Division to establish procedures for addressing vaccine shortages, to impose civil penalties in certain circumstances and to delegate certain authority to local public health administrators. Authorizes division to take title to and redistribute supplies of vaccine under certain conditions. Requires payment for vaccine obtained for purposes of vaccine shortages.*]

Requires Health Division to adopt by rule Oregon Vaccine Education and Prioritization Plan. Specifies contents of plan, including civil penalty of $500 for knowing violation. Describes circumstances for implementation of plan.

A BILL FOR AN ACT

Relating to vaccine shortages.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Section 2 of this 2001 Act is added to and made a part of ORS 433.001 to 433.045.

SECTION 2. (1) As used in this section, "vaccine" includes vaccines, immune products and chemoprophylactic medications.

(2) When the State Health Officer of the Health Division determines that there is clear evidence that adverse and avoidable health outcomes from a preventable and acute communicable disease are expected to affect identifiable categories of high-risk individuals throughout Oregon and that assistance with the administration of vaccine is warranted due to a vaccine shortage to protect or treat such individuals, the health officer shall implement the Oregon Vaccine Education and Prioritization Plan as provided in subsection (3) of this section.

(3) The Health Division shall develop and adopt by rule the Oregon Vaccine Education and Prioritization Plan to protect the public health during a vaccine shortage. The plan shall consist of:

(a) Guidelines for physicians, nurses, hospitals, health systems, pharmacies and others that hold vaccines for the distribution and administration of vaccines. The guidelines shall include, but are not limited to, a definition of high-risk groups for priority protection or treatment in the event a vaccine shortage is imminent;

(b) Rules for imposing a civil penalty of $500 against persons who knowingly violate the guidelines for each repeat violation of the guidelines; and

(c) Procedures for:

(A) Mobilizing public and private health resources to assist in vaccine distribution and

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

administration; and

(B) Notifying health professional regulatory boards and licensing authorities of repeated violations of the guidelines by health professionals regulated by the board or licensed by the authority.

SECTION 3. By March 1, 2003, the State Health Officer of the Health Division of the Department of Human Services shall report to the Seventy-second Legislative Assembly on the development, use and any problems encountered in the implementation of the Oregon Vaccine Education and Prioritization Plan established by section 2 of this 2001 Act.

Senator WYDEN. Very good, thank you and an excellent panel.

Let me begin with you, Dr. Fukuda. What are the odds this year that it's going to be like last year?

Dr. FUKUDA. Do you mean in terms of the supply or in terms of the——

Senator WYDEN. The overall problem. What are the odds that we are going to have seniors like Mary Keene traipsing all over town trying figure out where to get this, and where to turn and same sort of problem?

Dr. FUKUDA. Well, it is difficult to give you really good odds on what is going to happen. You have probably heard that it is a very complex process getting vaccine made and out to people. And it is possible for the system to breakdown at any place. For example, the egg supply can be bad and so on.

And so, as I mentioned in my testimony, it is not really going to be until later—probably toward the end of summer or the early part of the fall that we really know what the picture is going to be like. And that is the reality that we face every year. We are never certain what the supply is going to be like until well into the season.

Senator WYDEN. No, I understand that. I think that we have got a plan for good times and bad times alike. So, is it 50/50 that we are going to have another year this year like we had last year, or 10 percent or what is your sense?

Dr. FUKUDA. The information that we received from the manufacturers tells us that their estimates are up to 84 million doses of vaccine. So far, the indications that we have that the estimates are good, and we have not heard about any production problem.

Senator WYDEN. So, at this point then, you think that there is a probability that we won't have another year like last year?

Dr. FUKUDA. Well, there is always that possibility yes.

Senator WYDEN. I guess, you know, policymakers rely on people like you so that you give us a sense of what we are heading into. We have got to have a system that works for good times as well as bad times. What you told me is you don't think it is very likely that this upcoming year will be like last year.

Dr. FUKUDA. It is fair to say that right now it does not look like there are any production problems. We do know that there are ongoing discussions with one company and the FDA about continuing good manufacturing practice issues. And I think we all need to wait and see how those resolve. I think that we are very mindful that what happened last year could happen this year. It could happen the year afterwards. So, we are really keen to push ahead with whatever things can be done to strengthen the whole system.

Senator WYDEN. But you don't think it is very likely at this point?

Dr. FUKUDA. It is possible, and I don't think I can go much further than that. I don't think I can tell you it is 10 percent, or it is 50 percent, or it is 100 percent. I think that it is possible. It is possible enough that we are seriously pushing ahead with several efforts to make the supply and distribution better. And I don't think I can prognosticate more than that.

Senator WYDEN. When do you think you will be able to tell the public that we are not going to have another year like last year?

Is this going to be in September or August, or when do you think you will be able to tell us?

Dr. FUKUDA. Well, I think during the summer, if something goes really bad, we are going to know about it. We are going to be able to tell people. If things go along well, and we don't hear about any significant problems, then I think it is again really at the end of the summer or the early part of the fall time before we can say that things look really pretty good.

Senator WYDEN. Now, you heard me talk about my discussion with the Secretary this morning.

Dr. FUKUDA. Yes.

Senator WYDEN. I really do want to bear down on getting ideas of what you would like to see done in the next 60 days. I am going to leave the record open, as I have done with everybody else for the next 2 weeks, but what do you think needs to be done in the next 60 days to increase the prospects that we won't have our constituents like Ms. Keene traipsing all over town trying to figure out what's going on?

Dr. FUKUDA. Sure. Well, Senator, to be practical and realistic about what can be done, I think there are three things that really ought to be kept in mind and considered for action. The first point as has been pointed out by many of the speakers, is that the system is complicated but has worked well in general. Last year was an unprecedented situation for the United States. In general, this very complex system has done a good job about getting the vaccine made, getting it out to people.

Senator WYDEN. The Oregon Medical Association says the system is chaotic and irrational. These are not far out, wild-eyed kind of people. I mean, these are folks on the front lines, and they say it's chaotic and irrational.

Dr. FUKUDA. Well, clearly, the past year did bring up some severe issues, which we have to keep in context in the big scope of things. The second point is that we have to think about actions that we can do in the short-term and those that need to be done in the long-term. Both are clearly needed. In the short-term, I think it is clear that some of the things which have to be done is that these private and public sector discussions are needed—the kind that took place at the American Medical Association Headquarters in March, those kinds of discussions need to take place both at the local level and at other meetings, such as the kind of meetings that you are proposing with the Secretary. In these meetings, everyone needs to understand how the system really does work, what are the challenges, what are the real problems inherent in trying to make an enormous amount of vaccine and getting it out to people.

Another thing that we need to do a better job about is education. The misinformation that Ms. Keene received she was told that she is not at high risk, is a good example. We need to do a better job of getting educational messages out there such as, who is high risk? Who needs to get vaccine? We need to make those messages accessible.

Again, I think that at CDC, the National Immunization Program has really forged ahead in this area. It has been holding focus

group meetings trying to figure out what is the best way to get information to people.

A third step is that contingency plans are going to be needed for manufacturers, for distributors, for providers, and for State health agencies. If we do come into another situation like last year, how are you going to get vaccine to high risk people? That is the big issue. The plans are likely going to vary depending on who you are and where you are in the country as to exactly what you ought to do, but those plans definitely are needed.

Senator WYDEN. But you believe then—I want to be clear on this—that this effort that would be developed in 60 days ought to lock-in some contingency plans?

Dr. FUKUDA. They ought to push ahead with the contingency plans. This kind of effort that you are talking about can be very helpful in pushing forward those plans.

Now, these actions have mentioned are what can be done in the relative short- and medium-term. But we really have to look at some long-term issues also. One major issue is that we really need to change behaviors in the country about how flu vaccine is administered. We recommend giving vaccine in October and November as the optimal time period because that gives high-risk people the best chance of getting high risk people vaccinated, but it is clear every year that there are a lot of high risk people who don't get vaccinated in that time period. It is also clear that in many years, influenza activity doesn't substantially pick up until later than November. So, we must teach physicians and recipients, it is OK for high-risk people to get vaccinated after November if they weren't vaccinated earlier.

The second major issue is vaccine supply. There used to be seven vaccine manufacturers; we are now down to three. And this is in the face of growing demand. As you know serving on the Aging Committee, the population of elderly people is increasing very rapidly in the United States. This is only going to drive up demand. It is only going to increase the need for vaccine in the future.

The third issue is that we really do need to improve our ability to deliver vaccine to adults. This combination of short-term approaches and long-term approaches will be needed to have a realistic solutions for these sorts of vaccine problems.

Senator WYDEN. How do you all intend to use your web site? I understand that you want to try to get information out regularly to physicians. Is this going to start in August, or when will you start this year so that providers can know what place to turn to get information on how often they can anticipate updating it?

Dr. FUKUDA. Well, I believe that the National Immunization Program has already begun these every 2 week updates. The information is posted on the Internet, and is also sent out to a wide variety of users in different organizations and to providers. I believe that this will continue through the year.

Senator WYDEN. How is CDC identifying the providers who serve the high risk population?

Dr. FUKUDA. This is a difficult problem. For some of it, it is easy, you know, nursing homes, physicians who take care of certain kinds of patients, patients with diabetes or heart conditions. But what is more difficult is that there are a lot of physicians who see

a mix of patients out there, and there are organizations who see a mix of patients out there. I think that this issue is difficult to get at.

CDC has instituted a number of different surveys in attempt to get information from providers and from healthcare organizations about what kinds of patients they see, and also, to try to evaluate what happened last season. So, those attempts are ongoing right now.

Senator WYDEN. How do you all work with the Health Care Financing Administration in this area, and do you anticipate any changes there?

Dr. FUKUDA. Well, in this particular problem, the CDC has been working closely with HCFA to get letters and information out to those providers who work in the Medicare program, to remind them about who should get vaccinated, and to remind them to get their vaccine orders in now. And there have been ongoing discussions about the pricing of flu vaccines. And we know that this is a concern to providers, and it is an important issue. These are ongoing areas of discussion with HCFA.

Senator WYDEN. How do you all see the question of flu stocking up to the issue of trying to increase the number of seniors vaccinated against pneumonia? Clearly, there are competing concerns here, and I would be curious what resources are needed, and how do you go about coming up with an approach to deal with flu vaccine shortages at a time when you are trying to increase the number of seniors vaccinated against pneumonia?

Dr. FUKUDA. There are a couple of useful ways to look at this. One is that a lot of the people who are at high risk for flu are also at high risk for pneumonia. So, there are not really competing issues here. These same groups of people need to get both the pneumococcal vaccine and the influenza vaccine. But I think another way to look at it is that if you have a big, broad-based pyramid, there are many more influenza vaccinations—or many more cases of influenza every year, and these cases of influenza really set up a lot of people for developing pneumococcal pneumonia and other pneumonias. So influenza vaccine in many ways is a key to preventing these pneumonias and other pneumococcal infections in addition to getting a pneumococcal vaccine directly into people. We need both, but there is this sort of pyramid in terms of what precedes what.

Senator WYDEN. All right. We are going to look forward to getting your recommendations within 2 weeks, as well, and they will be particularly important since—while there is vigorous debate about what to do in this area, almost everybody seems to think CDC ought to be driving Federal policies. You will have that challenge to deal with, for sure.

Mr. Kaufman, same questions I asked Dr. Fukuda. What do you think the prospects are for another year like last year with respect to flu vaccines?

Mr. KAUFMAN. Well, without risking a percentage directionally, I would say the probability is low that there would be a repetition of last year. Last year was sort of a—as we put it in some cases, almost a triple witching hour in that the last strain that was named, it was named slightly late last year—I believe the first

week in April—also happened to be the same strain that all manufacturers had a problem growing. It was a low yielding strain which took some time before they found the key to getting it to grow in the eggs, combined with the fact that there were two manufacturers that had GNP problems, with one of them totally walking away from the market. So, that confluence of three events, I would say the probability is low of a repetition. Combined with the fact that this year, the yields, at least so far, seemed to be very good.

Senator WYDEN. What role, if any, do you and other private industry, you know, representatives feel that the government should play here? That is really central to this debate. As you know, the State Legislature and the Congress where some say the government ought to step in under the following circumstances and the like.

I would be curious what you and other private industry representatives think ought to be the government role, if any, during the kinds of problems we had last winter.

Mr. KAUFMAN. I think there very clearly is a government role. And what evolved over the years was a disconnect between market demand and when it was medically advisable to give the shots. People were demanding that we ship them vaccines as early as possible. Maybe it gave them a feeling of security because now they had the vaccine in August or very early September, which they would keep in their refrigerators for their clinics which were going to be held in late September and October.

I think what last year's problems brought into focus is the fact that it was really needed that the market demand be shifted to fit more with the optimal time to immunize. And I think there have been steps taken for that. Several of the speakers have referred to the AMA meeting that took place. This year, the CDC already has begun to issue—I believe there may have been something in the MMWR—already talking about the optimal time to immunize, including through November, in fact, into December.

Senator WYDEN. What would you like to see go into this 60-day push to try to ensure that we don't have another year like last year?

Mr. KAUFMAN. First of all, I think that what I just mentioned, the fact that there should be ongoing meetings as there were last time where all of the stakeholders are brought together where the CDC met with the AAFP, the AMA hosted the meeting as a way that there could be early warning that we could work with them.

I think that the hardest part of all of this is there is a number of hard things. One of them is, it seems to us, at least from where we sit as manufacturers, that all channels of distribution, no matter where you look, have high risk patients. It's very difficult not to ship, for example, a lot has been talked about the supermarket chains. The best of our information is that approximately 5 percent of the doses distributed—a relatively small amount—ends up going into these, what we call private access programs, these supermarket types——

Senator WYDEN. But that really isn't the appropriate barometer. If 5 percent are engaged in activity that, in effect, skews everything else that's going on because of all the advertising and the

hype and the like, it is really not about, you know, 5 percent. It is about activity that can drive the market and create chaos.

Mr. KAUFMAN. Well, and it got publicity way out of proportion to the amount of doses that were there. I agree with you. What I am saying is high risk people went there too. I believe Mrs. Keene went there first. So, from a manufacturer's——

Senator WYDEN. She went to a doctor's office first.

Mr. KAUFMAN. I'm sorry. Doctor first and——

Senator WYDEN. She tried to use a doctor twice. She tried to use the doctor at her senior center, and she tried to use the doctor in the office.

Mr. KAUFMAN. Right, but for whatever reason, high risk people end up at the end of all these distribution chains. So, guidance to us which has been mentioned—and I don't know how they do that. But how do we know who to ship to? We have a very efficient system there. How do we know—a better way to look at it is, who not to ship to so as not to prevent people from getting access?

Senator WYDEN. All right. Mr. Rowan, with respect to your membership, are there any, in your view, that are trying to exploit this situation and jack up prices unreasonably?

Mr. ROWAN. Not that we are aware of. I mean, I think from the testimony earlier today, I think bears that out. If you look at the earlier testimony from Dr. Sattenspiel—I believe is how you pronounce his name—and Mr. Allred from GetAFluShot.com is that these early—it is really a misnomer to call them precontracted orders. They are actually pre-booked orders that give flexibility to both sides, both the customer and the distributor, or even in many cases, the manufacturer.

As both of those gentlemen earlier testified, they got their orders, and they got them at the pre-booked price. The reason anybody pre-books an order is to lock in the price. Anybody who waits until the flu season is in full swing and tries to make a purchase on the spot market is going to experience somewhat higher prices. Again, the testimony earlier bears that out that there were some modest price increases.

The bigger concern, I think, from our viewpoint is that what are prices doing this year with many distributors, particularly the small distributors who, more than likely, serve smaller physician practices being cut out of the market, we see prices—from our information—is that prices will double. And so, you know, we get back to the reimbursement issue. We get back to the issue of how do we deal with this as a public health issue and access to healthcare for, you know, 70, 75, 77 million patients a year?

Again, our information is that most of our small distributors had no vaccine to distribute at any price, pre-booked or otherwise.

Senator WYDEN. So, you were surprised at what we heard about today?

Mr. ROWAN. Well, I do want to follow with the testimony from the GAO earlier. I would be surprised if there was a pre-booked order, and then there was a subsequent offer for—we can't fulfill that pre-booked order, but we have this supply at a higher price. I think more than likely, the vast majority of providers and distributors had an experience much like what Mr. Allred and Dr. Sattenspiel earlier testified to.

Again, I think in the instance of Mr. Allred who was approached by unscrupulous wholesalers—don't know who they are, but I believe he did the right thing in turning away that offer—spurning that offer.

Senator WYDEN. I guess the one thing we know now is there are predictions for big price hikes next year.

Mr. ROWAN. Right.

Senator WYDEN. I mean, you have said it, and you are representing an industry standpoint. Mr. Allred said it. Who is raising the prices, the manufacturers or distributors? Who is raising the prices?

Mr. ROWAN. My estimation of that would be at the manufacturer level. Again, the distributors largely are being cut out of the market in the 2001–2002 flu season that—our understanding anyway—is that wholesale orders are not being accepted——

Senator WYDEN. I would give you——

Mr. ROWAN [continuing.] By domestic manufacturers.

Senator WYDEN [continuing.] Equal time on that, Mr. Kaufman.

Mr. KAUFMAN. I was hoping you would.

Senator WYDEN. The distributors say that the manufacturers are raising the prices, and now I want to hear from you with—Mary Keene ought to know that she is going to get a reasonably priced vaccine that she can get access to, and she is not going to be so much interested in who is pointing the finger at who. But the distributors said it was the manufacturers. Now, the manufacturers ought to have a chance to respond.

Mr. KAUFMAN. I could speak for our price. And our price that was announced—I can't give you the exact date, but the pre-book price on flu vaccine last year—this year—current vaccine was $5.00 a dose. I believe the vaccine was priced in the three—you may be able to help me—but in the $3.00, $3.50 price for a number of years from about 1992 up to around 1998, 1999. There was a small increase then. And now, we have increased the price to $5.00 a dose. It is not a doubling of the price. I think, quite frankly, there are those who would still argue that it is an undervalued vaccine.

This may not be a popular statement, but one of the vaccine manufacturers is based in the U.K. The reason, we believe, that they do not make more vaccine available in this country—and I think they make available somewhere in the neighborhood of 10 to 15 million doses only—is because they find it much more profitable to sell the vaccine at a considerably higher price in Europe.

So, we, as a manufacturer—and again, I only speak for Aventis Pasteur—have raised the price for a number of reasons. One of which is the cost of compliance—and this is, in no way, a complaint, but Team Biologics at Ceber has raised the bar considerably in what it takes to be a GNP compliant. And I think that was evident with what happened with two other manufacturers last year. And second, we are investing considerable money to increase our capacity to fermenters, I believe, require——

Senator WYDEN. So, you are going to raise prices how much next year?

Mr. KAUFMAN. It's at $5.00 a dose.

Senator WYDEN. From?

Mr. KAUFMAN. I can't swear. I believe in the high threes, $3.80 or $3.90. Somewhere in there. I could send you the exact price.

Senator WYDEN. Yeah, I would like to have that.

Mr. KAUFMAN. It is somewhere in that neighborhood, but it is certainly not doubled.

Senator WYDEN. Mr. Rowan, what role, if any, do you think the Federal Government should take in times of shortage with respect to distribution?

Mr. ROWAN. Well, I think they should take the same role that they take in any sort of emergency situation. If you liken it to what FEMA does in terms of having contingency plans in place for non-standard events, whether the CDC seems to be a logical place to centralize some of this contingency planning.

You asked earlier, you know, was the situation chaotic and irrational as characterized by the Oregon Medical Association. I would agree that it was probably chaotic, but I think it was rational in the sense that everybody thought they were doing the right thing. The one piece that was missing last year that I think should be addressed in the contingency plan is that all entities in the supply chain need to recognize that they are part of something bigger than what goes on in just their factory or just their warehouse or just their doctor's office. And to that end, I think that the role that the government and the CDC should play is one of education. Educating the patients to educate whether they are high risk so that they know. To educate them to the expanded flu season. We have providers that need that education. We heard earlier today that a particular place—a customer contact point is the receptionist at a doctor's office. That is an individual that needs to know the specifics of the CDC recommendations, in particular.

Suppliers need direction and education. If again, specific to the facility so that we position doctors and nurses to do what they do best, which is assess a patient's risk status and make a diagnosis and administer a flu shot, if it is appropriate.

I think another thing we heard today is that apparently we need to educate the CEOs of Wal-Mart and Target and Safeway. They need to understand that flu shots are not a marketing vehicle, that it is a public health issue and that they shouldn't be trying to attract customers at inappropriate times of the year that go against the CDC recommendation.

So, I think the CDC, as an educational role is key, and it is critical.

Senator WYDEN. Well, you know, again without belaboring this, it doesn't sound very rational to me when our docs who are on the front lines—I'm just paraphrasing this letter from the Oregon Medical Association—the docs on the front lines can't get vaccine. The public health departments can't get it. And then, we have got various kinds of, you know, private entrepreneurs spending weeks giving people various kinds of deals. Then we run short. That doesn't strike me as a rational system, folks.

I am telling you, over the next 60 days, I'm going to do my best to shake it up and turn this around because this isn't working very well. For those of you in the private sector, I would submit to you that this is an invitation from the Secretary and now from the bipartisan leadership of the Aging Committee to move aggressively.

This issue has been studied now for a full decade, and yet, you know, my constituents—and I'm not the only Member of Congress who faced this—found themselves last winter traipsing all over town from doctor's office to doctor's office trying to figure out what to do and how to get this done. In a country as strong and as good as ours, it is unacceptable to me that getting a dose of flu vaccine ought to be a rare privilege that you secure only after you have navigated through a health system that is, at best cumbersome and characterized by professionals as chaotic and irrational.

Mr. ROWAN. I agree with that 100 percent and look forward to being a resource for you in your committee work moving forward——

Senator WYDEN. OK. The only other question I had for you, Dr. Higginson. What else would you like CDC to be working on, particularly in this effort over the next 60 days? I share your view that State health departments ought to be in a position to play a key role in trying to deal with potential shortages. Tell us what you think over the next 60 days ought to be done.

Dr. HIGGINSON. Right. And Senator, one thing I already mentioned is, I do think they need to be working with the manufacturers to give us at the earliest time, you know, what the forecast for flu vaccine looks like so we can start planning for contingencies early on, if we need to.

I think that CDC definitely needs to be very actively involved in these discussions with the manufacturers, with you over this next 60-day period to try to figure out what exactly is needed. And again, I think just summarizing what a lot of people have said is, I think that there is really two things we are were looking at here. One is, what happens in a normal year. And most of the time, things do work well, and the system does work. And I think I have heard things from the distributors today and from the manufacturers that they are willing to work to tweak that system that usually works to make it even better.

But I do think that we do have to plan for contingencies for bad years. I mean, we are going to have bad years. There is going to be a pandemic 1 day, and which is going to be a very bad year. And for those contingencies, I think some real effort needs to be put into what has to happen when things go bad. Some people said that it was a chaotic system last year. The way I see it is that there was a non-system. When things went bad, there simply was not a system to deal with how are you going to distribute the vaccine appropriately, and how are you going to get the right people to the vaccine? Those are the issues that I really think need to be worked on. And I think that there are rules that both at the Federal level and the State level. The Federal level, I really don't know so much about what you have in way of authority around the distribution of vaccines.

Senator WYDEN. The General Accounting Office does. The Federal Government doesn't seem to need much additional existing authority. They have the authority to do it.

Dr. HIGGINSON. And I do know down on the State level that it is something that we are working on already. I think that it would be good if the CDC and the Department of Health and Human Services was to get out the message to State health departments

that this is something that they should seriously consider and start at the State level developing contingency plans at same time that you are developing them at the Federal level.

Senator WYDEN. Well, the Federal level, it seems to me—and this is what we have heard today—is going to have to make sure that the States play a leading role. This is not going to be Federal Government goes off and has a little discussion with itself, and then waits for the States to do it. The Federal Government ought to, under this important and significant offer from the new Secretary of Health and Human Services, have all of you from the State health departments at the table and walk away after 60 days with a plan that has you all play a leading role in the effort to ensure that this doesn't happen again.

I will let all of you go, but to me, I mean, the measure of success this time is going to be real simple, and that is, are there going to have to be more hearings in another year to plow over the same ground? I think what we want to do with a Secretary of Health and Human Services who has moved today to make it clear that he wants to be part of a solution, bipartisan leadership with Senator Craig and Senator Breaux. We want to make sure that we are not having hearings like this again in another year. It's just that simple.

Unless you all would like to add anything further, we are going to excuse you at this time.

Dr. HIGGINSON. Well, the other thing I would like to add—I said this already—I do think that resources is an issue. We have talked a lot about the need for public education. We talked a lot about the need for developing web sites and 1–800 numbers so that people do know where vaccines are available in a time of shortages. We have talked about local planning, the need for coordination with local providers and public health agencies and others who are actually providing the vaccine. That all does cost money. There is some infrastructure dollars that are needed to support adult immunizations the way that we support childhood immunizations at this time.

Senator WYDEN. Well, I am prepared to see additional resources devoted to this, but I will tell you, I don't think this is primarily an issue of resources. I think this is a question of political will, and whether we are going to step in and say, enough. This has been studied for years and years. We have had meetings now for years and years. And it is time to make the tough calls about how we are going to come up with a plan to deal with the problems that we had last winter. If, out of this, a bunch of recommendations to spend more money—I think that is going to miss the point. I think what we have seen there is a lot more to this than throwing money at it. It may take some additional dollars for Medicare reimbursement. What this is going to take is some clearheaded thinking about how to keep the kinds of problems we saw last year from developing. I'm not sure all that is about money.

Any other comments from our witnesses?

Dr. FUKUDA. Just one more comment, Senator, to address some of the issues brought up by Dr. Higginson. We would all really like to have those early forecasts about when a problem is coming down the road. But again, I think everyone needs to realize that last

year, we didn't know there was a problem until pretty late into the season. That is what made it partly so difficult to deal with. It is just a reality of the flu vaccination supply situation that things can go wrong pretty late into the year. So, though we would love to know early on we often do not.

Senator WYDEN. The point is, however, we now need to come up with a system so that if you don't know until late that you have got a problem, you have developed a system to deal with it if the problem takes place. That is what we don't have. And we are going to get after it.

All right. Anything else you all would like to add?

The Aging Committee is adjourned.

[Whereupon, at 11:37 a.m., the committee was adjourned.]

APPENDIX

Congress of the United States
House of Representatives
Washington, DC 20515

Statement of Rep. Gary A. Condit
before the Senate Special Committee on Aging
Portland, Oregon
May 30, 2001

I would like to thank Senator Wyden and the Special Committee on Aging for hosting this field hearing on flu vaccines. I appreciate very much the opportunity to share my concerns.

I first became involved with last season's flu vaccine delay in October - when I heard from local folks that they couldn't get their flu shot. At first I believed this problem was confined to California's Central Valley, but soon found out it wasn't. Instead it was a national crisis.

The United States was incredibly fortunate last year to have one of the mildest flu season's in a decade. This fortune, however, could have been equally disastrous given the manufacturing and distribution problems for flu vaccines. The San Francisco Chronicle said it best in their March editorial *U.S. Dodges a Flu Crisis*.

> "It was only by sheer good fortune that this year's flu season was a mild one, but it could have been catastrophic because of vaccine shortages."

A series of events led to what should be a wake up call for the healthcare industry – flu vaccines arriving late for physicians and public health agencies, distributors taking unheard of steps to put profit ahead of people, and our most at risk populations not receiving their much needed vaccines.

The cause of this dilemma is far beyond a simple miscalculation or blunder in the flu vaccine production cycle. A completely private distribution network allows for price gouging and market manipulation when shortages or manufacturing problems arise. In turn, the government's Center for Disease Control and Prevention has no infrastructure developed to deal with flu vaccine shortages. We cannot allow vaccines to be sold to the highest bidder in the most time of need.

I have developed legislation designed to give the Centers for Disease Control and Prevention the funds and direction needed to become actively involved with flu vaccine manufacturers and distributors. We need to ensure our government takes a more pro-active approach for flu vaccine distribution – it must be equitable in times such as last years crisis.

The American Medical Association "strongly support the enactment of this bill." In addition, the American College of Physicians – American Society of Internal Medicine and California Medical Association have endorsed this legislation.

I am certain that today's hearing will help resolve our current problem.

United States General Accounting Office
Washington, DC 20548

CCAR-01-0789-02

June 12, 2001

The Honorable John B. Breaux
Chairman
The Honorable Larry E. Craig
Ranking Minority Member
Special Committee on Aging
United States Senate

The Honorable Ron Wyden
United States Senate

This letter elaborates on our May 30 testimony on flu vaccine shortages before the Special Committee on Aging.[1] At the Committee's hearing Senator Wyden stated that the Department of Health and Human Services (HHS) had committed to completing a plan in the next 60 days that would address possible future shortages. He asked that we comment on key components of an effective HHS plan.

Our work concluded that the circumstances leading to the delay and early shortage of flu vaccine during the 2000-2001 flu season could repeat themselves.[2] Therefore, advance planning is important to help mitigate possible delays and shortages in the future. Specifically, our work showed that it would be beneficial for HHS to include the following components in its plan:

- the type of provider and public education effort to be used,
- guidelines regarding the distribution of influenza vaccine in times of shortages,
- strategies for collaboration amongst the various stakeholders, and
- steps for fully coordinating its efforts to improve pneumoccocal immunization rates.

Each of these areas is discussed in more detail below.

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[1]See *Flu Vaccine: Steps Are Needed to Better Prepare for Possible Future Shortages* (GAO–01-786T, May 30, 2001).
[2]See *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People* (GAO-01-624, May 15, 2001); and *Influenza Pandemic: Plan Needed for Federal and State Response* (GAO-01-4, Oct. 27, 2000).

Plan Should Specify Types
of Public Education Efforts

The effects of the production delays in the 2000-2001 season were exacerbated by the belief of providers and the public that flu shots should be received by Thanksgiving or not at all. In most years, however, a flu shot after this time would provide a reasonable level of protection. Educational efforts are needed so that both providers and the public recognize the benefits of flu shots administered later in the flu season. While HHS undertook several outreach and educational efforts, such as posting information on Web sites and conducting media campaigns in selected cities, the relative effectiveness of these various education activities remains unknown. Therefore, HHS needs to first assess the relative success of its past outreach and educational efforts so it can identify approaches that are the most effective in changing behavior. These means should be specified in the HHS plan as the primary method for educating flu vaccine providers and the general public and this educational process should begin well before the start of the traditional fall vaccination period.

Plan Should Include Guidelines
for Distribution

The distribution of flu vaccine is mainly a private-sector responsibility. Consequently, HHS actions to initially target vaccine in short supply to high-risk groups rely to a great extent on collaboration with those that manufacture and distribute vaccine. HHS can take a leadership role through organizing and supporting efforts to bring together stakeholders to formulate voluntary guidelines that would provide consistent strategies to direct vaccine to high-risk groups in times of shortage. For example, some purchasers such as nursing homes and in some cases public health departments administered almost all their vaccine to high-risk individuals. On the other hand, employer sponsored clinics are a much less likely source of vaccine for high-risk elderly. HHS has begun efforts to discuss distribution practices so that vaccine can be targeted first to providers that see many high-risk patients. However, more effort is needed before consensus can be achieved and guidelines disseminated.

Developing voluntary guidelines could also enhance HHS efforts to complete and publish its Influenza Pandemic Preparedness plan. While this document is expected to apply only to a severe and worldwide flu outbreak, the planning for vaccine distribution in the event of a shortage in epidemic years may also be useful in pandemic years.

Plan Should Include Methods
for Fostering State and Local Collaboration
Among Stakeholders

Our work also showed the importance of collaboration between the public-sector and the private sector to develop and implement initiatives to address flu vaccine shortages at state and local levels. States where public- and private-sector entities,

including providers, collaborated early to deal with the delay in vaccine shipments reported some success in targeting high-risk populations for vaccination. The HHS plan should recommend action for state and local health departments that could help them collaborate to finalize contingency plans to address delays in distribution or shortages of vaccine. These plans could include steps to quickly disseminate information to private-and public-sector entities involved in flu vaccine distribution and immunization.

Plan Should Provide for Coordination of Efforts to Improve Pnuemoccocal Vaccination Rates

Another HHS effort that could mitigate the impact of a flu vaccine shortage is to increase adult immunization rates against pneumococcal disease, which causes a type of pneumonia that frequently follows the flu. The population most at risk for pneumococcal pneumonia includes the elderly and those with chronic illnesses—the same group at high risk for complications or death from the flu. Because pneumoccocal vaccine provides immunity for at least 5 to 10 years, it can provide some protection against one of the serious complications associated with the flu if the annual flu vaccine is unavailable. Despite these benefits, widespread use of pneumoccocal vaccine among high-risk groups is relatively low. Both the Centers for Disease Control and Prevention and the Health Care Financing Administration within HHS have activities underway to increase pneumococal vaccination rates. To assure that it is maximizing the use of its resources, the HHS plan should provide for a fully coordinated effort within the department to improve pneumococal vaccination rates.

I enjoyed the opportunity to present the results of our work at the Committee's hearing. If you or your staffs have additional questions, please contact me at (202) 512-7119.

Janet Heinrich
Director, Health Care—Public Health Issues

(990001)

BACKGROUND ON INFLUENZA IMMUNIZATION AND VACCINE MANUFACTURING AND DISTRIBUTION IN THE U.S.

Introduction

This background paper and appendices summarize the history, annual challenges and complexities involved in providing influenza vaccines for the prevention of the leading cause of deaths from infectious disease in the U.S., especially for the elderly. Influenza vaccines in the U.S. are unique from all other drugs and biologicals regulated by the Food & Drug Administration (FDA). Each year, influenza vaccines generally change in composition and are essentially new biological products. Influenza vaccines are developed, manufactured, re-licensed and distributed within an urgent timeframe so that the vaccines can be available for immunizations prior to the annual influenza season. This process requires the close cooperation of federal and international health authorities.

Influenza Vaccine

Influenza vaccine is an inactivated virus vaccine prepared from influenza viruses grown in individual fertilized chicken eggs (with a living chick embryo). The basic vaccine technology is more than 50 years old, but has been highly automated and has seen the processes of viral inactivation, potency standardization and vaccine purification become highly refined. The eggs are supplied (hundreds of thousands delivered each day during full-scale manufacturing) by carefully qualified suppliers whose flocks and facilities are screened and monitored to assure high quality, clean eggs. The selected strain of live influenza virus is introduced into the allantoic cavity of the egg. The egg is incubated for three days, during which the virus grows. The allantoic fluid is then harvested and collected in tanks, treated with formalin for viral inactivation and purified and standardized for potency under validated processes. Each strain is prepared separately and the final multivalent vaccine is formulated by pooling the individual monovalent vaccine components.

Influenza Vaccine Efficacy

For practical purposes, immunity following influenza vaccination rarely exceeds one year. Due to this fact, and as the circulating virus constantly changes, immunization is necessary each year. Priming by prior infection with a closely related strain or prior vaccination enhances immunologic response after vaccination. Influenza vaccine efficacy varies in accord with the similarity of the vaccine strain(s) to the circulating strain(s) and the age and underlying illness of the recipient. Vaccines are effective in protecting up to 90% of healthy young adult vaccinees from illness when the vaccine strain is very similar to the circulating strain. However, the vaccine is only 30% to 40% effective in preventing illness among frail elderly persons.

Although the vaccine is not highly effective in prevention of clinical illness among the elderly, it is effective in prevention of complications and death. Among elderly persons, the vaccine is 50% to 60% effective in preventing hospitalization and 80% effective in preventing death.

Efficacy data within the pediatric population show that influenza vaccines can play an important role in controlling the spread of this virus. Many believe that school-age and pre-school-age children act as reservoirs and are largely responsible for the spread of this virus to the entire population. By examining infection rates vs. hospitalization rates in the pediatric population, it is easy to see that this population is at as high risk as the elderly population, if not more so.

Unique Challenges of Influenza Viruses and Vaccines for Disease Prevention

Unlike many other infectious bacterial and viral agents that cause human disease, the influenza viruses undergo continuous antigenic change, which makes complete control and eradication not attainable with current vaccine and preventive technologies. These changes in turn require the development and licensure nearly every year of new influenza vaccines to protect against new influenza subtypes, that periodically emerge in many areas of the world. For instance, during most of the 1997-1998 influenza season, Type A (H3N2)/Wuhan/359/95 was the predominant strain isolated in the U.S., but at the end of the season a drifted variant virus (Type A (H3N2)/Sydney/5/97) appeared and became the dominant strain during the 1998-1999 season. As a result, new trivalent influenza vaccine products for the U.S. had to be formulated, tested, and licensed.

The last major "antigenic shift" involving a substantial change in a surface antigen (H or N) occurred in 1968 when a new Type A, H3N2 (Hong Kong) influenza strain completely replaced the previous Type A, H2N2 (Asian) influenza strain that had been circulating around the world for about 10 years.

More recently, an avian strain of influenza virus identified in Hong Kong in 1997 (Type A, H5N1), infected humans and may have been transmitted from human to human, although H5 strains were not previously known to do so. A total of eighteen people developed illness from this strain and six died. It was widely feared that this new H5 strain might represent a new and highly lethal pandemic strain. Radical measures were quickly taken to kill al domestic chickens and ducks in the Hong Kong area. No pandemic occurred. However, it is uncertain as to whether this H5 strain was, in fact, a pandemic strain and if sacrificing thousands of domestic fowl saved the day.

Selection, Development, Manufacturing and Licensing of Influenza Vaccines

Because of constant antigenic and antigenic changes in the influenza viruses responsible for flu in the U.S. and overseas, the selection, development, manufacturing, and licensing of an effective influenza vaccine in the U.S. is a unique and complex challenge almost

every year. This process can easily consume eight to ten months and sometimes longer before vaccines are actually delivered to healthcare providers for administration to patients.

First, for many months before the production of vaccines is initiated, U.S. government and international public health officials monitor the strains of circulating influenza virus strains around the world and gather global disease surveillance data. With these data, they make scientifically based predictions regarding which strains are projected to become the major causes of influenza illness during the upcoming influenza season and issue recommendations for the component influenza strains for the next season's flu vaccine. These investigations, predictions and recommendations and the virus isolates from people with influenza infections, serve as the basis for determining the formulation of the vaccine to be manufactured over the next several months for subsequent use in the U.S. and overseas.

In December and January of each year, leading U.S. and international vaccine experts from the CDC, FDA, academic institutions, medical professional societies and industry hold many meetings and conference calls to review the global influenza disease surveillance data and laboratory data from analysis of the many influenza virus isolates. This is the first of several steps prior to a determination by U.S. and WHO public health authorities regarding which strains need to be included in the vaccines to be used later that year. Each year, at least one and perhaps two of the previous year's vaccine strains will change. On very rare occasions, none of the strains may change or all three are changed. Candidate strains are provided to the manufacturers. The manufacturers work with these strains to optimize them for growth in embryonated chicken eggs while retaining their original antigenic characteristics.

Usually, the final vaccine formulation recommended and used in the U.S. is composed of three major influenza strains – two Type A (H1N1 and H3N2) strains and a Type B strain. Each of these strains must be produced as separate "monovalent" vaccines before their final formulation into a "trivalent" vaccine product. Production time for each monovalent vaccine strain varies among manufacturers, but requires a minimum of 90 days. Vaccine manufacturers must commit to the delivery of millions of embryonated chicken eggs well in advance of the season to provide sufficient media for growth of all three vaccine strains. In consultation with public health authorities, vaccine manufacturers also review the early surveillance data and laboratory testing results and begin the early manufacturing process for one of the three vaccine strains. This first vaccine strain selected is based on an educated guess regarding the strain from the previous year's vaccine that s thought most likely to be carried over to the new vaccine. All of this investment and early production is "at risk" to the manufacturer, since later surveillance data may lead authorities ultimately to select other virus strains.

In late January of each year, the FDA convenes a panel of leading government and independent medical and public health experts to make tentative recommendations to the U.S. Department of Health and Human Services regarding the viral strains to be included in the next vaccine formulation. The FDA Vaccines and Related Biological Products

Advisory Committee (VRBPAC) meets in January to recommend at least one or two of the three vaccine strains for the upcoming season and optimally concludes its recommendations regarding the final strain selection in early March. The formulation will be manufactured during the next few months for distribution beginning in August to September of that year. As described above, a change in one and sometimes two vaccine strains is usually recommended based on these expert assessments of surveillance and laboratory isolate data. Sometimes another month or so elapses before the final strain is selected by US, WHO and other governmental authorities. The timing of these decisions is critical and one or two months delay can result in delayed availability of vaccine at the onset of the influenza infection season. It is essential that this process begin and conclude early each year so that final vaccine dose production can be completed in time for distribution and administration of the patients before the onset of the influenza season.

Once the last strain is selected by U.S. public health authorities for the trivalent vaccine to be used in the upcoming season, manufacturers must produce vaccine continuously to supply as much vaccine as possible for administration to patients in August through October. By November, most public and private mass immunization campaigns have ceased and demand for the vaccine is significantly diminished. Given that in most flu seasons, the incidence of flu peaks in January or after, the timing of immunizations could be extended to later in the year and even into January. Although this has not been done in the past, the CDC is expected to expand the recommendation for influenza immunization to the end of November starting in the 2001-2002 season.

In a normal year, total vaccine production time averages six to eight months, but it can take longer. FDA is responsible for the first four to ten-week step of the manufacturing process, since it develops the new reference virus strains for production. After each vaccine strain is selected and provided to the manufacturers, the manufacturer must spend another two to four weeks "passing" the vaccine seeds to attain sufficient vaccine virus production yields to meet the domestic and international requirements for that vaccine formulation. FDA also provides the potency test reagents, which requires about ten to twelve weeks. If one of the viral strains selected by public health authorities is low-yielding in the number of doses that can be produced, the manufacturer has little time to do additional viral seed passages and must go forward with manufacturing almost immediately thereafter. The total amount of the formulated trivalent vaccine that can be produced at any time is likewise limited to the total amount of the least-productive monovalent vaccine concentration. Under normal circumstances the final stage of manufacturing and testing by the manufacturer and FDA usually takes about ten to twelve weeks, except when a longer time is required for strains that are low yielding.

Vaccine Lot Release Requirements

Adding to the complexity and timing of annual influenza production and shipment to the ultimate customer is the requirement that each lot of vaccine manufactured must be individually released not only under the manufacturer's internal lot release testing protocols but also those of the FDA. If any seemingly minor delays occur in any of these

critical steps in strain selection, production timelines or regulatory lot release requirements, they tend to magnify any subsequent delays in making the final trivalent vaccine product available to healthcare providers.

Influenza Vaccine Delays and Spot Shortages During the 2000-2001 Season

The most recent example of a slow-growing monovalent vaccine component was the new Type A, Panama H3N1 strain selected by U.S. officials for inclusion in the product for the 2000-2001 influenza season. The difficulties and time required for manufacturers to grow this monovalent vaccine strain contributed to a significant delay in the formulation and availability of the final trivalent product for immunization prior to the influenza season.

This uncontrollable, technology-based delay was further complicated by the sudden loss of one of the four influenza manufacturers supplying the U.S. In late September, 2000, the Monarch-King Parkedale Pharmaceuticals subsidiary, suddenly withdrew from all further production of influenza vaccine for the U.S. market. Parkedale failed to provide any vaccine doses for the 2000-2001 influenza season. Parkedale announced this after they failed to resolve FDA regulatory Good Manufacturing Practices (MANUFACTURING) compliance issues that arose earlier in the year. During the summer of 2000, another U.S. manufacturer, Wyeth Lederle, also had FDA regulatory compliance issues associated with meeting MANUFACTURING requirements, which had needed to be resolved before they could supply influenza vaccine during the 2000-2001 season. All of these events significantly contributed to delayed production and delivery of vaccines during the 2000-2001 influenza season. Delayed deliveries of vaccine orders to healthcare providers who placed their orders later in the year were especially impacted, often resulting in their receiving only partial orders.

In order to assure the availability of an adequate amount of vaccine and offset the regulatory problems and market withdrawals by other companies, the CDC contracted with Aventis Pasteur to manufacture an additional nine million doses of flu vaccine even though it would not become available until later during the season than usual (December through early January).

Cost Issues

Influenza vaccine historically has been sold at significantly lower prices as compared to other vaccine products. In fact, influenza vaccine pricing in the US historically is one of the lowest priced markets globally. The financial costs and resources committed to maintaining and/or upgrading U.S. vaccine manufacturing facilities to meet modern FDA guidelines and regulatory requirements has been substantial during recent years for all these companies. New investment by the industry for improving existing facilities to meet regulatory requirements and expand existing facilities to add new capacity has in turn forced some manufacturers to announce increases in the prices of their vaccines.

Nevertheless, the overall costs per dose for the public and private-sectors of influenza vaccines are still well below the costs of other vaccines and remain highly cost-effective to the healthcare system and society.

It is noteworthy that during the vaccine delays and spot shortages associated with the 2000-2001 influenza season, the catalog and contract prices charged at the beginning of the season by manufacturers to providers and distributors remained in place throughout the season. However, these prices are not necessarily the same as those paid by the ultimate customer or patient for vaccines furnished through a commercial distributor or healthcare provider. Vaccine distributors, providers and other intermediaries usually include a mark-up of the price for their services. Manufacturers have no control over the ultimate price paid by the consumer when vaccines are purchased from a distributor, healthcare provider or other intermediary.

Current Influenza Vaccine Distribution System

The current private-sector vaccine distribution system delivers most vaccine orders to customers within 24 to 48 hours. This system relies on both direct shipments from manufacturers and a national network of wholesalers and distributors. Each link of this vaccine distribution and delivery network is required to meet stringent FDA regulatory and manufacturing requirements and provide for special handling and monitoring to maintain the integrity of the cold chain for vaccines throughout shipment. Even the most remotely situated U.S. healthcare provider, who relies on resellers and subcontractors of other distributors for their vaccines, almost always receive their shipments within a few days.

The current state-of-the-art U.S. private-sector influenza vaccine distribution network has an unparalleled, time-tested record of efficiency, reliability, safety, and cost-effectiveness. The existing infrastructure provides optimal flexibility for the most expeditious delivery to the thousands of healthcare providers who administer them. These attributes are particularly important where timing is critical in getting vaccine to patients before the onset of the flu season.

Vaccine manufacturers and U.S. pharmaceutical and healthcare product-distributors now distribute healthcare products including influenza vaccines to more than 130,000 pharmacy outlets, physician offices and clinics around the country. An estimated 56% of the influenza vaccine doses distributed in the U.S. are shipped directly by the manufacturers to public and private healthcare providers and contractors. Of this percentage, non-contract physician customers receive 8%, public-sector contract customers receive 15% and private contract customers receive 33%. The remaining 44% of U.S. vaccine doses are distributed by independent pharmaceutical wholesalers and health product distributors.

Approximately 80% of U.S. influenza vaccine doses are distributed to private-sector healthcare providers with less than 20% distributed to federal, state and local

governmental entities in the public-sector. Private-sector providers include physician offices, HMOs, food stores, chain drug stores, mass merchandisers, independent pharmacies, hospitals and integrated health systems. Private-sector manufacturers and distributors have the existing capacity to efficiently manage available vaccine inventories to optimize product availability and simplify distribution so these products are available when and where they are needed.

Any vaccine distribution system must meet detailed, extensive regulatory requirements to assure product integrity, proper handling, safety and efficacy.

In addition to efficiently delivering vaccines with next-day delivery as the standard, U.S. vaccine manufacturers and distributors protect product safety , quality and integrity through proper storage, packaging and handling. Private-sector distributors select, purchase, and store vaccines in close proximity to community physicians offices, clinics, pharmacy outlets, hospitals and other healthcare providers.

Both vaccine companies and distributors are required to meet numerous federal and state regulations to insure the safety and integrity of these products and are subject to inspections by both the FDA and state officials. The Federal Food, Drug and Cosmetics Act and the Prescription Drug marketing Act impose numerous requirements on manufacturers and distributors. These include detailed storage and handling procedures that address sanitation, facility and product security, around the clock temperature and humidity control and documentation, inspection of incoming and outgoing product shipments for damage and accuracy, processing recalls and returned goods, and training in storage and handling requirements.

Government and Insustry Response to Influenza Vaccine Manufacturing and Distribution Delays during 2000 and Plans for 2001 and Influenza Seasons

To meet U.S. production requirements and plan for long regulatory and manufacturing lead times, Influenza vaccine manufacturers must begin accepting vaccine orders early each year long before the products are manufactured. This is necessary because all influenza vaccine strains are often not identified by CDC, FDA and their experts until April of each year. By that time, significant "at-risk" manufacturing is already underway so that vaccine production and the FDA regulatory process can be completed in time for the influenza season.

During temporary vaccine shortages or distribution delays such as the one that occurred in 2000, major U.S. vaccine manufacturers already cooperate with the CDC by adjusting vaccine shipment priorities to assure to the extent possible that sufficient quantities are available for immunizing high risk populations. For example, on October 25, 2000, Aventis Pasteur modified its shipping schedule to assure customers still awaiting vaccine delivery received by November 17th a minimum of 25% of the doses they ordered. The company then shipped the balance of these orders in December and each vaccine

shipment included a copy of the latest CDC recommendations for prioritization for of vaccine use targeting high-risk patients. This arrangement allowed healthcare providers to immunize high-risk patients as recommended by the CDC.

However, the manufacturer, distributor and government agencies cannot completely control how the end user ultimately utilizes vaccine supplies shipped to them. Compliance with the CDC recommendations must rely on the broad cooperation and extensive and persistent educational efforts by medical professional societies, state and local health departments, healthcare providers and the general public.

In an effort to ameliorate any potential influenza vaccine supply problems during the upcoming 2001-2002 influenza season, Aventis Pasteur announced on February 13, 2001, that effective in 2001, the company does not plan to ship influenza vaccines until after Labor Day. Second, all private and public-sector customers will receive a partial shipment of approximately 25% of their orders, which should be adequate for immunizing their high-risk patients. To the extent that these shipments may not be adequate for a provider's high-risk patient population, they can contact the company at its toll-free 1-800- VACCINE telephone number to obtain additional quantities, which will be provided on a case-by-case basis. The balance of all customer orders will be shipped thereafter as additional vaccine lots are manufactured and are released by the FDA. Third, the company will implement a "no return" policy to prevent providers and distributors from hoarding supplies or hedging the market.

Aventis Pasteur further announced on February 21, 2001, that it plans to manufacture 38 million doses of influenza vaccine for the upcoming season and has the capacity to increase production by 17 million doses to 55 million doses if the following conditions are met. First, vaccine strain selection must be finalized in March, 2001 to allow an extra four weeks for production. Second, the Advisory Committee on Immunization Practices and the CDC must recommend that influenza immunization be continued through the end November before each season. Finally, that the company receive final FDA approval of its pending application for expansion of its influenza vaccine manufacturing facility capacity.

There is a critical role for the government in mounting an extensive professional and public education effort during a vaccine supply delay, shortage or pandemic. No voluntary efforts to control vaccine distribution and supply by manufacturers or distributors or the implementation of regulatory controls by government agencies can solve the practical problem of noncompliance by some healthcare providers and patients during a vaccine shortage or manufacturing delay situation. It is extremely important to emphasize that the only practical approach for addressing noncompliance with recommendations for targeting immunizations for priority high risk populations is an greatly expanded educational effort by governmental and healthcare professional organizations. It is critical that federal, state and local government health agencies implement more aggressive, extensive, visible and consistent health professional and

public education efforts regarding the issuance of influenza immunization prioritization recommendations issued by the CDC and medical societies.

Proposals for Government – Run Influenza Vaccine Distribution Networks or Regulatory Allocation Authority

Federal and state governments and the private-sector have been planning many years for the next potential influenza pandemic causing more serious disease. If a pandemic were to occur, the current annual U.S. vaccine production capacity would be sufficient to immunize the elderly, other high risk individuals and a substantial number of other individuals, but it would be insufficient to immunize the entire U.S. population.

In preparation for a potential future vaccine supply delay or shortage, such as the one that occurred during 2000 or in a pandemic situation, some have suggested that the federal and state governments assume responsibility for storage and distribution of influenza vaccines in the U.S. Alternatively, others have suggested that regulatory authority be provided to federal and state government agencies to control allocation and distribution of vaccine inventories by manufacturers and distributors. Legislation has been introduced in Congress to provide the Secretary of Health and Human Services with regulatory authority to declare an "emergency" during a vaccine supply delay, shortage or pandemic. The legislation is intended to allow the government to direct shipments of limited vaccine supplies to designated healthcare providers conditioned on requirements that the vaccine usage be prioritized for immunization of populations at greatest risk from influenza. The theory underlying all of these proposals is that governmental distribution or allocation authority would provide improved control over vaccine distribution, so that limited vaccine supplies will optimally reach the populations at greatest risk of serious morbidity, hospitalization and mortality from influenza. However, these proposed regulatory solutions do not address the real problem and would cause new problems.

Overwhelming resources and costs will be required for implementation of a government-run distribution network or regulatory allocation authority.
The cost to the federal and state governments of duplicating the current extensive and multi-faceted private influenza vaccine distribution infrastructure, comprised of vaccine manufacturers and the over one hundred independent distributors, would be prohibitive as a stand-alone vaccine distribution network. In contrast, private-sector distributors provide economies of scale and allocate their fixed and operating costs over a wide range of biological, pharmaceutical and other healthcare products to significantly reduce vaccine distribution expenses. Due to limited refrigerated storage capacity in the offices of most physicians, small clinics and community pharmacies, government distribution systems would require the capability of filling and distributing several vaccine orders each month as now provided by the private-sector. Larger monthly or less frequent bulk vaccine shipments would be unacceptable for most healthcare providers, which typically lack the necessary inventory management expertise or refrigerated storage capacity.

In 1991, the General Accounting Office (GAO) examined the feasibility and cost effectiveness of creating a government-run healthcare products storage and distribution network. In its December, 1991 report titled "DOD Medical Inventory: Reduction Can Be Made Through Use of Commercial Practices", the GAO concluded that the private-sector is more efficient at distributing healthcare products than the federal government.

Another government-sponsored study, published in September 1992 by the Logistics Management Institute, reached similar conclusions for the Department of Veteran Affairs. It found that the expense levels of government-run depot systems were over 12 times higher than subsequent bids by commercial distributors.

In addition, these studies found no evidence that these government-run systems could provide the same high level quality of service, product freshness and timely availability that could be provided by private-sector distributors.

A government-run influenza vaccine distribution or regulatory allocation system will not solve the problems it seeks to remedy and will likely make matters worse. Realistically, it is difficult to imagine that a government-run influenza vaccine distribution capability matching that in the private-sector could be established during a short period of time, given the many years required for its development in the private-sector. During the transition, the speed and efficiency of vaccine distribution in the public-sector is certainly likely to fall significantly below the high quality standards traditionally met by the private-sector.

Assume hypothetically that the necessary vast resources are allocated by federal and state governments and a multi-faceted vaccine distribution network is developed that is comparable to that in the private-sector. The new government-run network will face the same types of practical difficulties in controlling compliance by healthcare providers with the recommendations of CDC and the medical societies, which are intended assure that vaccine supplies will actually be used for immunization of targeted high-risk populations. In addition, millions of doses of vaccines may have already been obligated and shipped early during the season to customers under contracts with the manufacturers prior to government recognition of the potential of a vaccine supply delay, shortage or pandemic.

Similarly, new governmental regulatory authority for issuance of orders to private-sector distributors for allocation and control of vaccines will only add additional layers of complexity, bureaucracy and delays in distribution, not to mention many opportunities for errors. Added delay of vaccine distribution is unacceptable, as timing is critical in the face of an influenza epidemic to assure that high-risk patients are immunized and adequately protected.

Conclusion

The annual U.S. influenza vaccine selection, development, manufacturing, regulatory and distribution processes are complex and time-sensitive. This cooperative effort of the

public and private-sectors has been amazingly successful in efficiently providing these important vaccines for protecting the U.S. population from infectious and life-threatening illness year after year.

It is important to learn from the lessons of past influenza epidemics and pandemics, the near misses, and the technological realities of vaccine strain selection and production. It is essential that government, industry and medical and public health organizations continue to work cooperatively to improve the efficiency of the system. Is likewise essential that these organizations greatly expand efforts to educate healthcare professionals and the public about prioritized recommendations for early immunization of high risk patient and healthcare worker populations during any future influenza vaccine shortages or manufacturing delays. These initiatives are critical for maintaining this important, cost-effective preventive healthcare intervention.

It is likewise important for government officials involved in its influenza pandemic preparedness planning to recognize the critical role of the U.S. private-sector influenza vaccine manufacturing and distribution base. The private-sector already has the existing infrastructure and successfully distributes the vast majority of influenza vaccine doses in the U.S. today. It stands willing and able to partner with federal and state agencies and public and private providers in the face of any future vaccine supply challenge including preparation for a potential influenza pandemic.

Appendix A

What is "influenza"?

Influenza was first described by Hippocrates in 412 B.C. The name "influenza" originated during the first recorded 15th Century epidemic of illness in Italy, which was thought to be caused by the "influence of the stars." Influenza is a highly infectious viral illness in humans and some birds and animals. Humans infected by viral influenza illness spread the virus primarily through coughing and airborne transmission of tiny droplets, which are inhaled into the pharynx or lower respiratory tract by others.

Influenza viruses are classified as orthomyxoviruses, meaning they are associated with and identified in mucus secretions. Influenza viruses frequently change their antigenic makeup and their resulting antigenic characteristics. Minor changes are referred to as antigenic "drift", while major changes are referred to as antigenic "shift". Antigenic drift is seen frequently. Antigenic drift is reflected in the constantly changing component strains in each year's influenza vaccines recommended by the health authorities who monitor cases of influenza around the world. These health authorities assess the most recent data regarding antigenic drift and make their best estimate on the probably predominant strains for the upcoming flu season. Antigenic drift is associated with epidemics of flu year-to-year. Antigenic shift occurs much less frequently and reflects a change in the antigenic characteristics that are totally new. As humans have not had any experience with these totally new flu strains, they have no immunity and thus the virus will spread rapidly causing widespread disease. If the virus is especially virulent, it can

cause severe disease and mortality among those normally at high risk from influenza as well as in healthy people. Antigenic shift is associated with pandemics – worldwide influenza.

There are major reservoirs of influenza virus in bird populations, especially migrating waterfowl, in pigs and in horses. Pigs are known to be able to harbor swine, avian and human influenza viruses at the same time. It is this factor that leads to exchange of new antigenic material and is likely the source of most antigenic shift.

Influenza viruses that infect humans are characterized as Types A, B, and C. Type A influenza is described in subtypes that are determined by its genetic material that, in turn, determines the hemagglutinin (HA) surface protein antigens (eg. H1, H2, and H3) and neuraminidase (NA) surface protein antigens (e.g.. N1 and N2). These surface proteins play an important role in the infectivity of the virus.

Influenza A causes illness in all age groups of humans and other animals, such as pigs, horses and birds. Influenza B virus infections occur only in humans, and generally cause milder disease than type A in adults, yet can trigger serious consequences and even death in children, particularly those with serious underlying medical conditions. Influenza Type C is rarely reported in humans and has not been associated with epidemics.

Appendix B

Morbidity and Mortality from the "Average" Influenza Epidemic

The Government Accounting Office (GAO) recently estimated that during an average winter influenza season, the disease contributes to as many as 20,000 deaths and 114,000 hospitalizations in the U.S. Certain individuals face an increased risk of morbidity and mortality (disease or death) from the complications of influenza. These include everyone over 50 and especially those over 65 years of age as well as "high risk" younger individuals and children with severe chronic health conditions (e.g., heart diseases, lung diseases, asthma, diabetes, and immune system impairments).

The U.S. Centers for Disease Control and Prevention (CDC) estimates that 90% of the influenza morbidity and mortality occurs in the elderly population, which continues to increase as a percentage of the U.S. population. In addition, more than half of all U.S. hospitalizations and more two-thirds of all deaths in the elderly population are triggered by influenza and its complications, including pneumonia. During major influenza epidemics, hospitalization rates increase between two- and five- fold. In nursing homes, the influenza attack rate may be as high as 60%, with up to 30% fatality rates.

In studies of the "average" influenza epidemics occurring from 1972 through 1995, excess deaths associated with the disease occurred during 19 of the 23 years studied. An estimated 20,000 or more influenza-associated deaths (pneumonia and influenza or "P&I") occurred during five of these epidemics. Over 40,000 P&I deaths occurred during

six epidemics. The most severe epidemic during this interval caused upward of 50,000 deaths.

The most frequent complication from influenza disease is pneumonia, most commonly secondary bacterial pneumonia (*Streptococcus pneumoniae, Haemophilus influenzae,* and *Staphylococcus aureus*). Other complications include myocarditis (inflammation of the heart) and worsening of bronchitis and other chronic pulmonary diseases. In children, Reye's syndrome is a severe complication associated with influenza type B. It causes severe vomiting, disorientation and may progress to coma from swelling of the brain.

The Costs to the U.S. from Influenza-Associated Illnesses

In addition to the high toll from morbidity and mortality caused by illness from influenza, the disease results annually in a huge medical and societal economic burden in the U.S. and globally. A CDC analysis conducted many years ago estimated the cost of the periodic severe epidemic in the U.S. to be $12 billion. Another more recent CDC study projects the total societal costs of a pandemic with a dangerous variant influenza virus strain as potentially exceeding a range of $50 billion to $150 billion.

Over many years, dozens of cost-benefit studies and analyses have confirmed that immunization of elderly and other high-risk populations is highly cost effective in addition to being life-saving. Further, recent published cost-benefit analyses conclude that routine influenza vaccination is cost-effective even for healthy working adults.

Studies have suggested that influenza viruses cause ranges of 10% to 30% of middle ear infections (otitis media) in children. This is significant considering that the total annual cost to the U.S. of otitis media has been estimated to exceed $5 billion annually.

Appendix C

Global Influenza Pandemics

The first recorded worldwide epidemic of influenza, referred to as a "pandemic," occurred in 1580. Three global pandemics occurred worldwide during the 18th century, including one during the Revolutionary War in the U.S. At least seven pandemics have occurred during the 19th and 20th centuries.

The 1918-19 pandemic of the so-called "Spanish flu" caused an estimated 21 to 40 million deaths worldwide, including 25 million cases of illness in the U.S. and an estimated 500,000 to 675,000 deaths. More soldiers were actually hospitalized from this epidemic during World War I than from wounds. Subsequent research has led scientists to discover that this virus was passed from birds to pigs and then onto humans. Such cross-species transmission can induce antigenic shift – new antigenic "reassortants" with totally new genetic characteristics that provide the most dangerous strains of influenza. The two other 20th century pandemics, "Asian flu" in 1957 and "Hong Kong flu" in 1968

also caused a significant incidence of illness and fatalities in the U.S. with 70,000 deaths and 34,000 deaths respectively.

Appendix D

The 1976 "Swine Flu Non-Epidemic"- Lessons Learned

In February, 1976, 13 soldiers were hospitalized at Ft. Dix, New Jersey after they had become infected by an influenza virus Type A strain. This virus strain was identified as Hsw1N1, indicating that it came from pigs and was thought to closely resemble the deadly strain of 1918-19 pandemic. The severity of the illness in these cases, including one death of a young, apparently healthy, soldier immediately created a significant public health concern for experts, since its occurrence was unusual in a normally healthy military population. Based on rough projections derived from the 1918-19 data even with the availability of modern antibiotic therapy to treat complications such as pneumonia, public health officials at CDC and their outside expert advisors estimated that this influenza strain could cause as many as one million deaths in the U.S. if it triggered another pandemic.

On February 14, 1976, federal experts from the National Institutes of Health (NIH), FDA, CDC, the U.S. Army and others met and agreed to begin immediate preparation of antibodies for use in the laboratories and seed strains for the production of a vaccine. On February 20, 1976, the CDC Advisory Committee on Immunization Practices (ACIP) met and agreed that vaccine production and immunization should go forward. The meeting was attended by the two heroes in polio vaccine development, Dr. Jonas Salk and Dr. Albert Sabin, both of whom agreed that immunization against the Swine Flu strain was advisable. After the meeting, then Department of Health, Education, and Welfare (DHEW) Secretary David Mathews asked his multi-agency expert staff what were the odds of an epidemic and what would happen if an epidemic did not develop? They responded that the answer was unknown, although the ACIP experts informal unpublished estimates varied from 2% to 20%. At that time, Dr. Edwin Kilbourne, a world renowned influenza expert, concluded that it was better to vaccinate and not have an epidemic than to have an epidemic without a vaccine.

Based on this information, the federal government decided to immediately implement a crash program with the vaccine companies to gear up vaccine production with the inclusion of the new strain and prepare for a mass immunization campaign. This decision had to be made immediately if development, licensure and production of a new flu vaccine were to be completed as required. The influenza vaccine companies faced the prospect of significant adverse economic consequences, including sustaining huge economic losses if the feared epidemic did not materialize and the vaccine went unused. The companies were also faced with potential increased liability exposure associated with the licensing of a new vaccine strain to be administered to tens of millions of individuals with and without preexisting medical problems. While the vaccine manufacturers were committed to full cooperation with the government on an expedited development and manufacturing schedule, they insisted that they could not proceed unless the government

guaranteed purchase of the vaccine and assumed the liability risk. The debate continued until a serious outbreak, including deaths, of what was to become known as "Legionnaire's Disease occurred in Philadelphia. As this disease had not been previously identified and was thought by some to possibly be influenza, a greater sense of urgency emerged. After meetings with government, healthcare provider groups and industry officials, the key decision makers in the Federal Executive Branch and Congress agreed on the enactment of emergency legislation (The Swine Flu Act of 1976), which provided for the federal government to assume the unpredictable economic risks of losses associated with vaccine production, product returns and liability claims.

Almost as soon as the 1976-1977 influenza season began, the incidence of swine flu was conspicuous by its absence. By that time millions of doses of the vaccine had been manufactured and administered to citizens, mostly the elderly and other high-risk groups in the U.S. After public health authorities reported that the potential epidemic was a non-starter and adverse reactions were becoming an increasing concern, the program was discontinued. As a result, millions of doses of vaccine that were never administered by healthcare providers were returned to the manufacturers and public health departments for disposal.

Of the key "lessons learned" from this experience, one was the need for earlier and improved global influenza surveillance to provide sufficient time to identify new influenza strains and changes in virulent strains. Another lesson was the recognition by government and public health authorities of the need for a more streamlined vaccine strain selection and expedited regulatory licensing process to provide sufficient time for the vaccines to be manufactured, distributed and administered to the public. Finally, the ensuing litigation surrounding the Guillian-Barre Syndrome (GBS) as an alleged adverse reaction to swine flu vaccine in thousands of vaccinated individuals, confirmed the manufacturers' worst concerns about liability exposure from such mass immunization programs.

Appendix E

The 1997 "Chicken" Flu Non-Epidemic- Lessons Learned

In March, 1997, chickens began to die, including a total of 6,800 on three farms in Hong Kong's rural New Territories. In May, 1997, influenza type A (H5N1) virus was isolated from a three year old child, who died with Reye's Syndrome in Hong Kong. The "chicken flu" viruses, that initially attacked the respiratory and intestinal tract of the chickens, had changed by October and began attacking every tissue in the chickens, including the brain. New avian strains of influenza viruses are typically genetically modified in mammals, like pigs, before infecting humans. This new H5N1 virus subtype was unique because it crossed the avian-human species barrier before adoption in another mammal species. Intensive surveillance by public health authorities revealed a total of 18 cases in humans by the end of 1997, all of them in Hong Kong. Six of these cases resulted in deaths. After the last case occurred on December 28, 1997, no further human cases were identified.

The Hong Kong influenza outbreak was over almost as suddenly as it started. No one knows if the H5 virus is still circulating and there is no evidence of its further reassortment into a more virulent form. Since then, the CDC, FDA and NIH have continued their programs of multiple H5 vaccine strain and reagent development. These efforts are intended to anticipate the need for these materials and to prepare for the future possibility that another dangerous H5 strain may be passed from avian to human hosts. If this occurs again, it may indeed trigger a real epidemic of serious human illness similar to that in 1918-19, which would require the rapid development and availability of new modified vaccine strain to protect our population.

Patricia -
This should go in the hearing record for on the hearing.
Thanks.
Stephen

Aventis Pasteur

June 8, 2001

Senator Ron Wyden
SH-516 Hart Senate Office Building
Washington, DC 20510-3703

Dear Senator Wyden:

Once again, I want to express our appreciation for the opportunity to testify at your field hearing in Portland on May 30. The exchange of information and viewpoints was very productive.

As you requested, I'm providing our suggestions for inclusion in the plan you will be developing with Secretary Thompson to address influenza vaccine delays or shortages, if there should ever be a repetition of last year's situation.

First, as was the case this year, every effort should be made to name vaccine strains as early in the year as possible. The timing of these decisions is critical and delays can result in delayed availability of vaccine. It is essential that this process begin and conclude early each year so that final vaccine dose production can be completed in time for vaccine distribution and administration before the onset of the influenza season.

Second, efforts should continue to bring the market demand for influenza vaccine more in line with medical requirements. We are pleased that this year's recommendations from the CDC are moving in this direction and those efforts should continue. Demand from providers for influenza vaccine has been in the September-October time frame. Current recommendations are that immunizations should take place from October to mid-November. Ideally, designated high-risk groups should be immunized between October and the end of November, with healthy populations immunized from October through the end of December.

Third, Aventis Pasteur believes that there is a critical role for the CDC and medical organizations, such as the AMA, to play in mounting an extensive, professional education effort during any vaccine delay or shortage. It can not be emphasized enough that the only practical approach for addressing non-compliance is a greatly expanded educational effort by government and healthcare professional organizations. We are also pleased that this effort has been initiated and is being endorsed by all members of the vaccine enterprise.

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Aventis Pasteur

Fourth, as others and I mentioned at the hearing, there are high-risk patients seen by all types of providers and are reached through all channels of distribution. Those facts make it difficult for those distributing vaccine to prioritize shipments. Part of the educational message to providers is to immunize high-risk patients first. Since all providers have some high-risk patients, Aventis Pasteur is taking the following steps: Aventis Pasteur will not be shipping vaccine until after Labor Day. At that point, all of our public and private customers will receive a partial shipment of approximately 25 percent of their order, which should be adequate to immunize their high-risk patients. If that quantity is not adequate, adjustments will be made on a case-by-case basis. The balance of the orders will be shipped thereafter (October-November) as additional vaccine becomes available. Additionally, we are implementing a "no return" policy to prevent the hoarding or over-ordering of vaccine supplies and we will offer no guarantees or penalties for designated shipping dates, thereby eliminating any preferential treatment for one customer over another. Any broader plans that can be developed that addresses this problem should prove productive.

Aventis Pasteur remains committed to assuring a reliable supply of influenza vaccine and is anxious to participate in any planning effort that will achieve this objective. We appreciate your leadership in this area and look forward to a strong working relationship in the future.

Sincerely,

Sanford J. Kaufman
Director, Public Policy

SJK/ls: 268

OMPRO
A Healthcare Quality Resource

May 30, 2001

OMPRO's Written Comments
for the
United States Senate Special Committee
on
Aging
Field Hearing, Portland, OR

Presided by Senator Ron Wyden

Overview of Influenza Season 2000

As the Medicare Peer Review Organization for the state of Oregon, OMPRO's Medicare beneficiary outreach focuses on patient education for preventive services. Promoting flu and pneumococcal immunizations, staffing the beneficiary hotline to respond to beneficiary complaints about Medicare-covered healthcare services are key functions. OMPRO's quality improvement program is effective through partnerships with hospitals, ambulatory clinics/medical groups, and long term care facilities.

OMPRO is an active participant in the Oregon Adult Immunization Coalition. The Coalition is the statewide body that coordinates flu information, outreach, and statewide educational materials for Oregon residents.

OMPRO's educational outreach for flu season 2000-2001was extensive. Significant delays in distribution of flu vaccine was a major obstacle to neeting the needs of patients in our state. OMPRO's outreach was coordinated with many community partners including:

- Senior centers
- Loaves and Fishes meal distribution center for the Tri-County area
- Fred Meyer Pharmacies statewide
- Albertson Pharmacies statewide
- Bi-mart Pharmacies statewide
- Oregon State Pharmacy Association, independent pharmacies, statewide
- Public service announcements to 45 radio stations statewide by Governor Kitzhaber, the Honorable Barbara Roberts and Mr. Jim Bosley of KATU TV
- Library systems distributed bookmarks with flu message in four of largest counties in the state
- Oregon Seniors and Disabled Services Division
- Oregon Health Division
- Oregon Health Care Association
- Oregon Alliance of Seniors and Health Services
- Oregon SafeNet

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Through our work in the medical community, we learned first hand from medical practices of the challenges they faced in providing vaccines to their patients and the cancellation of flu clinics due to lack of vaccine. Long term care facilities were directed to call the Oregon Health Division if they were in need of vaccine. We assisted one facility in obtaining vaccine for staff vaccination from the local hospital in their community.

In preparing for this hearing, OMPRO staff contacted Fred Meyer Pharmacy regarding their experience with last year's flu vaccine delays. Rachael Branson stated that Fred Meyer did not hold flu clinics until December 1 due to vaccine delays. They took names and numbers of people who were high risk and contacted them when vaccine arrived. Fred Meyer adhered to the CDC recommendations regarding prioritization. Fred Meyer received 80% of their order in December. They did share vaccine with local physicians who did not have enough vaccine for their patients.

OMPRO mailed 23,000 pieces of information to new-to-Medicare beneficiaries regarding their immunization benefit during last flu season. OMPRO received 26 calls to the beneficiary hotline for questions about benefits, clinic access, and billing issues. Oregon SafeNet's calls for access to immunization clinics by those over 60 years of age increased by 30% from the year previous.

OMPRO is also involved in a project to increase influenza and pneumococcal immunizations in the long term care facilities of this state. We are working with facilities to implement standing orders for flu and pneumococcal immunizations. A standing order is a protocol that allows a long term care resident to be immunized by a nurse without a specific physician's order. This is a Health Care Financing Administration (HCFA) sponsored project.

Submitted by Melody Long, RN, MPH, CPHQ

OMPRO
A Healthcare Quality Resource

OMPRO is a nonprofit organization dedicated to improving the quality and effectiveness of healthcare. We collaborate with practitioners, providers, public agencies, and private organizations on a wide range of healthcare improvement projects and programs. Our work spans the continuum of care, reaching all age and economic levels, and all delivery settings.

We accelerate the pace of improvement in healthcare quality

Assistance in any setting

Our extensive experience in facilitating quality improvement helps provider organizations of every type and size. We work with hospitals, clinics, private offices, managed care organizations, long term care facilities, and other specialized settings of care. We adhere to rigorous standards of confidentiality in all our work.

Support for your goals

Whatever your patient population or care setting, OMPRO's knowledge and techniques can help you achieve your improvement goals. Tap the expertise of the physicians, nurses, coding professionals, data analysts, statisticians, and communications specialists on our staff. Call us or visit our Web site to see what we can do for you and your patients.

Experience with diverse populations

Our work strengthens systems of healthcare delivery, improving care for everyone. The work we do serves many groups of people, including

- infants and children in well-child and immunization programs
- adolescents in residential psychiatric treatment facilities
- older or disabled people in treatment for heart failure, acute myocardial infarction, stroke, diabetes, pneumonia and other chronic or high-risk conditions
- communities with health disparities
- underserved rural communities

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OMPRO
A Healthcare Quality Resource

A sample of our clients and partners

Public agencies

Health Care Financing Administration (Medicare)

OMPRO has been the peer review organization for Medicare in Oregon since 1984.

Social Security Administration

State of Oregon

Oregon Health Division

Mental Health and Developmental Disability Services Division

Office of Medical Assistance Programs (Medicaid)

Senior and Disabled Services Division

State of Washington

Medical Assistance Administration (Medicaid)

Private organizations

American Diabetes Association

American Heart Association

Foundation for Accountability

Health Information Institute

Heart Failure Society of America

Oregon Adult Immunization Coalition

Oregon Alliance of Seniors and Health Services

Oregon Association of Hospitals and Health Systems

Oregon Health Care Association

Oregon Medical Association

Osteopathic Physicians and Surgeons of Oregon, Inc.

PEO Sisterhood

Portland Citywide Outcomes Research Group

Resources for continuous improvement

OMPRO helps providers deliver effective, efficient care. We offer an array of resources for implementing systematic, evidence-based improvement.

Healthcare quality improvement

- Continuous quality improvement training for healthcare professionals
- Development of healthcare systems modeled on evidence-based practices that better serve patients and providers
- Consultation on project design and implementation
- Process, outcome and performance measurement

Healthcare quality assessment

- Expertise on Medicare patient rights
- Medical record review for
  - quality of care
  - utilization management
- Quality assessment in all care settings and payment systems
- Expertise in Medicare inpatient coding and billing requirements
- HEDIS®* data abstraction and performance measurement

* HEDIS® is a registered trademark of the National Committee for Quality Assurance

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