THE PERPLEXING SHIFT FROM SHORTAGE TO SURPLUS: MANAGING THIS SEASON'S FLU SHOT SUPPLY AND PREPARING FOR THE FUTURE

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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THE PERPLEXING SHIFT FROM SHORTAGE TO SURPLUS: MANAGING THIS SEASON'S FLU SHOT SUPPLY AND PREPARING FOR THE FUTURE

THURSDAY, FEBRUARY 10, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis, Shays, Mica, Gutknecht, Duncan, Marchant, Dent, Waxman, Maloney, Cummings, Clay, Watson, VanHollen, and Norton.

Also present: Representative Boozman.

Staff present: Melissa Wojciak, staff director; David Marin, deputy staff director/communications director; Jennifer Safavian, chief counsel for oversight and investigations; Anne Marie Turner, counsel; Rob White, press secretary; Drew Crockett, deputy director of communications; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Sarah D'Orsie, deputy clerk; Corinne Zaccagnini, chief information officer; Kristin Amerling, minority deputy chief counsel; Karen Lightfoot, minority communications director/senior policy advisor; Anna Laitin, minority communications and policy assistant; Sarah Despres, minority counsel; Josh Sharfstein, minority professional staff member; Jean Gosa, minority assistant clerk; and Cecelia Morton, minority office manager.

Chairman TOM DAVIS. Good morning. A quorum being present, the Committee on Government Reform will come to order.

I want to welcome everybody to today's oversight hearing regarding this year's U.S. influenza vaccine supply.

This hearing will consider how public perceptions and needs will be managed and addressed for the remainder of this flu season and discuss what actions are being taken to begin planning for next year's flu season.

As many of you know, this flu season has been an unusual and difficult one. As a result of last fall's vaccine shortage, millions of healthy people and thousands in the high-risk population were unable to get vaccinated in a timely manner. Phones to doctors' offices, clinics, and hospitals rang off the hook with questions of where to seek flu vaccine, and hundreds of clinics were either forced to turn away or cancel altogether.

Public health authorities responded immediately, demonstrating coordination and cooperation between Federal, State, and local public health officials and private providers. Officials scrambled to identify and prioritize groups for vaccination and redistribute vaccine to areas where none existed. They were also able to procure additional vaccine from foreign sources to help compensate for the loss of Chiron's vaccine. The two remaining Food and Drug Administration licensed flu vaccine manufacturers increased production capabilities to maximize the number of doses produced for the season.

Recently the Nation's flu vaccine shortage turned into a surplus, with approximately 4.4 million doses remaining to be administered. The current surplus has led to confusion among Americans, with immunization recommendations varying from State to State and uncertainties of where ample supplies of vaccine exist.

As the peak of the flu season approaches, it appears demand for the flu vaccine has all but disappeared and the public has lost motivation to get vaccinated. Only a few months ago our senior citizens were waiting for hours in long lines to get vaccinated, and now there are no lines at all. We can't afford for Americans to underestimate the seriousness of the flu or take the importance of vaccination against the flu lightly. An unconcerned public will only provide to make future flu seasons more difficult. Vaccines are lifesaving devices, and administering them is an easy way to prevent contracting and spreading a disease.

In previous committee hearings we had discussed proposed solutions to fixing the supply side of the equation. We have considered whether new mechanisms and incentives are necessary to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually. Today we also need to consider the demand side of the equation. Without a steady demand from a public that is confident the flu vaccine will be available to them each year, precious vaccine will be thrown out at the end of each flu season.

Questions continue to mount, and hopefully some will be answered. How did we go from a shortage of vaccine to a surplus in just a matter of months? What happened to demand for vaccine? Are new public awareness campaigns or programs needed to increase and stabilize demands for the flu vaccine? What are we doing now to minimize the amount of vaccines thrown away at the end of this flu season? As we approach next year's flu season, will the message on who should be vaccinated change again?

We also need to consider if new mechanisms and incentives are necessary to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually.

I look forward to our witnesses' testimony today and a constructive dialog on this matter.

I said this before and reiterate today that we all share the same goal at the end of the day: a public health system prepared to deal with the annual influenza season. Let us not let the efforts to respond to this season's flu shot shortage be in vain. Everyone should continue to seek immunization, as it is not too late and the flu season has yet to peak.

As you will hear our witnesses testify, there are still at least two more months of the flu season. As a result I am pleased to announce that today in Rayburn 2247 from 1 to 3 p.m., the George Washington Medical Faculty Associations will be sponsoring a flu shot clinic. This clinic is open to anyone and the shot is free of charge. I would encourage those who chose to forego receiving the flu shot because of the shortage to take advantage of this important opportunity.

The committee thanks the George Washington Medical Faculty Associates for offering to sponsor the clinic and for its continuing motivation to protect the public by encouraging flu vaccinations.

We have an excellent roster of witnesses today and I want to thank all of them for appearing before the committee. I look forward to their testimony.

[The prepared statement of Hon. Tom Davis follows:]

Statement of Chairman Tom Davis
Committee on Government Reform Hearing
"The Perplexing Shift from Shortage to Surplus: Managing This Season's Flu Shot Supply and Preparing for the Future"
February 10, 2005

Good morning. I want to welcome everyone to today's oversight hearing regarding the U.S. influenza vaccine supply. This hearing will consider how public perceptions and needs will be managed and addressed for the remainder of this flu season and discuss what actions are being taken to begin planning for next year's flu season.

As many of you know, this flu season has been an unusual and difficult one. As a result of last fall's vaccine shortage, millions of healthy people and thousands in the high-risk population were unable to get vaccinated. Phones at doctors' offices, clinics and hospitals rang off the hook with questions of where to seek flu vaccine, and hundreds of clinics were either forced to turn people away or cancel altogether.

Public health authorities responded immediately, demonstrating coordination and cooperation between federal, state and local public health officials and private providers. Officials scrambled to identify and prioritize groups for vaccination and redistribute vaccine to areas where none existed. They were also able to procure additional vaccine from foreign sources to help compensate for the loss of Chiron's vaccine. The two remaining Food and Drug Administration (FDA) licensed flu vaccine manufacturers increased production capabilities to maximize the number of doses produced for this season.

Recently, the nation's flu vaccine shortage turned into a surplus with approximately 4.4 million doses remaining to be administered. The current surplus has led to confusion among Americans, with immunization recommendations varying from state to state and uncertainties of where ample supplies of vaccine exist. As the peak of the flu season approaches, it appears demand for the flu vaccine has all but disappeared and the public has lost motivation to get vaccinated. Only a few months ago our senior citizens were waiting for hours in long lines to get vaccinated, and now there are no lines at all.

We cannot afford for Americans to underestimate the seriousness of the flu or take the importance of vaccination against the flu lightly. An unconcerned public will only prove to make future flu seasons more difficult. Vaccines are life saving devices and administering them is an easy way to prevent contracting and spreading a disease.

At previous Committee hearings, we have discussed proposed solutions to fixing the supply side of the equation. We have considered whether new mechanisms and incentives are necessary to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually. Today, we also need to consider the demand side of the equation. Without a steady demand from a public that is confident

the flu vaccine will be available to them each year, precious vaccine will be thrown out at the end of each flu season.

Questions continue to mount, and hopefully today some will be answered. How did we go from a shortage of vaccine to a surplus in just a matter of months? What happened to demand for vaccine? Are new public awareness campaigns or programs needed to increase and stabilize demand for the flu vaccine? What are we doing now to minimize the amount of vaccines thrown away at the end of this flu season? As we approach next year's flu season, will the message on who should be vaccinated change again? We also need to consider if new mechanisms and incentives are necessary to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually.

I look forward to our witness testimony today and a constructive dialogue on this matter. I've said this before and reiterate today: we all share the same goal at the end of the day – a public health system prepared to deal with the annual influenza season. Let's not let the efforts to respond to this season's flu shot shortage be in vain. Everyone should continue to seek immunization as it is not too late and the flu season has yet to peak. As you will hear our witnesses testify, there are still at least two more months of the flu season.

As a result, I am pleased to announced that today in Rayburn 2247 from 1:00-3:00pm, the George Washington Medical Faculty Associates will be sponsoring a flu shot clinic. This clinic is open to anyone and the shot is free of charge. I would encourage those who chose to forgo receiving a flu shot because of the shortage to take advantage of this important opportunity. The Committee thanks the George Washington Medical Faculty Associates for offering to sponsor the clinic and for its continuing motivation to protect the public by encouraging flu vaccination.

Chairman TOM DAVIS. I would now like to yield to Mr. Waxman for an opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to thank you, Chairman Davis, for your continued interest in the flu vaccine and the need to assure a stable vaccine supply for the United States. Because of your leadership, our oversight on flu has been more sustained than that of any other committee of Congress.

When we held our last hearing in November, it was a time of crisis. There was not enough vaccine to protect the most vulnerable Americans. There were lines of panicked citizens in grocery stores and pharmacies, and local health officials did not have a clear understanding of who had vaccine in their communities.

During that hearing we heard from administration officials about emergency plans to cope with the shortage. The administration also expressed a commitment to taking steps to make sure our public health system is better prepared in the future.

Today we are meeting at a time when there is no crisis. While there is still not enough vaccine to immunize the entire high-risk population, there appears to be enough to meet demand. Furthermore, at least for the moment it seems that this flu season has not been particularly severe.

This moment provides an important opportunity to make plans to avoid future shortages. The challenges are no secret. We are forced to rely on too few companies to produce vaccines, leaving us vulnerable to the kind of shortage we experienced this year with the flu vaccine. We have not been able to maintain adequate stockpiles of important pediatric vaccines. And, finally, there are major gaps in immunization coverage because of inadequate Federal support of State and local immunization efforts.

It is a mystery what happened to this administration's resolve. Earlier this week the President presented his fiscal year 2006 budget to Congress. This budget cuts the Center for Disease Control's budget by over $500 million and slashes funding for public health preparedness at the State and local level by almost $130 million. The budget eliminates the preventive services block grant, which has been used to support immunization activities. And while the budget provides for some increase in funding for State and local efforts on flu immunization, it provides no new funding for States that cannot now provide other lifesaving pediatric vaccines. The budget also fails to propose any solution to the problem of maintaining adequate stockpiles.

This budget ensures for another year that there will be children who will go without access to critical vaccinations such as a lifesaving vaccine against the most common cause of childhood meningitis.

In place of vital public health programs, the President wants to boost funding for so-called "abstinence only" education programs by 40 percent. Many of these programs teach erroneous and false information to thousands of teenagers, including that tears and sweat can transmit HIV infection. These programs also teach gender stereotypes as scientific fact: for example, that boys need respect and value accomplishments while girls need financial support and value relationships. Well, public health threats are frightening and real. We need to confront them with the best possible science

and policy. We also cannot afford to have anything less than strong oversight over vaccine manufacturing by the Food and Drug Administration.

Today's "USA Today" contains a detailed analysis of what went wrong at the flu vaccine plant at the center of this year's shortage. Experts who reviewed documents released publicly by this committee found a history of serious problems with the vaccine, including contamination, improper filtering, and potency failures. "USA Today" also reported that the facility had a history of failing to investigate its errors appropriately and then failing to tell FDA about the problems promptly. Yet, despite this record and despite the fact that our country was depending on the facility for half of our flu vaccine, FDA's oversight lapsed.

In June 2003, FDA rejected the initial recommendations of its own inspectors to pursue official enforcement action against the facility. "USA Today" quotes a former senior executive at GlaxoSmithKline, "If you look at what is in FDA's own documents, it is stunning they didn't get a warning letter or something worse" after the 2003 inspection. Instead, the company received a letter stating FDA would not return to the plant for full inspection for 2 years. "USA Today" concluded that problems persisted from 2003 to this year when British regulators shut the facility and triggered the shortage.

This year's flu vaccine shortage is not just a wakeup call for those of us concerned about vaccine supply; it is a wakeup call for an agency and for an administration that appears to give companies the benefit of the doubt at every turn. The next FDA commissioner must change this approach and empower expert and dedicated FDA scientists and inspectors to do their jobs well.

I look forward to the hearing today. I plan to use the information presented at this hearing to design legislation to fix the gaps in our vaccine system before the next crisis hits.

I look forward to working with you, Mr. Chairman, and our colleagues, and hearings such as this serve such a valuable role. I want to thank the witnesses for coming in. I look forward to their testimony.

Chairman TOM DAVIS. Thank you.

[The prepared statement of Hon. Henry A. Waxman follows:]

Opening Statement of Rep. Henry Waxman
Ranking Minority Member
Committee on Government Reform
Hearing on
"The Perplexing Shift from Shortage to Surplus: Managing This Season's Flu Short Supply and Preparing for the Future"

Thursday, February 10, 2005

Thank you, Chairman Davis, for your continued interest in the flu vaccine and the need to assure a stable vaccine supply for the United States. Because of your leadership, our oversight on flu has been more sustained than that of any other Committee in Congress.

When we held our last hearing in November, it was a time of crisis. There was not enough vaccine to protect the most vulnerable Americans, there were lines of panicked citizens in grocery stores and pharmacies, and local health officials did not have a clear understanding of who had vaccine in their communities. During that hearing, we heard from Administration officials about emergency plans to cope with the shortage. The Administration also expressed a commitment to taking steps to make sure our public health system is better prepared in the future.

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In place of vital public health programs, the President wants to boost funding for so-called "abstinence only" education programs by 40%. Many of these programs teach erroneous and false information to thousands of teenagers – including that tears and sweat can transmit HIV infection. These programs also teach gender stereotypes as scientific fact – for example, that boys need respect and value accomplishments, while girls need financial support and value relationships.

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Yet despite this record, and despite the fact that our country was depending on the facility for half of our flu vaccine, FDA's oversight lapsed. In June 2003, FDA rejected the initial recommendations of its inspectors to pursue official enforcement action against the facility. USA Today quotes a former senior executive at GlaxoSmithKline as stating, "If you look at what's in FDA's own documents, it's stunning they didn't get a warning letter or something worse" after the 2003 inspection. Instead, the company received letter stating FDA would not return to the plant for a full inspection for two years. *USA Today* concluded that problems persisted from 2003 to this year, when British regulators shut the facility and triggered the shortage.

This year's flu vaccine shortage is not just a wake up call for those of us concerned about vaccine supply. It is a wake up call for an agency and for an Administration that appears to give companies the benefit of the doubt at every turn. The next FDA Commissioner must change this approach and empower expert and dedicated FDA scientists and inspectors to do their jobs well.

I look forward to the hearing today. I plan to use the information presented at this hearing to design legislation to fix the gaps in our vaccine system before the next crisis hits.

I thank the witnesses for coming and I look forward to their testimony.

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Chairman TOM DAVIS. Any other Members wish to make opening statements? Yes, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank you, too, for holding this critically important hearing to discuss the current status of our Nation's influenza supply.

As we are all aware, in October 2004 Chiron Corp., one of the three flu vaccine manufacturers licensed by the Food and Drug Administration, announced that the company would be unable to supply the United States with the flu vaccine we anticipated for the 2004–2005 flu season. Chiron was expected to provide us with some 46 to 48 million doses of flu vaccine, representing approximately 50 percent of the nationwide supply. One facility's failure to meet product sterility standards in Liverpool, England, did a great deal to expose the fragility of our flu vaccine system.

As one might expect, such a shortage in flu vaccines and the resulting long lines and lotteries that followed in some areas garnered much-deserved attention. Inquiries into who knew what and when, what was done to prevent and mitigate the flu vaccine shortage, and who should be held accountable have been thoroughly debated within this very committee. In fact, I personally asked many of these questions, myself.

While we may continue to disagree about the answers to those central questions, we must agree to look forward in the best interest of the Nation and achieve our ultimate objective of ensuring that the American people have ready access to a flu vaccine that is safe, affordable, and effective. To that end, Mr. Chairman, every year 36,000 people die and over 200,000 more are hospitalized from complications arising from the flu, so let us never forget the importance of getting it right this time around for the upcoming flu season.

Looking forward, we need to ensure that we have a diversity of suppliers that can meet our flu vaccine needs so that we are not overly reliant on any one of them. We need to explore what the Federal Government can do to provide meaningful incentives to encourage and retain the production of flu vaccines. Some have suggested tax credits and patent extensions for companies that manufacture vaccines, and we should probably explore those options.

In the upcoming flu season, we must also address any uncertainty that may exist in the public about the availability of flu vaccines and any confusion about who should be vaccinated. I was troubled to read in a recent survey conducted by the Harvard School of Public Health entitled, "Experiences with Obtaining Influenza Vaccination Among Persons in Priority Groups During a Vaccine Shortage," that over 50 percent of high-risk adults believed that they would not successfully receive a flu vaccination and therefore never tried to get one.

The fact that we are experiencing flu surplus today is not necessarily good news. We must ask how many vulnerable seniors and other high-risk individuals attempted to get vaccinated but were unable to do so due to demanding waits and distribution problems.

We should also ask how many Americans are still not vaccinated that need to be. While I am somewhat pleased that we can report a flu vaccine surplus today, it seems too bittersweet to celebrate in

light of the fact that so many Americans needlessly suffered due to poor planning for the flu season.

We must also be mindful that the Federal Government cannot assume today's vaccine surplus safeguards the Nation from another potentially devastating shortage. Our Nation must be prepared to safeguard our citizens by providing them with either the proper treatment for disease or a means to prevent infection in the event of an outbreak.

If the American people are to expect excellence of our public health preparedness, then we must provide the proper means by which this can be accomplished. With that said, I was troubled to see that the administration's budget for fiscal year 2006 proposes cuts in funding to the Centers of Disease Control and Prevention and the Health Resources and Services Administration for State and local public health preparedness.

It should also be noted that, while the budget would positively increase funding for pandemic influenza programs, it also proposes an overall cut of approximately 7 percent or $530 million to the CDC.

Our citizens depend on us to ensure that adequate vaccines or other medicines are available to protect them.

I look forward to hearing from our witnesses.

Once more, thank you, Mr. Chairman, for holding this hearing. I yield back the balance of my time.

Chairman TOM DAVIS. Thank you very much.

Do any other Members wish to—Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman. And thank you for continuing this series of hearings that we began when there was a so-called "shortage," and now we are facing a surplus. I sometimes wonder what the public thinks when they hear all this. First they are told not to get vaccinations. First they are told that the supply is limited. We have women, children, people at health risk, elderly who don't know which way to go. And now we are told there is a surplus.

One of the great things about serving for a number of years in Congress is—and I am to 12 on this committee and in my service—that you see things from the long-term perspective. I remember—again, I repeat this—when we held hearings on lack of childhood vaccination, immunization vaccines, and we have heard the drug companies bashed then, that the problem was the drug companies and that they were charging too much. Then we heard the accusations against the insurers. Well, certainly they are price gouging and making huge profits on vaccination, vaccines. Soon we had no drug companies or almost no one in the United States producing these vaccines, and soon we had no one insuring. So our next round when we found out there was an alleged shortage was to blame the bureaucrats, blame the agencies, because certainly they should have anticipated all of this.

It was interesting. Over the weekend I attended a conference and heard the head of our State and local medical society. I heard their speeches and their plea was for physicians not to leave the State of Florida and for physicians really not to even leave their profession. I was thinking this is sort of a microcosm of what we are creating for health care. We are forcing providers and people who

produce things like vaccine offshore or out of our States or jurisdiction.

I think you have to go back and look at the basic things that have created this situation: still tort medical malpractice; liability reform for manufacturers, whether it be vaccines or other products; the regulation of the industry and some of the things that we have artificially imposed. Why would you manufacture if you can't make a profit?

I was pleased to hear the previous speaker, who I respect, Mr. Cummings, say maybe it is time to look at incentives and some other things. That is certainly what we need to do. But we need to get to the core of the problem so that we are not flying people to Great Britain or to France or some place else to see what the problem is; that we actually manufacture and we have incentives to produce vaccines, to provide medical services in this country.

I think we have to look at some solutions. We are going to hear from the bureaucrats, and God bless the CDC. I think they have done as good a job as they could. But the way we are operating is wrong, and the lack of again reliance on domestic production or domestic medical services or domestic medical professionals, having them here in the United States and available is the only long-term solution. I am anxious to hear from them. We do need to plan ahead, but we do need to look a that core of the problem.

Thank you.

Chairman TOM DAVIS. Thank you.

Do any other Members wish to make opening statements? The gentlelady from the District of Columbia?

Ms. NORTON. Mr. Chairman, I want to thank you and Ranking Member Waxman for focusing in on this hearing. I think it is very important to do so, because I think what we have had is a loss of confidence in the two agencies that have been responsible, and part of our job is to help restore confidence across America when up became down and down became up. People were asking what happened, and they expect us to find out what happened. The reason I want to know what happened is because if you don't know what happened you don't know how to keep it from happening again.

I think that the two agencies, FDA is already undergoing great scrutiny and huge bipartisan criticism which may, indeed, be related, or at least not unrelated, to the failure to act when they could have acted at the manufacturing level overseas. It calls into question the competence of the agency, their diligence in pursuing any hints of problems.

Then, of course, the public turned to the CDC, which showed it didn't have a clue about what to do, had no worst case scenario, and were no further along than Members of Congress who asked them questions as they tried literally to cobble together a way to deal with a crisis that was absolutely predictable. Half your supply is overseas. Guess what? Something could happen to it. What would you do? Very troublesome.

In a real sense, it was like the anthrax scare, except that who could have predicted that? But you would have thought that the anthrax scare would have helped us prepare for this kind of emergency, which, indeed, was predictable.

Mr. Chairman, I am concerned because of larger issues raised here and that have been raised in the Homeland Security Committee. We don't do a lot on health systems, but I don't see any evidence that we are able to deal with unanticipated health emergencies. This was a test case. We failed it. For those of us who think it doesn't matter, this is an epidemic. I don't know what the number of deaths are, but we do know that tens of thousands of people die every year from flu, so it was important.

The problems at the plant in England are so deep. Inspections still have to go on, and apparently we still don't know whether it will be able to produce, so I am sure we must have a plan as to what to do next year.

I want to embrace what my colleagues have said about incentives. Nobody expects that the pharmaceutical industry is any different from any other industry: they go for the highly profitable drugs. We have known for a long time that there is little or no profit in flu. Why haven't we done something about it? It is our responsibility on this side of the podium, and it is the responsibility of the agencies and of the administration to push us to do something about it. If this crisis doesn't do that, I don't know what will.

I believe the most important thing the two witnesses could tell us today would be what their worst case scenarios are given a set of circumstances and whether they have taken themselves through worst case scenarios so that, indeed, they are prepared for whatever comes along. That is what the American people expect from their public health system.

I appreciate that both of you have come, and I particularly appreciate the chairman calling this early hearing.

Chairman TOM DAVIS. Thank you.

Mr. Duncan.

Mr. DUNCAN. Mr. Chairman, very briefly, I don't have a formal opening statement but I just would like to say this: now that this shortage has turned into a surplus, you know, we have certainly found out that the way to get everybody to take their flu shots is to tell them that they can't have one. Human nature—people always want something they don't have or can't have. We certainly found that is true, even in regard to flu shots. I know the Knox County Health Department, my largest county, gave out more than double their ordinary number of flu shots this year.

Leading from that, we need to make sure in all of this that I know we are going to do everything possible to make sure there is no shortage next year, but I am wondering if, in doing that, when people think there is no shortage will the numbers drop off once again that get these flu shots. I think that is something we need to take into consideration when we are going through all this.

Thank you. This is very important, and I appreciate very much that you are continuing to hold hearings on this. Thank you.

Chairman TOM DAVIS. Thank you very much.

We are going to move now to our first panel of witnesses: Dr. Julie Gerberding, who is no stranger to this committee, is Director of the CDC; and Dr. Jesse Goodman, the Director of the Center for Biologics Evaluation and Research at FDA, will discuss efforts taken at the Federal level to manage the flu vaccine situation this season with focus on the most recent strategies announced by CDC

in January. They will also describe their efforts to coordinate distribution recommendations with local and State authorities and what steps are being taken in preparation for next year's flu season. Additionally, Dr. Goodman will provide the committee with a status report regarding the implementation of Chiron's remediation plan and how FDA is working with both British health authorities and Chiron to ensure Chiron is capable to manufacture for next flu season.

Let me thank both of you for reacting to this crisis. Whatever mistakes people think that could have gone on before, it certainly doesn't lie with the two of you. You have been most cooperative, and we have taken a deficit into a surplus. Maybe we will send you over to OMB next at the administration. But I personally appreciate the efforts that you have made on this and we look forward to your testimony and answering some questions. Thank you both for, I think, taking something that potentially could have been worse. I think we have been lucky so far with a mild flu season, but turning this around and reacting. We can have a talk about what happened and why, but most importantly where we are going next year.

As is our policy, we swear you in first.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you both for being here. You know the rules. Your entire statement is in the record and the questions will be based on your entire statement. Take about 5 minutes. You have the lights in front of you—orange after 4 minutes, red after 5. I won't cut you off, but we want to leave time for questions and the next panel.

Again, thanks for your efforts and thank you for being with us this morning.

Dr. Gerberding, we will start with you.

STATEMENTS OF DR. JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND DR. JESSE L. GOODMAN, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

STATEMENT OF DR. GERBERDING

Dr. GERBERDING. Thank you. We really do appreciate your continued interest in this issue. It has been a very challenging flu season for all of us, and I think very frustrating for the people who have been unable to get vaccine.

I have a map here showing the current distribution of influenza in the United States. As you can see, there are many red States. Those are States that are now showing widespread flu activities.

Chairman TOM DAVIS. So red States are not the good States in this thing? I mean, Mr. Waxman would agree with that, but I just want to get that on the record.

Dr. GERBERDING. I am not going to comment on that.

The activity——

Chairman TOM DAVIS. Who chose what is red and blue on this? I am just kidding. Go ahead.

Dr. GERBERDING. We really wanted to confuse the political process.

What we are seeing is that there is an increase in widespread flu activity across our Nation week by week by week. This morning we checked and we know that there is widespread flu activity in Virginia and we do not know yet whether the season has peaked, so there still is a need to immunize people against this infection.

We have three big challenges. One is that flu, itself, is unpredictable. We can't say at the beginning of the year what this map is going to look like or how fast the flu is going to spread across the country.

On the next graphic I also remind people about the evolution of flu viruses. We don't know from year to year what virus will emerge. We don't know what strain will be causing the majority of disease. And of course now we are also worried about the avian influenza in Asia. So we are dealing with a very unpredictable virus and one that remains a biological and sociological challenge.

We have a second big challenge, and that, of course, is the unpredictable nature of the vaccine supply, itself. That is, in part, because we are still using antiquated manufacturing methods that impart enormous risk to the manufacturers. We also do not have a stable market and historically we have had low prices for the vaccine and low rates of reimbursement.

Last, we have the challenge of the unpredictable demand for vaccine, and that is something, as you pointed out, the shortage certainly drives demand. We saw last year that a severe flu season drove demand, at least at the beginning of the season. But we also know that no matter where we are in flu season and how much we encourage immunization, it is very difficult to create demand late in the season, and that is what has created this national shortage of vaccine, but a local mismatch between supply and demand, and in some cases excess vaccine beyond the demand of the population.

So what can we do about that? Well, first, we can't change the virology of the virus, per se, but we can innovate. There are a number of innovations that have occurred even in the last year that will help us get a better handle on flu.

I will just point out that the laboratory capability for flu detection has expanded dramatically throughout our public health system this year, our ability to detect H–5 strains, the avian strain, but in addition CDC is conducting enormous amounts of research related to characterization of the virus, conducting the reverse genetics to look for novel ways to create vaccine strains, doing studies to look for drugs, and trying to understand why older people are more vulnerable and less successfully immunized against the flu.

We have also initiated a system to track in real time the emergence of vaccine in cities using biosense, which is an electronic surveillance system including data from the Department of Defense medical facilities and the VA medical facilities. This year for the first time we were able to see flu emerge on a jurisdiction-by-jurisdiction basis much earlier than we could through some of our traditional tracking mechanisms.

We also for the first time got proprietary information from Aventis, now known as sanofi pasteur, to tell us who is receiving the vaccine, where it was being utilized, and how we can do a bet-

ter job of reapportioning and reallocating that vaccine to treat people's needs. So while we can't change the virus, we can improve our abilities to detect and respond to it.

On the next graphic I have illustrated the changes in funding for flu. I know this doesn't show up well, but I think you can see that trends over time do show a steady and dramatic increase culminating in the President's 2006 budget with a request for $197 million for influenza. That is an unprecedented budget request, and it includes dollars to purchase vaccine, it includes purchase of drugs for the stockpile, it includes expansion of the vaccine for a children's program to include 5,500 immunizationsites that aren't currently covered, and a number of other steps to support CDC and the NIH research and science enterprises.

So we are making investments to help stabilize the supply. We know that the manufacturers need a modern production facility capability, and we know that manufacturers need a market.

Over the last decade, the recommendations about who should receive vaccine have steadily increased so that now we recommend vaccine to about 188 million Americans. This in itself incentivizes manufacturers. We have also raised the reimbursement rate for administration at CMS from less than $4 to more than $18, and we have increased the price we pay for vaccine to more than $10 through our Medicare program. So some of these efforts underway will certainly help stabilize the market, and we think help incentivize. That, with the advent of our capability to purchase vaccine and guarantee part of the market, at least, is something that the manufacturers tell us is very important in their progress.

The last challenge is the challenge of demand. This has been very difficult. I have detailed our communication efforts in my written testimony, but we do still need to work very hard to reach out to all cultures and all people and explain the need for vaccine.

Let me end with a picture of what our achievements have been this year. I think it is very important to notice that, compared to last year, the vaccine coverage rates across the United States in some cases are better for high-risk groups. For example, we have immunized about 50 percent of children between the ages of 6 and 23 months of age, compared to a very low immunization rate last year. Of course, it in part is due because we didn't recommend vaccine for this group last year. Also, compared to last year we have improved the coverage of high-risk children and we have improved the coverage of health care workers for flu vaccine. We haven't quite achieved the same level of immunization of our population over 65, but we have come close. About 60 percent of those individuals have received the vaccine.

Importantly, our targeting worked in that immunization of the non-risk people was less than half that it was last year, and we thank those people who stepped aside. So, despite having 50 percent of the doses we thought we needed to begin the year, we have achieved almost the same coverage of high-risk groups this year as we did last year. This represents a public health success and is in large part due to our public health system, our clinicians, and the vaccine manufacturers, and particularly the heroic people who stepped aside to let the high-risk people go first. So we thank all

of those individuals, as well as the team at CDC and NIH and FDA for their efforts.

Thank you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Gerberding follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

US Influenza Supply and Preparations for the Future

Statement of
Julie L. Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00AM
Thursday, February 10, 2005

Mr. Chairman and members of the Committee, I am pleased to be here today to update you on the Centers for Disease Control and Prevention's (CDC) efforts to address the influenza vaccine supply status and our planning for the 2005-06 influenza season. We faced unprecedented challenges during this current influenza season. Due to tremendous collaboration among our public health and private sector partners, our collective ability to modify and enhance our response strategy as circumstances changed, and the cooperation of the public, I am pleased to report that we have been successful in our effort to promote and protect the public's health.

Vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza. In the face of this season's influenza vaccine supply crisis, CDC, state and local public health officials, vaccine manufacturers and distributors initiated extraordinary partnership activities to address this public health challenge. For example, sanofi pasteur (formerly Aventis Pasteur) provided access to vaccine distribution information to aid in the allocation of the available vaccine supply to those people most in need this season. State and local public health officials also worked closely with CDC to ensure equitable distribution of vaccine to those areas with the greatest need. Together we found new and effective ways to address the sudden, late emergence of a substantial influenza vaccine shortage that had never before occurred. And, importantly, this public-private partnership has successfully distributed 95 percent of the 58 million doses of inactivated influenza

vaccine supply that was available. The unused supply – approximately 3.5 million doses of vaccine are still available for distribution - is about the same percentage we have had remaining at this time in prior years. (3.1 million doses of vaccine remain in the stockpile and sanofi pasteur has approximately 300,000 – 400,000 doses available.)

A total of 61 million doses of influenza vaccines were produced for the 2004-2005 influenza season. This includes approximately 58 million doses of inactivated influenza vaccine and three million doses of the live, attenuated influenza vaccine delivered through nasal spray (e.g. FluMist produced by MedImmune). Of the total supply of influenza vaccines, 93 percent of the doses have been distributed through public and private efforts. Over the past six years, between 87-99 percent of the influenza vaccines produced have been distributed. CDC is doing all it can to ensure that the remaining vaccine gets to those most in need, while at the same time providing state and local public health officials with the flexibility to offer vaccination to other groups as local supply allows.

I also want to acknowledge and thank the nation's health protection heroes -- the people not at high-risk who heeded the call to step aside and forgo vaccination so that those at highest-risk could be protected this influenza season. The cooperative and collaborative spirit of Americans helped us meet this serious

challenge. I also commend the public health and medical communities for their incredible efforts helping to manage this difficult situation.

In addition, we are fortunate that the flu season has been relatively moderate so far this year. I want to caution, however, that the flu season continues into March and April. Influenza is unpredictable and the situation could change in coming weeks.

Despite the challenges this year, I would like to note the tremendous progress we have made in recent years to expand the capacity to respond to an influenza crisis. DHHS has begun investing in new technologies, securing more vaccines and medicines, and preparing stronger response plans. We have made significant investments in protecting the nation against influenza, including increases for CDC influenza vaccine funding for both 317 and VFC purchases, from $5.5 million in FY 2001 to $104 million in the FY 2006 budget request, and creation of Strategic Reserves/Stockpiles, from $0 in FY 2001 to an investment of $70 million in the FY 2006 budget request. These investments are further detailed as follows:

- **New Technologies:** In each of the previous three budgets, the Department of Health and Human Services (DHHS) has asked for at least $100 million. We received $150 million for FY 04 and FY 05 in total. We have asked for $120 million for FY 06. This will help foster introduction of

new technologies for producing influenza vaccine, including cell culture, recombinant protein and DNA based vaccines and ensuring a year-round supply of eggs to grow vaccine viruses and respond to supply and surge capacity. Over the next several years, these new technologies and steps to strengthen existing production capacity may help produce influenza vaccine more efficiently and provide more adaptability to unexpected problems or losses in production.

- **Creating the Nation's First Stockpiles of Influenza Medicines:** For the first time ever, we have created stockpiles of both influenza vaccine and antiviral medications. DHHS initially spent $19 million in FY 2004, and is planning to spend another $50 million in FY 2005 ($70 million in the FY 2006 budget request) to develop a strategic reserve of influenza vaccine. In addition, $21 million in carryover funding originally designated for Chiron vaccine stockpiles in FY 2004 will be allocated for use as appropriate in FY 2005 and FY 2006. CDC purchased Tamiflu, for a total of $87.5 million. The total invested for Rimantadine should be $36 million in FY 2005 to treat 4.25 million adults and on Rimantadine syrup to treat 750,000 children. These stockpiles of influenza vaccine and antiviral medications total about $200 million and give the government new ability to respond when there is a shortage of vaccine.

- **Strength and Stability of the Market:** Maintaining an abundant influenza vaccine supply is critically important for protecting the public's health and improving our preparedness for an influenza pandemic. It is essential to add stability and strength to the U.S. influenza vaccine market. DHHS is trying to strengthen the supply by developing financial incentives for manufacturers to increase production and encouraging new manufacturers to enter the domestic market with licensed vaccine. CDC is also considering plans for the use of Investigational New Drug (IND) influenza vaccine to supplement the licensed vaccine when needed.

- **Improving Access by Covering Costs:** The Centers for Medicare & Medicaid Services (CMS) within DHHS have more than doubled the payment rates for the influenza vaccine and its administration since 2000. Estimates from CMS indicate that $18.75 is expected to be paid for administration costs in FY 2005, up from $3.98 in FY 2002. This increase is helping to encourage providers to administer the vaccine by offsetting some of their costs.

In the remainder of my testimony, I will comment on the status of the current influenza season. I also will summarize events that led to the vaccine shortage announced in October 2004, the steps CDC took to address the problem, and what CDC is doing to prepare for the next influenza season.

THE 2004-05 INFLUENZA SEASON

As I mentioned previously, influenza seasons are highly unpredictable. Although epidemics of influenza occur virtually every year, the particular viruses and the beginning, peak, severity, and length of the epidemic can vary widely from year to year. When compared to the 2003-2004 influenza season, the 2004-2005 season has been more moderate so far. However, based on available data influenza in the United States has continued to increase and does not appear to have peaked. As of the week ending January 29, 2005, many states continue to report considerable activity. Sixteen states reported widespread activity. Nineteen states and New York City reported regional influenza activity.

CDC also is monitoring cases of Avian A (H5N1) influenza in Southeast Asia, in collaboration with the World Health Organization (WHO). H5N1 is a potential pandemic threat, and we are communicating each day with our colleagues to assess this situation and what steps should be taken.

CDC RESPONSE TO THE 2004-05 INFLUENZA VACCINE SHORTAGE

On October 5, 2004, Chiron Corporation notified DHHS that none of its influenza vaccine (Fluvirin®) would be available for distribution in the United States for the 2004–05 influenza season. This action prevented the release of its vaccine for this influenza season, reducing by approximately one-half the expected supply of inactivated influenza vaccine available in the United States for the 2004–05 influenza season. In response to the loss of Chiron vaccine, both sanofi

pasteur and MedImmune increased production of influenza vaccine to provide additional doses for the season, with sanofi pasteur producing approximately 58 million doses of inactivated vaccine and MedImmune producing approximately three million doses of the intranasal, live attenuated vaccine. HHS and CDC acted quickly in response.

Interim Influenza Vaccination Recommendations for the 2004-05 Season

On October 5, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for influenza vaccination during the 2004-05 season. The interim recommendations identified the priority groups of people that should receive the limited supply, including people who are most vulnerable to develop serious complications and even death from influenza: adults 65 years of age and older, children 6 to 23 months of age, individuals with certain chronic underlying medical conditions, pregnant women, residents of nursing homes and long-term care facilities, and children on chronic aspirin therapy. In addition, the ACIP recommended vaccination for individuals who might otherwise spread influenza to high-risk individuals, including household contacts of infants less than six months of age and healthcare workers providing direct, hands-on patient care. These interim recommendations took precedence over earlier recommendations.

In December 2004, the ACIP broadened the interim influenza vaccination recommendations to include older adults 50-64 years of age and household contacts of all high-risk persons six months of age where state and local public

health officials judged the supplies of vaccine to be adequate. The revised recommendations went into effect January 3, 2005. In addition, ACIP expanded the use of vaccine for children Vaccines for Children (VFC)–purchased influenza vaccine to include VFC eligible household contacts of high-risk VFC children six months of age and older.

On January 27, 2005, CDC issued a Health Alert Network announcement encouraging the continued targeting of vaccine to the priority groups while also encouraging state and local public health officials to make the best use of the remaining vaccine by broadening vaccination recommendations further, as warranted by local supply and public demand.

Influenza Vaccine Supply and Allocation Plan

Following the Chiron withdrawal, sanofi pasteur – which had already distributed 33 million doses by October 5, 2004 - announced that it would work with CDC to develop a plan to target the remaining 25 million doses of influenza vaccine toward providers serving the populations at greatest risk for serious complications from influenza. In addition, state and local health officials have worked together with CDC, sanofi pasteur, and a number of vaccine distributors to assure the most equitable and efficient means of distributing the remaining, limited supply of vaccine across the nation. The significant contributions and leadership of these public health professionals has contributed to our nation's effective response to this public health challenge.

Every effort has been made to distribute vaccine to as many providers serving high-risk populations as possible in a timely fashion. The vaccine distribution process this season reflected constant feedback to CDC, and changes were made based on evolving information about vaccine supply, need and demand. Initially, CDC worked closely with sanofi pasteur to fill the public and private orders of health care providers and facilities serving high-priority persons, including orders placed with both sanofi pasteur and Chiron. During the months of October and November, approximately 13 million doses of vaccine were distributed to:

- State and local health departments;
- The Vaccines for Children Program;
- Pediatric providers and other primary care providers;
- Healthcare providers who had ordered sanofi pasteur's preservative-free influenza vaccine (licensed for use with children 6-35 months of age);
- The Department of Veterans Affairs;
- The Indian Health Service;
- Long-term care facilities and acute care hospitals;
- The Visiting Nurses Association of American; and
- The Department of Defense.

In early November three to four million doses were used to fill the remaining public health orders. In addition, state health officials and CDC worked together,

in consultation with local health departments, to develop a formula for the equitable distribution of the eight million remaining influenza vaccine doses to be shipped. This formula took into account the population of high-priority individuals in each state and the number of influenza vaccine doses that had already been shipped to each state. Based on state reports regarding the adequacy of their vaccine supply to meet the needs of the priority populations in their jurisdiction, CDC made three re-apportionments of vaccine across the states to assist those states that continued to have unmet need for vaccine.

To further ensure the equitable apportionment of vaccine, CDC implemented a secure web-based application, the Flu Vaccine Finder, and made it available to state health officials to identify doses of inactivated influenza vaccine shipped to their state during the 2004-05 influenza season in relation to the location of priority populations within their jurisdiction. This secure web-based application also served as the mechanism through which states placed their vaccine orders.

Some states purchased vaccine to distribute and administer. However, the majority of vaccine was allocated for purchase by private sector providers and facilities. During the months of November and December 2004 and January 2005, states allocated approximately 4.6 million doses to health care providers.

Finally, to enhance continued use of late season influenza vaccines, CDC developed two strategies to make vaccine available to public and private providers with minimal financial risk.

- CDC made available to sanofi pasteur the remaining 3.1 million doses of influenza vaccine in the federal government's emergency reserve. Sanofi pasteur, in turn, is marketing the vaccine to public and private providers. This strategy will allow providers to order vaccine directly from sanofi pasteur or a vaccine distributor, instead of working through state or local health departments. Doses purchased in this way may be used in any person in accordance with the Advisory Committee on Immunization Practices (ACIP), state, and local recommendations for vaccine use.

- CDC is taking steps for the remainder of this influenza season to make limited amounts of VFC influenza vaccine that currently exists within states available to state health departments for non-VFC use where the demand for influenza vaccine among VFC-eligible children has already been met.

Additional Sources of Influenza Vaccine

Approximately three million doses of MedImmune's intranasal, live, attenuated influenza vaccine, FluMist, were produced for the 2004-05 season. This vaccine

was recommended for use among healthy persons ages 5–49 years who are not pregnant, including healthcare workers (except those who work with severely immunocompromised patients in special care units) and household contacts of infants less than 6 months of age. CDC continues to make people aware of this alternative to inactivated influenza vaccine.

DHHS successfully located and purchased approximately 1.5 million doses of influenza vaccines licensed for use in many countries around the world. Because these vaccines are not currently licensed in this country, they must be administered under special protocols with written consent. Preparations for the use of these vaccines have been completed through the Food and Drug Administration's approval of Investigational New Drug (IND) protocols and implementation of a contract with a contract research organization that is prepared to administer the IND vaccine and complete the required follow-up activities in areas with unmet demand and inadequate supply of licensed vaccine during this season.

Monitoring Influenza Coverage

To assess influenza vaccine coverage among the priority populations and to learn more about the reasons members of the priority populations chose to go unvaccinated, CDC included additional influenza questions on the Behavioral Risk Factor Surveillance System (BRFSS) survey. BRFSS is a telephone survey

conducted by state health departments that provides state level and national estimates regarding health behaviors, such as immunization behaviors.

Data collected January 1 through 22nd, 2005 suggest that influenza vaccination uptake continued through the month of December. Vaccination coverage among adults in all priority groups was 43 percent this year, while coverage among non-priority adults was eight percent, suggesting that targeting of influenza vaccine has been effective. Among adults aged 65 years of age and older, nearly 59 percent reported influenza vaccination this season. Vaccination coverage among children in priority groups was 51 percent.

Antiviral Medications

Although vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza, influenza antiviral medications are an important adjunct to influenza vaccine in the prevention and treatment of influenza. CDC has developed interim recommendations on the use of antiviral medications for the 2004-05 influenza season. The interim recommendations were developed to reduce the impact of influenza on persons at high risk for developing severe complications secondary to infection. The recommendations are not intended to guide the use of these medications in other situations, such as outbreaks of avian influenza in humans.

Influenza antiviral medications have long been used to limit the spread and impact of institutional influenza outbreaks. They are also used for treatment and chemoprophylaxis (prevention) of influenza in other settings. In the United States, four antiviral medications -- amantadine, rimantadine, oseltamivir, and zanamivir -- are approved for treatment of influenza. When used for treatment within the first two days of illness, all four medications are similarly effective in reducing the duration of illness caused by Strain A influenzas by one or two days. Only three antiviral medications (amantadine, rimantadine, and oseltamivir) are approved for prevention of influenza.

If supplies allow, CDC encourages the use of amantadine or rimantadine for prevention of influenza, and use of oseltamivir or zanamivir for treatment of influenza. People who are at high risk of serious complications from influenza may benefit most from antiviral medications.

The United States has a supply of influenza antiviral medications for both adults and children stored in the Strategic National Stockpile for emergency situations. Procurement of additional supplies of antiviral medications, and shipments arrive weekly. Antivirals will be made available to states and territories for use in outbreak settings, as might occur in a hospital or long-term care facility, if supplies from commercial sources become depleted or are not available quickly enough to be of use. Our stockpile includes antivirals effective against Avian A

(H5N1) influenza, which we will work to maintain in reserve to be used in the event of an influenza pandemic.

Communicating the Public Health Message

The October 5 Chiron announcement led CDC to rapidly revise its influenza message strategy, and target considerably narrower population subsets than had been originally planned. Key messages provided a rationale for reserving limited influenza vaccine for the most vulnerable populations, while appealing to all others to defer vaccination in the interest of reserving the limited vaccine stocks for those at greatest need.

In refocusing its campaign, CDC set specific objectives:

- To encourage specific groups at greatest risk of influenza complications to receive the vaccine;
- To gain voluntary approval of all others to step aside;
- To encourage late season vaccination beyond the typical high-demand months of October and November, by reminding both the public and health care providers that influenza vaccination is effective throughout the winter influenza season; and
- To introduce the concept of offering imported vaccine, under special arrangement, as an alternative source to help meet demand and public health need for additional vaccine.

CDC outreach included:

Communication with state/local public health partner audiences via the electronic Health Alert Network (HAN).

Between October and January, six HAN dispatches were shared with the public health community detailing the interim recommendations for influenza vaccine, antiviral medication, the reallocation of vaccine stocks, and guidance for late-season influenza vaccination.

Continuous information updates through The National Public Health Information Coalition (NPHIC).

The NPHIC is a group of professional public health communicators from all 50 states and large city public health agencies. Through frequent conference calls, this group became aware of upcoming communications materials, and identified specific communications needs for their areas. The messages developed through these interactions included advice for minimizing the risk of influenza and encouraging late-season vaccination, in areas where sufficient stocks remained.

Hotline, website and media relations outreach

Through its information hotline, website, and news media relations, CDC communicated openly with the public from the start of the influenza vaccine

shortage. For example, from October 1, 2004 through January 31, 2005 the hotline fielded more than 60,000 calls. The CDC flu website recorded 12 million page views during this same period. CDC has also handled almost 1400 media calls related to vaccine availability and participated in satellite media tours to provide the latest information to broadcast media representatives.

CDC sustained a focused effort to maintain regular communications with doctors, clinicians, and other health care providers through a variety of channels, including providing detailed updates to 40,000 health care providers who subscribe to CDC's clinician registry e-mail list-serve and through conference calls. CDC also established a special Clinician Information Line, which was available 24 hours a day, 7 days a week. More than 2,600 calls, answered by professional registered nurses, have been answered through the end of January.

In addition to these efforts, CDC has issued news releases concerning influenza vaccine availability, conducted formal news briefings, and worked to incorporate both radio and television recorded new releases into its outreach efforts.

CDC also made specific efforts to reach business and educational institutions with critical information about the priority populations recommended for vaccination and alternative methods for preventing transmission of disease in the workplace and educational settings.

PREPARATIONS FOR THE 2005-06 INFUENZA SEASON

Anticipating and planning for the next influenza season is an enormous and highly-complex challenge, involving numerous public health and private sector entities. The production of influenza vaccine is a lengthy and complicated process. There are currently two manufacturers licensed to produce influenza vaccines for the United States. Currently one manufacturer produces inactivated influenza vaccine and one manufacturer produces the live, attenuated vaccine administered through nasal spray. Manufacturers must predict demand and decide how much of the vaccine to produce six to nine months before the influenza season begins. Moreover, the severity of influenza season and potential public demand for vaccine are highly unpredictable from year to year.

Currently experts from the four World Health Organization (WHO) Collaborating Centers in the United States (Atlanta), Australia, Japan and the United Kingdom, along with regulatory authorities including the FDA, are in Geneva at WHO making decisions about which vaccine strains to include in next year's Northern hemisphere vaccine. They are analyzing global data including important surveillance information gathered by CDC. On February 17-18, experts in the U.S. will meet in Washington at the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to make decisions about the influenza vaccine for the upcoming season in the U.S.

CDC has already begun its planning efforts for the 2005-06 influenza season in anticipation of continued challenges in meeting the nation's vaccine supply needs. To date, CDC has:

- Developed possible scenarios for vaccine supply for the coming season, including the possible exit of current influenza vaccine manufacturers from the U.S. market; the entry of new vaccine manufacturers into the U.S. market; and the possible need for use of IND influenza vaccine to meet demand.
- Worked with ACIP to develop more refined prioritization plans that can be used should there be another critical vaccine shortage.

In addition, CDC is:

- Meeting with U.S.-licensed and other vaccine manufacturers to discuss their plans for the next season, including production, distribution, and pre-booking plans.
- Planning a vaccine contracting strategy that addresses routine influenza vaccine purchase and stockpile purchase.
- Preparing for the possible use of IND influenza vaccine as part of the 2005-06 influenza vaccination program.
- Monitoring antigen-sparing studies which are designed to determine if reduced vaccine dosages can provide sufficient immunity against influenza and thus allowing for the protection of more persons with fewer doses of vaccine will help control the spread of influenza.

- Developing infection control strategies.
- Developing and implementing an evaluation plan.
- Preparing communication strategies with appropriate messages to respond to the fluctuations in supply and demand anticipated throughout the season.

These comprehensive planning efforts are intended to help us achieve important public health objectives to increase domestic production of influenza vaccine, increase demand for vaccine in order to protect and improve public health, and increase vaccination coverage, particularly among high-risk groups.

CONCLUSION

CDC's agency-wide influenza budget request for FY 2006 totals $197 million, nine times more funding than in FY 2001. In addition, DHHS has increased its investment in influenza-related activities from $42 million in FY 2001 to $439 million in FY 2006.

Our nation's response to the circumstances presented in October 2004, as well as the efforts now underway to prepare for the next season and beyond, indicate the seriousness of influenza as a public health threat. We addressed the urgent situation as effectively and expeditiously as possible to provide vaccine to those most in need of health protection. Our targeting efforts were highly successful,

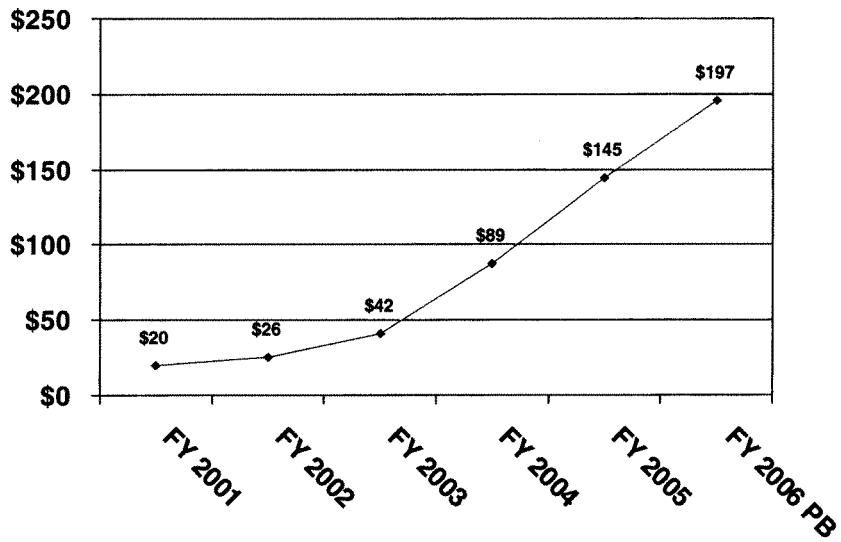
and in our future-year planning, we already are applying lessons learned from the challenging experiences of the 2004-05 influenza season.

Thank you for focusing attention on this important public health issue and for the opportunity to provide an update on our current efforts. CDC is committed to protecting and promoting health for all Americans, preventing disease and disability through public health research and public outreach, and supporting important public health interventions, including vaccination. We appreciate your interest in this issue and your support of CDC's efforts to protect the public's health.

I will be happy to answer any questions.

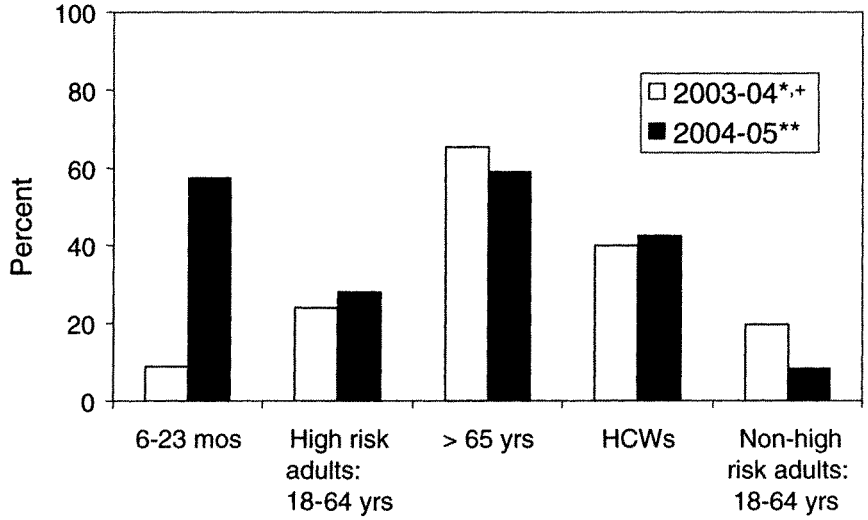
CDC Influenza Funding

(dollars in millions)



CDC's agency-wide influenza budget for FY 2006 totals $197 million, nine times more funding than in FY 2001.

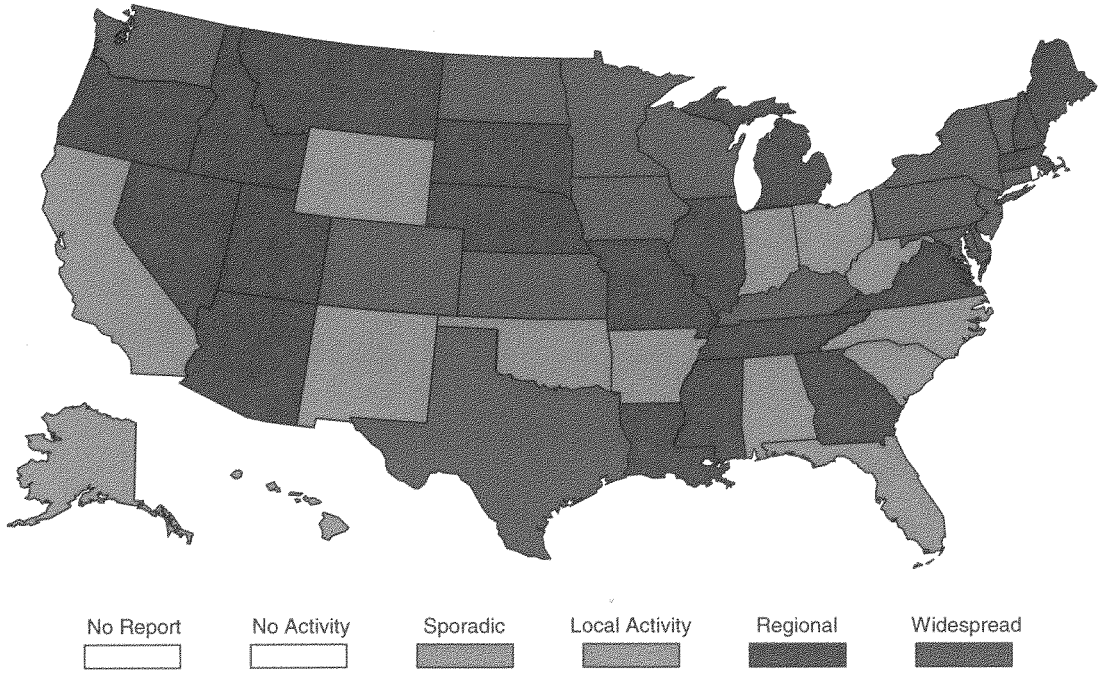
Annual Influenza Vaccination Coverage Levels 2003-04 and 2004-05

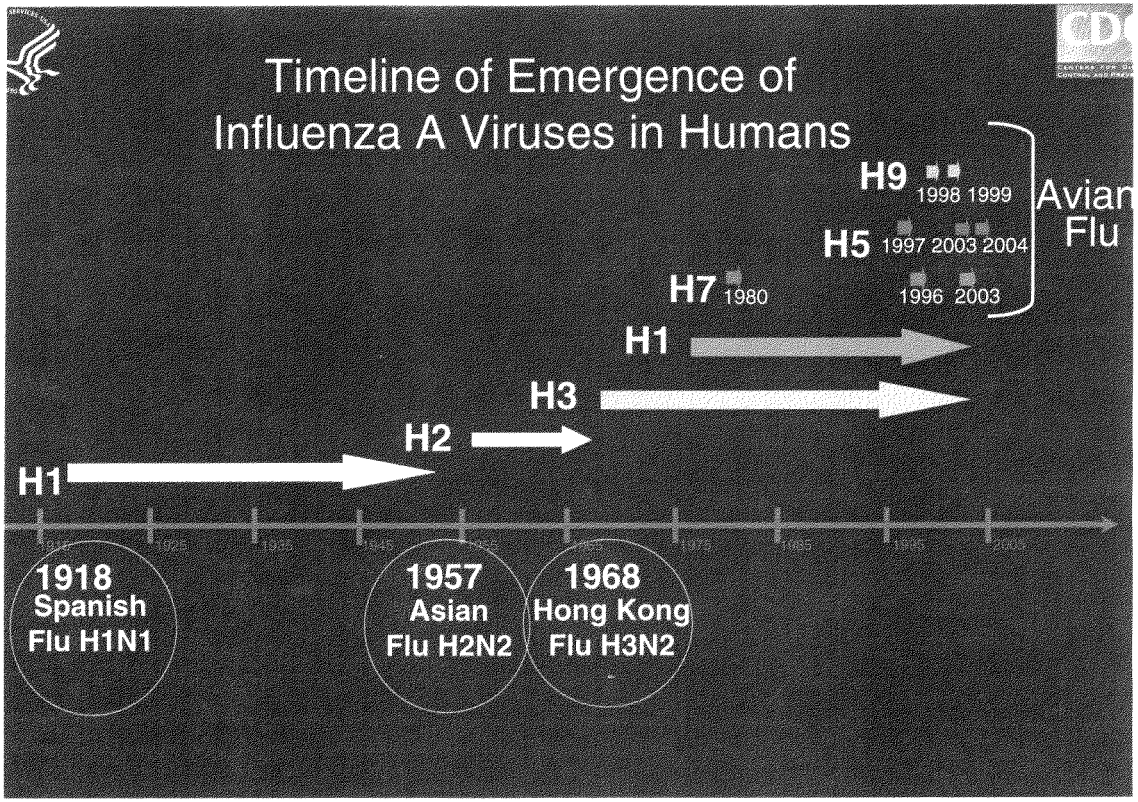


Sources: * National Health Interview Survey
** Behavioral Risk Factor Surveillance System
+ National Immunization Survey

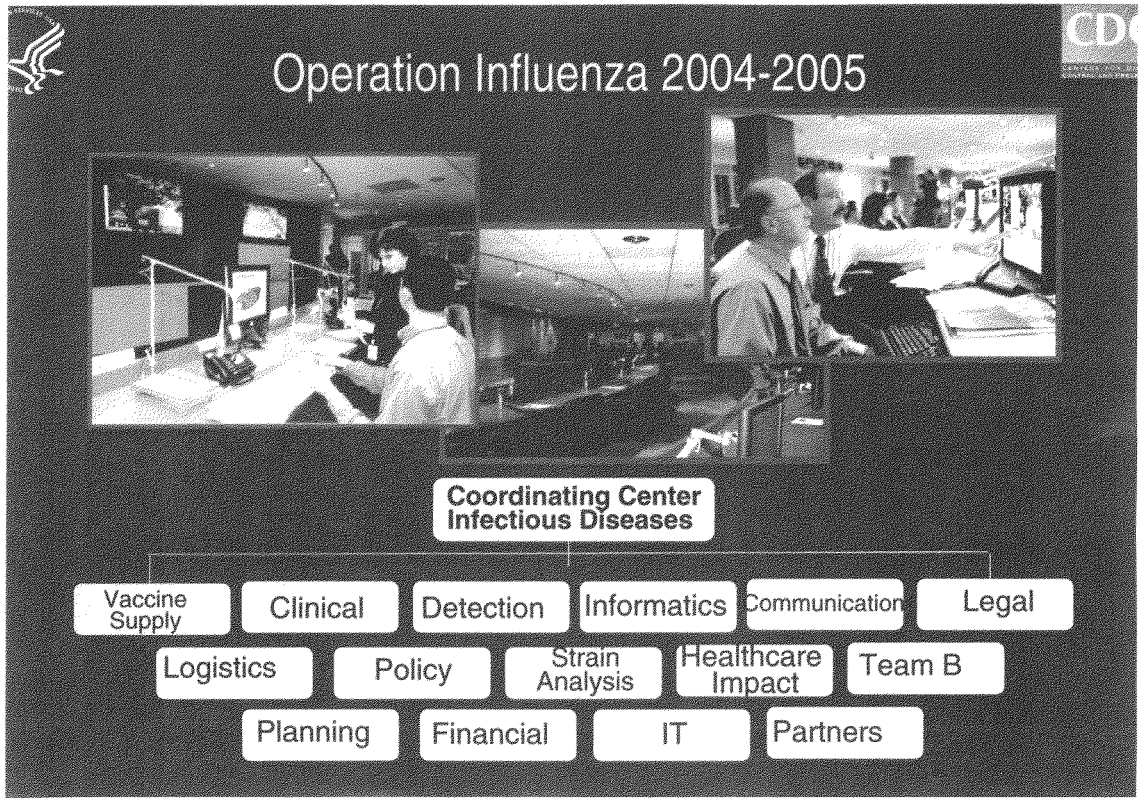
Weekly Influenza Activity Estimates Reported by State & Territorial Epidemiologists

Week ending January 29, 2005 - Week 4




Timeline of Emergence of
Influenza A Viruses in Humans
H9
1998 1999
H5
1997 2003 2004
1996 2003
Avian
Flu
H7
1980
H1
H3
H2
H1
1918
Spanish
Flu H1N1
1957
Asian
Flu H2N2
1968
Hong Kong
Flu H3N2

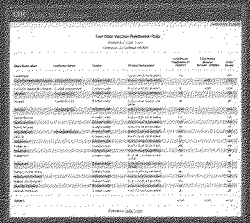
Timeline for Influenza Vaccine Development and Use
United States
STEPS
Surveillance
Select strains
Prepare reassortants
Standardize / test antigen
Review labels / license
Assign potency
Release vaccine
Produce concentrates
Formulate & test
Fill, test, package
Distribute
Vaccinate !
CDC/ WHO
FDA
Manufacturers
Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec
CDC


Operation Influenza 2004-2005
Coordinating Center
Infectious Diseases
Vaccine Supply
Clinical
Detection
Informatics
Communication
Legal
Logistics
Policy
Strain Analysis
Healthcare Impact
Team B
Planning
Financial
IT
Partners

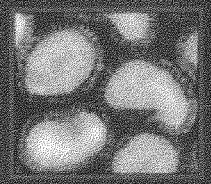
Tracking Influenza…Targeting Prevention
New Innovations

Household Survey:
Vaccine Use

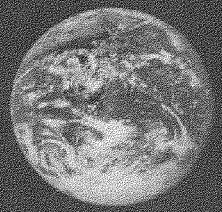
Long-term Care:
Vaccine Needs Survey



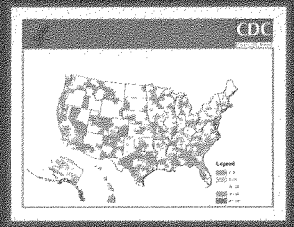
State & Local Health
Officials: Secure Vaccine
Allocation Database



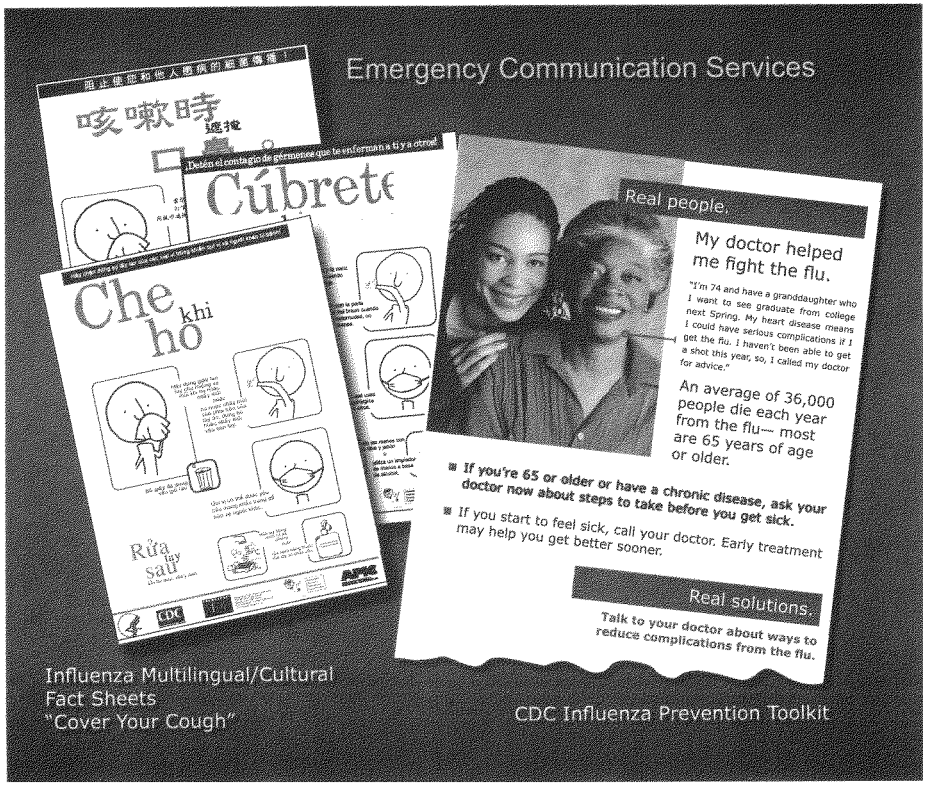
Laboratories: Virus
Genetic Sequencing
& Rapid H5 detection



Global Biodetection
Network



BioSense:
Influenza-like Clinic Visits


Emergency Communication Services
咳嗽時
Cúbrete
Che khi ho
Rửa tay sau
Real people.
My doctor helped me fight the flu.
"I'm 74 and have a granddaughter who I want to see graduate from college next Spring. My heart disease means I could have serious complications if I get the flu. I haven't been able to get a shot this year, so, I called my doctor for advice."
An average of 36,000 people die each year from the flu— most are 65 years of age or older.
If you're 65 or older or have a chronic disease, ask your doctor now about steps to take before you get sick.
If you start to feel sick, call your doctor. Early treatment may help you get better sooner.
Real solutions.
Talk to your doctor about ways to reduce complications from the flu.
Influenza Multilingual/Cultural Fact Sheets "Cover Your Cough"
CDC Influenza Prevention Toolkit

Chairman TOM DAVIS. Dr. Goodman, thanks for being with us.

STATEMENT OF DR. GOODMAN

Dr. GOODMAN. My pleasure, Mr. Chairman. Mr. Chairman and members of the committee, I am Dr. Jesse Goodman. I am the Director for the Center for Biologics and Evaluation at FDA. I am also an infectious disease specialist and I think we share many common goals here today.

I do appreciate the opportunity to be here today with Dr. Gerberding and to update you on FDA's efforts to address influenza vaccine needs and what we are doing to prevent the kinds of problems we have had this year from recurring.

I do want to assure the American public also that the safety, effectiveness, and availability of vaccines are among FDA's highest priorities.

As we have emphasized in previous testimony, influenza vaccine manufacturing is complex and challenging and the market is very fragile, in part because increasing demand has been coupled by a decline in the number of manufacturers. For the 2004–2005 season, only three licensed manufacturers began production. As you know, on October 5, 2004 the British Medicines and Health Care Regulatory Agency, MHRA, suspended Chiron's license without prior notice to FDA.

FDA also concluded that the safety of Chiron's vaccine could not be assured. As soon as we learned Chiron's vaccine would not be available, we worked with great urgency and close cooperation with CDC and the private sector—and I want to emphasize this was really a public/private effort—to explore all viable options to get additional doses. With sanofi pasteur and MedImmune we got approximately 5 million additional doses of U.S.-licensed vaccine, increasing the availability of supply to 61 million doses. I think that helped us come close to the kind of coverage results of previous years.

Because there was a concern, though—and we were all very worried, because this is still a lot less vaccine than we have had in previous years, and because of that concern we sought additional vaccine licensed in other countries that, if needed, could be made available under investigational new drug applications.

We immediately sent teams to facilities of potential sponsors in multiple countries to evaluate their manufacturing processes, and we reviewed a huge volume of manufacturing and clinical data, all within a few weeks. These efforts resulted in FDA being able to approve INDs that permitted the potential use of 4 million from GlaxoSmithKline and 1 million doses from Berna Biotech if we needed them.

These interactions and those with other influenza vaccine manufacturers who also were highly cooperative provided valuable information, and they have created and strengthened relationships that we think importantly will lead to successful U.S. licensure of new vaccines.

I want to also say that is one of the constructive outcomes of the challenges we have faced and that I am extremely proud of all this hard work from over 50 FDA employees, as well as our colleagues at HHS and CDC who worked very collaboratively for long hours,

often on weekends and during vacations, to help meet this challenge. We took this quite seriously, because we share all your concerns.

I wanted to mention that it is often overlooked that pneumococcal pneumonia is one of the most important and common serious complications of influenza, and it, itself, is preventable through use of inexpensive yet, even more than flu vaccine, under-utilized vaccine. In cooperation with HHS, Merck tripled its production of its vaccine from 6 to more than 17 million doses, and availability of that vaccine can help further protect Americans from that complication.

Well, you want to know about what our plans are, what we are doing, what the plans are for 2005 and future years. First, we are doing everything we can to improve supply for future years. We are doing this with a dual-track strategy. Because Chiron is a major issue, our first track refers to trying to help Chiron be able to produce again. We are doing everything we can to facilitate that effort of its correcting its manufacturing problems.

In a dramatic change from where we were in October, FDA and MHRA, the British regulatory agency, now have an agreement with Chiron that allows full information sharing. We have used that agreement to collaboratively review Chiron's remediation plans and activities, and we are providing continuing and extensive feedback to both Chiron and MHRA in all directions. We are working together and actively communicating, in addition, on inspection activities.

Only after passing MHRA and FDA inspections will Chiron be able to provide vaccine to the U.S. market. In the spring, when critical stages of manufacturing are taking place, we plan a comprehensive inspection to verify whether Chiron has adequately addressed its problems. While much work remains to be done, I am pleased to report that it appears that Chiron is making progress.

While working with Chiron, it is important to emphasize that we are also working on a second track to facilitate overall greater capacity and diversification in the U.S. influenza vaccine supply, something several of the Members identified as important in their remarks. It is important to recognize—and you have also remarked on this, but I want to emphasize it—that the demand for vaccine, the demand and other economic issues are the primary factors that determine whether a manufacturer will seek and maintain a license in this country, the strength of our manufacturing infrastructure here, and the amount of vaccine that manufacturers will produce.

One important and often overlooked strategy that CDC and us are in full agreement on is to encourage vaccination throughout the flu season, including January and February. To increase the total doses available, manufacturers can produce vaccine over a longer time period, and that becomes available during these months. Because influenza cases usually continue well after November and December when most people are seeking immunization, later vaccination is beneficial. We need to better communicate this important public health message, and the clinic that you have sponsored today is a great way to do that.

In addition, we have also been doing everything we can to stimulate foreign license manufacturers to provide or, where needed, develop the safety and effectiveness data to get U.S. licensure. We have actively engaged with several interested companies. We have informed manufacturers that we are willing to consider creative approaches to licensing, such as accelerated approval based on surrogate markers like the patient's immune response to the vaccine.

Finally, while we are doing all we can to have licensed vaccines for next year's needs, the experience and relationships we have built this year will help us if we again need to obtain additional vaccine under INDs.

I just want to conclude with a few remarks on something I think is very important, which is we have challenged ourselves to identify other lessons learned from this year's influenza season and how we can use this experience to prevent similar events in the future. It is not all under our control, but we are making significant changes in response to our sort of after-action and continuing analysis. One is that we plan to conduct inspections of influenza vaccine manufacturers on an annual basis. Another is this need to share more information. We are completing or have completed agreements that allow information sharing with numerous foreign regulatory agencies. We have also initiated a vulnerability analysis of other licensed products that we regulate that are critical to public health to identify other areas where actions to support supply might be needed, and we have increased efforts at global regulatory collaboration on approvals and standards.

I think it is very important, because I know you are interested in pandemic flu, to know that the insights gained from these experiences are critical in informing us on pandemic preparedness. This is something we all care a great deal about, given the eventual likelihood of pandemic and the outbreaks of avian flu Julie mentioned in Asia. It is very, very important to emphasize that more widespread vaccination during periods before pandemics has not only its direct health benefits but it increases vaccine production capacity and it will help America and the global community better prepare for an influenza pandemic.

As Julie mentioned, the administration is making the largest investment ever made by the Federal Government in these areas. I do want to mention a couple of specific things that were not in her testimony.

In November 2004, HHS awarded a contract to sanofi pasteur to help ensure year-round availability of increased egg supply in case it is needed for the pandemic or for this kind of future vaccine shortage. Research supported by HHS through the National Institutes of Allergy and Infectious Disease will help us move from egg-based production technology to newer technologies. While much work remains, these newer technologies provide important alternatives that could potentially shorten the time needed to produce vaccines.

We welcome the continued support of Congress for this work, and we view preparedness as a critical responsibility and an opportunity. I see this as a teachable moment. What have we learned? What do we need to do to prepare for the future?

In conclusion, when an adequate vaccine supply supplemented by effective anti-viral medicines is available, we can greatly decrease our vulnerability and provide protection against influenza. We recognize the need to work with multiple partners, including manufacturers, to increase supply and move toward more modern, dependable methods of production. All of the steps we have described will not only help address our current challenges, but help protect us from flu every year and prepare us for future seasons or in the event of a pandemic.

All of us welcome the opportunity to work with Congress to accomplish these shared public health goals.

Thanks very much.

Chairman TOM DAVIS. Thank you very much, Dr. Goodman.

[The prepared statement of Dr. Goodman follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

Influenza Vaccine: Current Status, Lessons Learned and Preparing for the Future

Statement of
Jesse L. Goodman, M.D., M.P.H.
Director,
Center for Biologics, Evaluation and Research,
Food and Drug Administration
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00AM
Tuesday, February 10, 2005

INTRODUCTION

Mr. Chairman and members of the Committee, I am Dr. Jesse Goodman, Director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) and also a practicing Infectious Diseases specialist. I appreciate the opportunity to update you on FDA's recent and ongoing efforts, in collaboration with other Department of Health and Human Services (HHS) agencies and with the private sector, to address influenza vaccine needs for the current flu season and to do what we can to prevent such problems from recurring. These efforts should also help better prepare us for the next global influenza pandemic.

FDA is responsible for the regulation and oversight of vaccines in the United States. Vaccines are among our most important and cost-effective medical interventions, preventing disease in those who receive them and reducing the spread and risk of infections through our communities. I want to assure the American public that the safety, effectiveness and availability of vaccines are among FDA's highest priorities.

THE 2004-2005 INFLUENZA SEASON

As you know, influenza vaccine is unique because its active ingredients – the virus strains used to develop the vaccine – change almost every year.

Therefore, manufacturers must produce millions of doses of a new vaccine each year. While promising new technologies such as cell culture and recombinant protein and DNA-based vaccines are in the research and development stages and we are working with our HHS colleagues to advance their development, the most efficient vaccine production methods currently available involve the use of millions of live, non-sterile eggs to grow three different strains of influenza viruses annually. This is a complex process that spans several months where manufacturers cultivate the appropriate strains to make the vaccine. These factors present an enormous challenge for manufacturers and create uncertainty for vaccine supply.

Each year, FDA begins working with manufacturers at the earliest stages of vaccine development, and we continue to assist them throughout the production phase. We do this not only through our regulatory evaluations, but also by providing needed influenza strains that can be used for efficient manufacturing. Specifically, we provide reagents to assure that the vaccine is potent and further evaluate the vaccine through the use of laboratory tests that help assure the safety and efficacy of the vaccine. Throughout this process, FDA frequently discusses technical issues with manufacturers.

Influenza vaccine is highly cost-effective and beneficial to the public. Over the last decade, health care providers, the Centers for Disease Control and Prevention (CDC) and others have been very successful in expanding the

number of Americans who receive the vaccine. However, as we have emphasized in previous testimony before Congress, the influenza vaccine market is very fragile because the increasing demand has been coupled with a decline in the number of U.S-based and U.S. licensed manufacturers. Importantly, the market returns for producing this and many other vaccines are usually minimal while the financial and other risks involved are great. Further, vaccine manufacturing requires careful and comprehensive controls, a complex manufacturing process and highly specialized facilities that can be expensive to maintain and update. For the 2004-2005 season, only three U.S. licensed manufacturers began production of influenza virus vaccine: Chiron Corporation and Aventis Pasteur (renamed sanofi pasteur in December 2004) produced inactivated vaccine, the form currently used for most high-risk individuals, while MedImmune, Inc. manufactured FluMist, a recently approved live attenuated (weakened and safe) influenza vaccine.

As you know, on October 5, 2004, the British Medicines and Healthcare products Regulatory Agency (MHRA) suspended Chiron's license to manufacture influenza vaccine due to sterility failures in filled vials of the vaccine. FDA and MHRA's review of Chiron's investigation of the root causes of the company's sterility failures and our own review and inspections of their facility pointed to general problems that led FDA to the conclusion that the sterility, and therefore safety, of the vaccine Chiron produced for the 2004-2005 influenza season could not be assured.

Efforts to Obtain Additional Vaccine

The loss of Chiron's planned contribution to the U.S. influenza vaccine supply posed serious challenges. FDA worked with urgency, aggressiveness and in close coordination with CDC and other components of HHS and the private sector to explore all viable options to secure additional doses of influenza vaccine. FDA worked with sanofi pasteur and MedImmune to secure approximately five million additional doses of U.S. licensed vaccine. Sanofi pasteur increased production to 58 million doses of Fluzone, and MedImmune scaled up to produce three million doses of FluMist. FluMist is currently recommended for healthy individuals 5 to 49 years of age, and therefore provides an option for those who would not receive vaccine under CDC's priority guidelines, such as the U.S. military. Therefore, to expand further the supply of vaccine to those with the greatest need, Secretary Thompson, in cooperation with the Department of Defense, announced that the military would maximize its use of FluMist as a substitute to the inactivated vaccine, making an additional 200,000 doses of injectable vaccine available to HHS for high-risk civilian populations. Because sanofi pasteur produces pediatric dosage forms of vaccine for the U.S. market, the supply of vaccine available for high-risk children was, fortunately, not reduced. Through these collaborative efforts, manufacturers increased the available supply of licensed influenza vaccine for the U.S. population to 61 million doses for this influenza season, compared with

approximately 83 million doses distributed in 2003-2004 and in 2002-2003, 77 million doses in 2001-2002 and 70 million doses in 2000-2001.

Because there was a concern that the need and demand could still outstrip supply, particularly if we face a severe influenza season, we sought additional doses of vaccine that could be safely used in an emergency. Thus, in addition to enhancing the supplies of vaccine approved for use in the U.S., we were able to rapidly identify suppliers of approximately five million doses of additional vaccine, licensed in other countries, that could potentially be made available under an FDA investigational new drug (IND) application. With remarkable cooperation from several companies and from other regulatory agencies (including the Paul Ehrlich Institute, Germany; Therapeutic Goods Administration, Australia; Swiss Medic and Health Canada) FDA immediately sent inspectors and scientists to the manufacturing facilities of potential IND sponsors to evaluate their manufacturing processes. Coupled with these efforts, we also reviewed a large volume of manufacturing and clinical data, all within in a few weeks. These efforts resulted in FDA approving INDs that permitted the potential use of approximately four million doses from GlaxoSmithKline (GSK) and one million doses from Berna Biotech, if needed. Of the five million doses potentially available under an IND, FDA understands that CDC has purchased approximately 1.5 million doses. HHS and FDA's coordinated interactions with these and other influenza vaccine manufacturers and regulatory agencies also provided valuable information and strengthened relationships that we hope will help stimulate interest by additional

influenza vaccine manufacturers and potentially lead to successful U.S. licensure. This is one constructive outcome of the challenges we faced this flu season. I am very proud of the efforts and accomplishments of more than 50 FDA employees, from multiple offices, as well as our HHS and CDC colleagues, working collaboratively for long hours to help meet this public health challenge.

Efforts to Enhance Antiviral and Pneumococcal Vaccine Supplies

Following the loss of the Chiron vaccine, FDA contacted manufacturers worldwide in an effort to identify additional supplies of antiviral medications that could be used, if needed, for treatment of millions of influenza cases and for prevention in high-risk individuals in epidemic settings.

Serious morbidity and mortality from influenza is often due to the complication of bacterial pneumonia. In particular, pneumococcal pneumonia is one of the most important and common serious complications of influenza in high-risk individuals. This complication is, itself, preventable through use of an inexpensive, yet underutilized, vaccine. The influenza vaccine shortage provided an impetus to increase use of vaccine against pneumonia. In cooperation with HHS, Merck & Company tripled its production of its pneumococcal polysaccharide vaccine from 6 million to more than 17 million doses, and the availability of this expanded supply will help physicians and public health officials reduce the risk of this complication. The beneficial effects of pneumococcal vaccine last for five to ten years, and CDC and other public health agencies strongly encouraged its use.

PLANS FOR 2005 AND FUTURE YEARS

At the same time that we have addressed this past year's shortage by facilitating the availability of additional vaccine, antivirals, and pneumococcal vaccine, we are doing everything we can to improve supply for future years. We are taking a dual-track strategy.

First, the most important single factor that will determine the adequacy of the U.S. influenza vaccine supply for the coming year will be whether Chiron can correct its manufacturing problems at the Liverpool facility and supply vaccine for the U.S. market. To succeed in this, Chiron is proceeding with extensive improvements that must satisfy both FDA and the U.K. regulatory authority. MHRA would also have to lift its license suspension and allow export of vaccine, which it can do whenever Chiron's compliance with MHRA regulatory requirements is satisfactory. Therefore, FDA continues to interact intensively with Chiron as the company institutes its remediation plan. FDA and MHRA have collaboratively reviewed this plan and provided extensive feedback to the company, and we are continually evaluating Chiron's progress.

FDA and MHRA have also improved their respective information sharing, which has led to an enhanced ability for both regulators to monitor Chiron. We have come a long way since October 5, 2004, when MHRA could not legally communicate with FDA about its pending enforcement actions. FDA and MHRA

now have an agreement with Chiron that allows full sharing of information between FDA and MHRA, as the company works to address the problems in Liverpool. MHRA and FDA are in frequent communication, conducting frequent conferences by video or telephone to collaboratively share and review information and to evaluate and discuss Chiron's remediation activities. FDA and MHRA are also working together and actively communicating on inspectional activities. For example, FDA accompanied MHRA on a preliminary inspection of Chiron's Liverpool facility in late December. FDA will participate in the next MHRA inspection and continue to coordinate with and accompany MHRA on future inspections. FDA will continue to provide MHRA and Chiron with feedback and information. In the spring, at an appropriate time when all critical stages of manufacturing are in full swing, FDA plans to conduct a comprehensive inspection of Chiron's Liverpool facility to verify that Chiron has adequately addressed its problems. Only after passing MHRA and FDA inspections will Chiron be able to provide vaccine for the U.S. market. As the safety and efficacy of influenza vaccine is FDA's overwhelming concern, Chiron's vaccine will have to meet all required standards, including sterility and other safety testing, prior to distribution to the public. While it is too early to predict the outcome of Chiron's ongoing remediation activities, or MHRA's and FDA's regulatory decisions, Chiron appears to be making progress.

While working hard to facilitate Chiron's efforts to correct manufacturing problems, FDA is also simultaneously working on a second track to facilitate

greater diversification of the U.S. influenza vaccine supply. It is important to recognize, however, that demand for vaccine and other economic factors are, and will remain, the primary factors that determine whether a manufacturer will seek and maintain licensure, the strength of the manufacturing infrastructure in the U.S., and the amount of vaccine that manufacturers produce for the U.S. market. One important strategy is to encourage flu vaccination throughout the flu season, including January and February. To increase the total doses available, manufacturers can produce vaccine that becomes available during these months. Because influenza cases usually continue or peak well after the November-December time period when most people seek immunization, continuing vaccination is beneficial to recipients and should be encouraged. Also, while not a substitute for the protection of the following year's flu vaccination, this strategy may help provide added protection.

MedImmune has indicated that it is performing studies that, if successful, may support future use of its vaccine in additional age groups. They have also stated they have the capability to potentially produce as much as 40 million doses by 2007. Sanofi pasteur has indicated that it has the capability to produce the same or more doses of Fluzone for the 2005-2006 influenza season as it did in 2004-2005 but has not finalized its plans. Greater influenza vaccine production capacity and an increase in vaccination rates are critical for improving our preparedness for a global pandemic. In the event of a pandemic, we would need

the capacity to rapidly produce a new vaccine and make it available to all who need it.

While greater production by currently licensed manufacturers will enable us to meet some of these needs, recent events highlight the potential benefits of having more U.S. licensed manufacturers. In recognition of this, FDA has been doing everything possible to stimulate interested foreign licensed manufacturers to provide or, where needed, develop the safety and effectiveness data required to pursue U.S. licensure. FDA has interacted constructively with several interested firms in this regard. Where appropriate, FDA has informed manufacturers that it is willing to consider approaches to licensing such as accelerated approval based on likely surrogate markers (e.g. the degree of antibody response to the vaccine), followed by post-licensure clinical effectiveness evaluation. GSK has stated that it would like to use this approval mechanism and, thanks in part to clinical studies supported by the National Institute of Allergy and Infectious Diseases (NIAID), the company may be ready to seek accelerated approval of a new licensed influenza vaccine for the U.S. market in time for the 2005-2006 season.

Finally, we are doing all we can to have Chiron's and GSK's vaccines available to meet next year's needs. If difficulties arise, they should become apparent by summer and the experience and relationships built this year through reviewing

and obtaining vaccines licensed by other regulatory authorities will be helpful if needed to obtain additional vaccine for use under an IND.

OTHER IMPORTANT ACTIVITIES

We have challenged ourselves to identify other lessons learned from this year's influenza season and to examine how we can use our recent experience to help prevent similar problems in the future. For example, we have identified the need to share more information with our international regulatory counterparts, and vice versa. We have now completed confidentiality commitments that allow information sharing with regulatory agencies in Australia, Canada, the European Commission, Japan, Mexico, Switzerland, Singapore, and South Africa. We are also in final negotiations on agreements with the U.K. and New Zealand. In addition, we are conducting an ongoing inventory of foreign manufacturing to identify any additional needs for information sharing, and we plan to seek agreements with other national regulatory authorities, where necessary. These commitments help assure that legal barriers do not inhibit critical communication between these agencies and FDA.

CBER has also initiated a vulnerability analysis of foreign manufacturing of U.S. licensed products that are critical to U.S. public health. This analysis will cover influenza and other vaccines and help identify areas where consideration of actions to support supply may be needed, such as stockpiling or seeking

additional licensed manufacturers. In addition, in the hope that more vaccines can be licensed and available to multiple regions of the world, FDA has been working with our foreign regulatory counterparts and with manufacturers to encourage internationally harmonized and more efficient product development, and the development of scientific and regulatory standards for safety, potency and effectiveness that will help achieve these goals. FDA serves as a designated Collaborating Center of the World Health Organization (WHO), and we work closely with our sister agencies at HHS and WHO on pandemic preparedness and responding to other emerging infectious diseases.

Under FDA's Critical Path initiative, we are working collaboratively with HHS agencies and the private sector to facilitate the rapid development, evaluation and availability of medical products; and related manufacturing, safety and effectiveness standards. A good example of the effectiveness of this type of a collaborative public-private approach to public health product development to meet the threat of emerging infections was the rapid development and implementation of West Nile Virus screening for the blood supply.

As in past years, FDA will work closely with CDC, WHO and others to develop materials for standardization and evaluation of influenza vaccine for the 2005-2006 flu season. FDA will continue to identify and evaluate influenza virus strains suitable for manufacturing purposes, and provide the high growth

reassortant viruses to manufacturers that they need to help to facilitate efficient production of vaccine and a timely and adequate supply.

Recent events highlight the importance of FDA's technical support for the U.S. and global vaccine manufacturing infrastructure and the need for manufacturers to invest in more efficient, reliable and modern methods for producing influenza vaccine. With adequate supply and widespread immunization, we will be more likely to meet the challenge of annual influenza epidemics and future pandemics.

To help manufacturers overcome challenges such as the problems Chiron is experiencing, FDA, under its current Good Manufacturing Practice for the 21st Century initiative, is working with industry to encourage the use of advanced technologies as well as quality systems and risk-based approaches that build quality into the manufacturing process. FDA is also using the same quality systems and risk-based approaches to modernize its manufacturing-related regulatory responsibilities.

Recent experiences, particularly those of the past six months, have taught us important lessons about manufacturing and inspectional activities with respect to influenza vaccine. Although FDA has always interacted extensively with influenza vaccine manufacturers throughout the vaccine production cycle, the annual changes in the flu vaccine and the increased dependence on a smaller number of manufacturers highlight the risks of unexpected manufacturing

difficulties. For these reasons, in 2005 and the future, we plan to conduct inspections of influenza vaccine manufacturers on an annual basis, with additional interactions with manufacturers and, in the case of foreign facilities, their regulatory agencies where appropriate, based on findings or events that raise concerns.

PANDEMIC PREPAREDNESS

HHS is working together to help transform the influenza marketplace and reinvigorate influenza vaccine infrastructure by investing in promising new technologies, securing additional licensed vaccines and medicines and preparing stronger response plans and capacity. Furthermore, the lessons we have learned and insights gained from recent experiences with influenza vaccine are critical in preparing for an influenza pandemic. This is something that FDA and others in the public health community are very concerned about, given the eventual likelihood of a pandemic and the recent outbreaks of avian influenza in Asia. More widespread vaccination during periods between pandemics not only has direct health benefits but also will increase vaccine production capacity and help America and the global community better prepare for an influenza pandemic.

In response to the threat of an influenza pandemic, the continuing importance of influenza as a threat to public health, and the potential to continue to reduce

illness and death from influenza and its complications, the Administration made an initial pandemic preparedness investment of $50 million in fiscal year (FY) 2004. Congress provided $99 million for this activity in FY 2005. The President's budget for FY 2006 proposes a $21 million increase for this program, to $120 million. The Administration is making the largest investment ever made by the Federal government to protect against influenza. We welcome the continued support of Congress for this work, and view influenza preparedness as a critical responsibility as well as an important opportunity.

In August 2004, the Department released its draft Pandemic Influenza Preparedness and Response Plan. This draft document contains the basis for a coordinated national strategy to prepare for and respond to a pandemic.

Consistent with the draft plan, HHS continues to make progress in preparing to respond effectively to the next influenza pandemic. As one component of this preparedness, the Department has announced two Requests for Proposals designed to encourage U.S.-based influenza vaccine manufacturers to have both the capacity and raw materials necessary to produce large quantities of vaccine using current egg-based methods, which are efficient and have a long and generally successful history. In November 2004, HHS awarded a contract to sanofi pasteur to help ensure year round availability of an increased egg supply in case it is needed for a pandemic or for future vaccine shortages. These contracts and other research supported by HHS through NIAID will also help us

move from dependence solely on egg-based production technology to the development of domestically-produced U.S. licensed cell-culture based and/or recombinant protein and DNA-based vaccines. While work remains to obtain sufficient vaccine yields and evaluate cell-based vaccines for their safety and effectiveness, moving from an egg-based production to a cell-culture production can potentially shorten the time needed to produce vaccine as well as decrease the risk of contamination inherent in egg-based production.

In an important new development, HHS is supporting development of vaccines against potential pandemic strains. Through this effort we hope to obtain experience in the formulation and use of such a vaccine and to prepare in the event that these strains become pandemic. As part of HHS' efforts to support pandemic preparedness, NIAID contracted for the production of pilot lots of potential pandemic vaccines from the two licensed U.S. manufacturers of inactivated influenza vaccine. HHS contracted for the production of two million doses of vaccine against H5N1 avian flu, the influenza type of current concern in Southeast Asia. NIAID is preparing to initiate clinical studies of the first H5N1 vaccine under INDs that FDA oversees, and both agencies will be working together to evaluate the results. While much work remains, these steps to produce and evaluate pandemic influenza vaccines are a critical component of our preparedness efforts.

In addition, studies supported by the National Institutes of Health and FDA will try to develop vaccine strategies that could lead to longer lived immunity and to vaccines that help protect against multiple strains of influenza. FDA is actively engaged with sponsors and manufacturers that are interested in developing such new technologies and has approved cell-based and recombinant vaccines for prevention of other infectious diseases such as chicken pox, mumps, measles and hepatitis.

FDA's goal is to establish a process to produce pandemic influenza vaccine in the shortest amount of time possible and protect the largest number of people, using a vaccine that is safe, effective and easy to deliver. The full details of the draft Pandemic Influenza Preparedness and Response Plan are located on the HHS website at: *http://www.dhhs.gov/nvpo/pandemicplan/annex5.pdf.* Through all these efforts, and with enhanced global surveillance by CDC and its partners, we have the unique opportunity to effectively intervene and potentially blunt a global pandemic, should one occur.

CONCLUSION

HHS has announced that it plans to spend $439 million Department-wide on influenza related activities in FY 2006. This amount is an increase of nearly $400

million over the FY 2001 level of $41 million, and represents the Administration's commitment to addressing this important public health concern.

Although we may never completely prevent influenza outbreaks, with an adequate vaccine supply supplemented by effective antivirals we can greatly decrease our vulnerability and provide protection against influenza. FDA recognizes the need to work with multiple partners, including manufacturers, to increase supply and to support progress toward more modern, dependable methods of production. All of the steps we have discussed will not only help protect Americans from flu every year but will help prepare us for future influenza seasons or in the event pandemic strikes. We welcome the opportunity to work with manufacturers and Congress to accomplish these important public health goals.

Once again, thank you for inviting me to testify on this very important issue. I am happy to respond to your questions.

Chairman TOM DAVIS. Let me start with you. "USA Today" had an article discussing how a couple years ago some batches of the flu vaccine might have lost their potency too soon. I know that you can't talk about specifics because it is against the law for you to do that, but could you explain generally about potency and what it would mean to an individual who had received a shot that was less potent?

Dr. GOODMAN. I would be happy to. Every year we actually assist the manufacturers by providing standards and the agents needed to assess potency. The major thing there is it helps the manufacturer of the vaccine. They have to decide how much of each component to mix into the vaccine, so we help get them to the appropriate amount.

But then, in addition, they are required to perform testing on the vaccine to show how its stability is maintained over time, that it doesn't lose large amounts of that potency so that a person might not have the protective response you would want them to have. We require them to monitor that and report those events to us.

We also require other testing. For instance, we test every new large lot ourselves for potency, but the stability testing is then what happens thereafter.

In this case there was a problem. The company noted diminishments in excursions from the specified stability limits. This is information that our inspectors found during that inspection they performed a complete analysis of, and they determined that this is a concern, particularly that they were not reported to us, but that, given the way this vaccine is rapidly utilized and the nature of the excursions and all the other information available to them, they did determine that they did not believe this was at that time a threat to the effectiveness of the vaccine. But that is still saying we were concerned and told them to correct that.

Chairman TOM DAVIS. Should there have been a recall of those flu shots?

Dr. GOODMAN. That possibility was certainly examined, but, again, because it was believed that these changes, while of concern and outside of their specification—I want to emphasize we were not happy with these, but the analysis was that these would not affect the efficacy of the vaccine at that point in such a way as to make a recall needed. I should also point out that would not affect safety of the vaccine.

Chairman TOM DAVIS. What does FDA do to ensure a manufacturer properly tests and reports its findings to FDA?

Dr. GOODMAN. Things that we think are critical are specified in the license, itself, of the manufacturer. In fact, there are a broad number of tests that manufacturers are required to do as part of their license and as part of the quality assurance, and these occur at multiple, multiple steps during manufacturing, and then also with the final product.

If problems develop they have certain procedures. For example, for certain procedures they have to reject that vaccine for the U.S. market if certain kinds of test results are obtained. For others they are supposed to notify us within a certain amount of time or perform an analysis of those results and decide whether in their judg-

ment the vaccine is acceptable. So all those are things that are required.

In addition, we do testing, as I mentioned, on the bulk lots and at other parts and final vaccine and other parts of the process as we deem needed. In this case, the manufacturer did not report these excursions in stability to us in a timely manner as required, and they were cited for that.

Chairman TOM DAVIS. OK. Thank you very much.

Dr. Gerberding, CDC has been telling the public that it isn't too late to get vaccinated, as the flu season can last through April. If we are stuck with a surplus every year, why doesn't the CDC consider extending the flu shot campaign through at least February or March to avoid throwing away vaccine? Would this help, or does it just vary with the flu season?

And another question: how many deaths have we had this year due to flu in the United States? Can anybody tell me?

Dr. GERBERDING. The truth is we are working very hard to try to continue to encourage vaccine. One of the things we have done is make the emergency supply of CDC's vaccine on loan to the manufacturer available to clinicians, and if they don't use it they can get a rebate, as an effort to get them to reach out and get the vaccine, especially for these high-risk people. So every year we put out information and communications around late-season vaccine, but it is human nature, apparently, not to be interested in that immunization, despite what we think is a pretty gold standard campaign.

We have to work on that. We have to do the formative research to find out why and change our communication strategy accordingly, and we need to also work with clinicians and the public health system to make this a visible priority.

In terms of the number of deaths overall from flu, it is too early for us to have that accurate information. Influenza per se is not a reportable disease. We do know that there have been at least four pediatric deaths from influenza this year, which is less than we saw last year but still unnecessary and tragic.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman, you have 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Before I get into the topic for today I just want to tell Dr. Gerberding my appreciation for the work that the CDC did in coming to terms with the obesity issue and reviewing the matter internally, convening further discussions, making pledges to changes so similar problems wouldn't occur in the future. I just want to commend you for the work your agency did on that.

Dr. GERBERDING. I am very grateful to hear that, and I will take that back to Atlanta, as well. Thank you.

Mr. WAXMAN. Thank you.

I want to ask you about immunization funding, because we have seen an increase of $1.5 billion over the last decade, largely due to the congressionally mandated vaccines for children program, but there is another immunization program that is called the 317 program. This is run by the States, and the States are supposed to make up for those who don't qualify for the vaccines for children

program to make sure they are eligible for vaccines, as well as some adults.

I think this is an important program, and I am sure you share that concern, as well.

Dr. GERBERDING. Absolutely.

Mr. WAXMAN. A number of States are telling us that they can't ensure that all kids get the vaccines they need, and we are going to hear today from the health commissioner of Virginia who has testified a number of times to this committee that his State cannot provide the life-saving prevnar vaccine. Is it true that by expanding the 317 program we could ensure that all children in the United States get all their shots?

Dr. GERBERDING. It is very difficult to do that on the basis of 317. What is proposed but not yet approved is that we expand the eligibility for the VFC so that we could immunize these under-insured kids in facilities that are run by State and local health delivery programs. Right now those kids have to go outside of the system and they can't afford to pay for the vaccine so they essentially don't get it. So the proposal is that we add to the VFC eligibility to achieve this kind of coverage. If that proposal doesn't pass or isn't approved, then we would certainly need to rely on 317 to continue that effort.

Mr. WAXMAN. I guess my concern is I think we are not funding adequately the 317 program, and that will provide a gap where some people who could be covered by it are going to fall through it. I just hope we can find more funding for that effort.

Dr. GERBERDING. Thank you.

Mr. WAXMAN. Before I go to Dr. Goodman, there is another very peculiar issue that you are dealing with with the stockpiling of childhood vaccines. There is some SEC issue that is preventing some of the companies—this may be too esoteric an issue, but I just hope that this issue is being approached with some urgency, because it looks like the money that was allocated for the stockpile is not going to be used because the companies are not going to be able to do this because the SEC is not allowing them.

I guess the only point I would make there is that we have to do something to straighten this out. It seems absurd to let it go on and start making assumptions that we are never going to get that stockpile for those vaccines, which will assure that we have the supply for.

Dr. GERBERDING. Thank you. That is a revenue recognition issue and it is complicated. We have to figure a way through that, and I know the companies are eager to do that, too. Thank you.

Mr. WAXMAN. Dr. Goodman, I have been critical of the FDA. At our last hearing this certainly came out, and I think the "USA Today" article also was pretty damning of the FDA's inaction in light of the FDA's own inspectors coming back in 2003 and saying they were learning about problems at that Chiron facility and recommending that some action, enforcement action, be taken.

Just to review the facts, the plant had a terrible record of compliance with FDA regulations, even a history of failing to report problems to the agency. This potency issue is one of the problems they evidently failed to report to the agency. The plant was making half our flu vaccine supply. And in June 2003, the inspectors found seri-

ous problems again and recommended enforcement action, yet FDA decided not to conduct a full inspection for another 2 years. We learned at the last hearing FDA refused to even request to meet with the company to provide guidance on how to improve, and then eventually the plant was shut down by the British.

I reviewed this because I think we need to learn from this, and I appreciated your testimony that the FDA is taking that constructive approach. I think there is a silver lining. If FDA is able to increase its enforcement and if the agency can empower its inspectors and scientists, then FDA can prevent situations like this from developing in the first place, but it is going to take a commitment from FDA leaders like you and whoever the new Commissioner will be. I want to underscore that point.

You don't disagree with me, do you?

Dr. GOODMAN. No. I don't think, unless you have specific questions, it would be constructive for me to go over the old ground. I know Dr. Crawford answered your questions about that before. But I would just reiterate we are—and I can speak for him and myself—totally committed to doing everything we can to get high-quality manufacturing and also to get the appropriate kind of inspectional enforcement activities. I am working closely with John Taylor, the head of Office of Regulatory Affairs. We have considered this issue very carefully of whether the annual inspections I talked about, which is a real change, may be helpful. We think if it may be, given the dwindling number of manufacturers and how vulnerable this all is, that even if it just may be and we can approach it in a very preventive manner it is a good thing to do.

Mr. WAXMAN. Let me just say I appreciate that approach and I think it is constructive and I think there are certainly good intentions on everybody's part, but I was very disappointed in Dr. Crawford's testimony. I don't think he took responsibility for FDA's pretty much hands-off approach, just trusting the company and not going out there to the British plant, itself. But I don't think we have time to go over all the past record. It may not be all that helpful. I just do want to register my concern.

Dr. GOODMAN. I appreciate that. One comment I would make, without wanting to re-engage the whole thing, is that in 2003 when the inspectors went in there they did find significant issues and concerns. A number of the ones that were of most concern were from 2001 and 2002, and when they were in there on the ground a number of those problems had been corrected. The initial recommendation of the inspectors was as you discussed, but the normal FDA—they did follow the normal FDA process. They came back, discussed those internally, looked at the company's response, looked at the company's record, met with the scientists in the center and the additional scientific specialists, and they did make that decision.

Mr. WAXMAN. But rejected the recommendation of the inspectors to do more.

Dr. GOODMAN. Again, I would just characterize it as actually the inspectors, themselves—this is my understanding, because I have asked about that. I think it is a legitimate question. Everybody looked at all the data, and my understanding is they unanimously agreed, including the inspectors, that there were a number of im-

portant observations, but this wasn't a situation where they had a safety concern at that time or—and I think it is important to say, and I have heard this from the people who were on the ground that the situation that we found in 2004 going in there was different by order of magnitude and from a situation where, with an extensive inspection such as in 2003, you would find significant observations, you would want to make improvements in quality. We would expect those changes. But in 2004 it was very quantitative and qualitative. The basic systems weren't working.

Mr. WAXMAN. My time is up. I just want to make one sentence here. From 1999 to 2001, FDA sent 36 warning letters to biologic manufacturers for manufacturing violations. From 2002 through 2004 FDA has sent six. This is a decline of over 80 percent. I think we need to do more, not less. That is why I believe we ran into the problem we did. You may disagree with me, but that is my view.

Dr. GOODMAN. Well, I appreciate your input.

Chairman TOM DAVIS. Thank you.

Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman.

First I will ask the question the chairman wanted to ask and didn't get a chance. First, will the CDC follow the lead of some of the States and drop the remaining restrictions on who should or can be vaccinated?

Dr. GERBERDING. The decisions about the high priority groups are made in collaboration with the Advisory Committee on Immunization Practices, and though we see coverage rates that are close to what we normally perceive, we still have millions of very high-risk people who haven't been vaccinated. So from a national perspective, we have been consistent from day one. The highest priority still has to be our seniors and the people who are at very high risk from death or severe complications.

But at a local level where some providers have it and others don't, it is the local health officer or the State health officer who has to make the decision in their jurisdiction what is the most common sense way to make the best use of the vaccine. We don't want to waste it. So we are really encouraging them to use what they have if they need it. If they can't get the high-risk people, then give it to whoever wants it.

Mr. GUTKNECHT. So that was kind of a no. It was a good answer, but I think the answer is no, you are not going to follow the lead of the States.

Second, doesn't that create confusion among the public about who should be vaccinated and who shouldn't?

Dr. GERBERDING. The dilemma is that there are areas where there still is a vaccine shortage. We have surveyed all the States, and there are specific jurisdictions where they need vaccine and they can't get it. So for us to say it is wide open for whoever wants it nationally really creates an additional burden on those places that are still desperately seeking vaccine.

So we have tried to equalize that by moving vaccine from one State to another or one jurisdiction to another, but it is not feasible to do that with the kind of precision that would allow us to give a single recommendation for the Nation. So our dilemma is how do we support making sensible use of the vaccine and still protect

those areas that have shortages and are even still talking about using the investigational vaccine if they can't get what they need through the manufacturer.

So we still have a shortage, and that I think is something that—I know the committee is talking about a surplus, and there are areas where we have excess vaccine, but fundamentally we don't have enough.

Mr. GUTKNECHT. Just for my own benefit, when you move vaccine around or when it was shipped here from Germany, how did they ship it?

Dr. GERBERDING. When we move it from jurisdiction to jurisdiction it is generally either Federal Expressed or moved through some kind of a courier that meets the FDA's requirements for chain of custody, if you will. And likewise, when we move it from the international sources to the United States, it goes through a similar process to assure that the cold temperature is maintained and that we document the appropriate transport and storage procedures.

Mr. GUTKNECHT. So importing these vaccines from Germany caused no concern for health?

Dr. GERBERDING. Well, I will let Jesse answer that question because it is really an FDA requirement.

Mr. GUTKNECHT. Actually, you don't have to answer that. That was a facetious question.

Dr. GOODMAN. Well, I think I should answer it because it is a good question, too. Vaccines and some of the other biologics are particularly sensitive to, for example, cold, other storage conditions, handling, so what we want to do—and this is true with licensed vaccine or the unlicensed vaccine under the IND because, of course, Chiron's vaccine would have been imported into the United States because it would have been finished in England.

What we do is we have very detailed—the manufacturer actually has to submit to us detailed protocols that they have validated that show that the temperature is maintained, that the storage conditions are suitable, for example, for shock, that the temperature is monitored. Just like those stability testing that Congressman Waxman asked me about, if there are significant deviations they need to report those, and in certain cases they cannot use that vaccine.

Mr. GUTKNECHT. I just wanted to get on the record that it is possible to move drugs and/or vaccines across State and national borders safely as long as you follow the right protocols.

Dr. GOODMAN. And it is well controlled.

Mr. GUTKNECHT. And you can do it with FedEx. That is on another subject for another day, which we will pursue perhaps in this committee and others.

The other issue I want to get to—and I am sorry my time is almost exhausted here, but I am very concerned about viruses that are migrating from one species, particularly from poultry to pigs, for example, and then to human beings. I want to know how much research you are doing.

I have a very parochial interest in this. There is a small lab in my District that is doing some amazing things on vaccines for pigs. Literally you can send them a sample overnight FedEx and the next morning they will analyze what particular virus that is and

they will send the next day out the right vaccine for that for your herd of animals. In many respects, they have technology at this little lab that is all world.

My interest in this is trying to bring some other researchers in because I am concerned. I mean, I don't like to use the term "pandemic" and I am not a scientist, I am not a doctor, I don't play one here in the Congress, but I am concerned that we are not doing enough in the event that there were some new strain of virus that did begin to jump from animals to human beings.

I am curious in terms of what the CDC is doing on that and what we can do to advance that particular kind of research.

Dr. GERBERDING. Thank you for your question. I would actually look forward to learning more about the facility in your District so we can followup with you on that.

The problem you are describing is one that we refer to as "zoonotic infections." Actually 12 out of the last 13 new infections in people have arisen from animals, so it is an extremely high priority for CDC. In fact, we just recruited the dean of the school of veterinary medicine from the University of Michigan to CDC to help us, in part, with our strategies and our innovations in this area because we think it is so important.

Mr. GUTKNECHT. I would love to have you come out and visit these guys, because it was one of the most amazing things that I have seen. As I say, the research stuff, the equipment that they have is amazing, and that they can do this that quickly.

I yield back the balance of whatever time I might have.

Chairman TOM DAVIS. Thank you, Mr. Gutknecht.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

I just want to followup on something that Mr. Gutknecht was talking about. As you all were answering his questions, particularly you, Dr. Goodman, about the transfer of medicine drugs from one country to another, I want to make sure I heard you correctly, because it seems like there are different things coming out of the FDA. You said that could be done safely?

Dr. GOODMAN. The question that I was answering——

Mr. CUMMINGS. Then answer my question.

Dr. GOODMAN. I will. OK. Your question is: can, in this case, all drugs? Or is your question about influenza vaccine?

Mr. CUMMINGS. Let's just deal with vaccines right now.

Dr. GOODMAN. OK.

Mr. CUMMINGS. Because they seem to be very sensitive.

Dr. GOODMAN. Yes, I understand.

Mr. CUMMINGS. They have shelf life. They have all kinds of issues.

Dr. GOODMAN. Yes. With all that in mind, with extremely careful controls over transportation conditions, including monitoring, etc., and in this case there had to be extensive FDA and company involvement. In other words, this is normal procedures for these companies and all the resources that would be involved in that. Two critically important things could be dealt with and protected. Those are: is that the product you think it is? And has it been under total custody and control? It is almost like criminal evidence. You don't want the consumers, the people in the District and in Maryland to

get a vaccine and have that not be flu vaccine. And then is that vaccine still going to be safe and effective because of how it was handled, etc.? If it is properly made, and then with exquisite, appropriate monitored controls, and then FDA oversight of that and all the resources that are entailed in that, I think that particular transportation issue can be met.

I want to mention one thing here.

Mr. CUMMINGS. Let me just say why I asked the question. I have seniors who are sitting there right now looking at C-Span and they are hearing all this, and I have to go back to my District and explain this, that they can't get their prescription drugs because FDA says they can't be done safely. But let me move on, because I only have a minute.

Dr. GOODMAN. OK.

Mr. CUMMINGS. I, too, was disappointed with Dr. Crawford's testimony, extremely disappointed. I want to know. Let's say we go through all the things we are supposed to go through in making sure Chiron is doing what it is supposed to do, and let's say we find out that we do have a major problem, what exactly are our contingency plans?

Dr. GOODMAN. That is an excellent question.

Mr. CUMMINGS. Thank you.

Dr. GOODMAN. We are working with CDC and HHS—and I do want to mention that coordinating and planning function is in the Secretary's office at HHS, but let me tell you what we are doing in answer to that. You are absolutely right. While we are doing all we can to get Chiron on board to produce, and if they do and they do it in a timely manner that would be a good situation and it might be able to restore supply to a reasonable level.

There is a lot of uncertainty in there. Ultimately it is up to Chiron to succeed, and it is a really complex, demanding process. They are making huge changes. Also, our British counterparts have to do their job and decide that it is OK, too, and then we do. So there is a lot of unpredictability so we need to do what we can to prepare.

Some of the things we are doing that I mentioned; we are extensively interacting with several foreign manufacturers who have been working with us and who have indicated their interest in seeking U.S. licensure. We are hopeful that at least in one case that may be possible in time for the coming year. It is not guaranteed because again it has to meet the standards of safety and effectiveness that your constituents and I as a physician would expect.

The other thing, as I mentioned—and I think it was valuable—we did go out and get additional vaccine under all these controls and I would say spent thousands of hours reviewing the manufacturing, the clinical records, the adverse event records in these facilities of vaccines licensed by what we would consider competent regulatory authorities in other countries, and we did decide, as you know, that in at least two cases our sponsors who were interested in providing vaccine in an emergency, that it could meet standards to be used under what we call an IND, where people would know they are not getting licensed vaccine. They would have to consent, but it could be available, and we believe it would be safe.

So we have that system in place now, and if we have signals that Chiron or the other manufacturers we are hoping to get onboard, if that isn't working out we would plan to engage that.

Finally, I have to say that both the other licensed manufactures, Aventis, now known as sanofi pasteur, and MedImmune have been incredibly cooperative and had indicated their willingness, if needed, to do what they can to increase production.

There is still uncertainty. I am very concerned about the risk. There are bad scenarios like those that played out this year. But what I am here to say is we are all doing everything we can to be prepared and, in the long term, to diversify this vaccine supply, strengthen it, and prevent those problems.

Mr. CUMMINGS. Thank you.

Chairman TOM DAVIS. Mr. Shays.

Mr. SHAYS. Thank you.

I have three organizations that are on the top of my list of groups that I admire. One is the World Health Organization, the other is the FDA, and the other is the CDC. I think you have extraordinarily difficult jobs and I think you do it quite well. And I also believe we are never going to get supply and demand to be equal. We are not a communist society. We can't make people do things that they don't want to do. And so in the realm of things I would rather have surplus rather than a shortage, but I don't want this surplus to be created because we encourage people not to take a vaccine they should take.

The first question I just want to ask you is about the avian flu. When I was at the World Health Organization this past month, they talked about this flu basically being in 20 countries. I want to know what kind of representation—and they said it could become a pandemic if we are not careful. I just want to know the views that each of you have.

Dr. GERBERDING. We are very concerned about the avian virus in West Asia right now. We know at this moment it is present in at least nine countries, and there is a new cluster of transmission from chickens to people, although we still have not seen efficient transmission from one person to another. The virus has not evolved significantly over the past year, but it could do that at any time, and when that happens there is an increasing probability that it could adapt and become something capable of causing a pandemic.

Mr. SHAYS. They basically said it was more likely than less likely to happen; that the trend lines are in the wrong direction.

Dr. GERBERDING. The situation there is you have an amazing juxtaposition of pigs, people, and poultry, and those are the three ingredients for creating new strains of flu virus that can be very effectively transmitted. We have so much virus there in this incubator of new strains that there is a very strong statistical probability that we will see emergence. We can't say for sure, but we are certainly doing everything we can to be on top of it.

Mr. SHAYS. In Thailand I am told there is one farm that has 5 million chickens, and I am told that a country like Ireland no longer produces chickens because it is just so cheap to get it from a place like Thailand. So it is something I just want to register my concern to both of you.

Dr. Goodman, did you want to comment on that?

Dr. GOODMAN. I did. When the pandemic subject came up before I wanted to mention one thing that I think we are all involved in doing that is very positive. I mean, first of all this is an absolutely huge threat and we are taking it very seriously, and CDC and us and our colleagues at NIH are at frequent communication, including the WHO, etc. We are tracking this, but we are also trying to say what more can we do to be better prepared.

I mentioned more vaccine production capacity. I also wanted to mention one accomplishment of HHS that I truly think is a bell weather and remarkable, and that is that we have begun production of vaccines and testing of vaccines that may never be used. The HHS let contracts to two different companies to produce pilot lots of vaccine that might be able to help protect against that avian flu were it to become pandemic.

Mr. SHAYS. Just a quick answer on this. The flu shot that people take here, would that protect them against it?

Dr. GOODMAN. No.

Dr. GERBERDING. No.

Dr. GOODMAN. That is the whole problem is that this is a new coat on the outside of the virus that our generation of people have never been exposed to, so when you are exposed, you don't have the existing antibody, nor is it in our current vaccines.

Mr. SHAYS. Let me quickly get an answer to this. How far behind are we in planning for the next flu season? I have been made aware that major vaccine distributors have refrained from taking pre-orders because they are unable to calculate next season's market.

Dr. GERBERDING. At the moment discussions are underway about what strains should be in the new vaccines, and that is an important step toward predicting the timing of the manufacturing.

Mr. SHAYS. Is that guesswork or is that——

Dr. GERBERDING. It is based on what strains are emerging at the end of this season here, as well as what strains are in the southern hemisphere as we speak. So the first step is the experts meet in Geneva at WHO to look at all the data, and then they meet with FDA here, I think in about 2 weeks——

Dr. GOODMAN. Yes.

Dr. GERBERDING [continuing]. To put their heads together and pick the combination of the three strains that would go into the vaccine.

If I can just add one very quick thing, that is that Secretary Levitt has just been on the job for a few days as secretary of HHS, and already I have had two opportunities to brief him about avian flu and influenza preparedness with my colleagues, so I can tell you that this is a very high priority for the Department and we are all focused on it.

Mr. SHAYS. Thank you for all of your good work.

Dr. GERBERDING. Thank you.

Dr. GOODMAN. Thank you.

Chairman TOM DAVIS. Ms. Norton.

Ms. NORTON. Thank you very much, Mr. Chairman.

It is clear from both of your testimony that you are doing the things that one would expect one to do to try to make up for prob-

lems beyond your control, things that can be planned for, and I appreciate that you are doing that.

I am interested far more in the meaning of this crisis for the future of the flu vaccine and for other similar crises that could come up. Dr. Gerberding, I remember that when this crisis arose CDC did not even have access to the purchaser list, even though the purchaser list of the company that had produced vaccine, and thus initially CDC was unable to account for who had vaccine and who did not have vaccine in the first place. Apparently after some time Aventis did share its list with you. Are Aventis and other such companies required to give you their lists now as a matter of course?

Dr. GERBERDING. I would ask Dr. Goodman to answer that from the FDA perspective since they regulate that. But we are hoping that, even if the law does not mandate it, that we would be able to engage their cooperation in the future. We had a very successful cooperation. They provided us with very important market information of a highly competitive nature. We kept it confidential, utilized it for public health purposes, and I think established some real trust between the public health system and the manufacturer.

I will let Dr. Goodman talk about the regulatory perspectives.

Dr. GOODMAN. Yes. We don't actually control who they distribute or to whom, and as Dr. Gerberding said, that is an important part of their marketing strategy and it is protected information. So I think you identify an issue that in a public health crisis as occurs can be a challenge.

Dr. Gerberding could comment more because she was involved in those difficult distribution issues, but when faced with this problem my impression is that they have been forthcoming and shared information. But I think this is an issue. You have a system where the private distribution system is efficient under normal circumstances, and then when it is stressed by extraordinary circumstances it is a challenge to figure out how you deal with that.

Dr. GERBERDING. I would add that I can imagine in our scenario planning situations where we would very much like to have additional proprietary information about other products, so it is a gap in our capability of managing a public health emergency.

Ms. NORTON. Even through your regulatory authority, even saying in the event of a finding by the FDA or the CDC or whoever is the appropriate authority, the list had to be turned over, then surrounding those lists with the appropriate protections in advance seems to me would be helpful.

Again, my concern is with worst case scenarios. The fact is that Aventis did not immediately say, "Here is my list." They did eventually give it, but the fact is that should have been forthcoming instantly. And you were left there, Dr. Gerberding, without any basis to proceed because you didn't even know where the vaccine was. This vaccine is going to continue to be in the private sector. This is the United States of America. It is the kind of gap I would have expected by now you would have begun to move on.

I would like to ask you, since I think that one is obvious, what exercises have you gone through in the nature of worst case scenarios? I have read both of your testimony. They do indicate that you are doing the proper planning. My concern is with unantici-

pated health emergencies and with restoring the confidence of this committee and of the public that, given anthrax, now given flu, if there is an unanticipated emergency these are the kinds of things we do.

I hate to use this analogy, but that is how the military, for example, prepares for the unforeseen. That is how the, God help them, Secret Service and security officials prepare for the unforeseen. Well, some of us regard health emergencies as more likely and at least as important, so I would like to know if you have a regimen of what to do——

Mr. DUNCAN [presiding]. Let me just say, Ms. Norton, we have a vote, so make this answer very, very short if you can please.

Dr. GERBERDING. The answer is we are constantly exercising scenarios. Just this week we had an anthrax scenario. This is a part of our preparedness planning for terrorism as well as for avian influenza and other health events. So on an ongoing basis around the tabletop and around the country we are engaged in scenario-based exercises. That is one of the backbones of preparedness.

Mr. DUNCAN. I would like to ask just a couple of quick questions. I am assuming that the United States has a much higher vaccination rate than most other countries, and particularly the countries in southeast Asia, and I am wondering what that comparison is, if you know. And second, how much higher is the rate of flu in some of those countries where they have almost no or very low vaccination rate.

Dr. GERBERDING. We have three things: we have the best ability to measure vaccination, we have the most vaccine, and we have the highest vaccination rates. Totally in the world we produce each year about 300 million doses of vaccine, and we had 61 million of those doses in the United States this year, so you can see we really do have very high rates compared to the developing world.

Mr. DUNCAN. Is the rate of influenza much, much higher in those countries?

Dr. GERBERDING. It is difficult to say because the surveillance systems aren't there with the kind of high-tech capabilities we have here, but flu is a ubiquitous problem in all societies, and it certainly is a problem in Asia.

Mr. DUNCAN. As far as we know, the flu shots that people have gotten this year, are they for the strains of flu that are out there?

Dr. GERBERDING. It is a good match this year.

Mr. DUNCAN. A good match.

Dr. GERBERDING. The Fujian strain has been the dominant strain, and that is the strain that the vaccine is targeted to.

Mr. DUNCAN. And you said earlier you will put three strains in the vaccine for next year, but I remember from another hearing—how many strains are there? There is a large——

Dr. GERBERDING. There is an infinite number of flu strains. It is constantly evolving. But each year we pick two A influenza strains and a B strain based on our scientific evidence that suggests what the most likely circulating strains will be.

Mr. DUNCAN. All right. We are going to have to be in a very brief recess. Chairman Davis will be back in just a very few minutes. We will be in recess.

[Recess.]

Chairman TOM DAVIS [presiding]. Our meeting will come to order.

Dr. Gerberding and Dr. Goodman, let me just say thanks for staying here, but I think I am going to do everybody a favor at this point and allow you to go and move to the next panel. You have been very, very helpful.

If there is anything you would like to add before you go that maybe you didn't get to say or answer?

Dr. GERBERDING. Just thank you. Thank you for your interest.

Chairman TOM DAVIS. Thank you very much. Thanks for the job you are doing.

Dr. GOODMAN. I would second that thank you. This is an important subject. We are very committed to working with you.

Chairman TOM DAVIS. All right. We will get you a better microphone next time. Thank you.

We are going to move to our second panel now. I want to thank these witnesses for appearing. We have invited our second panel. We have Dr. Fay Boozman. We also have Dr. Robert Stroube, the Virginia State Health Commissioner. He is here to discuss Virginia's response to the shortage turned surplus over the past few months. Dr. Walter Orenstein is associate director of the Emory Vaccine Center, who will discuss recommendations. And last but not least, Dr. Alan Wasserman, chairman of the Department of Medicine at George Washington University Medical Center, who is here to provide an academic perspective into issues surrounding the annual influenza vaccine. He will also share with us his experience last month when GW sponsored a free flu clinic at the Foggy Bottom Metro Station and they couldn't give away all their shots.

Before we swear in, Mr. Boozman, would you like to make an introduction, the gentleman from Arkansas, our colleague from the Third District.

Mr. BOOZMAN. Thank you, Mr. Chairman. It is a pleasure to have my brother here with us, Dr. Fay Boozman.

Chairman TOM DAVIS. Obviously, your younger brother, right?

Mr. BOOZMAN. Obviously.

Chairman TOM DAVIS. And former State Senator.

Mr. BOOZMAN. I thought that you would say, "Isn't this your Dad?" But my brother and I, I am an optometrist and my brother is an ophthalmologist, and we practiced together for many, many years. We were in an area that is one of the fastest-growing areas in the country, so whatever you did, you were successful at, and we were blessed in that way.

His background is such he was a pediatrician before he became an ophthalmologist. After practicing for many, many years he got interested in public service and became the Health Department director for the State of Arkansas for Governor Huckabee. True to form, he went back and got his master's in public health from Tulane. I guess he is probably one of the longest-serving continuous public health directors in the country right now. Evidently they don't last very long.

It really is a pleasure to have him here, both panels talking about such an important topic.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. That is the best you can do for your brother?

We are happy to have all of you here. Dr. Stroube has survived a long time in Virginia, and before that in Fairfax County, my home county, where he grew up and had our public health. We are happy to have all of you here.

Dr. Wasserman, thank you for being here from G.W. I want to thank the medical faculty associates for being able to offer the flu shots this afternoon. I hope you can give them away here, Dr. Wasserman. Thank you.

It is the policy of this committee that we swear everyone in, so please rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Dr. Boozman, I will start with you and we will work our way down. We have lights there. The orange light means 4 minutes are up, red light means 5. Your entire written statement is in the record and questions will be based on that.

Were you in the House or the Senate in Arkansas?

Dr. BOOZMAN. Senate.

Chairman TOM DAVIS. So you know how to talk. If we can keep it to 5 minutes here, we usually have a tough time, but do your best. Say what you need to say and then we will get on to questions. Thank you very much for being here today. Your brother is doing a good job, by the way.

STATEMENTS OF DR. FAY W. BOOZMAN, PRESIDENT-ELECT, ASSOCIATION FOR STATE AND TERRITORIAL HEALTH OFFICIALS; DR. ROBERT B. STROUBE, COMMISSIONER, VIRGINIA DEPARTMENT OF HEALTH; DR. WALTER A. ORENSTEIN, ASSOCIATE DIRECTOR, EMORY VACCINE CENTER; AND DR. ALAN WASSERMAN, CHAIRMAN, DEPARTMENT OF MEDICINE, GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER

STATEMENT OF DR. FAY W. BOOZMAN

Dr. BOOZMAN. Thank you, Mr. Chairman and distinguished members of the House Government Reform Committee. I am Fay Boozman, director of the Arkansas Department of Health, and I am honored to be testifying before you today on behalf of the Association of State and Territorial Health Officials.

I want to thank the chair and the Members for convening this hearing on this very important public health topic.

Let me begin by noting that from the start there has been tremendous cooperation among Federal, State, and local public health agencies. The experience this year is a classic example of how our Nation's governmental public health system can and should work.

In October 2004 Arkansas and every other State and territory faced an unanticipated public health challenge when we learned that we would receive only half of our flu vaccine orders. Over the next few days we worked with our partners to formulate a plan to deal with this shortage. We used the health alert network to contact health providers throughout the States, telling them about the situation, asking them to provide us with information about how much vaccine they had ordered, how much they had on hand, and how much they needed for their high-risk patients.

The Arkansas Department of Health typically purchases about 40 percent of flu vaccine supply in Arkansas, which meant that from the start we controlled a substantial portion of the vaccine that had been delivered to the State. I need to point out that in many cases most flu vaccine is purchased by the private sector, so some of my colleagues initially had much less control over the vaccine supply in their States and the distribution of that than I did.

In Arkansas we decided to exercise our mass vaccination plan which we developed with the CDC bioterrorism preparedness funds to distribute our supply of vaccine. November 3rd was the day that we chose to do that. We enlisted the help of media outlets and health care professionals to get the word out. Thousands of people called our newly created 1–800 hotline or logged onto our Web site to get information about where to go for the shots. Thankfully, the plan worked. On November 3rd in a matter of hours we administered over 53,000 doses of vaccine to high-risk individuals in 83 clinics.

Despite everyone's best efforts, we may experience future vaccine shortages. A national plan should be developed that would provide guidelines for Federal, State, and local health departments to follow when Federal Government determines that a shortage exists. For example, when Health and Human Services determines that a shortage exists, it should immediately create a secure data system that provides each State department with reliable and up-to-date information about vaccine orders and supplies in the States. The sooner public health officials have that information, the sooner they can work with their local health departments and health care providers to get information out to combat the public panic.

ASTHO agrees that we should provide incentives to manufacturers to stay in or enter the U.S. market. Under a vaccine for adult program similar to vaccines for children program now in place, the Federal Government would purchase flu vaccine and supply to States for use by uninsured, high-risk adults for whom flu vaccine is recommended. That would help needy Americans get vaccine while creating a market entry incentive by growing and stabilizing the flu vaccine market.

Last but not least, we need to increase the CDC's 317 national immunization program funding so that State and local departments can build adult immunization infrastructure, as recommended by the Institute of Medicine in its Calling the Shots Report.

CDC immunization funding should be sufficient to allow States and local health departments to purchase flu and other recommended vaccines for all under-insured children, adolescents, and adults.

I wish to thank this committee for its continuing interest in this important issue. The public health community is committed to ensuring that all individuals in need of vaccine receive it. We look forward to working with you to ensure that we have the resources and tools to do our job of protecting the public's health.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Boozman follows:]

Statement of

FAY BOOZMAN, MD, MPH

DIRECTOR
ARKANSAS DEPARTMENT OF HEALTH

Before the

COMMITTEE ON GOVERNMENT REFORM

of the

UNITED STATES HOUSE OF REPRESENTATIVES

Hearing on

U.S. INFLUENZA VACCINE SUPPLY

February 10, 2005

Mr. Chairman and distinguished members of the House Government Reform Committee, I am Dr. Fay Boozman, Director of the Arkansas Department of Health, and I am honored to be testifying before you today on behalf of the Association of State and Territorial Health Officials (ASTHO). I would like to thank the Chair and the Committee members for convening this hearing on an important public health topic – this year's flu season, and the issues surrounding influenza vaccine supply and distribution.

My remarks will focus on 1) how our state and others have handled the flu season 2) what states presently are doing to encourage influenza vaccination and 3) what future actions should be taken to prevent the situation we faced this year from happening again.

Let me begin by noting that from the start there has been tremendous cooperation among federal, state and local public health agencies. The experience this year is a classic example of how our nation's governmental public health system can and should work. We have collaborated with our partners at each level of government to meet the challenges that have arisen every day during this flu season.

In October of 2004, Arkansas and every other state and territory faced an unanticipated public health challenge when we learned that for the moment -- and possibly for the season – our nation's public and private providers would have only half of the influenza vaccine we had expected available to us. Over the next few days, we worked with our partners to formulate a plan to deal with the shortage. We used the Health Alert Network (HAN) to contact health providers throughout the state, telling them about the situation and asking them to provide us with information about how much vaccine they had

ordered, how much they had, and how much they needed for high-risk individuals. The state typically purchases about 40% of the influenza vaccine supply in Arkansas, which meant that from the start we controlled a substantial portion of the vaccine that *had* been delivered to the state. I should point out that in many states most influenza vaccine is purchased by the private sector, so some of my colleagues initially had much less control over vaccine supply and distribution in their states than did I.

All of the states promptly sought ways to assess their vaccine supplies. Some states used the Health Alert Network to gather information, others used telephone surveys, and others used web based surveys. Many state health officials have indicated that assessing supply by asking private providers - physicians, nursing homes, HMOs, etc. -- to report information voluntarily posed challenges. There were questions about the possible validity of the information received – were providers going to be willing to state that they had a significant amount of vaccine given the shortage? What could we do about providers who did not respond to the request for information?

State law in Arkansas requires that we provide influenza vaccine to nursing home residents and employees. That accounted for 45,000 doses of an initial supply totaling about 107,000 doses. The question was how best to distribute the rest of our initial supply.

Arkansas recently developed a mass vaccination and/or medicine dispensing plan as part of our ongoing terrorism preparedness efforts. Thanks to the CDC state terrorism

preparedness grants, we now have a Health Alert Network that allows us to communicate rapidly with the public health and health care communities and a plan to vaccinate (or dispense medicine to) large portions of our population quickly. We decided to exercise our mass vaccination plan by giving influenza vaccine to thousands of Arkansans on November 3rd.

Preparation for November 3rd was extensive. We enlisted the help of media outlets and health care professionals to get the word out about vaccination day. Thousands of people called a newly created 1-800 hotline or logged on to our influenza website to get information about where to go for a shot. Our local health departments focused resources on making sure that things went as smoothly as they could. That meant communicating with police about traffic control, talking to the National Guard about using their Armories as vaccination sites, identifying volunteers who could help with crowd control, and setting up chairs so the elderly and infirm could sit while waiting for their shots. Some local health clinics were forced to suspend services other than providing flu shots for the day. I am proud to say that it worked -- on November 3rd, we administered over 53,000 doses of influenza vaccine to high risk individuals in 83 clinics statewide.

It is now early February and we have approximately 15,000 doses of vaccine available, primarily Vaccines For Children purchased vaccine donated to the State in the last two weeks. The Arkansas Department of Health is continuing to remind our citizens that flu

season can last through or beyond the end of March and it is still not too late to receive a shot.

Flu supply and utilization situations across the Nation vary tremendously. Some state health officials indicate that they still have substantial quantities of vaccine, despite best efforts to encourage vaccination. In other states remaining supplies are small. Once the flu season is over, we will have to assess the factors that contributed to differences in utilization and end of season supplies.

I would like to conclude by suggesting three actions, supported by ASTHO, that the federal government should consider to avoid a repeat of the challenges that face us this year: 1) a national plan to deal with vaccine shortages 2) a Vaccines For Adults Program and 3) expanded funding of CDC's 317 National Immunization Program to allow states and localities to enhance adult immunization programs and provide sufficient funding to ensure that all our underserved citizens - children and adults - receive the vaccines they need.

Despite everyone's best efforts, we may experience future vaccine shortages. A national plan – developed with the input of all relevant parties - would provide guidelines for federal, state and local health departments to follow when the federal government determines that a shortage exists. For example, when the Department of Health and Human Services (DHHS) determines that a shortage exists it should immediately create a secure data system that provides each state health department with reliable and up-to-date

information about vaccine orders and supplies in the state. The sooner public health officials have that information, the sooner they can work with their local health departments and health care providers to get information out to combat public panic. Among other things, a vaccine shortage plan would provide information about how to safely transport vaccine from one provider to another, and how one provider could resell vaccine to another provider (a complex and highly uncertain process at the moment). Having answers and protocols *before* a vaccine shortage arises would be enormously helpful.

ASTHO agrees that we should provide incentives to manufacturers to stay in or enter the US market. Under a Vaccines For Adult program (similar to the Vaccines For Children program now in place) the federal government would purchase influenza vaccine and supply it to states for use by uninsured high-risk adults for whom influenza vaccine is recommended. That would help needy Americans get vaccine even as it created a market entry incentive by growing and stabilizing the influenza vaccine market. And because influenza is a communicable disease, increasing the vaccination rates would benefit not only those who receive such vaccine, but the nation as a whole.

Last, but not least, we must significantly increase CDC's National Immunization Program 317 funding so that state and local health departments can build adult immunization infrastructure, as recommended by the Institute of Medicine in its Calling the Shots report. Every health department needs the capacity to mount education campaigns about the importance of adult immunization, to work with health care

providers to ensure that they are immunizing their patients, to track and monitor vaccine supply and use, and to deal with shortage situations. CDC immunization funding should be sufficient to allow states and local health departments to purchase flu and other recommended vaccines for all underinsured children, adolescents, and adults. If the United States is to meet its goal of vaccinating 90% of children and adults, we must provide resources to states and localities to ensure that those in need of immunizations receive them.

I wish to thank this Committee for its continuing interest in this important issue. The public health community is committed to ensuring that all individuals in need of vaccine – influenza and all other life protecting vaccines - receive it. We look forward to working with you to ensure that we have the resources and tools to do our job of protecting the public's health.

I would be pleased to answer any questions you may have.

Chairman TOM DAVIS. Dr. Stroube, thank you for being back with us.

STATEMENT OF DR. ROBERT B. STROUBE

Dr. STROUBE. Thank you.

Mr. Chairman, distinguished members of the committee, my name is Dr. Robert Stroube. I am the State Health Commissioner for Virginia. I am honored to be testifying before you today. I would like to thank the chair and the committee members for convening this hearing and for the amount of time you have devoted to this critical issue.

Since news broke that British regulators suspended the license of flu vaccine manufacturer Chiron last October, State and local public health officials have been working to ensure the best use of available vaccine. Initially that meant prioritizing vaccine availability to individuals at greatest risk for developing serious complications from the flu. More recently it has included responsible relaxation of vaccine recommendations to include individuals outside the original high-risk groups to ensure the use of the remaining doses.

VDH had ordered 90 percent of its total flu vaccine from Chiron, approximately 110,000 doses. However, the Health Department provides a very small proportion of flu vaccine that is typically provided to the public. During our typical year, we provide about 70,000 doses of vaccine. Most of the vaccine is through the private sector.

In response to the vaccine shortage, we immediately implemented the ACIP's recommendations regarding the prioritization of flu vaccine. In addition, every effort was made to educate the medical community about the recommendations and urge compliance. A message was sent out to health care providers through our health alert network. We issued press releases, including information about the vaccine shortage, and encouraged prioritization of available flu vaccine.

State and local health departments received hundreds of phone calls from concerned citizens and numerous media interviews were conducted. We diligently worked to provide the best information available. From the beginning of the flu vaccine shortage, CDC has worked closely with Aventis to allocate and distribute all the remaining doses of vaccine.

In the weeks and months following, VDH received four shipments of redistributed vaccine, with each targeting a high-risk population. In November we received 80,000 doses of flu vaccine. The decision was then made to distribute the vaccine to each health district based on its population. Local health districts in Virginia developed flu vaccine distribution plans tailored to meet the needs of their high-risk populations in their area.

As the first doses of flu vaccine from the CDC allocations began to arrive in late October and early November, the health districts began to implement their plans. Individuals not included in the priority groups were asked to defer vaccination in order to preserve the limited amount of vaccine. We received approximately 77,000 doses in mid-November, and this was primarily given to long-term

care facilities across the State. This enabled nursing homes and assisted living facilities to vaccinate their vulnerable residents.

In mid-November we began to request vaccine through CDC's Web-based secure data network. This network allowed State public health officials the ability to order flu vaccine on behalf of private health care providers directly from CDC. As a result, we were able to distribute approximately 98,000 doses to Virginia's doctors and pharmacists.

By the end of November, CDC and Aventis had distributed about 255,000 doses in Virginia. We sought to reach as many high-risk populations as possible, providing flu vaccine to health departments, long-term care facilities, and private doctors. By late December it appeared that the majority of high-risk persons in most parts of Virginia who wished to be vaccinated had obtained vaccine.

A late December inventory revealed an ample supply of flu vaccine in many parts of the State. To help ensure that available flu vaccine did not go to waste, I authorized the expansion of vaccine recommendations to include individuals age 50 to 64 and household contacts of those in high-risk categories. This took effect on January 10th. The expansion was in agreement with the revised ACFB recommendations. Even with expansion, there was little interest by private providers in placing an order for Virginia's fourth allocation of vaccine of approximately 55,000 doses. By the time the CDC orders were due to CDC on January 13, only 30,000 doses had been requested.

In late January, CDC began to support the expansion of vaccine eligibility for States and localities with ample supplies; on January 26, authorized district health directors to lift their flu restrictions in the localities if they thought the demand for vaccine within priority groups had been met.

On January 27, CDC made VFC vaccine available to health departments for non-VFC children and adults in localities where demand for flu vaccine among eligible children had been met. Local health departments were then authorized to redistribute this vaccine to other public facilities, free clinics, community health centers, and private nonprofit facilities. Despite VDH's effective response to unexpected shortage of flu vaccine, the continuing problems with flu vaccine availability caused great difficulties for our State in planning for the next flu season. We do not know what the availability of flu vaccine will be next year. Will there be enough for everyone, or high-risk groups only? If there is a continuing shortage, what will be the role of State and local health departments in vaccine distribution? Will things be done as in previous years with private sector handling most of the distribution? Or do we need to build on this year's ad hoc system using State and local health departments to coordinate distribution?

Historically in Virginia the private sector has administered the great majority of flu vaccine. This crisis led to much government intervention in the distribution and administration of vaccine. We wonder will the private sector return to its former level of involvement.

In Virginia the trend has been for large businesses such as WalMart, drug chains, grocery store chains to provide much of the vaccine. Long lines, traffic congestion, unfavorable publicity this

season may make them wary of continued participation. Private health care providers have been less active in flu administration over the last few years, and shortage may make them even less willing to deliver vaccine through their practices.

The public has received many mixed messages about flu vaccines as the crisis developed. There were public campaigns urging widespread immunization, then campaigns to ask people not at high risk to defer vaccine. There was a severe shortage of vaccine, then a surplus of vaccine, with changing recommendations.

Fortunately, to date we have had a light flu season; however, this confusion has led to the belief in some of the public that there was less vaccine but we have less flu and maybe we didn't really need the vaccine in the first place. How willing are they going to be to take flu vaccine in future years?

Throughout the crisis our State and local health departments devoted incredible amounts of our time to get to our most vulnerable citizens the vaccine they need. CDC has provided national leadership in a difficult and changing environment and worked very closely with us to meet the needs of our citizens, and we are appreciative of their efforts.

The ultimate solution is development of adequate, secure, and stable supply of vaccine, as we have stated in previous testimony. We appreciate the amount of time and effort your committee has devoted to these issues, and we thank you for the opportunity to speak today.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Stroube follows:]

Robert B. Stroube, M.D., M.P.H

Virginia State Health Commissioner

Testimony prepared for U.S. Committee on Government Reform

Presented on February 10, 10:00 a.m., in Room 2154 of the Rayburn House Office Building

Mr. Chairman and distinguished members of the House Government Reform Committee, my name is Dr. Robert Stroube. I am the State Health Commissioner for the Virginia Department of Health (VDH), and I am honored to be testifying before you today. I would like to thank the Chair and the subcommittee members for convening this hearing.

As State Health Commissioner I serve as the principal advisor to Virginia Governor Mark Warner, Virginia Secretary of Health and Human Resources Jane Woods and the Virginia General Assembly on a wide range of public health issues. I earned a Doctor of Medicine degree from the Medical College of Virginia, a Masters in Public Health from Johns Hopkins University, and an undergraduate degree from the College of William and Mary. I am a specialist in preventive medicine and certified by the American Board of Preventive Medicine.

Since news broke that British regulators suspended the license of flu vaccine manufacturer Chiron last October, state and local public health officials have been working to ensure the best use of available doses of vaccine. Initially that meant prioritizing vaccine availability to individuals at greatest risk for developing serious complications from the flu. More recently it has included responsible relaxation of vaccine recommendations to include individuals outside of the original high-risk groups to ensure use of remaining doses.

When news reports disclosed that Chiron had lost its licensing privileges, VDH stood to lose 90 percent of its total flu vaccine order -- approximately 110,000 doses. The loss of Chiron vaccine, however, did not significantly impact the 115,000 doses of flu vaccine ordered from Aventis for children enrolled in the Vaccines for Children (VFC) program. This program serves uninsured and underinsured children, Native American children, and those on Medicaid.

The health department provides a very small proportion of the flu vaccine that is typically provided to the public. During a typical year the health department provides about 70,000 doses of flu vaccine. Most vaccine is provided by the private sector.

In response to the vaccine shortage, VDH immediately implemented the Advisory Committee on Immunization Practices (ACIP) recommendation regarding the prioritization of all injectable flu vaccine. In addition, every effort was made to educate the medical community about the recommendations and urge compliance. A message was sent out to health care providers through Virginia's Health Alert Network. VDH issued a statewide press release, including information about the vaccine shortage and encouraged prioritization of available flu vaccine. State and local health departments received hundreds of phone calls from concerned citizens and numerous media interviews were conducted. VDH diligently worked to provide the best information available, during the developing situation.

From the beginning of the flu vaccine shortage, the CDC worked closely with Aventis to allocate and distribute all remaining doses of vaccine. In the weeks and months following, VDH

received four shipments of redistributed vaccine, with each targeting a different high-risk population.

In November, VDH received 80,000 doses of flu vaccine to distribute to its 119 local health departments. The decision was made to distribute the vaccine to each health district based on population. Local health districts developed flu vaccine distribution plans tailored to best meet the needs of high-risk populations in each community.

As the first doses of flu vaccine from the CDC allocations began to arrive in late October and early November, health districts worked to implement their vaccine distribution plans. Individuals not included in the priority groups were asked to defer vaccination in order to preserve limited doses of vaccine. The live nasal spray (Flu mist) was encouraged for healthy people of ages 5–49 years who were not pregnant.

Another allocation of approximately 77,000 doses was sent in mid-November primarily to long-term care facilities across the state. This enabled nursing homes and assisted living facilities to vaccinate their vulnerable residents. At this time the VFC program also received the remainder of its order.

Also in mid- November, Virginia began to request vaccine via CDC's Web-based secure data network. The network allowed state public health officials the ability to order flu vaccine on behalf of private health care providers directly from CDC. As a result, VDH was able to distribute approximately 98,000 doses to Virginia's private physicians and pharmacists.

By the end of November, CDC and Aventis had redistributed a total of 255,000 doses to VDH. VDH sought to reach as many high-risk populations as possible by providing flu vaccine to health departments, long-term care facilities, and private physician offices throughout the state.

Throughout November and December, VDH continued to recommend flu vaccine to individuals in the priority groups and publicize vaccine availability via press releases and media interviews; however, demand in many areas had begun to diminish significantly.

By late December it appeared that the majority of high-risk persons in most parts of Virginia who wished to be vaccinated had obtained vaccine. According to a December study by the CDC's Behavior Risk Factor Surveillance System, 63 percent of people 65 and older and 46 percent of chronically-ill adults received an influenza vaccination in October or November. However, more than half of adults at increased risk did not try to get the influenza vaccine. In Virginia, as in other states, it appears many high-risk individuals self-deferred from vaccination due to the vaccine shortage.

A late December inventory survey revealed an available supply of flu vaccine in many parts of the state. To help ensure that available flu vaccine did not go to waste, I authorized the expansion of the vaccine recommendations to include individuals aged 50 to 64 and household contacts of those in high-risk categories to take effect on
January 10, 2005. This expansion was in agreement with revised ACIP recommendations. Even with the expansion there was little interest by private providers in placing an order from

Virginia's fourth allocation of vaccine, approximately 55,000. By the time orders were due to the CDC, on January 13, little over 30,000 doses had been requested. A survey conducted on January 20 revealed that 35,000 doses of VFC vaccine were still sitting unused, available for distribution.

In late January, the CDC began to support the expansion of vaccine eligibility for states and localities with ample supplies. On January 26, I authorized district health directors to lift flu vaccine restrictions in their localities if they felt the demand for vaccination within priority groups had been met. Administration of flu vaccine to members of the general population would allow remaining doses of vaccine to be used judiciously to provide protection against influenza for as many people as possible.

As of January 27, CDC made VFC influenza vaccine available to health departments for non-VFC children or adults in localities where the demand for influenza vaccine among eligible children had likely been met. VDH is working closely with private physicians, advising them of the opportunity to purchase additional vaccine directly from Aventis with a provision that would allow for the return of unused vaccine for a full refund. VDH has also notified all private providers enrolled in the VFC program that they may contact their local health department for the transfer of their unused stock of VFC influenza vaccine. Local health departments have been authorized to redistribute transferred vaccine to other public facilities, free clinics, community health centers or private non-profit facilities.

Despite VDH's effective response to the unexpected shortage of flu vaccine, the continuing problems with influenza vaccine availability pose great difficulties for our state in planning for

the next flu season. We do not know what the availability of flu vaccine will be next season. Will there be enough for everyone or high-risk groups only? If there is a continuing shortage what will be the role of state and local health departments in vaccine distribution? Will things be done as in previous years with the private sector handling most of the distribution or do we need to build on this year's ad hoc system using state and local health departments to coordinate distribution?

Historically, in Virginia, the private sector has administered the great majority of flu vaccine. This season's crisis led to much greater government intervention in the distribution and administration of vaccine. Will the private sector return to their former level of involvement? In Virginia, the trend has been for large businesses such as Wal-Mart, drug chains, and grocery store chains to provide much of the vaccine. Long lines and traffic congestion and unfavorable publicity this season may make them wary of continued participation. Private health care providers have been less active in flu administration and the shortage may make them less willing to deliver vaccine in their practices.

The public has received many mixed messages about flu vaccine as the crisis developed. There were public campaigns to urge widespread immunization, then campaigns to ask people not at high-risk to defer vaccination. There was a severe shortage of vaccine, and then there was a surplus of vaccine with changing recommendations. Fortunately, we have had a light flu season to date. However, this confusion had led to the belief in some of the public that there was less vaccine, but less flu so maybe individuals really didn't need to be vaccinated in the first place. We need to have a good idea about next season's vaccine availability as soon as possible to craft our campaign strategies.

Throughout this crisis our state and local health departments have devoted incredible amounts of time to try to get our most vulnerable citizens vaccinated. The U.S. Centers of Disease Control and Prevention has provided national leadership in a difficult and changing environment and has worked very closely with us to meet the needs of our citizens and we are appreciative of their efforts. The ultimate solution is the development of an adequate, secure, and stable supply of vaccine as we have stated in our previous testimony before your committee. We appreciate the amount of time and effort your committee has devoted to these important issues. Thank you for the opportunity to speak with you today. I would be pleased to answer any questions you may have.

Chairman TOM DAVIS. Dr. Orenstein, thank you for being with us.

STATEMENT OF DR. WALTER A. ORENSTEIN

Dr. ORENSTEIN. I am Dr. Walter Orenstein, association director of the Vaccine Center at Emory University. Prior to joining Emory in March 2004 I was the Director of the National Immunization Program at the CDC. I want to thank the Committee on Government Reform for the opportunity to address public health implications of the recent influenza vaccine shortages, assess strategies used to minimize their impact, and recommend potential steps that may be taken to avert future shortages.

Averting future shortages includes providing incentives, one to manufacturers to enter or stay in the U.S. market, to providers to order and administer influenza vaccine, and to people for whom influenza vaccine is recommended to seek and accept vaccination.

A critical incentive for manufacturers is to decrease financial risk for vaccine that is produced but must be discarded each year, since last year's influenza vaccine cannot be used for the following season. One way to accomplish this is through a back-end guarantee program in which the Federal Government asks manufacturers to produce more doses than they usually would and pays the manufacturer at the end of the season for those extra doses that go unsold on the private market.

For example, if usual production is 80 million doses and the Federal Government wants 90 million doses produced to cover more of the 188 million persons for whom influenza vaccine is already recommended, then the Government can guarantee the companies that they will pay some discounted price for each of the 10 million doses that may go unsold.

As a further incentive to the companies, an effort should be undertaken to increase demand for influenza vaccine and thereby increase the size of the market. This should include at least three components: first, a national, State, and local educational effort directed at both the medical community and the public to promote use of vaccine; second, an adult immunization grant program modeled after the successful childhood immunization program should be undertaken, which provides grants to States and localities to build immunization infrastructure for immunization of adults. This would include components such as outreach workers who can perform educational efforts, staff who can provide technical assistance to health care providers to improve their performance, development of data systems to track and monitor vaccine supply and use and measure immunization coverage, and personnel who can assist nursing homes in conducting immunization programs.

Third, influenza vaccine should be purchased by the Federal Government and supplied to States for uninsured, high-risk adults for whom influenza vaccine is already recommended to minimize financial barriers to access and increase vaccine use.

Incentives for providers include provision of free vaccine for their uninsured patients, decreasing their financial risk of potentially ordering vaccine that goes unused; access to technical assistance from State and local health departments; and provision of edu-

cational materials for their patients from those health departments.

The major concern about the present problem is the potential for backsliding in our efforts to prevent the significant burden of influenza. While it is too early to tell if this season will be mild, if it turns out to be, many of the people who might have received the vaccine in the past but were unable to receive it this year may have a false sense of security that they do not need vaccine. Unfortunately, influenza is difficult to predict, and if a mild season were to occur this year it does not mean next year will be mild. If it turns out the season is moderate to severe, unfortunately many people who might have gained benefits from vaccination may suffer, either because they did not seek it or because they were unable to obtain vaccine.

One of the more effective strategies in reducing influenza is to reduce exposure of high-risk persons to influenza by vaccinating their close contacts. Many more high-risk persons may be exposed because their contacts were not vaccinated due to supply problems.

Given the shortage, could anything have been done differently to minimize its burden? I think CDC did the best it could under the circumstances. There was a need to prioritize vaccine and priorities chosen by the experts on the Advisory Committee on Immunization Practices were reasonable. This meant delivering messages to others to forego vaccination.

In conclusion, the influenza virus can cause a substantial health burden. Influenza vaccination is the best way to prevent this burden. The shortages are a result of lack of manufacturer incentives to enter and stay in the U.S. market. Averting future shortages and averting the influenza burden involves providing incentives to manufacturers to produce vaccine, providers to order and administer it, and the general public to seek and accept vaccine.

Thank you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Orenstein follows:]

Hearing on US Influenza Vaccine Supply – February 10, 2005
House of Representatives - Committee on Government Reform

Averting Future Influenza Vaccine Shortages

Walter A. Orenstein, MD
Director, Emory Vaccine Policy and Development
Associate Director, Emory Vaccine Center
Associate Director, Southeastern Center for Emerging Biologic Threats

I am Walter A. Orenstein M.D., Director of a new program on Vaccine Policy and Development at Emory University and Associate Director of the Emory Vaccine Center and Associate Director of the Southeastern Center on Emerging Biologic Threats. Prior to joining Emory University in March 2004, I was Director of the National Immunization Program at the Centers for Disease Control and Prevention. I want to thank the Committee on Government Reform for the opportunity to address public health implications of the recent influenza vaccine shortages, assess strategies used to minimize their impact, and recommend potential steps that may be taken to avert future shortages.

I will briefly discuss my major recommendations for averting future shortages (Table 1), provide background for those recommendations, and discuss efforts made this year to take maximal advantage of the limited supply available.

Averting future shortages involves providing incentives: 1) to manufacturers to stay in or enter the US market, 2) to providers to order and administer influenza vaccine, and 3) to people for whom influenza vaccine is recommended to accept vaccination. A critical incentive for manufacturers is to decrease financial risk for vaccine that is produced but must be discarded each year since last year's influenza vaccine cannot be used for the following season. This can be accomplished through a "back-end guarantee" or "buy-back" program in which the Federal Government asks manufacturers to produce more doses than they usually would and pays the manufacturer at the end of the influenza season for doses that go unsold on the private market. For, example, if the usual production is 80 million doses and the Federal Government wants 90 million doses produced to cover more of the 188 million persons for whom influenza vaccine is already recommended, then the Government can guarantee the companies that they will pay some discounted price for each of the 10 million doses that may go unsold.

As a further incentive to the companies, an effort should be undertaken to increase demand for influenza vaccine and thereby increase the size of the market. This should include at least three components. First, a national educational effort directed at both the medical community and the public to understand the personal and public health benefit of influenza vaccine. Second, an adult immunization grant program, modeled after the successful childhood immunization program, should be undertaken which provides grants to states and localities to build immunization infrastructure for immunization of adults. This would include components such as staff who can provide technical assistance to health care providers to improve their performance, development of data systems to track and monitor vaccine supply and use, and measure immunization coverage, and personnel who can assist nursing homes in conducting immunization programs and outreach workers who can perform educational efforts. Third, influenza vaccine should be purchased by the Federal government and supplied to states for uninsured high-risk adults for whom influenza vaccine is recommended to minimize financial barriers to access and increase vaccine use.

Incentives for providers include provision of free vaccine for their uninsured patients decreasing their financial risk of potentially ordering vaccine that goes unused, access to technical assistance from state and local health departments, and provision of educational materials for their patients from those health departments.

Incentives for patients include removing the financial barrier for vaccine purchase for the uninsured and provision of this vaccine in convenient locations.

Influenza is a serious health burden accounting for an estimated 36,000 deaths and more than 200,000 hospitalizations annually. Reducing the burden of influenza through vaccination is associated with much greater challenges than any of the other diseases against which vaccines are routinely recommended. There are a number of scientific and programmatic obstacles that must be overcome.

The influenza virus frequently mutates or changes. The more the virus changes from strains circulating the previous year, the greater the number of people who become susceptible, and the greater the potential for severe epidemics. Because the virus changes, the influenza vaccine is usually different each year from the previous year.

The process for making influenza vaccine is complex. It requires fertilized or embryonated chicken eggs, selection of which strains should go in the vaccine, assuring those strains grow in the eggs, producing and testing each individual stain and combining vaccines against each of three types of influenza viruses into a single dose of vaccine. Selection of strains, which usually occurs by February or March of the preceding season, to actual distribution of vaccine to providers, takes about 6-8 months. The process is not very flexible and has difficulties in meeting surges in demand or making changes in the vaccine should newer emerging and circulating strains be identified late in the process. Demand forecasting usually must occur many months prior to actual production and distribution.

Because of the need for rapid identification of new strains, a comprehensive global surveillance system is required. Most new strains have their origins outside the United States, particularly in Asia.

In addition to the scientific challenges noted above there are a variety of programmatic challenges. The fragility of the vaccine supply, itself, serves as a disincentive to promote its use. Health care providers and others may be reluctant to promote vaccine if they cannot be assured they will receive needed vaccines. Thus, solving the supply problem for the long term is critical to efforts to try to enhance prevention of influenza beyond current levels and avert backsliding.

The CDC estimates that approximately 188 million Americans should be vaccinated annually against influenza. However, even in years with supplies adequate to meet demand, only about 80-85 million persons are vaccinated. Thus, there is a critical need to expand coverage. This will not only improve prevention but will increase the market and hopefully stimulate more manufacturers to enter the market.

A further programmatic challenge is the relatively short vaccination season. Influenza vaccine is typically administered in October and November. While efforts have been made to extend the vaccination season through December and even into January and beyond, because influenza disease often peaks during February and March, these efforts have not been successful to date. Any vaccine not used during the vaccination season must be discarded. Thus, there is a built-in disincentive for manufacturers to make more vaccine than they know they will sell and for

providers to order more vaccine than they know they can administer. Both can suffer substantial financial liability if they overproduce or over order, respectively.

Vaccine that becomes available after November is unlikely to be used. Even as we try to extend the influenza vaccination season, the goal should be to have all the vaccine projected to be needed available and distributed by October 1st or shortly thereafter.

Other programmatic challenges include the need to not simply provide information to the public and health care professionals but also the need to correct common misperceptions. For example, many members of the public and health care community mistakenly believe that the influenza shot can cause influenza, that it is not effective in prevention of influenza, and/or that vaccine is not indicated for them when in fact it is. The inactivated influenza vaccine contains both killed and disrupted virus and cannot cause influenza, itself. The live vaccine given as a spray in the nose may cause mild cold-like symptoms but not classical severe influenza. Influenza vaccines are effective against infections caused by the influenza virus. However, many respiratory illnesses are caused by other viruses. No protection is offered against these other viruses even though most refer to all of these conditions as "the flu". Influenza vaccine is recommended not only for the frail and elderly but also for healthy household contacts and healthy health care workers who come in contact with persons at high risk of complications from influenza to prevent exposure of these high risk persons to the virus.

For example, while influenza vaccine is beneficial to frail elderly persons in nursing homes, it is only about 30-40% effective in preventing illness. In contrast, vaccination of healthy workers in those same homes is 70-90% effective. Thus, vaccination of these health care workers could add substantial benefit to vaccination of the nursing home residents themselves by effectively reducing the chances that the health care workers get infected and spread the virus to the residents.

Finally, in contrast to childhood vaccination programs where the public sector plays a major role in control and distribution of vaccine, influenza vaccination of adults is primarily a private sector program. Less than 10% of influenza vaccines are purchased off of the Federal contract established by the CDC. Thus, the public sector has little leverage with regard to distribution and redistribution of vaccine during a shortage situation. The limited public sector infrastructure devoted to promotion of influenza vaccine is a barrier to developing the kinds of public/private sector partnerships necessary for collaboration in a shortage situation. Such collaboration is critical for assessing supplies at different levels of the system and redistributing vaccine, if needed from those with surpluses to those without adequate supplies.

The immediate cause of the recent shortage was bacterial contamination of vaccine prior to release from one of the two licensed manufacturers of inactivated influenza vaccine in the United States leading to only one producer distributing. However, there are a variety of underlying causes that over the years have made the United States vulnerable to influenza vaccine supply disruptions.

In 2000, there were four influenza vaccine manufacturers. Two were found to be in violation of compliance with current Good Manufacturing Practices (cGMP). One of these two companies

made the assessment that investments in their plant to bring them into compliance were not worthwhile and stopped distributing. The other manufacturer paid a fine and made improvements to come into compliance. They wound up distributing late and had some difficulties in selling all of their doses produced. This continued into the 2002-2003 season when that manufacturer was left with millions of doses that had to be discarded. Following the 2002-2003 season, this second manufacturer dropped out of the market leaving only two active distributors in the United States going into the 2003-2004 and 2004-2005 seasons. In addition, there was one manufacturer of a live attenuated nasal spray vaccine which produced limited quantities of vaccine.

Several factors decrease manufacturers' incentives to stay in the US market or enter the market. Vaccine produced but unsold at the end of the vaccination season must be discarded. The price of influenza vaccine is relatively low compared to other vaccines. While the catalogue price per dose has increased from about $2.15 during the 1997-1998 season to more than $8.00 per dose this season, it is still cheaper than any of the other routinely recommended vaccines. And there is a tension between increasing that price to obtain better return on investment and trying to increase market size from the 80-85 million doses that are distributed in good supply years to the more than 188 million doses that would be needed with full implementation of current influenza vaccine recommendations. Finally, the production process is complex and requires continued investments in plants to assure they are current with improving state of the art "Good Manufacturing Practices". Such investments require a good return on investment and minimization of risk for vaccine produced but not sold.

To reduce manufacturer risk and stimulate increased production, an influenza "buy-back" program is warranted for doses produced but not sold. Because any funds used in the buy back program are in essence "wasted" since they pay for doses that are discarded, and to attract manufacturers to the US market, a major Federal effort should be undertaken to increase demand for vaccine from the usual 80-85 million doses to close to the more than 188 million doses that would be needed for full implementation of vaccination of persons for whom influenza vaccine is already recommended. Demand generation should consist of an ongoing national, state, and local educational effort targeted to the health care community as well as the general public. Such an effort can be facilitated by developing an adult immunization Federal grant program for states and localities, modeled after the successful childhood 317 grant program. Funds should be provided for public sector infrastructure to implement efforts such as conducting outreach, developing and disseminating educational materials, providing technical assistance to providers to improve their immunization performance, and developing data systems to track vaccine distribution, use and to measure immunization coverage. In addition, a Federal Vaccines for Adults (VFA) should be established to provide free vaccines to uninsured adults, for whom influenza vaccine is currently recommended, in physician offices and other settings, working through State and local public health departments. This reduces risk to providers of ordering vaccine and not using it and provides incentives to uninsured patients to receive vaccines. This program also establishes a public/private partnership to improve immunization coverage for adults.

The major concern about the present problem is the potential for backsliding in our efforts to prevent the significant burden of influenza. While it is too early to tell if this season will be

mild, if it turns out to be, many of the people who might have received a vaccine in the past but were unable to receive it this year, may have a false sense of security that they do not need vaccine. Unfortunately, influenza is difficult to predict and if a mild season were to occur this year, it does not mean next year will also be mild.

If it turns out this season is moderate to severe, unfortunately many people who might have gained benefits from vaccination may suffer either because they did not seek vaccine or because they were unable to obtain it. One of the more effective strategies in reducing influenza is to reduce exposure of high risk persons to influenza by vaccinating their close contacts. Many more high risk persons may be exposed because their contacts were not vaccinated due to supply problems.

Given the shortage, could anything have been done differently to minimize its burden? I think CDC did the best it could under the circumstances. There was a need to prioritize vaccine and the priorities chosen by the experts on the Advisory Committee on Immunization Practices (ACIP) were reasonable. This meant delivering messages to others to forego vaccination. Unfortunately, there was a limited amount of live attenuated influenza vaccine for administration in the nose that could have been given to some persons who were not in the high risk groups that may now go unused. However, the quantities available of the live vaccine were not sufficient to meet usual demand. While there were clear messages suggesting the live vaccine as an alternative for those not in high risk groups, it was difficult to deliver that message in the face of the overall shortage and prioritization as evidenced by the fact that not all of the approximately 3 million doses of this vaccine were used this year. Since the live vaccine shows great promise of high effectiveness, I hope that it continues to be produced and distributed.

In conclusion, the influenza virus can cause a substantial health burden. Influenza vaccination is the best way to prevent this burden. The shortages are a result of lack of manufacturer incentives to enter and stay in the US market. Averting future shortages and averting the influenza burden involves providing incentives to manufacturers to produce vaccine, providers to order and administer it, and to the general public to seek and accept this lifesaving vaccine.

Table 1

Major Recommendations for Averting Influenza Vaccine Shortages in the Future

Minimize Manufacturer Risk

- Establish an influenza "back end guarantee" to compensate manufacturers for doses of vaccine above normal production that go unsold
- The Federal government would determine quantities of vaccine above usual production that it would guarantee

Increase Demand for Influenza Vaccine to Increase Market and Better Prevent Disease

- Establish an ongoing educational effort at national, state and local levels
- Establish an adult influenza immunization grant program to enhance infrastructure at the state and local levels
    - Outreach
    - Education
    - Data and tracking systems
    - Enhance provider immunization performance
- Establish a Federal "Vaccines for Adults" Program to purchase influenza vaccine doses for uninsured adults for whom influenza vaccine is recommended
    - Supply the vaccine through state and local health departments to public and private sector providers whom could administer it to their patients

Chairman TOM DAVIS. Dr. Wasserman, thanks for being with us.

STATEMENT OF DR. ALAN WASSERMAN

Dr. WASSERMAN. Thank you, Mr. Chairman and members of the committee.

At the height of influenza season last year, more than 10 percent of all deaths were related to pneumonia and influenza. In 12 of the past 21 years, the peak month for flu activity in the United States has been in February or March. We may get lucky this year and see fewer cases, but the chances are the greatest threat from influenza is still before us, and yet we cannot give away flu vaccine.

We are only now seeing our offices filled with patients with flu-like symptoms, and our hospitals had to close on multiple occasions in the past week because beds are filled to capacity with patients with flu and complications from flu. It is not just the Pope who has been hospitalized with influenza-induced pneumonia. And yet we cannot give away free flu vaccine.

After treating our high-risk patients, we have been left with approximately 3,600 doses of vaccine, and when the city relaxed restrictions we hastily convened an all-day flu vaccine fair at the Foggy Bottom Metro Station on February 13th. Thanks to the local media, we were able to publicize this event widely, with constant radio reminders that included a live telecast onsite throughout the day. Our doctors, nurses, interns, and residents spent the day administering free flu shots, but in the end we were left with over half our remaining supply.

The headline in the "Washington Post" had it correct, "G.W. Stuck it to 1,889 People," but where were the others? Where was the passion, the anxiety, the response that we saw in November and December to those free sessions that were offered before restrictions were put in place?

We stood outside for over 8 hours, and yet we couldn't give away all our free flu vaccine. We will probably end up the year with over 1,500 doses going unused. Therefore, we and many health care organizations like us will be left with incurring the cost of unused vaccines, but, more importantly, thousands of Americans will get sick needlessly.

Now this has been a very unusual year and this is a complicated issue involving the health of our community and our country, but it is our hope that this committee could address some important questions that have health care workers and probably the public perplexed.

If vaccinating our population for influenza is such a priority, why is there no safeguard in producing vaccine? Which would cost more, redundancy in vaccine production with risk of over supply, or the significant added cost to the Government in Medicare and Medicaid payments for flu-related illnesses and hospitalizations? Why does our country's grocery stores receive their vaccine shipment well before most health care providers? Is that the way we will assure that high-risk patients will be vaccinated?

Debilitated patients, those on oxygen, and others usually do not have the stamina to fight their way in line and stand for hours. Is this really a public service, or a setup for public panic?

Can we continue giving mixed messages to the public? One year it is, "Get your vaccine in October and November," and the next year the public is told it is still OK to get a shot in January or February.

Skepticism is very high among the public now that we are pushing vaccine at this very late date. Some may think that we are only doing so not to look foolish ending the season with a surplus, while others certainly may think it is just the greedy physician out to make the extra dollar.

To add to confusion, the District of Columbia, Maryland, and Virginia each had different regulations, some with monetary penalties, for flu vaccine distribution. In such inter-related areas where patients from one jurisdiction often see physicians in another, shouldn't uniform policies be considered?

There is much to be learned from what happened this year, but this year is not over. People remain at risk for what could be a virulent next 2 months. Earlier this year Members of Congress and their staff set the example by not being inoculated, thereby encouraging the public to refrain from getting flu shots so there would be enough for the high-risk group. I believe now the time has come for Congress to once again lead the way in getting inoculated now to encourage others to come forward while there is still time.

Throwing away vaccine and filling our hospital beds would be a sad ending to a very difficult season.

On that note, Mr. Chairman, as you mentioned, we will be administering free flu vaccine starting today at 1 p.m., upstairs in room 2247. We will be here until we run out of vaccine. I hope that is not too long.

Thank you very much.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Wasserman follows:]

Alan G. Wasserman, M.D.
Eugene Meyer Professor of Medicine
Chairman, Department of Medicine
President, Medical Faculty Associates, Inc
The George Washington University Medical Center

Re: Hearing, February 10, 2005, Committee on Government Reform regarding the U.S. influenza vaccine supply

Mr. Chairman, my name is Dr. Alan Wasserman and I am Professor and Chairman of the Department of Medicine at the George Washington University Medical Center and President of the Medical Faculty Associates, the clinical faculty of the University's Medical Center.

At the height of influenza season last year, more than 10% of all deaths were related to pneumonia and influenza. In 12 of the past 21 years, the peak month for flu activity in the United States has been in February or March. We may get lucky and see fewer cases this year, but the chances are that the greatest threat from influenza is still before us, and yet, we can not give away flu vaccines.

We are only now seeing our offices filled with patients with flu-like symptoms, and our hospital has had to close on multiple occasions in the past week because beds are filled to capacity with patients with flu and complications from flu. It is not just the Pope who has been hospitalized with influenza induced pneumonia. And yet we can not give away free flu vaccines.

We ordered and received over 9,000 vaccine doses this year as we have for the past 4 years, expecting to use every dose. Ironically, supermarkets had their vaccine supplies before we had any. When restrictions were placed to inoculate only high-risk individuals we looked for ways to utilize our supply. We sent 1,000 doses to our hospital for use on their staff (as they never received their shipment). We attempted to inoculate all of our health care workers, but less then half chose to take a shot, many expressing their desire to save vaccine for our high risk patients. We supplied many of the private practices in the area with enough vaccine to give to their workers as many or most did not receive any supply. And as of yesterday, we successfully vaccinated over 4,000 of our high-risk patients.

We were left with approximately 3,600 doses of vaccine, and when the city relaxed restrictions we hastily convened an all-day flu vaccine fair at the Foggy Bottom Metro Station on January 13th. Thanks to the local media, we were able to publicize this event widely with constant radio reminders that included a live telecast on site by WTOP throughout the day. Our doctors, nurses, interns and residents spent the day administering free flu shots, but in the end we were left with over half our remaining supply. The headline in the Washington Post had it correct, G.W. stuck it to 1,889 people, but where were the others? Where was the passion, anxiety and response that we

saw in November and December to those free sessions that were offered before restrictions were put into place? We stood outside for over 8 hours, and yet we couldn't give away all our free flu vaccine. We will probably end the year with over 1500 doses going unused. Therefore, we and many health care organizations like us will be left with incurring the cost of unused vaccines and more importantly thousands of Americans will get sick needlessly.

This has been an unusual year, and this is a complicated issue involving the health of our community and country. But I would hope that this committee could address some important questions that have health care workers and the public perplexed:

1. If vaccinating our population for influenza is such a priority why is there no safeguard in producing vaccine? Which would cost more, redundancy in vaccine production with the risk of oversupply or the significant added cost to the government in Medicare and Medicaid payments for flu-related illness and hospitalization?

2. Why do our country's grocery stores receive their vaccine shipments well before most health care providers? Is that the way we will ensure that high-risk patients will be vaccinated? Debilitated patients, those on oxygen and others, usually do not have the stamina to fight their way in line and stand for hours. Is this really a public service or a set up for public panic?

3. Finally, can we continue to give mixed messages to the public? One year it is "get your vaccine in October or November" and the next year the public is told "it is still ok to get one in January or February." Skepticism is high among the public now that we are pushing vaccination at this late date. Some may think that we are only doing so to not look foolish ending the season with a surplus. Others may just feel that the greedy physician is out to make an extra dollar.

4. To add to the confusion, the District of Columbia, Maryland and Virginia each had different regulations, some with monetary penalties, for flu vaccine distribution. In such interrelated areas, where patients from one jurisdiction often see physicians in another, shouldn't uniform policies be considered?

There is much to be learned from what happened this year, but this year is not over. People remain at risk from what could be a virulent next two months. Earlier this year members of Congress and their staff set the example by not being inoculated thereby encouraging the public to refrain from getting flu shots so that there would be enough for the high risk group. Now the time has come for Congress to once again lead the way in getting inoculated now to encourage others to come forward while there is still time. Throwing away vaccine and filling our hospital beds would be a sad ending to a difficult season.

Chairman TOM DAVIS. Again I want to thank the generosity of George Washington University Medical Faculty Associates for making this available. We are going to get the word out here.

I will start questioning with Mr. Dent. Mr. Dent, are you ready?

Mr. DENT. Thank you.

Dr. Orenstein, I represent eastern Pennsylvania just south of the Aventis pasteur plant in Swiftwater, PA. I know you have talked a lot about incentives. Are you satisfied with what has been done to date to make sure that Aventis and perhaps any other pharmaceutical manufacturers will be ready to deal with this situation next season?

Dr. ORENSTEIN. I think there has been some major progress that has been done. I think very good collaborative relationships have been developed. I think it potentially can be done. I know we are focused very much on high-risk individuals, but if you look at for whom the vaccine is recommended, it is recommended for contacts of those people. There are substantially more people who need to get vaccinated. It is not clear to me that we have enough incentives right now in order to really boost production.

I think in essence we ought to be considering perhaps a 5-year plan to get to close to the 188 million Americans for whom we already recommend vaccine. I think to me the people who can actually answer that question best are the manufacturers, themselves, but I am concerned that perhaps we have some but not all the incentives we need.

Mr. DENT. I guess I am somewhat concerned, too, in that beyond Aventis it doesn't seem that there are too many domestic manufacturers of this particular product, and selfishly I would certainly like to see Aventis get the business because my constituents work in that plant where they manufacture it, it would probably be in the public's interest and this country's interest to diversify the base.

Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Boozman, your brother and the chairman had very nice things to say about you, and I am pleased that you are here. I just want to say something nice about your brother, because he and I have been working together on legislation to protect children from harm from contact lenses that have not been prescribed and not appropriately placed in their eyes. He has been a great legislative ally.

As the person in charge of the State and territorial health officials, could you tell us about the financial difficulties States have in providing all the routinely recommended vaccines to children?

Dr. BOOZMAN. Yes, sir. Thank you.

Mr. WAXMAN. And let me follow that up with another question at the same time. Does the President's budget fully address the problems that you do have at the State level?

Dr. BOOZMAN. The problems that we are having and have had—and we have all tried to solve them in different ways—is that we are getting more and more vaccinations, most recently prevnar, and the cost per child keeps going up. Now, we have the vaccine

for children's program, which enables us to give that eligible child a full complement of vaccination, but many children fall through that crack, and so then we are left with the 317 side of the system to try and serve children.

For a year in Arkansas we had a two-tiered system where we simply couldn't fill that gap. Now the way we solved that was through the federally qualified community health centers. They deputized our clinics, the health department's clinics, and that made children coming in to us eligible on the vaccine for children's side.

We have new vaccines coming even more, and so I think this problem is going to get bigger. So the answer to your question is: no, we don't have enough funding right now to be able to vaccinate everybody the way we ought to. As somebody that comes from a pretty conservative perspective, there are not many things that Congress can spend money on that they get a better return on.

Mr. WAXMAN. Absolutely.

Dr. BOOZMAN. Every dollar that you spend—I think I saw a figure this morning of $27 in reduced medical costs, and it was mentioned about what it is costing for people to be in the hospital with pneumonia and things like that.

Mr. WAXMAN. Certainly less expensive to prevent the disease than to have to pay to treat a disease that could have been prevented.

Dr. BOOZMAN. That is exactly right.

Mr. WAXMAN. You testified that you would support a vaccines for adults program modeled on the very successful vaccines for children program. That certainly seems like a sensible idea to me. If the Federal Government could expand and guarantee a vaccine market like it does with pediatric vaccines, this could be, I think, a powerful incentive for the manufacturers, the companies to get into the business and stay in the business, because we do have this question of what business decision they will make if they have this uncertain market.

Do you think that this would shore up our fragile vaccine supply?

Dr. BOOZMAN. I think it certainly would be a great step in the right direction, because, as you have said, it creates a market. Our country has a history of where there is a market people fill in. Just as Representative Dent mentioned, I think there will be other people that see that potential and I think other manufacturers would enter in. I think it is certainly a first step, and see what happens. Other things may be necessary, but that certainly to me is a very important first step.

Mr. WAXMAN. We have heard from local health officials that they can't provide important vaccines such as the hepatitis B vaccine even to high-risk people such as people who come to sexually transmitted disease clinics. They can't provide it because the cost is so high. Do you think that a vaccines for adults program should be broad enough to include all routinely recommended vaccines for adults, including the hepatitis B vaccine?

Dr. BOOZMAN. Yes, sir, I do.

Mr. WAXMAN. Dr. Orenstein, you used to direct the national immunization program at CDC. You are an expert on the vaccines for children program. In your testimony said you would also like a vac-

cines for adults program. How do you think they would differ? And do you think this would help us set up a reliable distribution system and expand the number of adults that will be vaccinated?

Dr. ORENSTEIN. What I was proposing in my testimony is a beginning vaccines for adults program. It could be expanded to cover other groups. The big group that I am concerned about, just like the vaccines for children program is concerned about, is uninsured adults. The Institute of Medicine has estimated that somewhere around 8 million high-risk uninsured adults are in need of influenza vaccination.

I think having a vaccines for adults program that would provide vaccine to doctor's offices, potentially other sites that are more convenient, such as grocery stores, goes a long way to reducing the financial challenges.

We made a statement when we covered influenza vaccine by Medicare that reducing the financial barriers to access was really critical. For the uninsured, who may very well be in some of these high-risk groups or contacts of high-risk groups, I think we also need to reduce that problem.

The other advantage that takes place with the vaccines for children program, and I hope with the vaccines for adults program, it establishes a public-private partnership. If you bring vaccine to the table and you give it to a physician, it allows you to work more effectively with that physician at trying to work on their immunization performance. That has been a big boon, I think, in terms of the vaccines for children program in helping to cement that kind of relationship.

Mr. WAXMAN. What vaccines should be included?

Dr. ORENSTEIN. I think the initial one I focused on is influenza. I think certainly others could be added over time. I think the one you raise is a very important one. Hepatitis B now is primarily a problem among high-risk adults, many of whom we access in STD clinics, in HIV clinics, and a variety of other places. We don't have the vaccine to provide it. That might be one other group to consider.

Mr. WAXMAN. Thank you very much.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you.

Dr. Boozman, millions of doses of flu vaccine are thrown away every year at the end of the season. Have States ever considered extending the annual shot campaign, which usually takes place in the fall, through January or February to maximize the amount of Americans vaccinating?

Dr. BOOZMAN. Yes, sir, we have. The problem is—and Dr. Gerberding alluded to this—is that the demand just falls off. No matter, it seems like, what we do, we are conditioned almost that in October and November you get your flu shot, and after that you don't—again, no matter what we say. We have tried——

Chairman TOM DAVIS. Maybe at this time of year they think they have made it.

Dr. BOOZMAN. They think they have made it. And, again, the testimony that you have just heard, this is the time we are the most worried about is right now. But in the past we have hoped that we

could get people covered so that they can go into this time of the year without.

The rock and the hard place this year was we didn't have vaccine and so we pushed and got the high risk. I think we have a better cover of high risk. In Arkansas anyway we have better coverage of high-risk people than we have ever had. But then you have a little vaccine left over and you are afraid to open it up too much because you get a run.

Chairman TOM DAVIS. I guess, Dr. Stroube, you have the same problem in Virginia—that there is just little interest by private providers in placing an order after our fourth allocation?

Dr. STROUBE. Yes. And they are scared that they are going to get stuck with the vaccine and people aren't wanting it any more. I know my wife hasn't even gotten a vaccine. I haven't been able to talk her into getting one and she is at high risk, and she has deferred, even though she shouldn't have. I am going to have to take a dose home and shoot her, myself.

Chairman TOM DAVIS. I am not going to touch that one, but good luck. If you need a place to stay, you know where I am.

Dr. STROUBE. She is from Fairfax County, too.

Chairman TOM DAVIS. Exactly.

Well, let me ask you also, Dr. Stroube, we have had problems—and also Dr. Wasserman—Dr. Wasserman talked about confusion of patients living in the different regions, that we really weren't very regionally coordinated at this point. Is there anything we can do to try to get better regionally coordinated? A lot of Virginia patients have doctors in Maryland and vice versa. Anything we can do on a regional basis? And I will ask Dr. Wasserman the same thing.

Dr. STROUBE. What we tried to do was go by what the ACIP and CDC were saying so it would be a uniform message that we would match up with the country. I was under pressure from different areas and different situations to do different things, and I resisted that. I think the more all the States follow the national guidelines, the better off you are.

Now, some of the issues had this with the regulatory part. In Virginia we didn't have a regulation that said that you had to give it only to high risk. We did it only by public information and getting information out to the doctors, and other places went ahead and made it actually a violation of the rules and regulations if you gave it to people outside. So there is probably some need there for uniformity.

Chairman TOM DAVIS. OK. Dr. Wasserman, have you got any thoughts on that?

Dr. WASSERMAN. Well, there has to be some standardized policy. We had some jurisdictions that were assigning monetary penalties to physicians if they gave it to the wrong patients, and they had a surplus of vaccine, and therefore they couldn't use it for fear of being fined.

Chairman TOM DAVIS. That is what happens when the government gets involved legislatively. You lose your flexibility, I think. You can get the wall of unintended consequences. But you have a lot of Virginia patients at MFA and a lot of Maryland patients that come down.

Dr. WASSERMAN. That is correct. Is it fair for only Virginia patients that come to us to be able to get it and not the Virginia patients that stay in Virginia? It just seems to me that we are so closely knit here that there has to be some way to coordinate.

Chairman TOM DAVIS. Is there a consensus this has been a fairly mild year by flu standards across the country?

Dr. WASSERMAN. Up to now, but if you look at the recent papers, look at the recent reports, CNN just reported yesterday the Governor of Maryland has asked the public to stop calling 9–1–1 because of the overwhelming calls because of flu. I mean, we are just starting to see a greater peak now than we have ever seen, so this may turn out to be mild and it may not. I think the next couple of weeks will tell.

Dr. STROUBE. It is similar in Virginia. We are beginning. This week we went to widespread flu for the first time this year.

Chairman TOM DAVIS. So this is a good time to get your shot, actually.

Dr. STROUBE. Sure.

Chairman TOM DAVIS. Dr. Orenstein, you state in your written testimony that you believe CDC did its best under the circumstances earlier this year, but you still recommend establishing an education effort at the national, the State, and the local levels. How would the educational effort you envision add to the work of CDC to inform the public?

Dr. ORENSTEIN. I think what it would do is develop a cadre of people, a cadre of materials, and an ability on a year-round basis to continue to educate.

One of the great hurdles is dealing with the medical care community. The coverage rates in the medical community have only been about 43 percent, I think was the last data that I saw from CDC. A few years ago it was only 38 percent. We have some real re-education to do, and that I think is where the grant program will be helpful, because these are the kinds of people who would go into hospitals and give grand rounds to work with Dr. Wasserman and others in terms of trying to champion it among his staff. One of the most effective interventions that has occurred was in Rochester a number of years ago where staff from the health department went in and reviewed doctors' records and set up a target population for them to reach in vaccination. That significantly improved their coverage.

So the educational effort is not simply a media campaign, although that is probably an important part of it. It involves a whole series of kinds of education efforts.

Chairman TOM DAVIS. Thank you.

Ms. Watson.

Ms. WATSON. I am sorry that I wasn't here for panel one, but with panel two what are we doing to be able to plan for future flu seasons? And are we doing enough here in our country to manufacture the flu vaccine so we don't have to depend on foreign suppliers? Anyone on the panel who feels they can tackle that?

Dr. ORENSTEIN. I can talk about the manufacturing issue and perhaps one of the health officers will talk about the other.

Ms. WATSON. OK.

Dr. ORENSTEIN. I think at the moment it is going to be very difficult to try and get a U.S. manufacturing base back.

Ms. WATSON. Explain.

Dr. ORENSTEIN. What we have had is we had in 2000 three U.S. manufacturers and one foreign manufacturer. Two dropped out of the market. I think to try and bring the two that dropped out back might be very difficult at this point because you would have to redo their plants, you would have to give substantial investments. There is some hope with some foreign manufacturers coming into the U.S. market. GlaxoSmithKline has a plant in Germany, and they have announced interest in coming into the U.S. market. I.D. Biomedical has a plant in Canada. They are interested in coming in.

I think if we provide incentives there may be more manufacturers that come in, but we have to provide substantial incentives. I think the 188 million person market, which is what potentially is there, if it could begin to move forward in that way, more companies would come in. I think we are getting the interest from the two European manufacturers—Canadian and European manufacturer—purely because they see a much bigger market here.

Ms. WATSON. Anyone from CDC at the table? Well, maybe I can ask this of the chair. Why is it that we could not put in CDC's budget a line that would start to promote the manufacturing here in this country? You said we had four and two have dropped out. Why couldn't we pump up American manufactures of the flu vaccine? Do you have any idea?

Chairman TOM DAVIS. I can just say on the CDC side, CDC's budget has gone up nine-fold, I think, nine times since 2001, but it is really the FDA that would be responsible for that, and I think that as a result of this year no one had planned on the Chiron plant being closed down, which supplied about 45 percent of what was going on, and now we are looking for other folks. But it is a risky business, as you know. You produce vaccines, and you may end up producing stuff that can't be sold. It is not a high margin material. Once you produce it, you don't make a lot on each dose the way you do with a prescription drug or something like that.

Ms. WATSON. Let me ask this: can the vaccines that are in the surplus supply now be held over to another season?

Chairman TOM DAVIS. You can hold them over, but they won't be any good because you get a different strand every year. That is the difficulty with this.

Ms. WATSON. It seems to me some of the big pharmaceutical manufacturers here in this country would maybe take this on as one of their divisions, so if it is a slow year 1 year and they lose money it can be compensated for in another division. But I think we need to be able to monitor the development of the vaccine right here in this country because it was a supply that we were counting on Chiron that had some problems. I don't know how we anticipate this, but I think that if we had it, if we had the supply—and I would say at least if it is not the majority supply, a supplemental supply—constantly being developed here by our manufacturers we would be able to guard against the foreign manufacturers who run into problems in their research labs. This is something that I am just throwing out.

Chairman TOM DAVIS. Right. FDA in their testimony earlier talked about how they are trying to find more product and make sure that we get more product coming in. A lot of these facilities are done overseas because it is, frankly, cheaper to produce them that way. Why would you overpay for something if you can produce it and keep it as clean? And for the most part there is no evidence that vaccines that are produced wholly or partly abroad have any less power or potency.

Ms. WATSON. My concern in this particular era is always going on the cheap, and I have that concern in other products that are produced abroad and we consume here in this country. We have very little control over the process of production. So I want to start the debate of not always looking for the cheapest way out. I think this flu vaccine problem heightens our motivation to start looking at is cheaper always better and should we not invest in quality when it comes to a life-saving or a life-sustaining product like a flu vaccine?

I just throw that out, Mr. Chair, as food for thought and as continuing debate.

Chairman TOM DAVIS. Nothing like a crisis to get everybody to put their thinking caps on and see what can happen on this.

Ms. WATSON. Exactly.

Chairman TOM DAVIS. I think you gentlemen have worked under extraordinary circumstances. You said, if anything, we have done a better job than we thought. We found supply that we didn't think we would find. Now the people that were demanding flu shots, we can't get people to take them. There is still time to tell. In a couple months we could still hit the peak.

Let me just ask this question. Can you tell from what is happening in other parts of the world how virile and tough the flu shot could be by what is happening in other countries, or are they just so different when it comes up here there is no way of telling? Do you know what I am saying?

Dr. ORENSTEIN. Last year with the Fujian strain we were hearing about outbreaks in other parts of the world that were moderate to severe, and so that gave us a picture that we were probably going to get a moderate to severe year in the United States, which we wound up having.

There is some potential that what goes on there will have a similar impact here, but it is still not 100 percent predictability. As Dr. Wasserman said, I think this still could turn out to be a problematic year. We just don't know yet. It is still fairly early. Most flu seasons peak in February. In fact, we have had flu seasons peak in March, April, and even May, so that has potential to occur, but it is difficult to predict.

What is really important in looking at what happens overseas is to look at which strains are emerging so that we can determine what ought to go in the vaccine. Last year we were behind on that, and so we had—although the vaccine was effective, we had a mismatch.

Chairman TOM DAVIS. Right. I guess if anything, if I have any quarrel with today's testimony it wasn't from this panel. It was the first panel, where they had the States that had the most significant

infestation of flu as red States. But you would have liked that, Ms. Watson.

I think everybody has closed ranks pretty much. This has been and hopefully stays a mild year so that the damage won't be too great. We can use this as a learning experience and maybe avert something worse at a later time.

Thank you all for being here. I think it has been very, very helpful to us.

In closing I want to remind everyone of the free flu shot clinic today in the Rayburn Building, 2247, from 1 to 3 p.m., and it is open to the public. You don't have to be a Capitol Hill employee. You don't have to be a Member of Congress. Basically, the last time George Washington University Medical School was giving away flu shot they couldn't give enough away at the subway station at Foggy Bottom. So it is open to the public today in Rayburn 2247 from 1 to 3 p.m.

Thank you. I again want to thank the witnesses for their testimony. I want to thank the committee staff that worked on this hearing.

I ask unanimous consent that the statement of Mark Mlotek of Henry Schein, Inc. be included in the hearing record. Hearing no objection, it is so ordered.

This hearing is now adjourned. Thank you.

[Whereupon, at 12:35 p.m., the committee was adjourned.]

[The prepared statement of Hon. Candice S. Miller and additional information submitted for the hearing record follows:]

Statement
Rep. Candice Miller

House Government Reform Committee

Full Committee Hearing
"The Perplexing Shift from the Shortage to Surplus: Managing This Season's Flu Shot Supply and Preparing For the Future"
February 10, 2005

Mr. Chairman, thank you for holding this hearing today. The nation's flu vaccine supply is an important issue that needs continued scrutiny.

The flu shortage that unnerved the nation this year is something that can not happen again. The lines of seniors and families that circled around buildings were agonizing and you could see the fear in their eyes. They were simply hoping to get the vaccine that could spare their lives. Because of this shortage, a widespread epidemic or a pandemic could have resulted in a substantial number of deaths.

After the shortage was realized, the problem was immediately remedied only to bring to fruition yet another problem. The nation was then confronted with a surplus of vaccines that were not used. Obviously, there was a glitch with the distribution of the vaccine.

In my opinion, the first responsibility of the federal government is to protect its citizens. While I am not a supporter of big government, this is one area that may need the assistance of the Congress to once again gain the assurance of the nation.

I am truly interested to hear the testimony of the witnesses before us today. Thank you for coming. There are many questions that still need answers and obviously a few new ones that have yet to be asked.

Thank you.

Statement for the Hearing Record of Mark Mlotek, Executive Vice President, Henry Schein, Inc.

House Committee on Government Reform Hearing:
"The Perplexing Shift from Shortage to Surplus
Managing This Season's Flu Shot Supply and Preparing for the Future"
February 10, 2005

Thank you for the opportunity to submit a statement for your well-timed hearing on how our country could swing from a record shortage of flu vaccine in October and November 2004 to an excess of supply by January 2005. Over the past year, the Government Reform Committee has conducted a thorough examination of the many complex factors involved with flu vaccine, and we at Henry Schein, Inc. believe that focusing on distribution is essential to understanding how to manage any future shortages or delays in vaccine supply. Recognize that when Chiron announced on October 5 that it would not be shipping any vaccine to the US market, the challenge for our country immediately became one of distribution - how to get available vaccine to the high risk population. The private U.S. healthcare distribution system is the most efficient and effective in the world. We could have helped.

Henry Schein, Inc. has been in the flu distribution market for 15 years and is the largest flu vaccine distributor in the country, with more than 20 million doses sold in 2003. While we do ship large flu vaccine orders to hospitals and others, our typical customer is a physician practice that orders between 10-20 vials -- or 100 to 200 doses of flu vaccine per year. We are also manufacturer-neutral. We distribute product from Sanofi Pasteur (formely Aventis), Chiron, and MedImmune, and have an agreement to distribute product from ID Biomedical. This season, prior to the Chiron announcement, we had pre-booked orders for over 30 million doses.

In previous vaccine shortages, it has been our plan -- which we've shared with HHS and the CDC -- to get a small amount of vaccine to as many practitioners as possible to allow them to give doses to those who need it most. Every physician across the country has high risk patients. The CDC estimates that 70% of flu shots are administered in a doctor's office, which means this has always been an effective way of reaching large numbers of high risk and elderly individuals quickly and most conveniently for them and their doctors. Because we also distribute a wide range of medical supplies to our extensive customer list, we are in regular communication with physician offices and can both receive and provide information about supply shipments, CDC guidelines, and vaccination strategies.

Our method of distributing a little vaccine to as many practitioners as possible could have massively increased the number of patients vaccinated before Thanksgiving, 2004. Regrettably, during this flu season, the distribution process was never clearly understood by distributors, doctors, or patients. State and local health departments worked with the CDC and Aventis to identify how much flu vaccine would be requested and how it would be distributed. Under this system, the only option for physicians was to contact the local public health officials and ask that an order be placed through the Secure Data Network ("SDN") established by the CDC.

Just before Thanksgiving, private distributors were brought into the allocation process to ship orders placed through the SDN. States came up with individual plans to distribute vaccine -- some purchased vaccine for distribution through public health clinics, some ordered the vaccine and passed along to the distributors the "orders" for vaccine. However, the "orders" really amounted only to "leads." By the time Schein and other distributors were able to make contact with these "leads," some were unclear about the ordering process, some cancelled, and others reduced their order. Distributors then communicated the cancellations or reductions in orders back to the CDC and the heads of the State Immunization Programs to get redirection orders. This process increased delays and confusion and placed an enormous burden on the state and local public health officials.

Unlike Schein which has a fleet of customer representatives who are in constant communication with physician offices, public health officials had to divert employees from other important tasks to handle logistics. The Washington Post reported two weeks ago on the issue of supply and demand in the flu shot market and quoted Greg Reed, program manager for the Maryland Center for Immunization, as fearful that doctors may avoid these hassles and "when it comes to flu season, they'll just tell their patients, 'Go to the health department'" -- a response that does not serve the patients and a level of demand that public health departments can't handle. Other articles have pictured public health officials carrying flu vaccine in Igloo coolers back to immunization sites -- not the most desirable cold-chain distribution system.

As we contemplate a potential vaccine shortage in the coming flu season, Schein asks that the government take advantage of the private healthcare distribution system's experience, communication infrastructure, and connection to the physician market to plan an effective public-private partnership for vaccine distribution. The government and private sector distributors each have important customers to serve. The country would be better off if we combine our resources to ensure that flu vaccine is most efficiently and effectively delivered where it is needed most.

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