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THE NATION'S FLU SHOT SHORTAGE: HOW IT HAPPENED AND WHERE WE GO FROM HERE?

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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FRIDAY, OCTOBER 8, 2004

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

The committee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Davis, Burton, Mica, Souder, Blackburn, Tiberi, Burgess, Waxman, Kanjorski, Cummings, Kucinich, Tierney, Watson, Van Hollen, Ruppersberger, Norton, Cooper, and McCollum.

Also present: Representative DeFazio.

Staff present: Melissa Wojciak, staff director; David Marin, deputy staff director; Keith Ausbrook, chief counsel; Ellen Brown, legislative director and senior policy counsel; Jennifer Savavian, chief counsel for oversight and investigations; Anne Marie Turner, counsel; Drew Crockett, deputy director of communications; John Cuaderes, senior professional staff member; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Robin Butler, financial administrator; Allyson Blandford, office manager; Corinne Zaccagnini, chief information officer; Todd Greenwood, staff assistant; Phil Barnett, minority staff director; Kristin Amerling, minority deputy chief counsel; Karen Lightfoot, minority communications director/senior policy advisor; Anna Laitin, minority communications and policy advisor; Sarah Despres and Rosalind Parker, minority counsels; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; and Jean Gosa and Teresa Coufal, minority assistant clerks.

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 recent developments in the U.S. influenza vaccine supply.

As many of you know, a major flu vaccine manufacturer announced on Tuesday it would be unable to deliver any of its flu vaccine to the United States. British regulators suspended the manufacture's license, and held up the doses destined for the United States because at least some of the supply was contaminated.

The loss of the Chiron flu vaccine poses a serious challenge to the U.S. vaccines supply for the upcoming flu season. Chiron was to export between 46 to 48 million flu shots this year to the United States, almost half of our Nation's supply.

The Department of Health and Human Services had planned for a vaccine supply of about 100 million doses this season, after a demand of about 87 million doses last flu season.

Today we will examine the contributing factors that led to the severe flu vaccine shortage, the public health implications of the vaccine shortage, and the U.S. Government and vaccine manufacturers plan to address this problem. Our government witnesses are here today to reassure and inform the public.

The public health implications of this development are potentially enormous. Every year approximately 36,000 die and 200,000 people are hospitalized due to complications from influenza. With a significant shortage of vaccines, the number of people who die from or are hospitalized for influenza could increase drastically this year.

The Center for Disease Control and Prevention issued interim recommendations for influenza vaccinations on October 5, 2004. They give priority for vaccination with Fluzone the primary vaccine that remains available to the high risk population.

And nasal spray is another alternative, but there will be, at most, 2 million doses ready for distribution this year. As a result of the shortage, millions of healthy people and even many in the high risk population will have to forego vaccination. We have been telling people for years now that the flu is not something to take lightly. It is no wonder that phones at hospitals, clinics, and doctor's offices have been ringing off the hook this week.

Vaccination clinics with shuttered doors do not inspire confidence or trust. People want to know how this happened. They want to know what it means for them and their families. They want to know how are we going to make sure that it doesn't happen again.

In the short term, coordination and cooperation between Federal, State and local public health providers will be crucial. It will be more important than ever to identify individuals who fall within the high risk population, and ensure that they receive priority.

We will collectively have to grapple with the public's understandable frustration and feelings of helplessness. Preparing for the annual flu season highlights the importance of strong cooperation between different health agencies and private sector companies at all levels.

However, this year's vaccine shortage starkly underscores the need to ensure that adequate production capabilities exist. We are not here today to point fingers, but we go into today's hearing already concluding that the current system is flawed.

In a committee hearing we held last February, witnesses discussed the possibility of a similar situation unfolding. The committee was concerned that Chiron did not have a manufacturing plant located within the United States. It was theorized that should a flu pandemic occur, the UK could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply.

With only a few vaccine manufacturers producing flu vaccines every year, we concluded then, and we reiterate today, we need to consider what can be done to strengthen the market and increase production capabilities.

The current vaccine shortage begs the question: Do we need new mechanisms, new incentives to guarantee that an adequate number

of safe and effective flu vaccines are produced and delivered annually?

Questions continue to mount, and hopefully today some will be answered. Why did both Chiron and U.S. officials anticipate that only 4 to 8 million doses would be lost? Why did they not know before Tuesday that a license suspension was possible? Are any of the Chiron doses salvageable?

Our witnesses today will discuss the factors contributing to the flu vaccine shortage, how the Government and vaccine manufacturers will respond to and manage this crisis, and the steps that must be taken to be prepared for next year's flu season.

I know we all share the same goal at the end of the day, a public health system prepared to deal with the annual influenza season. We have a great selection of witnesses today, and I would like to thank all of them for appearing before the committee, and I look forward to your testimony. I now yield to Mr. Waxman for an opening statement.

[The prepared statement of Chairman Tom Davis follows:]

Statement of Chairman Tom Davis
Committee on Government Reform Hearing
"The Nation's Flu Shot Shortage: How it Happened and Where We Go from Here"
October 8, 2004

Good morning. I want to welcome everyone to today's oversight hearing regarding recent developments in the U.S. influenza vaccine supply.

As many of you know, a major flu vaccine manufacturer announced on Tuesday it would be unable to deliver any of its flu vaccine to the U.S. British regulators suspended the manufacturer's license and held up the doses destined for the United States because at least some of the supply was contaminated.

The loss of the Chiron flu vaccine poses a serious challenge to the U.S. vaccine supply for the upcoming flu season. Chiron was to export between 46-48 million flu shots this year to the United States, almost half of our nation's supply. The Department of Health and Human Services (HHS) had planned for a vaccine supply of about 100 million doses this season, after a demand of about 87 million doses last flu season.

Today we will examine the contributing factors that led to the severe flu vaccine shortage, the public health implications of the vaccine shortage, and the U.S. government and vaccine manufacture's plan to address this problem. Our government witnesses are here today to reassure and inform the public.

The public health implications of this development are potentially enormous. Every year approximately 36,000 people die and 200,000 people are hospitalized due to complications from influenza. With a significant shortage of vaccines, the number of people who die from or are hospitalized for influenza could increase drastically this year. The Centers for Disease Control and Prevention (CDC) issued interim recommendations for influenza vaccination on October 5, 2004. They give priority for vaccination with Fluzone—the primary vaccine that remains available—to the "high-risk" population. A nasal spray is another alternative, but there will be at most 2 million doses ready for distribution this year.

As a result of the shortage, millions of healthy people and even many in the high-risk population will have to forego vaccination. We've been telling people for years now that the flu is not something to take lightly. It's no wonder phones at hospitals, clinics and doctors' offices have been ringing off the hook this week. Vaccination clinics with shuttered doors do not inspire confidence or trust. People want to know how this happened. They want to know what it means for them and their families. They want to know how we're going to make sure it doesn't happen again.

In the short term, coordination and cooperation between federal, state and local public health providers will be crucial. It will be more important than ever to identify individuals who fall within the high-risk population and ensure they receive priority. We

will collectively have to grapple with the public's understandable frustration and feelings of helplessness.

Preparing for the annual flu season highlights the importance of strong cooperation between different health agencies and private sector companies at all levels. However, this year's vaccine shortage starkly underscores the need to ensure that adequate production capabilities exist. We are not here today to point fingers. But we go into today's hearing already concluding that the current system is fatally flawed.

At a Committee hearing we held last February, witnesses discussed the possibility of a similar situation unfolding. The Committee was concerned that Chiron did not have a manufacturing plant located within the U.S. It was theorized that, should a flu pandemic occur, the UK could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply. With only a few vaccine manufacturers producing flu vaccines each year, we concluded then, and we reiterate today: we need to consider what can be done to strengthen the market and increase production capabilities.

The current vaccine shortage begs the question: Do we need new mechanisms, new incentives, to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually?

Questions continue to mount, and hopefully today some will be answered. Why did both Chiron and U.S. officials anticipate that only 4 to 8 million doses would be lost? Why did they not know before Tuesday that a license suspension was possible? Are any of the Chiron doses salvageable?

Our witnesses today will also discuss the factors contributing to the flu vaccine shortage, how the government and vaccine manufacturers will respond to and manage this crisis, and the steps that must be taken to be prepared for next year's flu season. I look forward to a constructive dialogue on this matter. I know we all share the same goal at the end of the day— a public health system prepared to deal with the annual influenza season.

Mr. WAXMAN. Thank you.

Chairman TOM DAVIS. Let me just start—I know Mr. DeFazio is here from another committee. I would ask unanimous consent that he would be allowed to participate. Without objection, so ordered.

Mr. WAXMAN. Well, thank you, Chairman Davis, for calling this hearing on a critical flu vaccine shortage facing the United States. Three days ago, one of the two major companies providing vaccines in this country announced it would not ship any flu vaccines this year.

Just weeks before the start of the flu season, it appears we have lost half of our vaccine supply. As a result, an estimated 40 million Americans who would otherwise have been protected against the flu will not. One key question is how this all could have happened?

In late August, the flu vaccine manufacturer, Chiron, which has a manufacturing facility in Great Britain announced that there were potential contamination problems with several million doses of the vaccine. The company began working with the Food and Drug Administration and British regulators to identify the problem, and to ensure the safety of the remaining lot of vaccines.

While the company was assuring the public that the problem was under control, and while FDA was reviewing the company's investigation, British regulators sent a team of inspectors that shut the plant down.

The British Government immediately announced that it had already purchased a back-up supply of vaccine, it nearly completely offset its reliance on Chiron. In the United States, public health officials appeared to have been taken completely by surprise. After the public announcement, senior FDA officials flew to Britain to determine whether any of Chiron's vaccines could be usable this year.

A second key question is, what can be done to ensure that the highest risk individuals are vaccinated? The CDC responded instantly to the crisis by issuing new flu vaccine recommendations with priorities for vaccination. But following those recommendations will be an enormous challenge. Some hospitals, clinics, doctors offices and State public health departments are scheduled to receive their full order from Aventis, the only major flu vaccine supplier left this year.

Other hospitals, clinics, doctors offices, and public health departments are left entirely without the vaccine. It is important to discuss what role the public sector can play in overcoming these disparities. While this hearing will, by necessity, focus on the current situation, I hope we can also find time to discuss a third key question, how can we shore up our fragile public health care system?

For 5 years we have seen a series of experts reports calling attention to major deficits in vaccine supply for both children and adults. In February, our committee heard testimony about the urgent need to improve flu vaccine supply and planning. And just last week, the Government Accountability Office testified before the Senate that "there is no mechanism in place to ensure distribution of flu vaccine to high risk individuals before others when the vaccines is in short supply."

This raises the question of what more can be done to better prepare for possible vaccine delays and shortages in the future? It is long past time for Congress to pay attention to these calls for ac-

tion. In May, Chairman Davis and I asked the Appropriations Committee to restore cuts and enhance public health funding in the President's budget. Even this minimal request was not granted.

I am very pleased that our Nation's leading public health officials and other distinguished witnesses have taken the time to testify this morning. We are all indebted to your efforts and eager to hear your testimony. Thank you.

Chairman TOM DAVIS. Thank you very much.

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

Statement of
Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
"The Nation's Flu Shot Shortage: How it Happened and Where We go from Here"

October 8, 2004

Thank you, Chairman Davis, for calling this hearing on the critical flu vaccine shortage facing the United States.

Three days ago, one of the two major companies providing vaccines to the United States announced it would not ship any flu vaccine this year. Just weeks before the start of flu season, it appears we have lost half of our vaccine supply. As a result, an estimated 40 million Americans who would otherwise have been protected against the flu now will not.

One key question is how this all could have happened. In late August, the flu vaccine manufacturer Chiron, which has a manufacturing facility in Great Britain, announced that there were potential contamination problems with several million doses. The company began working with the Food and Drug Administration and British regulators to identify the problem and to ensure the safety of remaining lots of the vaccine.

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I am very pleased that our nation's leading public health officials and other distinguished witnesses have taken the time to testify this morning. We are all indebted to your efforts and eager to hear your testimony.

Chairman TOM DAVIS. Any other opening statements?

Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman. I have taken a personal interest in this since I came to Congress. It is nice to talk about some of the effects of, say, vaccine or vaccination that went bad. My uncle, who has passed away, probably partly from a broken heart, he had two children who were vaccinated and they had adverse reaction.

And both of them went into convulsions. And at the time they didn't know, but both of them were brain damaged. Both of them are still alive, but they require constant care, and none of them have lived normal lives. So it is something that our family has dealt with. My brother, when he came to Congress, Dan Mica, worked on the Vaccine Compensation Fund, I think, with Mr. Waxman and Mr. Burton and others who were here.

And I took an interest and have tried several times to amend the fund so that it would be more effective. And, unfortunately, some folks walked away from revising that. But, how did we get here, with the United States basically relying on vaccines, flu vaccines and other vaccines, to other country's manufacturing?

The number of vaccine manufacturers in the United States has dropped from 20 to only 3 in the past 15 years, largely as a result of lawsuits filed on behalf of supposed victims. Now, everyone has—can have an adverse reaction. I have some of my pills here that I take. Some people actually can have an adverse reaction to aspirin. And some people actually can die from these, and do die from these.

But, one of the major problems is that we haven't dealt with the liability question. So we forced the manufacturer overseas or some place else for the large part. You know, they blame the insurance industry, but the insurance industry won't even cover liability in these cases. We blame the drug manufacturers. And they won't manufacture here. Doesn't somebody get it?

Go on the Web and look at—try to get a little information on vaccines. Pull up the Web. And this is offensive. The first thing that comes up is a law firm, vaccine injury. Sue. Sue. Sue. So what the hell do you get? Nothing.

So we have senior citizens and others put at risk, young and others, because this Congress and others won't change the law. I will tell you, it really—it is really sad that—and if it was just medicine, we are outsourcing the whole production of manufacturing. I come from the business sector. Most of the business people here in Congress don't have a clue as to how business operates. But it actually operates by making a profit and being able to exist without lawsuits, overly regulated and without oppressive taxation.

So we have run them all off, whether it is—you know, we don't even produce any ladders in the United States. Vaccines and ladders. Why? Because of the field day we have created for trial attorneys. So I am pretty bitter about it. This should have been changed a long time ago. We should have changed the liability laws, and we should have changed the vaccine compensation fund so that it works, and it does provide compensation.

Mr. Chairman, I yield back the balance of my time.

Chairman TOM DAVIS. Thank you. Any other Members wish to make opening statements.

Ms. Watson.

Ms. WATSON. Thank you, Mr. Chairman, for conveying this hearing so quickly. This is a very disturbing development. And it is very essential to have sufficient doses of flu vaccine available for millions of Americans that are at risk for complications due to the flu.

The number of anticipated doses falls far short of the CDC's goal of vaccinating at least 85 million people this year. The CDC guidelines to ration the vaccine to high risk adults, children between 6 and 23 months of age, health care workers and the elderly is an appropriate response.

I have concerns about what this means for our national bioterror response system. Yes, I know it is somewhat of a separate issue, but it can get—or we can get so caught off guard with distributing flu vaccines, and are we at risk for similar problems with emergency distributions of antibiotics or vaccines, or anthrax or small pox? I hope the witnesses can address this point.

In dealing with this crisis, we must make sure mercury, listed as Thimerasol in vaccines is removed from the dosages of young children. On September 28, 2004, our Governor in California, Governor Arnold Schwarzenegger signed a bill sharply restrict the mercury content in vaccines for women and babies.

Mercury is a known neurotoxic substance. Mercury inhibits brain function among other detrimental effects. Children between the ages of 6 and 23 months should not be subject to a substance that we would close down and—that we would close down a high school for 1 week after spilling a few of the grams.

Manufacturers in the last few years have voluntarily eliminated Thimerosal or reduced it to trace elements. The only exception is Aventis Pasteur, who is the sole supplier of flu innoculations for children under 2 years old. Vaccination is an important health policy for our society. And we have the ability to vaccinate without mercury used as a preservative.

In signing the message, Governor Schwarzenegger noted that the U.S. Food and Drug Administration and the American Academy of Pediatrics recommended the removal of Thimerosal from childhood vaccines in 1999. So we have a combination of issues here, Mr. Chairman, and we must get to the bottom.

I feel that here in our own country, we must support the research on inoculations and vaccinations and the elements that make these potent medicines, and we must see, as a policy body, that we contribute the necessary resources so that we can develop our own vaccinations without the harmful ingredients that we feel are present at the current time. Thank you so much.

Chairman TOM DAVIS. Ms. Watson, thank you very much.

Dr. Burgess, did you have any comment.

Mr. BURGESS. Thank you, Mr. Chairman. I will be very brief, because I do want to hear what our witnesses have to say this morning. And I do thank you for conveying this hearing. I thank the witnesses for coming together so quickly.

Mr. Mica made the plea about reforming liability as it reflects our vaccine manufacture in this country, and I just couldn't agree

more. I think his point was extremely important. We forget in this country, the success of vaccine preventable disease. We don't see diseases any longer that in my father's and grandfather's generation used to affect hundreds of thousands of children and adults in this country.

When I graduated from medical school in 1977, the year before, we all gathered around a hospital room in Houston because there was a child with diphtheria, and no one had seen diphtheria for so long, and everyone wanted to make sure that this class of medical students at least saw one case of diphtheria before they graduated.

It is a tremendous success story that you all have, and a story that is not often told. We get distracted by words such as outsourcing and Thimerosal. I urge this panel, though, to come to some conclusion about what we can do to alert the liability structure in this country so that we are not driving these manufacturing jobs offshore, and so that we are not tarnishing the good reputation that what vaccines have done for this country and what life—how much better life is without vaccine preventible diseases in our midst.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much. Any other Members wish to make opening statements? Ms. Norton.

Ms. NORTON. First, Mr. Chairman, I know we are near the end of this term, but I want to thank you and commend you for not letting us go home without looking into this matter, because I think all over the country there is a serious concern about—we see it in our own region, the region you and I live in, about entire parts of the region whose supply comes from this particular provider, and therefore who have no supply.

First, I want to say it is—I regard this as kind of a test or trial run. Ms. Watson spoke about bioterrorism. It ought to tell us that the failure to have a back-up plan for vaccines or medicines that can mean the lives of the American people simply must be allowed to happen again. It seems to me that it is much more serious when it happens with regard to the flu vaccine, because it is more likely that flu will take tens of thousands of lives whereas a bioterrorism attack would probably be contained maybe even to a small facility, who knows?

So I certainly hope this is a shot across our bow. For years there have been difficulties of one kind or the other with respect to the flu vaccine. I simply want to raise two points. One is the point of science. I look at the science. I will be interested to know when—how what we have done in the development of this science, where we identify the virus, apparently it has to be identified pretty late, here it was identified in the late winter or early spring.

But then we grow the strains in chicken eggs. The first thing that occurs to a nonscientist to me is by now shouldn't we have some alternative environment that allows us to grow the strains more quickly, especially this country, which has done, I must say, things that seem to me to be far more miraculous than what I have just asked.

Second, the notion of such a major provider, such a major provider of an insensible vaccine being offshore. Now, if there are li-

ability concerns, we need to bring those out. I think there may be other concerns as well.

But, there has been a lot of talk about jobs offshore, or outsourcing, the economic concerns that outsourcing raises. But, there has been almost no concern, no talk about what happens when you outsource a major medicine or vaccine that is indispensable to the American people. And I think that this crisis forces us to face it.

We raise it at the end of the session. I think it gives us time to follow it through and see whether we have made any movement as the new session begins. A third concern is how in the world this plant, this operation, passed FDA inspection in 2003, and yet the British have to shut down the place. I don't understand the difference between the regulators in both places. And my fourth concern is apparently the total absence of a back-up plan. Everybody knows that tens of thousands of people will die without the vaccine.

Everybody knows that half the supply was offshore, and here we are sitting here wondering what are we going to do with no backup plan? This is inexcusable and I think we have to begin to bring forward something that, one, gives us an explanation, and two gives us a road map to a solution in the future.

Chairman TOM DAVIS. Thank you. Any other Members wish to make opening statements? We will proceed then to our panel. I am very pleased to have a distinguished panel. We have Dr. Julie Gerberding, the Director of the CDC. Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases, and Dr. Lester Crawford, Acting Commissioner of the Food and Drug Administration here to discuss efforts being taken at the Federal level to respond to the flu vaccine shortage.

They will also describe coordination efforts with State and local authorities to manage this crisis. As you know, it is our committee's policy that we swear you in. So if you just rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you very much. I think you know the rules. There will be a light on in front of you. It will be green when you start. When it turns orange that means you are at the 4 minute mark. Red, it is your 5 minute mark.

We want you to make sure you say everything you want to say, but your entire written testimony is in the record, and we have read that and the questions will be based on that.

So we are just very pleased and honored that you could make time to be here with us today. This is an important and serious crisis. And we know you are working on it.

Dr. Gerberding, we will start with you. And thanks for being with us.

STATEMENTS OF DR. JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; AND DR. LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. GERBERDING. Thank you, Chairman Davis, Mr. Waxman, and the committee. We are very happy to be here to give you an update on the current flu situation.

On Tuesday morning, I was unhappily awakened by the CEO of Chiron to notify me that we were losing 50 percent of our flu supply this year, just as I was preparing to testify in front of a different House committee. So this has been certainly the top challenge that the CDC is facing this week.

While we were disappointed to learn this news, we were not entirely unprepared. We have been concerned about vaccine shortages for years. We knew in August that there may be a delay in shipping some doses from this manufacturer, and we are looking at avian influenza throughout Western Asia.

So the Department has been aggressive in developing the pandemic flu plan. Secretary Thompson and the administration requested for fiscal years 2004 and 2005 $100 million to expand our vaccine supply capability and modernize our vaccine supply capability, Congress provided $50 million this year, and we hope you will support the full $100 million in fiscal year 2005.

We also have initiated, for the first time ever, a stockpile for flu vaccines for children. We have 2½ million doses in that stockpile. We are procuring at least 2 million more doses from Aventis. We also have a stockpile of antiviral treatment, and are hoping to expand that stockpile eminently.

Within hours of the announcement, the Secretary conferred with all of the vaccine manufacturer CEOs, and the Secretary announced the new recommendations from the immunization advisory committee. These advisory recommendations had actually been developed by the CDC as a back-up plan for vaccine preparedness when we learned that we may have a shortage this year. So we had undertaken a contingency planning effort at the CDC just in case we ended up in this situation.

Within hours, we also had a press conference, we communicated to our health alert system to more than 90,000 clinicians and 88 partner organizations who resubmitted the information to their membership, so we were able to reach hundred of thousands of clinicians in just a matter of minutes, in part because of the investments bioterrorism preparedness.

Within the first 48 hours, the FDA was dispatched to the UK, as you have already mentioned. We have had several more press briefings, conducted media tours, stood up our clinician hotline and done everything we can to try to communicate the priorities for immunization under this new constraint supply situation.

Let me just describe the next steps that we will be taking. First and foremost, we will continue our traditional efforts to monitor flu activity in the United States, so that we know where the hot spots are emerging and we can use that as part of our prioritization efforts. In addition, we are working with the State and local health

officers through ASHTO and NASHO to assess the current supply of vaccine in individual counties as well as the estimated demand for vaccines in those counties.

Third, I am working with my colleagues at the CDC and the Department with the CEO of Aventis Pasteur to develop a distribution plan for the doses of vaccine that have not yet been distributed. I must say that we have had absolutely extraordinary cooperation from Aventis Pasteur as well as Chiron, who has let us know who their high priority recipients are, the people that they had contracted with who were serving the highest priority populations.

Unfortunately, for the flu vaccine, the government only procures about 10 percent of the total supply, so we have very little independent capacity to modify distribution, and this voluntary effort is something that we are very grateful for.

We are also, as I mentioned, taking steps to expand the stockpile, and also to expand our capacity to treat and prophalax people with antiretroviral—with antiviral therapy. And, finally, we are asking Americans and clinicians across the country to collaborate with us in this effort. This is really a tough time. There are going to be many frustrated people. Not all people who need flu vaccines are going to be able to get it.

And we are going to have to work together to do the very best we can to match the supply that we do have with the demand among the people who are the most vulnerable to the serious complications of flu.

And I really thank you, but I also hope that this committee and Congress would regard this as a call to action. The situation has gone on far too long. We continue to have a completely fragile vaccine production capability in this country, and it is getting more and more fragile every year. So we need to work together in a bipartisan way with the administration and Congress and really take the appropriate steps to protect all Americans who are at risk for vaccine preventable diseases. Thank you.

Chairman TOM DAVIS. Thank you very much.

Dr. Fauci.

Dr. FAUCI. Thank you, Mr. Chairman, for calling this hearing. And, Mr. Chairman, members of the committee, thank you for giving me the opportunity to testify before you today. I am going to spend a few minutes talking about the role of the research component of the Department of Health and Human Services, in this case the NIH, in the vaccine development process, but also in addressing some of the problematic issues that we face today with the recent events that have occurred over the past couple of days.

If you look over at these posters, this is just a schematic diagram of the role of the research endeavor in influenza vaccine development. All of the way to the left is where the academic and NIH community generally concentrates their effort in concept development and early basic research that feeds into and informs the production and development of vaccines that are done in very strong partnership with industry.

So of all of the endeavors that we engage upon, industry, academic, and government collaboration is not only important, it is essential to the ultimate endeavor. So what I am going to talk about

is some of the research endeavors that have occurred and how hopefully this will help us getting to where we want to go.

To give you an idea of the depth of the commitment to vaccine research, this is the budget of my institute, the Infectious Diseases Institute, which in 2004 was $4.3 billion. As can you see, a full 27 percent of all of our resources are directed at vaccine research to the tune of about $1.2 billion. What do we do with that? This poster designates schematically some of the issues that we address directly. We do a bit, a little bit of surveillance in epidemiology. The bulk of this is done extraordinarily well by the CDC.

We fundamentally concentrate on basic research, and the research capacity, to allow us to get to the end game of where we are going, which in this case is diagnostics, therapeutics and vaccines. Just a moment on therapeutics, because we are not specifically talking about that at this hearing, but it is an important component of the armamentarium, the development of new and better drugs to be used as antivirals in influenza.

But the question that was asked by at least a couple of Members of the question, particularly Ms. Norton when she asked about what we can do about going from the antiquated techniques that we have, there are two among several, but two very important components in vaccine development. One of them is isolating the virus that you are going to be dealing with, providing a seed virus for a pilot lot to start the production.

That was generally done in a way that was reliable, but in some respects unpredictable. If you look at the blue virus, that is a tried and true virus that we use all of the time in developing vaccines. If this were the virus in question, that we were looking to make a vaccine against, you put these together, and you hope that over a period of time, weeks or possibly months, but hopefully weeks, it would reassort and recombine to give you the genes expressed of what you want in this one with the other genes here.

New techniques developed by NIH grantees called reverse genetics allows us now to take the unpredictability out of this, by genetic manipulation, taking the genes directly from one of these viruses, and taking the genes directly here, put them a carrier component called a plasmid, and directly inserting them into the cell line that you want to make that seed virus in.

That is one thing that will take away some of the unpredictability. Importantly, the production has relied, and I think with good results over the years, on egg-based culture systems to grow the virus to make the vaccine. The difficulty with that is that it takes a lot of startup time. Chickens to eggs, eggs are there, you inject the virus in, you make it grow. And it really is cyclic. It is not something that generally grows year round.

We need to gradually move away from that, improve the efficiency of a cell-based culture in which you have more direct control over. If we had that as the major component of influenza, we would have much more flexibility, speed and dependability.

In fact, on this next slide, this shows the potential advantages of where we want to go with cell culture-based influenza vaccine. It is faster production, it allows a rapid response to the discovery of new and evolving flu strains. It requires less manufacturing space, and this is important, it circumvents possible problems that

are presented by highly virulent flu strains such as those that are lethal to chicken embryos and it is tolerated by people with egg allergies.

And on this final poster, it shows what we have been doing in the enormous increase over the past couple of years in our influenza research funding, particularly gauged not only at the possibility of the evolution of pandemic flu, but also understanding, as we have heard Dr. Berberding allude to, the fragility of the system that we and many components of the Department would like to address.

And hopefully the research component of this will contribute to the speed, the flexibility and the dependability of the process of influenza vaccine development, to allow us to respond better and to anticipate problems such as we are facing today. Thank you, Mr. Chairman.

[The information referred to follows:]

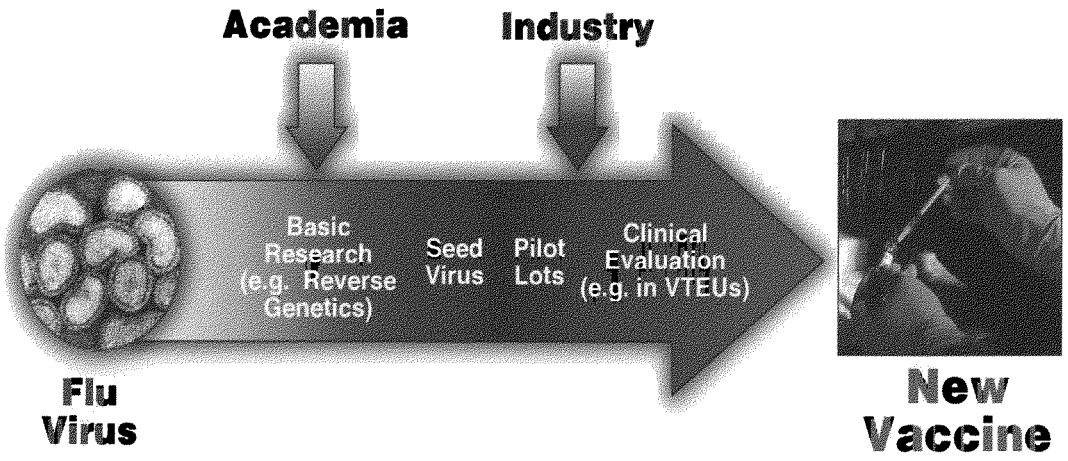
The NIH Biomedical Research Response to Influenza

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services

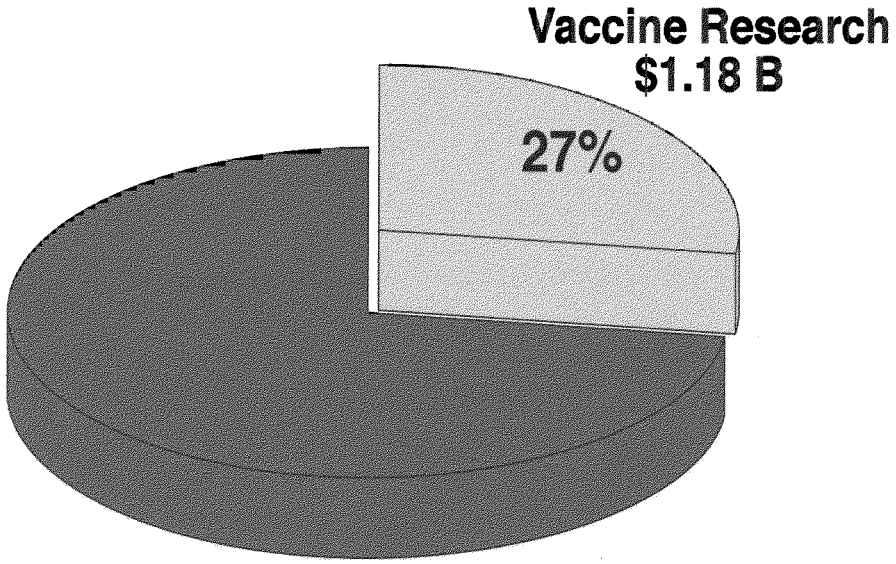
October 8, 2004

House Committee on Government Reform

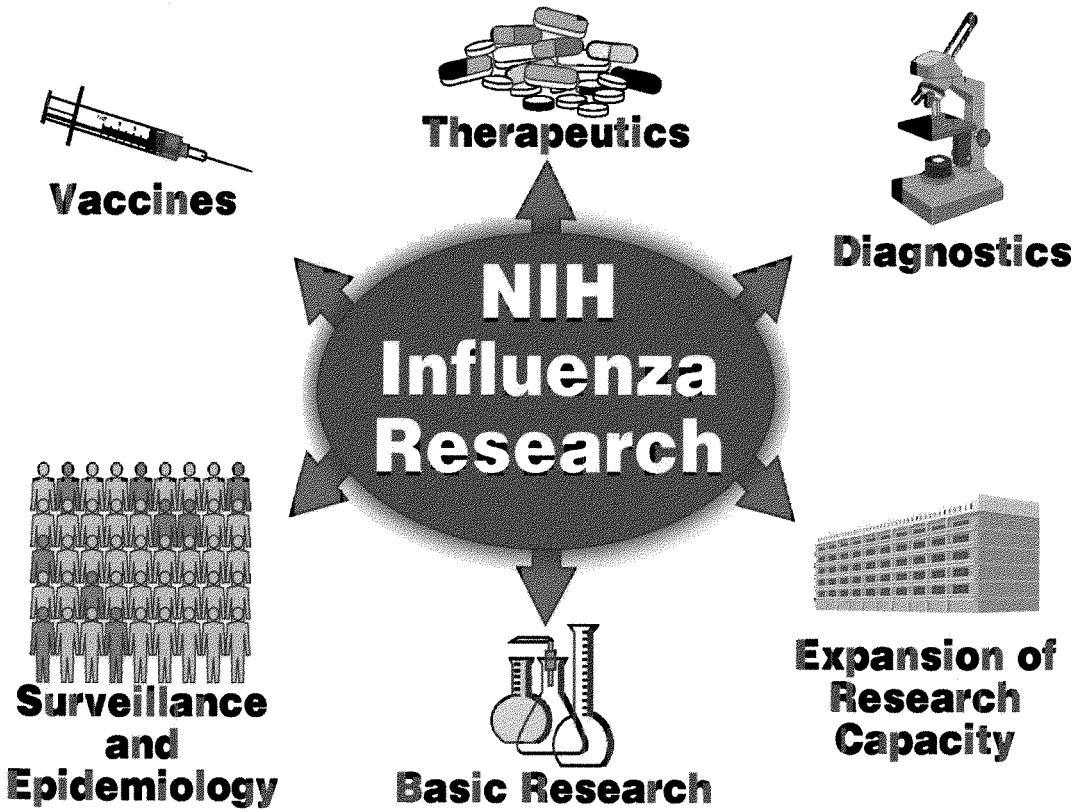
NIH Role in Influenza Vaccine Development



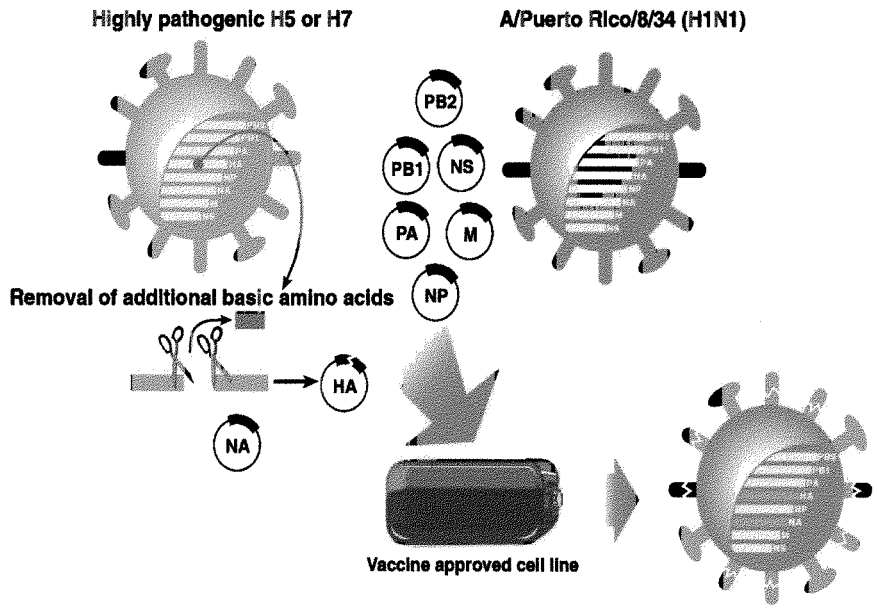
NIAID FY 2004 Budget



FY 2004 NIAID Budget
$4.30 B

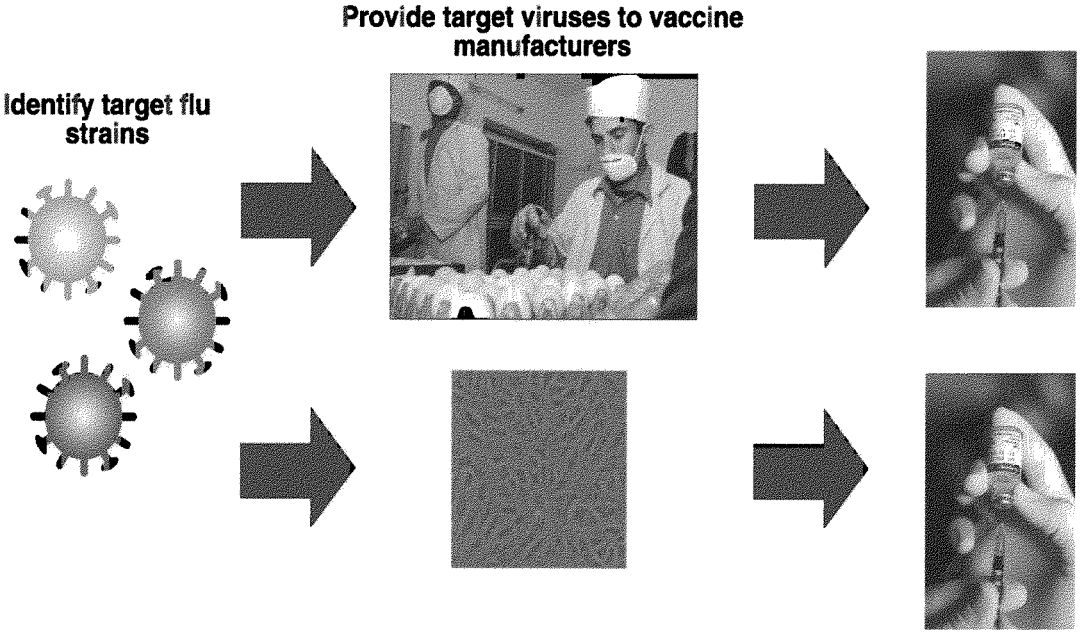

NIH
Influenza
Research
Therapeutics
Diagnostics
Vaccines
Surveillance
and
Epidemiology
Basic Research
Expansion of
Research
Capacity

Influenza Vaccine Seed Virus Production Using a Reverse Genetics System



Source: Webster et al: *Vaccine* 20:3165 (2002); Science 302:1519 (2003)

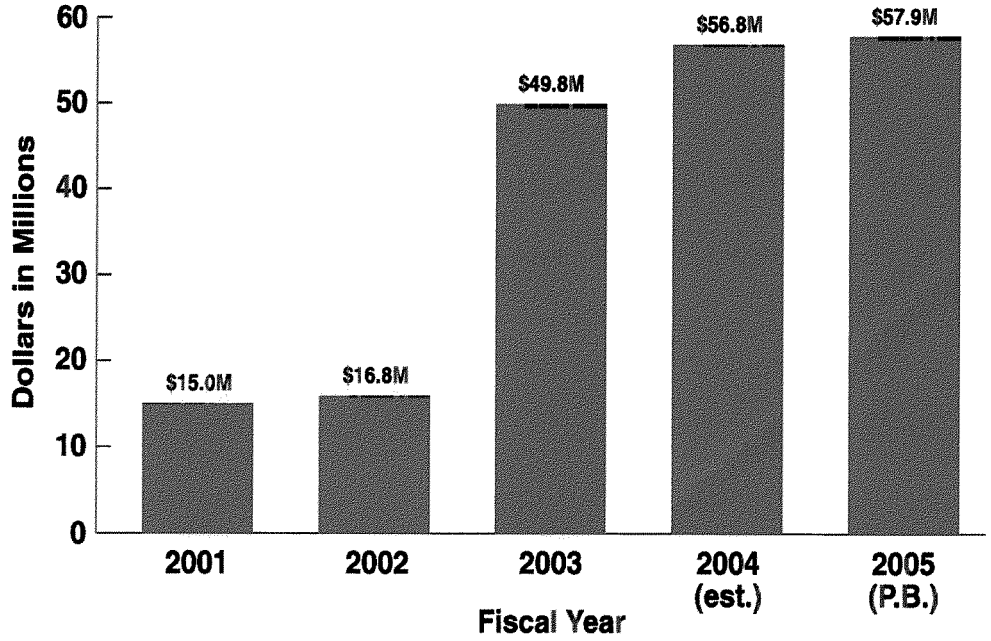
Influenza Vaccine Production: Cell Culture as an Alternative to Chicken Eggs



Potential Advantages of Cell Culture-Based Influenza Vaccines

- Supports faster vaccine production than egg-based vaccines
- Allows rapid response to discovery of new and evolving flu strains
- Requires less manufacturing space
- Circumvents possible problems presented by highly virulent flu strains (i.e., lethality to chicken embryos)
- Tolerated by people with egg allergies

NIAID Influenza Research Funding



Chairman TOM DAVIS. Thank you very much.

Dr. Crawford.

Dr. CRAWFORD. Thank you very much, Mr. Chairman. I want to assure the members of the committee and the American public that the FDA is very serious about its vaccine safety responsibilities.

Influenza vaccine is unique in that the active vaccine ingredients change almost every year, which as a result, present new manufacturing challenges. These viruses are continually evolving or mutating, and the recommendations for which viruses to include in the vaccine are based on the surveillance data provided from laboratories worldwide.

Early each year, public health experts evaluate the data to determine the strains of virus to include in the influenza virus vaccine administered in the fall. For this reason, it is impossible to stockpile influenza vaccine for use in future years, when there may be a shortage due to manufacturing issues.

The FDA works closely with manufacturers to facilitate the rapid production of influenza vaccine each year. As soon as the strains are recommended, manufacturers begin to grow the virus strains in fertile hen's eggs. These seed strains used by each manufacturer are tested by FDA's Center for Biologics Evaluation and Research [CBER], to ensure that they are the same as the recommended strains and to assure the safety and effectiveness of the vaccines.

Then, manufacturers submit the results of their testing along with sample vials from each lot for lot release by CBER. Lot release consists of a review by CBER of the manufacturer's test results for each bulk lot of the vaccine.

Finally, manufacturers and CBER perform additional testing prior to distribution to assure the safety and efficacy of these products. FDA inspected Chiron's manufacturing facility in 1999, 2001, and 2003. As is the case with most FDA inspections, FDA investigators identified compliance issues at each inspection.

Chiron's corrective measures in response to these deficiencies were reviewed by FDA and found to be adequate. On August 25, 2004, the company informed FDA that they had discovered bacterial contamination in eight lots of the final vaccine product, and that Chiron was thoroughly investigating the problem. Chiron was holding all vaccine lots during its investigation, and did not release any of the product.

Throughout September, FDA, CDC and Chiron had weekly conference calls to discuss the status of the investigation. Chiron informed the FDA that they had identified the cause of the contamination, and it was limited to specific lots.

The company indicated to FDA that there was no evidence that any other lots were affected. But, nonetheless, they were retesting all final lots. Chiron later informed FDA that results of the testing were negative. The company indicated that they were going to submit their final report on the investigation this week, and a call was scheduled for Tuesday.

The FDA had no knowledge of the British decision to suspend the firm's UK license to manufacture flu vaccine prior to being informed by the relevant agency from the UK this week.

Dr. Jessie Goodwin, director of CBER and a team of senior scientific and compliance officials, met with FDA's counterpart yester-

day in the UK to gain further understanding of their action. Today, they are meeting with Chiron officials onsite in England and will begin an inspection of the company's manufacturing facility over the weekend. During that inspection they will be joined by two senior inspection officials from the UK.

Clearly, the loss of this vaccine poses a serious challenge. However, it is important to remember that we have faced influenza shortages in the past. We work with our HHS colleagues, health officials and manufacturers on how to best use the limited supply. For example, Aventis Pasteur has indicated to the FDA that they will provide an additional 1 million doses, increasing their total number of available doses to 55.4 million.

Nonetheless, this is still well below last year's supply of 87 million doses. We are encouraging people to take advantage of the MedImmune FluMist vaccine. FluMist is 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 vaccine guidelines.

MedImmune anticipates having 1 to 2 million doses of FluMist available this year. Now, in the future, we must create more efficient ways to produce flu vaccine so we can better deal with shortages or unexpected problems.

Each of the past two budgets, the Department has requested $100 million to shift vaccine development to new cell-culture technologies, as well as to provide for year-round availability of eggs for egg-based vaccines. We received 50 million in the fiscal year 2004 budget for this activity, and urge Congress to fully fund $100 million request in the fiscal year 2005 budget.

FDA has also been investing its energy and resources in important initiatives such as the current good manufacturing practices for the 21st century, known as the CGMP Initiative, and the Critical Path Initiative.

These activities will also help increase the availability of vaccines and other medical products. It is imperative that we invest in the more efficient, reliable and modern method for producing influenza vaccines. With adequate supply and widespread immunization, the morbidity and mortality from influenza can be markedly reduced. Once again, I thank you for having me here today. I look forward to the rest of the hearing.

Chairman TOM DAVIS. Well, thank you all very much. We may be expecting votes in the 11 o'clock timeframe, which gives us about 25 minutes, about 5 rounds here. I am going start, Dr. Gerberding.

Virginia, Maryland and the District of Columbia were all heavily dependent on Chiron to supply vaccines for the public sector. Is the CDC exploring the option of acquiring the undelivered Aventis Fluzone doses, which I think is about 20 million, and then distributing it to States that contracted solely with Chiron?

Dr. GERBERDING. Thank you. The CDC is working with Aventis to look at the undistributed doses of vaccine. Of those, certain doses are considered to be very high priority, for example, those needed for force protection or for populations that we know are extremely high risk, and so Aventis will be certainly honoring their contracts in that regard.

A small number of doses have not been sold. CDC is hoping to purchase those. We will work with Aventis to ensure that they are used in the highest priority areas. Then there are doses in the middle, some of which go to high priority populations such as nursing homes. We are also working with Chiron, because we have gotten the information about where the unmet high priority contacts are.

Right now, it appears that we will be able to honor all public sector requests for vaccine purchase. I don't want to commit to that today, but it looks very promising. And we will be announcing the overall supply plan soon, after we are sure that we have accounted for the parts of the geographic distribution that are most vulnerable right now.

This is not going to be perfect. And we are still going to have to rely on prioritization. When we issued the guidelines this week, we were very careful to refer to them as interim guidelines, knowing as we got more information about where the demand is, where the supply is, and where the flu is, we may have to even make those recommendations more or less stringent.

Chairman TOM DAVIS. The priorities right now, would be as you would rank them. Seniors? HIV?

Dr. GERBERDING. People who are 65 years of age and older, are at the very highest risk for hospitalization and death due to flu. So they are the highest priority. Children between the ages of 6 months and 23 months are also a high priority, because they have a disproportionate hospitalization rate, and are at some risk of death.

Anybody with an underlying medical condition is at risk, so they are included in the prioritization risk. And then there are people who are caretakers of individuals in those other groups. So because they might spread flu to somebody else, they are included in the priority list right now.

Most of those people are well, and some of them certainly could qualify for FluMist. So we would like to emphasize the comment about using FluMist for those people who are otherwise healthy and between the ages of 5 and 49.

Chairman TOM DAVIS. Dr. Fauci, I have heard someone suggest that, because of the shortage, the possibility of diluting the vaccine doses in order to double the supply. Is that a possibility, or would there be a need or clinical trials beforehand?

Dr. FAUCI. Well, that is based on a study that was performed through NIH funding at six institutions throughout the country from the 2000–2001 vaccine trivalent vaccine. What it did was look at 1,000 individuals and give half of them a half a dose and the other half a full dose. And it was found that although the full dose gave more of a measurable response that you would correlate with protection, there was not substantial different, suggesting that in time of dire need, you might be able to do that.

These data are available. The NIH, as of a couple of days ago, submitted it to the FDA, and it is something that at least needs to be considered. There is certainly no decision or no promise that we can be able to do that. But, depending upon how things unfold, it is something that we will at least have on the table to look at.

And this importantly could only be used in individuals who are the healthy adults, because the study was done in that group of individuals.

Chairman TOM DAVIS. Dr. Crawford, I understand FDA currently has a team of scientists and researchers in Liverpool meeting with Chiron. We appreciate your proactivity there. Do you think any of the Chiron Fluviron doses are salvageable? And legally what can you do, because I understand there are already some doses in the United States?

Dr. CRAWFORD. It is not possible to say if any of them are salvageable at this point. The inspection of the facility itself and the examinations that would be attendant upon that sort of conclusion will begin tomorrow.

The meetings with the Chiron officials are going well, as they did with the MHRA people yesterday. But, I have to present to you a pessimistic point of view of whether or not we can clear any of these. As you know they are contaminated with a bacterium, in the gram negative range, and it is not clear to me whether or not we can or not. I would like to be able to say that there is some optimism. There is the possibility that we will consider this on a risk-based evaluation.

Chairman TOM DAVIS. My time is up, but just before I ask—I want to just ask one last question. What steps are we taking with Chiron to make sure that they are going to be able to produce vaccines next year? Because right now they are under suspension.

Dr. CRAWFORD. Yes. We are meeting with the MHRA, and they have pledged to work with us. That is the regulatory counterpart in the UK. And so I think together they are on the ground, and we are also on the ground. And I think we can work with them to bring them forward.

Frankly, we will have to provide some technical service, as we often do, to vaccine manufacturers. And I would be optimistic about that prospect. What I am concerned about, is that these kinds of events often result in a further consolidation of the industry, the lack of competition in that industry is something that we have testified about before. But that worries me a great deal.

Chairman TOM DAVIS. Thank you.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. Evidently in August, we had some idea that there was a contamination possible to the supply from Chiron that was the vaccine that was being produced in Great Britain. And the British knew about it. And they went out and made arrangements immediately to make sure they had a full supply for their needs.

Obviously their needs are less than ours, and, second, they have other companies they can go to other than the two that we have to rely on.

Dr. Gerberding, our system is so fragile, and contingency planning is so important. What happened in August when you first heard about the possible shortage? What actions did CDC take?

Dr. GERBERDING. The initial contingency plan was to assume the worse case scenario, that we wouldn't get vaccine from Chiron, and then identify what is the most restricted number of people who must get vaccines. And that is about 50 million people, based not

only on the numbers in the high risk groups but also on patterns of requests for vaccination that we have observed in previous years.

So, for example, in 2002, through our national health interview survey, we recognized that of the people who should have been receiving vaccines, what proportion actually were vaccinated. And we could extrapolate that into the current year, and make a guess at how many people were likely to request vaccines if these patterns held up.

That was about 50 million people, give or take several million, depending on the demand and the severity of the flu season. So that was the first step. It is also very important to remember that by August, vaccine was already under contract. We only have access to about 10 percent of the total supply, and we have procured what we could for the stockpile, with the $40 million appropriation that we had to do that. So we had no flexibility to go to a different manufacturer and buy vaccine, because they had already sold it.

Mr. WAXMAN. Now, Chiron—I mean, Aventis, which is now the only company that is supplying this vaccine, has its own contracts. They have contracts with clinics, but they also have contracts with the private sector.

Do you know, and more importantly, do the State and local people that run the vaccine programs know to whom they are selling the vaccine, to whom they have already delivered it, and whether there can be some redirection either of the existing supply that has already been distributed or that part of the supply that has yet to be distributed so that you can make a determination that the prioritization schedule is going to be met?

Dr. GERBERDING. The vaccine manufacturers consider that information proprietary and we have no legal authorization to demand it. However, we have been able to develop an arrangement with Aventis Pasteur where we are getting that information to the county level, which I think is a very reasonable approach, so that the county health officers or the local health officers, the State health officers can see how, for our population, we have a very large imbalance or we are doing OK or no shortages are reported.

We are hoping that will help us map out the patterns that we need to address with the reallocation of the remaining doses. And I think it is commendable that we are even talking about a manufacturer being willing to deflect some doses of vaccine from people who are expecting to receive it, to meet the highest priority demand.

So this is voluntary, it is very difficult, there is no mapping of vaccine supply authority in this country. But, we will do the best we can.

Mr. WAXMAN. Is there any mapping or knowledge within the county of who has the vaccine and who does not?

Dr. GERBERDING. The county health officials, as well as State health officials, have been surveying their members. The first survey to come out of the National Association of City and County Health Officers indicates that all of the jurisdictions are making an attempt to map availability within their jurisdiction, and they are certainly able to know what they have in the public sector.

But some private sector participants are not willing to disclose the amount of vaccine they have. We sense that there is probably

some hoarding going on, and people are waiting to make sure that their patients or their customers are served first.

Mr. WAXMAN. You could ask Aventis to give you that information. They don't have to, but you could ask for it, couldn't you?

Dr. GERBERDING. We have asked for it. And the one caveat is that some of the vaccine is purchased, for example, by a large drugstore, and then they redistribute it across the United States. So we don't have a one-to-one mapping of exactly where the doses of vaccine are.

Mr. WAXMAN. Dr. Crawford, in August Chiron announced several million doses of its flu vaccine might have been contaminated by bacteria. The British regulators immediately sent out an inspection team to review the manufacturing standards at the facility. FDA did not.

Was FDA aware that this extensive review by British regulators was going on? And why did FDA not conduct its own investigation of the facility, and is there a communication between the British equivalent of the FDA with you so that you know what they are up to and you can communicate freely and respond?

Dr. CRAWFORD. Actually, when those conclusions were reached we did have inspectors in the plant from the United States. They were in Liverpool at the time on August 25. And they did review the records. It looked like at that point, the maximum number of lots that might be turned down were something less than 10 percent.

We arranged, in cooperation with the Centers for Disease Control a weekly conference call to see what progress they were making. The United Kingdom did the same thing. And so what happened is, is that we obviously hoped for the best. It was too late on August 25 to start a new cycle of vaccine production, because that is a 6-month enterprise as we mentioned earlier.

But we hoped for the best. We gave them all we could in terms of help, as did the British. And I think it is fair to say that our final conference call with them where we would reached a go-or-no-go decision was on the same day that the British announced, the time differential made us a few hours behind. I was in a meeting in Geneva with one of the officials of the MHRA who told me about this situation very early in the morning. And also revealed that they would be—they would have 20 percent less vaccine in England than they had anticipated needing.

Their level of vaccination is not as great as ours, so they didn't have quite as much of an impact.

Mr. WAXMAN. Can I just ask you one question, Mr. Chairman if you permit? Could you contrast the FDA review with the British review? They seemed to be much more involved than FDA. You were looking at the records, but they were already inspecting the plant. Is that a fair statement?

Dr. CRAWFORD. No. Actually we were in the plant on August 25. So I think it was about the same thing.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. SOUDER [presiding]. Dr. Burgess.

Mr. BURGESS. Yes, Dr. Crawford. Following the same line of questioning that Mr. Waxman was taking. Was there some evidence that the British equivalent of the FDA had that was more

compelling than the evidence that you had, because it does seem that their decision was different? You have to wonder if the data that was presented to both was consistent.

Dr. CRAWFORD. The decision day, which was Tuesday of this week, was the same for the British as it was for the United States. They did have a meeting on Friday when they considered options.

But their final decision was not announced until Tuesday after further meeting on Monday afternoon and into the night. So I would say the availability of information was the same to the two governments.

Mr. BURGESS. The data presented was the same and the conclusion reached was identical with the two agencies.

Dr. CRAWFORD. Yes.

Mr. BURGESS. Are you at liberty to tell us what bacteria is involved in the contamination?

Dr. CRAWFORD. It's called serratia marcesens.

Mr. BURGESS. Dr. Gerberding, we saw headlines about the shortage of the flu vaccine and how it affected some of the youngest patients in this country. There was a contingency in place for this year if there was a similar bad actor from the flu standpoint where there was a run on the vaccine as we saw last year, is that correct?

Dr. GERBERDING. Yes, sir. We actually had expected a record number of doses of flu vaccine to be produced this year, in part to allow more surge than we had last year and in part because we had added the recommendation for children between the ages of 6 and 23 months to be immunized. Last year, 87 million doses of vaccine were administered—83 million doses were administered. This year, we had anticipated 100 million. Even with the loss of the 6 to 8 million doses from Chiron, based on their projections, we still anticipated we would have more vaccine than last year.

But, nevertheless, I am a pragmatic South Dakotan, and I always prepare for the worst-case scenario, and when you know that some doses are contaminated, even though all testimony—the CEO of Chiron was here a week ago testifying they expected full delivery in October. He met with the Secretary and expected full delivery in October. So we were prepared for the delay, but in the background we had a backup plan in case the worst case happened, and indeed it did.

Mr. BURGESS. Do you think that preparation that you undertook last year, perhaps it is fair to say that is going to blunt some of the potential trouble that is going to accrue from the loss of the British vaccine?

Dr. GERBERDING. It is very helpful that Aventis' production was higher this year than last year for several reasons. They tried to make more, but also the vaccine yield was very good. So we were able to get a few more doses from Aventis Pasteur than they had initially projected several months ago.

The opposite issue is that FluMist, which went unsold last year, only made 1.5 million doses instead of the 4.5 million doses. So we lost the opportunity to use the nasal vaccine for the healthy people who aren't on the priority list this year under the shortage condition.

So, again, flu is always unpredictable, but the demand for flu vaccine is equally unpredictable. What we need is a robust surge

capacity so that when demand exceeds supply we have some place to go to fill in the gaps.

Mr. BURGESS. Do you feel you have the pieces in place to make certain that the healthier members of the community understand that they need to use the internasal FluMist?

Dr. GERBERDING. We are engaged in full communication at CDC, so we are reaching out directly to consumers in those age groups. We are reaching out to employers across the business community. I have been interacting with the National Business Group on Health, and they have blasted out information to their memberships. We are working with stakeholder groups from our employee sector through NIOSH and other parts of CDC, and we are engaged—several CDC people are doing radio tours, and we are setting a satellite uplink up so that we can blast out through those mechanisms. There have been several press briefings already, and we will continue to try to use that menu for outreach.

Our next emphasis will be on translating this information into all relevant information so that people in all communities will have it. We are setting up an 800 number so that people who cannot find vaccine will have a place to call or people who are confused about whether they need vaccine or not have a place to call to get that information from the CDC. We will be mapping those calls by district and by county, and then we will use that information as helpful input to the local health officials to recognize supply and demand mismatches in their community.

So these activities are all ongoing, a lot of effort made to communicate. But with any public health situation of this magnitude and as challenging as this one is, you can never communicate enough. So we will continue to look for every opportunity to try to shape people's decision in a way that allows us to get the people who need the vaccine the most get vaccinated.

Mr. BURGESS. Dr. Fauci, you mentioned the funding difference between the 100 million that would help you go to a cell culture for technology. If you got that funding today from this Congress, that $60 million shortfall was made up, how quickly could we expect to see the end result?

Dr. FAUCI. I think we would be able to implement it almost immediately.

There are two components to that additional amount that the Department had asked for. One is to provide a guaranteed year-round availability of eggs for egg-based culture and the other is to push the envelope on the development of the cell-based culture. Since research is already ongoing on the cell-based culture, not only through our grantees and contractors but the companies themselves are starting to phase some of that in, the money as it becomes available will literally hit the ground running in making this happen.

Chairman TOM DAVIS [presiding]. The gentleman's time has expired. Mr. Kanjorski.

Mr. KANJORSKI. Thank you, Mr. Chairman.

Just being a total layman, it seems to me that you are testifying that we are involved in a crapshoot with vaccines. If there had been contamination at Aventis, we would be without a vaccine in the country and have no capacity to produce it. And I can under-

stand that, but I can't figure out that there is a definite plan until you get the new technology in place, but it will take probably 5 to 7 years. This shortage could happen this year or the following year, and there is no methodology in place other than that you have a great informative thing after the occurrence to notify people who can't get the vaccine.

My question is, what do we have to protect that next year this won't happen and what can we do or what role should the government play with the private sector to try and insulate? I am not hearing whether we should have duplicate manufacturing facilities, separate manufacturing facilities, onsite, constant inspection and when critical decisions will be made if there's a contamination problem. And this is just a contamination problem. It could have been a terrorist problem.

Dr. GERBERDING. You are absolutely right, that we are vulnerable to failures in the manufacturing process. We have known this for more than a decade. In the years 2000 to 2003 we saw this problem come up over and over again with childhood immunizations, and we need more manufacturing capability and we need more manufacturers of these vaccines.

Mr. KANJORSKI. Doctor, aren't we involved in a terrorism war, or am I missing something in the last 3 years? I seem to hear you testifying like we are in any age that we could have been in the 1980's and 1990's and that vaccines and responding to bacteriological problems should be one of our highest priorities. Can you tell me what Department of Homeland Security and this government has done in the last 3 years to make sure that this eventuality that has now occurred shouldn't have occurred or we should have had a backup plan?

Dr. GERBERDING. I agree with you completely. We have been trying to make a strong case for the fact that influenza is a public health threat and it deserves macroinvestments.

Mr. KANJORSKI. That is a given. We are talking about something that probably half a million people may die that wouldn't have died if they had vaccine. Is that probable?

Dr. GERBERDING. In an average year, 36,000 people die from influenza. We can't predict whether this year will be a severe flu season or a mild season.

Mr. KANJORSKI. And then we can say that because, with half the dosage, the likelihood we may suffer 18,000 additional deaths or at least 5,000. We are going to have people really die and as many or more people than died in the World Trade Center.

Dr. GERBERDING. Every year, even with an adequate vaccine supply, people die from flu because we don't get everybody.

Mr. KANJORSKI. Doctor, are any more people likely to die in the United States because of this contamination than otherwise wouldn't have died if we had adequate vaccination capacity?

Dr. GERBERDING. I don't know, but I'm worried about it.

Mr. KANJORSKI. You have no professional opinion that you can project, the likelihood? Because maybe we shouldn't spend anything in vaccination. If we can use half the production and we don't need the whole, then we obviously don't need that protection out there. There must be some mathematical scale that this is a life-death issue.

Dr. GERBERDING. I agree with you completely, and we cannot——

Mr. KANJORSKI. I'm not condemning your organization or the others at the table, other than we are 3 years into the war on terrorism and it doesn't sound right to me. I'm not condemning your agencies, your asking for money and preparation. I have visited these manufacturing facilities, and they have called my attention to the fact that they don't know what will happen to this country in a pandemic and how we are going to respond to it. Have you presented to the Congress and to the President a plan to meet terrorism and pandemics and have we responded to it?

Dr. GERBERDING. As we said, we requested resources to scale up the surge capacity for vaccine from Congress last year. Secretary Thompson and the administration requested $100 million; Congress appropriated $50 million. We have asked for the opportunity to expand the vaccine stockpile so we could purchase a reserve. We are making progress toward achieving that, but we haven't had the full appropriation to accomplish that yet.

Mr. KANJORSKI. So this Congress has failed to respond to the agencies of the executive department of this government that would have been a response to homeland security because we do not have the capacity potentially to meet the biological protections against biological warfare, is that correct?

Dr. GERBERDING. We requested $100 million, and we received $50. We are hoping Congress will support the full $100 million in fiscal year 2005.

Chairman TOM DAVIS. Mr. Souder.

Mr. SOUDER. Thank you, Mr. Chairman.

First, I would like to add my voice to the many others that Dr. Gerberding—I hope next time the network does a TV show they give you full credit. Your agency deserves full credit for the work that you do.

Based on conversations I have heard here, I want to ask you a couple of questions. My colleague from Indiana, Senator Bayh, introduced legislation a year ago that sounds to me like it attempts to address some of the things you raised. One of the things that Dr. Crawford raised was a seeming lack of competition in the marketplace. One of the things there would be to encourage through investment credit more people to get into the business. Do you think that would help at all? What do you think is the biggest stumbling block?

And I would appreciate a further comment on that, because—and let me add this, and we will start with Dr. Crawford and move through. A second part of the legislation deals with trying to make sure that the government buys—or if the market doesn't meet, the government will back up and purchase a larger supply so we have a backup supply.

It is not without precedent. I remember working as a staffer with MRE companies, because we have these pulses in Ready-to-Eat meals at wartime. So part of the goal had been to keep two or three of these companies in business so that when we had a policy we had the capability to do that.

How do you feel about what impact on the market that would have if we had a backup guarantee if the production rate were higher? One question is, can we get more people into an investment

credit; and, second, would having some backup guarantee for the high-risk population that guaranteed that if they produced it, like FluMist did—and my question along the same lines, FluMist is going to testify, who manufacture that, in the next panel that they had to cut back because the market didn't do it and they're restricted in the areas that the government backs up and we are losing manufacturers. What, if it isn't those two things that I mentioned earlier, would you do to try to get more manufacturers in the business?

Dr. CRAWFORD. What we are trying to do—as you know, we don't have funding for like startup companies and that sort of thing. We basically regulate them. We are the bad news for them, rather than the good news. What we are trying to do is improve our process so that we create a favorable regulatory environment for more companies to get involved.

I mentioned the good manufacturing practices, which we have just announced after a 2-year study; and what this will do would make it—it would be a newer approach to manufacture. It would be less onerous, more scientific, more systematic. And over time, along with the new research initiative that we are working with the National Institutes of Health on called the critical path, we believe it will make it a more predictable climate for vaccine manufacturers but one that produces better products with more certainty of success.

In the lots that we have now, I mentioned earlier that 8 of 100 were originally considered to be defective. As we go through our examination tomorrow, this will actually be a test case. We don't know how many or if any are badly contaminated until we do the inspection. But certainly a better regulatory environment where it is more modernized, if we take a newer approach at it, would help; and that is what we're committed to.

Mr. SOUDER. I agree that the regulatory environment in all kinds of things is a deterrent, and certainly all the manufacturers say that to some degree. We have only been able to move that slightly. I hope we continue to move that and keep people's health safe.

The question is also is there a tipping point here where a small investment or even a medium investment tax credit would, say, impact these new technologies or if we, in effect, backed up some of the purchases for pulse components. Dr. Fauci.

Dr. FAUCI. You bring up an important point that has many ramifications for what has been said thus far today as we keep referring to the fragility of the vaccine development industry. I think it boils down to things that we in the Department at all three of our agencies have been facing, and that is a real lack of a climate of incentivization to get companies involved. People say, how come you only had two companies involved for the vaccine for influenza? Those were the only two companies licensed in this country to make it and distribute it. It isn't as if we had 15 companies, and we decided on 2, and I think that sometimes gets misunderstood.

If you look at the climate of how we look at vaccine development, it's very risky business for a company to get involved, risky because of the profit margin, risky because you are dealing with biologics and they are much more difficult to predict the success of it. And there's the issue of the use of vaccine which is used once or twice

or three times in a person's lifetime, as opposed to the other possibility of the same company developing a blockbuster drug that someone would use everyday of their lives for the rest of their lives that they could make millions at.

What we are trying to do is to do everything from regulatory incentives to research by pushing the envelope more to take away some of the risks by the approaches that I showed in my opening statement about perfecting things like the reversed genetics or perfecting things like the use of cell culture base. And then, finally, it is the issue of pricing and how our culture views how much one is willing to pay for a vaccine.

This morning, in preparation for the hearing, I got on the phone in my office very early and I called up a pharmacy in Bethesda and I asked about the relative prices of things, because we talk about it a lot. And I asked them what would be the retail price of a year's supply of Lipitor, which is a blockbuster, cholesterol-lowering drug. $1,608. What would be the yearly cost of 50 milligrams of Viagra? $3,500 a year per person. What is the cost of the Aventis Pasteur vaccine? $7 to $10.

You are talking about the idea of any company wanting to go toward something that has a major profit margin. We need to help with incentives. We could do it researchwise or regulatorywise, but it is a rather broad, generic issue. We hope, working with the committee, we will be able to find solutions to that.

Mr. SOUDER. Could I see if Dr. Gerberding has anything to add?

Dr. GERBERDING. In the short run, before we are able to scale up and using some of the tools you described, that the backup plan of the government purchasing additional doses of vaccine is one that we are already doing on a small scale; and it is conceivable that, by expanding that, manufacturers would be incentivized to make as much vaccine as they could. The downside of that is that taxpayers would have to be prepared that, most years, we would throw vaccine away and it would be a waste of tax dollars. So there is a tradeoff with flu vaccine because we have to get a new vaccine preparation every year.

Chairman TOM DAVIS. Ms. Watson.

Ms. WATSON. Pass.

Chairman TOM DAVIS. Mr. Tierney.

Mr. TIERNEY. Dr. Crawford, does the Food and Drug Administration pretty much agree with the determination made by the British health authorities?

Dr. CRAWFORD. I can't answer that until we get through our inspection. We are looking through the lots and hoping for the best, but there is an air of pessimism, so probably we will.

Mr. TIERNEY. Is anything being done about the prospect of price gouging?

Dr. GERBERDING. We are concerned about price gouging. The first step is to identify where it's happening, and the second step is to alert the State and local health officials that it's happening in their jurisdiction and also the FTC who has the regulatory responsibility to evaluate and take the appropriate steps. I think it is tragic. We know in any market where there's a shortage of product that there is a tendency to raise the price, these unfair price increases; and they really add insult to injury.

Mr. TIERNEY. Are you satisfied that our officials are actually working on this issue, giving the proper notice to people?

Dr. GERBERDING. I don't have an answer on that today, just 48 hours into this, but we will be looking for it and also make our hotline available if there are reports of this so people can alert us and we can pass the information onto the appropriate response agencies.

Mr. TIERNEY. Dr. Fauci, you should have slept over last night. You were here yesterday on the West Nile virus.

Doctor, with respect to our research, MedImmune says they are developing vaccines for—and giving it for free to government inspectors or researchers, but they obviously charge others who create a profit from it for that. Do we need to address our patent laws at all to make sure that enough people have access to the reverse genetics processes or anything or is it fine the way it is?

Dr. FAUCI. I think what you are referring to is what is going on is a dispute about the pattern of the reverse genetics. I'm not sure we need to address the patent laws on that. We need to clarify pretty quickly what the patent issues are involved there so we can get the ball rolling on this, but I don't think this is a generic patent law problem.

Mr. TIERNEY. A moment ago you were talking about the different prices that you get for different prescription drugs. The fact of the matter is, it's not the government that is keeping the price of the flu vaccine low, is it? We don't set the price and keep it low?

Dr. FAUCI. Actually not. But one of the issues we face—what I was referring to was not that it's the government or industry.

Mr. TIERNEY. It's a market situation.

Dr. FAUCI. Culture of people feeling and maybe in some respects, appropriately so.

Mr. TIERNEY. It is the market. Because if people made more of a demand for it, the price could be raised higher. It it's raised higher, they're afraid people won't buy it at the higher price.

Dr. FAUCI. Also, the third party payers wouldn't necessarily pay it. That's an important issue.

Mr. TIERNEY. One of the things—I think Dr. Gregory Poland from the Mayo Clinic gave the options. We either have to subsidize or give incentives to manufacturers to get them into the business, or the government has to own or operate either themselves or to a contractor a plant to produce the vaccine. Seems to lay out some of the options that you say we went from regulation to doing it yourself.

But as long as we leave it entirely without a regulation to the industry, we get the lower prices, we get less demand, and we get two manufacturers instead of more, and it creates a problem. Anybody in any of these agencies before us right now debating this issue as a policy matter, whether the government ought to have a contractor get in there and somehow subsidize them to create this or get in the business themselves or regulate the price, is that discussion going on?

Dr. GERBERDING. That discussion is ongoing and has been going on for some time. Just on Monday, the National Vaccine Advisory Committee, who has responsibility for advising the Department and the government on those issues, issued some statements that

recommended that we look at those options that you just mentioned. There is not a long list of options, and we need to bite the bullet here and come up with a plan.

Mr. TIERNEY. This is absolute free market aspect when it comes to health care. It doesn't always seem to fit the same model as if you're selling widgets. Health care is a different item here, and we get that right across the spectrum of health care issues. I know that everybody is paranoid of the word regulation or any government involvement, but we expect the government to step forward for our safety and protection. I hope that debate accelerates. I think Congress ought to be involved in this debate, and there ought to be further hearings on this away from the ideology as to what is a practical matter of how we take care of health concerns, and that may mean a little less of absolute free market and more intervention here to make sure we have this product available.

Chairman TOM DAVIS. Mr. Mica.

Mr. MICA. I remember previous hearings on the subject of the cost of some of these vaccines. I remember someone holding up a vaccine vial, and in that testimony they said that the cost of the vaccine itself was less than $1 or around $1, but—I don't remember—if you can get insurance, the cost was like about $20 some. I don't know if that's still the case. Is that a typical ratio, Dr. Fauci? I think you were talking about some of the costs.

Dr. FAUCI. I'm not actually sure, and I would hesitate to make any statement about the relative costs of the liability insurance that they would have to pay.

Mr. MICA. Are they having trouble getting it, manufacturers? I heard you cite some incentives. Isn't that one of the major problems, the most significant problem to manufacturers in the United States?

Dr. FAUCI. I best leave that for the companies to answer. But I know when you are dealing with childhood vaccines we do have a childhood vaccine fund for compensation. But not in the adult.

Mr. MICA. Right now, we are looking at blaming sort of the bureaucrats, and you all haven't paid enough attention to this, and there probably will be horrible things like price gouging because the supply is down. You had a responsibility. And it was kind of interesting, someone said you had to fly—who flew over to check it?

Dr. FAUCI. The FDA.

Mr. MICA. So we had to fly to Europe to check the supply. I'm sure it is much more beneficial to manufacture this outside the United States and keep an eye on it. I understand you have an annual inspection?

Dr. CRAWFORD. Depending on what the risk is expected to be, it can be as little as every 2 years.

Mr. MICA. How many did we have here at the site that went bad? Can you supply a record of your visit for the committee?

Dr. CRAWFORD. Absolutely.

Mr. MICA. This is a research and development budget for the National Institute here, and it says vaccine research. We supply $1.18 billion in research. Mr. Sanders and I several years ago went over and met some of the drug manufacturers trying to figure out why—what was happening in the marketplace. At that time, they told us

there was no R&D in Europe, that it was all being done in the United States for most drug development and vaccines. Is that still the case?

Dr. CRAWFORD. For pharmaceuticals?

Mr. MICA. Yes.

Dr. CRAWFORD. Sixty-three percent of the profit, it is reported, from pharmaceuticals worldwide is gained through U.S. sales. So quite naturally——

Mr. MICA. We were told, quite frankly, that there is no R&D going on or very limited. Almost all of it comes from the United States. The U.S. taxpayers are financing R&D in vaccines and other pharmaceuticals, and then we are outsourcing because you can't manufacture in the United States because you get your butt sued. And you also certify or do you approve the drugs? The FDA approves those vaccines, right?

Dr. CRAWFORD. Yes, we do.

Mr. MICA. You know, I think it's time we looked at some system where we took responsibility and there would be plenty of drugs available at low costs if we limited the liability, if we set up some funds for decent compensation for victims, whether it is a pharmaceutical or a vaccine. Wouldn't that be a better solution, Dr. Fauci?

Dr. FAUCI. I think the idea of compensation is something that needs to be——

Mr. MICA. We have done some of it with children's immunization. We produce it.

Our responsibility is to have an agency like the FDA to say that this is a good drug. Now we force the manufacturing outside. We are paying for the R&D. It would behoove us to manufacture in the United States and have better control and we are certifying it whether it is manufactured in the United States or outside that it is good. So shouldn't we have some of that responsibility, FDA?

Dr. CRAWFORD. Yes, we should.

Chairman TOM DAVIS. The gentleman's time has expired.

Ms. Norton, you will be the last questioner.

Ms. NORTON. Look, having been caught without a backup plan already, I'm really compelled to ask what is the backup plan in case the volunteer sharing doesn't work out?

Now the most generous people in the world are health care people, so I'm sure everybody is doing what you'd expect them to do. What are you empowered to do if, in fact, your, quote, backup volunteer plan proves as insufficient as having no backup plan for half of the supplies which now are unavailable, what are you empowered to do? What would you do if in fact people begin to make their own assessments, particularly since the private sector controls most of the supply?

Dr. GERBERDING. Thank you. That's an important distinction between childhood vaccines for routine prevention of vaccine-preventible diseases and influenza where we have such a small proportion of the market share in the governmental control. CDC has no authority to regulate distribution of vaccine or to regulate the manner in which vaccine is supplied. We rely on our best technical advice. We rely on altruism, as you have described.

We have experience with this in 2000, 2001, where we had a similar vaccine shortage. We found that, overall, there was adher-

ence to the recommendations. In fact, we ended up in many areas with excess doses of vaccine because people complied so carefully with the recommendations.

What we are talking about here is a very fine line between what we have and who needs it the most. I just don't think it's a matter of doses, but it's a matter of where are those doses, and we have no authority to redistribute the vaccine.

Ms. NORTON. I don't want to take the entire time. Are you prepared to come back during the lame duck session and get some authority to do something now that you know full well that the private sector could turn you down and could decide on its own where the supplies go?

Dr. GERBERDING. We would be delighted to work on with Congress on solutions. Our colleagues at the FDA, who is the regulatory agency, has a role to play in this as well, but we would be willing to look at all possible solutions.

Ms. NORTON. I'm asking you and Mr. Crawford to, in fact, be prepared now that there is no backup plan, now that we cannot in our economy force the private sector to do things with respect to supplies in their hands, to be back here when we come here to tell us what it is we need to do. We can't just sit here saying we don't have the authority, there's nothing we can do about it.

In order to let other Members ask questions, I'm going to forego the rest of my questions.

Chairman TOM DAVIS. We have 3 minutes left to vote.

Mr. Cooper.

Mr. COOPER. Following up on my colleague's line of questioning, could this Congress save lives by passing a law making sure that only high-priority recipients got the vaccine—seniors, infants, people with chronic diseases, health care workers? Would that save lives in this country?

Dr. CRAWFORD. I should defer that to Dr. Gerberding. Basically, you are saying that you would codify their recommendations, CDC's recommendations?

Mr. COOPER. With the force of law behind the voluntary guidelines that Dr. Gerberding has mentioned, would that save lives in this country? Because, in response to Mr. Kanjorski earlier, it seemed like the normal casualty rate that we could face with influenza could go up substantially this year as a result of this manufacturing shortage. You only have voluntary guidelines at your disposal and you're not empowered to do more? Would you be able to save lives if you had that extra legal authority?

Dr. CRAWFORD. I'm not prepared to answer that. I think she expected good compliance based on past years, but I better defer to Dr. Gerberding.

Dr. GERBERDING. I don't have an answer for you either. This is a work in progress. In past years, we have been able to have a good match between what we expect and how people adhere to those recommendations. Whether we would have more benefit from codifying it or more mess from codifying it, I can't really tell you right now. I think enforcement of that would be a very difficult challenge to patch together on short notice, but we will look at that as an option and, as the Congresswoman suggested, come back with a set

of options that we could discuss with the committee during the next session.

Chairman TOM DAVIS. Thank you very much.

I'm going to dismiss this panel with our thanks. We will take a recess to go vote and be back in 15 minutes.

[Recess.]

Chairman TOM DAVIS. The committee will come to order.

The gentleman from Indiana is recognized.

Mr. BURTON. Mr. Chairman, you really are fast with that gavel, and I love it.

I'm sorry, Mr. Chairman, I wasn't here earlier today when the hearing started—and this is on a related subject. I got my flu shot this morning, and I guess a lot of Americans so far haven't been able to do it because of the shortage. But the concern that I have, part of the contents of the vaccination that people are getting. There is a substance called thermarisol, which is about 50 percent ethyl mercury in the flu vaccine, and most adult vaccines have mercury in it.

Governor Schwarzenegger of California recently signed a bill in California which prohibits children up to age 3 from getting a vaccination that contains thermarisol; and the reason for that is because the mercury in vaccines—and we have had hearings on this over the last 4, 5 years—the mercury in vaccines is seen by many scientists around the world as a major contributing factor to neurological disorders such as autism in children and Alzheimer's in adults.

Now we are getting it out of most of the children's vaccines. It's in about three or four of the children's vaccines today. In California, they are going to get it out of all of them, which is a giant step in the right direction, and I congratulate the legislature out there and the Governor for doing that.

We need to get mercury out of all vaccinations. Mercury is toxic to the human body, to the human neurological system. It is in the flu vaccine and in most of the adult vaccines. It needs to be removed. You can go to single-shot vials without having mercury in them; and, Mr. Chairman, it would be great for the American people and the world if we removed that.

Mercury toxicity is a major ecological problem for the whole world. It is in our water, in our fish. We are being told not to eat fish in many cases because there is mercury in them, and we continue to put it in vaccines that's injected in our children and adults.

We used to have 1 in 10,000 children that were autistic. It is now 1 in 166 according to CDC. We used to have Alzheimer's that was recognized quite frequently, but now it has become an epidemic. So we need to get these toxic substances out of our vaccines. I think the pharmaceutical industry has done a great job for the people of this country and for the world, but there are certain things that can be cleaned up. One of them is getting the mercury out of the vaccines.

Mr. Chairman, I thank you very much for yielding to me; and this is another shot across the bow, the pharmaceutical industry, to get the mercury out of all vaccines for the good of humanity.

Chairman TOM DAVIS. Thank you very much, and you have been consistent in your position on this.

We move to our next panel, and I thank our witnesses for appearing. They are the three flu vaccine manufacturers to discuss vaccine production capacities to respond to shortage crisis.

We will hear from Christine Grant of Aventis Pasteur, manufacturer of Fluzone, the vaccine. Dr. David Johnson accompanies Ms. Grant, and he is available to respond to questions.

We also have Dr. James Young from MedImmune, which manufactures the nasal spray vaccine, FluMist.

Unfortunately, a representative from Chiron is unable to attend this hearing, but the company has submitted written testimony for the hearing record. I ask unanimous consent that Chiron's testimony be included in the official hearing language. And without objection, so ordered.

[The prepared statement of Mr. Pien follows:]

CHIRON

Statement Presented To

House Committee on Government Reform

United States House of Representatives

By Howard Pien

President and CEO

Chiron Corporation

October 8, 2004

Introduction

Mr. Chairman, Members of the Committee: Thank you for the opportunity to submit a statement for the record to the House Government Reform Committee at today's hearing. I am Howard Pien, President and CEO of Chiron Corporation, a global biotechnology company headquartered in Emeryville, California, with 2003 revenues of $1.75 billion. Founded in California in 1981, Chiron is composed of three business units: BioPharmaceuticals, Blood Testing and Vaccines. Chiron is dedicated to research and innovation addressing global public health challenges.

We regret that we cannot attend the hearing in person today. We would welcome the opportunity to appear at a hearing when we have additional information regarding our discussions with the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom and the Food and Drug Administration (FDA). As we have from the beginning of this situation, Chiron intends to be open and transparent with you and Federal authorities regarding our manufacturing situation.

Over the last few days, Chiron has learned an extremely painful lesson that is particularly devastating to our company due to the public health consequences of our inability to deliver this important vaccine. Since its creation, Chiron's mission has been to address global public health challenges, and, in this instance, we are unable to deliver. Chiron is deeply saddened that, despite the hard work during the past six weeks of large numbers of people within the company, we are unable to help address the threat of influenza in the United States this season.

As of today, Chiron reaffirms its resolve to take all appropriate actions to discover how we can improve our operational and managerial procedures and to implement a program of change to ensure that we can expeditiously regain our license. Among the specifics are:

- Systematically examining our manufacturing capabilities, including quality control. Chiron will make the necessary investments to ensure that we meet the highest standards of Good Manufacturing Practices.
- Ensuring that, in addition to the routine inspections that our facilities undergo, we are in frequent contact with regulatory authorities to understand any concerns that may exist and address them proactively.
- Assessing our processes for communication with key public health stakeholders to identify any opportunities for enhancement.

Supply of Influenza Vaccine for the 2004-2005 Influenza Season

On August 26, Chiron Vaccines announced that in conducting final internal release procedures for our Fluvirin® influenza virus vaccine, our quality systems identified a small number of lots that did not meet product sterility specifications. This related to contamination with *Serratia marcescens*. Chiron therefore announced that we had delayed releasing any Fluvirin doses until completion of additional quality assurance tests, a process that was projected to delay release until early October. Recognizing the

public health implications of this projected delay, Chiron immediately began communicating with and informing key public health stakeholders, agencies and regulatory authorities, including the Centers for Disease Control and Prevention, the National Vaccine Program Office, the National Institutes for Health and Centers for Biologics Evaluation and Research, and the UK Department of Health. Chiron regularly provided updates on the status of our investigations to these public health stakeholders via weekly teleconferences and/or informal discussions.

On September 27, Chiron completed internal investigations, and the results were in line with our expectations that the variance was confined to the initial scope identified. On October 5, MHRA informed Chiron that the agency was temporarily suspending our manufacturer's license for Fluvirin with immediate effect for a period of three months on the grounds that Chiron had failed to conduct operations in accordance with Good Manufacturing Practice regulations of the United Kingdom. The order also prevented the release of any influenza vaccine produced in Liverpool for the 2004-2005 influenza season. The suspension means that Chiron will be unable to meet our previously stated expectation of delivering between 46 million and 48 million doses of Fluvirin to the U.S. market beginning in early October.

Chiron deeply and profoundly regrets our inability to meet our commitment to the United States due to the suspension of our manufacturer's license, and we understands and are distressed by the public health consequences that this might have.

Going forward, our primary objective is to ensure that we restore our ability as a reliable supplier of influenza vaccine to the United States and become a dependable partner to those who are battling to reduce the burden of influenza, a disease estimated to cause an average of approximately 36,000 deaths annually. The first step to accomplishing this goal is to ensure that we are in a position to supply influenza vaccine to the United States for the 2005-2006 influenza season and, if necessary, contribute to vaccine supply in the event of a pandemic.

In order to accomplish this Chiron's highest priority is to address the concerns raised by the MHRA in its letter of October 5. We have taken action to achieve this goal as rapidly as possible. On October 6, senior management representatives from Chiron Vaccines met with the MHRA and initiated a dialogue to better understand the agency's concerns about the Liverpool facility and how those concerns can be addressed. We hope this meeting will lead to a remediation plan that will permit the lifting of the suspension if in the MHRA's view the plan is successfully implemented.

It is of paramount importance that we focus our efforts on addressing the concerns of MHRA so that our manufacturing can be up and running in order to supply influenza vaccine to the United States for the next influenza season. The production cycle time for influenza vaccine is such that Chiron expects it will need to commence preparations for vaccine manufacture by March 2005 at the latest in order to supply vaccine by September 2005.

Prior to receipt of the letter from the MHRA on October 5, Chiron did not anticipate that the MHRA would temporarily suspend our manufacturer's license for Fluvirin. Chiron had completed internal investigations on September 27, and the results were in line with our expectations that the variance was confined to the initial scope identified. Chiron therefore expected to report our conclusions to the MHRA and, upon confirmation, proceed with releasing Fluvirin to the U.S. market in early October. Inspectors from the MHRA visited the Liverpool site between September 28 and 30. To facilitate their process, Chiron voluntarily complied with the MHRA's request dated September 24 that Chiron not release Fluvirin until the review was concluded. Chiron made CBER aware that we were awaiting completion of the MHRA process to release Fluvirin. The MHRA inspectors concluded their site visit by providing Chiron with informal written comments on Thursday, September 30. Chiron reviewed the informal written comments and addressed them in a written response sent to the MHRA on Monday, October 4. Chiron believed that we had addressed the findings raised by the inspectors and was therefore taken by surprise by the MHRA's conclusion communicated on October 5 that Chiron had failed to conduct our operations in accordance with Good Manufacturing Practice regulations.

We did not perceive that there was any indication from the MHRA prior to October 5th, that the outcome of the MHRA review would be the suspension of our manufacturing license for Fluvirin. Chiron appreciates that the MHRA's decision was rooted in concern for assuring product safety, a concern Chiron completely shares.

Chiron is committed to maintaining open, effective and transparent communications with key public health stakeholders. Chiron did not at anytime mislead public health stakeholders or the public. Chiron had no reason to anticipate that the MHRA would have concerns sufficient to warrant suspension of our manufacturing license. The results of Chiron's internal investigations confirmed our belief that our product was safe. We deeply regret that Chiron did not anticipate that the MHRA would have come to the decision that it did. Throughout, Chiron communicated with public sector stakeholders at the earliest junction.

Chiron recognizes the public health consequences of our inability to supply vaccine and the significant efforts that the CDC, NVPO, National Influenza Vaccine Summit and health care workers in the public and private sector will need to devote to working through the shortage. Chiron apologizes unreservedly for our inability to meet our commitment to supply vaccine to the United States. Chiron is also grateful for the leadership role that the HHS and its umbrella agencies CDC, NVPO, NIH and CBER have immediately taken in responding to our announcement. Chiron pledges to provide whatever assistance it can as the challenges of this season are being addressed. In addition, Chiron will work tirelessly to address the concerns of the MHRA to be in a position to supply vaccine for next season.

Looking Towards the Future

In conclusion, it is a public health tragedy of substantial magnitude that there is an insufficient supply of influenza vaccine. We vow to assist the men and women of the Public Health Service as they handle the challenges of this season. Chiron respects the MHRA's decision and is determined to work closely in partnership to develop and implement a remediation plan over the next few months to address its concerns. Our primary concern at this time is to do whatever it will take to have the suspension lifted in time to be in a position to supply influenza vaccine to the United States for next season. This has been a painful experience for our company and we resolve to ensure that this does not occur in the future. We wish we had not been taken by surprise by the MHRA decision, but we were. We wish we had been able to anticipate MHRA's inclination earlier, but we were not.

Chiron remains committed to supplying influenza vaccine to the United States. We will make all of the necessary investments in people and processes to bring our Liverpool facility up to the highest standards of regulatory compliance. In the next few weeks we expect to clearly establish the remediation plan with MHRA. We will continue to invest in the development of cell culture production, the next generation of influenza vaccine production technology, in order to have a more reliable and robust production process. We will continue to support pandemic preparedness efforts through research and development of new vaccines.

Chairman TOM DAVIS. We also have a visitor to this committee who I have known for many years, Dr. Robert Stroube. He is the Virginia State Health Commissioner. He is no stranger to this committee either. He's here to provide an assessment of State and local public health departments' ability to respond adequately to the vaccine shortage threat.

We swear all witnesses before you testify. So if you would rise and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Ms. Grant, we'll start with you; and we'll move straight on down. I can't thank you enough for being with us and being patient, but we'll try to get through questions as quickly as we can.

STATEMENTS OF CHRISTINE GRANT, VICE PRESIDENT FOR PUBLIC POLICY AND GOVERNMENT AFFAIRS, AVENTIS PASTEUR, INC., ACCOMPANIED BY DAVID JOHNSON; JAMES YOUNG, PRESIDENT, RESEARCH AND DEVELOPMENT, MEDIMMUNE, INC.; AND ROBERT STROUBE, STATE HEALTH COMMISSIONER, VIRGINIA DEPARTMENT OF HEALTH

Ms. GRANT. Good morning, Chairman Davis and members of the committee. Thank you for the opportunity to testify today on behalf of Aventis Pasteur.

During the past 10 years, Aventis Pasteur has been a reliable supply of influenza vaccine for the United States, consistently increasing our annual production. This year, we expect to produce 55.4 million doses, 33 million of which have already been distributed.

I'm here to communicate our company's pledge to continue to do everything we can to manage this influenza season consistent with the recommendations of Federal and State health authorities. Vaccines have proven to be the most cost-effective, preventive intervention in human history; and all of our employees are passionate about the contributions they make to lifesaving work.

Aventis Pasteur is the world's largest vaccine company with nearly 9,000 employees. The company's global experience has been utilized to manage influenza epidemics over many decades. Vaccine has been produced at the Swiftwater, PA, location for over 100 years and influenza vaccine produced there for more than 30 years. Today, we produce approximately one-half of the U.S. influenza vaccine supply. Although there have been years where disruption and shortages have ensued in the influenza vaccine marketplace, Aventis Pasteur has been able to deliver vaccine to our customers on a timely basis during influenza season.

As I previously stated, Aventis Pasteur intends to achieve its plan to produce approximately 55.4 million doses of Fluzone for the United States this season. Customers had already placed orders for more than 52 million of those doses prior to Chiron's announcement. This included approximately 4.5 million doses for the CDC, including the late season strategic reserve, which the CDC proactively and wisely planned. It is important to note that over 85 percent of all influenza vaccine is administered by the private health care sector.

So since hearing the announcement 3 days ago, we have worked with the CDC and the FDA to determine whether we can manufacture additional doses later this year. Any additional doses available from going back into production, however, would not be available until February or March; and such a decision would have implications for the amount of vaccine which can be produced for next 2005–2006 season.

Mr. Chairman, as we have heard today, the supply shortage has caused many policymakers to ask: Why are there so few vaccine manufacturers in the United States and what needs to be done to encourage vaccine manufacturers?

Over the last several years, we testified before Congress about the urgent need for Federal policymakers to do more to cherish and promote vaccine companies; and we suggest five recommendations to achieve this goal.

First, demand for vaccine drives supply. We need to work together to steadily increase annual reliable demand to achieve Healthy People 2010 goals. This will give companies confidence to continue to reinvest and thus increase supply.

Second, annualize the funding for CDC's strategic influenza vaccine reserve, which was only budgeted for two seasons yet is proving to be a very wise investment.

Third, liability exposure chills interest in this field. We are pleased to acknowledge the House of Representatives passage of the JOBS bill just late last night, which included the Influenza Vaccine Excise Tax; and we strongly encourage the Senate and White House to take quick action on the bill. This will ensure that influenza vaccine is now covered under the Vaccine Injury Compensation Program.

Fourth, we encourage the committee and Congress to begin now to plan to address special vaccine liability issues that will occur when there is an influenza pandemic.

Fifth, we encourage the committee to help resolve inconsistencies between SEC accounting guidelines for routine pediatric stockpiles and CDC's desire to implement such stockpiles, for which Congress has already authorized the appropriated funding.

We are aware that vaccine companies have left the U.S. market in the last decade. This included two companies that produced influenza vaccine. It's important to remember that, even if a new company were to plan a new facility today, it would require a minimum of 5 to 7 years to build, validate, license, manufacture and deliver vaccine to the marketplace. This is due to the inherent complexity of building reliable production facilities that meet necessary health and safety standards.

Aventis Pasteur has been a leader in introducing innovative technology. We have learned through experience it takes years to develop and incorporate new processes into routine manufacturing. For example, we are working on the promising technology known as cell culture, but we caution it is going to take years to transition this technique from research to full-scale production. Additionally, the technique will not substantially reduce the total production time.

Mr. Chairman, we share the committee's concern and frustration with this year's supply problem. However, government authorities

and the private sector have worked well together in the past to manage difficult situations to ensure optimal immunization rates; and we want to commend HHS, the CDC and the FDA's leadership for their immediate and decisive action to address what is inherently the unpredictable nature of vaccine production. In less than 12 hours, as you heard, the CDC's Advisory Committee on Immunization Practices issued interim recommendations to prioritize influenza immunization for high-risk populations.

The National Flu Summit, a public-private partnership of the CDC, professional associations, public health authorities and companies such as ours, has already discussed how best to implement those recommendations; and influenza professionals are recommending that health care providers who actually see patients are best equipped to determine who is at high risk.

In summary, Aventis Pasteur pledges to continue to do everything we can do to manage this season consistent with the recommendation of Federal and State health authorities; and we commend Congress for your prompt interest to address this issue during your busiest week of your session.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Ms. Grant follows:]

AVENTIS PASTEUR OPENING ORAL STATEMENT BEFORE HOUSE GOVERNMENT REFORM COMMITTTEE REGARDING RECENT DEVELOPMENTS CONCERNING THE US INFLUENZA VACCINE SUPPLY

October 8, 2004

Chairman Davis, Ranking Member Waxman, Members of the Committee:

Thank you for the opportunity to testify today on behalf of Aventis Pasteur. During the past ten years, Aventis Pasteur has been a reliable supplier of influenza vaccine for the US, consistently increasing our annual production. This year we expect to produce 55.4 million doses, 33 million of which have already been distributed.

I am here to communicate our company's pledge to do everything we can to manage this influenza season consistent with the recommendation of Federal and State Health authorities. Vaccines have proven to be the most cost-effective, preventive intervention in human history, and all of our employees are passionate about the contributions they make to life-saving work.

Aventis Pasteur is the world's largest vaccine company with nearly 9,000 employees. The company's global expertise has been utilized to manage influenza epidemics over many decades. Vaccine has been produced at the Swiftwater, Pennsylvania location for more than

one hundred years and influenza vaccine for more than thirty years. Today, we produce approximately one half of the US influenza vaccine supply. Although there have been years where disruption and shortages have ensued in the influenza vaccine marketplace, Aventis Pasteur has consistently been able to deliver vaccine to our customers on a timely basis during influenza season.

As I previously stated, Aventis Pasteur intends to achieve its plan to produce approximately 55.4 million doses of Fluzone® Influenza Virus - Vaccine for the United States this season. Customers had placed orders for more than 52 million of those doses prior to Chiron's announcement. This included approximately 4.5 million doses for the CDC, including the late season strategic reserve, for which CDC proactively and wisely planned. It is important to note that over 85% of influenza vaccine is administered by the private health care sector.

Since hearing the announcement three days ago, we have worked with CDC and FDA to determine whether we can manufacture additional doses later this year. Any additional doses available from going back into production now would not be available until February or March, and such a decision would have implications for the amount of vaccine that could be produced for the 2005-2006 season.

Mr. Chairman, as we have heard today, the supply shortage has caused many policy makers to ask: "Why are there so few vaccine manufacturers in the US?" and "What needs to be done to encourage vaccine manufacturing?"

Over the last several years, we have testified before Congress about the urgent need for federal policymakers to do more to cherish and promote vaccine companies. We suggest five recommendations to achieve this goal:

1) Demand for vaccine drives supply. We need to work together to steadily increase annual reliable demand to achieve Healthy People 2010 goals. This will give companies confidence to continue to reinvest and thus increase supply.
2) Annualize CDC's strategic influenza vaccine reserve, which was only budgeted for two seasons yet is proving to be a wise investment.
3) We are pleased to acknowledge the House of Representatives passage of the JOBS bill late last night, which included the Influenza Vaccine Excise Tax. We strongly encourage the Senate and White House to take quick action on the bill. This will ensure that influenza vaccine is covered under the Vaccine Injury Compensation Program.
4) We encourage the Committee and Congress to begin now to address special vaccine liability issues surrounding an influenza pandemic.
5) We also encourage the Committee to help resolve inconsistencies between SEC accounting guidelines for routine pediatric stockpiles and CDC's desire to implement the stockpiles, which Congress has authorized and appropriated funding for.

We all are aware that vaccine companies have left the U.S. market over the last several decades. This included two companies that produced influenza vaccine. It is important to remember that even if a new company were to plan a new facility today, it would require a minimum of five to seven years for it to build, validate and license in order to manufacture and deliver vaccine to the marketplace. This is because of the inherent complexity of building reliable production facilities that meet necessary health and safety standards.

Aventis Pasteur has always been a leader in introducing innovative technology to vaccine production. We have learned through experience that it takes years to develop and incorporate new processes into routine manufacturing. For example, while we are working on the promising technology known as cell culture, we caution that it will take years to transition this technique from research to full scale production. Additionally, this technique will not substantially reduce the total production time.

Mr. Chairman, we share the Committee's concern and frustration with this year's supply problem. However, government authorities and the private sector have worked well together in the past to manage difficult situations to ensure optimal immunization rates.

We want to commend HHS, CDC and FDA's leadership for their immediate and decisive action to address what is inherently the unpredictable nature of vaccine production. In less than 12 hours,

CDC's Advisory Committee on Immunization Practices (ACIP) issued interim recommendations prioritizing influenza immunization for high-risk populations.

The National Flu Summit, a public-private partnership of CDC, professional associations, public health authorities and companies such as ours, has already discussed how best to manage this year's influenza season. Influenza professionals recommend that health care providers are the best equipped to determine who is at high risk and needs priority vaccination.

In summary, Aventis Pasteur pledges to do everything we can to manage this influenza season consistent with the recommendation of Federal and State Health authorities and commend Congress for prompt interest to address this issue during the busiest week of session.

Thank you, and I look forward to answering any questions the Committee may have.

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

Dr. YOUNG. Good afternoon, Mr. Chairman. Certainly a pleasure for me to be here this afternoon to address the committee on this very important topic, and I commend you on inviting members of the manufacturing community here to provide their perspective.

My name is Dr. Jim Young. I'm president of research and development at MedImmune, a biotech company headquartered in Gaithersburg, MD. As you may know, MedImmune is new to the influenza vaccine business, having introduced a new type of flu vaccine this past year called FluMist, approved by the FDA for use in helping individuals 5 to 49 years old. Unlike the other flu vaccines which are injected into the muscle, this vaccine is simply sprayed into the nose to protect against influenza.

MedImmune currently has the manufacturing capacity to produce 20 million doses of FluMist. This year, however, we produced only 2 million doses of bulk vaccine and before this week's events had planned on filling and finishing only 1.1 million of those doses, which we did. That finished material, I'm pleased to report, was released for distribution by the FDA yesterday.

I'm sure you are sitting there thinking, with the capacity to produce 20 million doses of this innovative vaccine, why did we only fill 1 million doses? Quite simply, because, one, the product was approved with a very narrow label indication by the FDA; two, it has been faced with significant confusion and misinformation propagated in the marketplace; three, has not had strong support from the recommending authorities; and, four, was launched into a climate of overwhelming complacency and with a lack of awareness on the part of the public as to the severe illness and death that is associated with influenza.

It is these factors that account for an insufficient demand to justify increased production of FluMist.

Nearly 8 months ago, I sat before this committee testifying that close to 4 million of the 5 million FluMist doses manufactured last season would be destroyed at the end of the 2003–2004 influenza season, a season in which there was a vaccine shortage and 152 children died from flu. Thirty-nine of those children actually were eligible to receive FluMist and could have received the vaccine but didn't. The fact of the matter is that there were 4 million lost vaccination opportunities with product that we had available that went unused.

Consequently, as a result of last season's experience and based upon FluMist's existing licensure for the restricted population of healthy individuals 5 to 49 years, MedImmune planned very limited production this season, somewhere between 1 and 2 million doses. This was a substantial about-face from original intent when we decided to enter the influenza vaccine business nearly 3 years ago with the desire to increase the number of influenza manufacturers in the United States and worked to fulfill the stated goals of public health officials to expand the number of U.S. citizens receiving influenza vaccination.

However, in response to the vaccine shortage announced this week, we are committed to filling the remaining bulk material we have in inventory actually starting today and expect to produce up to 1 million additional doses of FluMist for distribution. Under nor-

mal circumstances, getting these additional lots of FluMist approved and released by the FDA would likely take well into December. However, we are in communication with the FDA and hopeful that, with their assistance, the timing of this release can be expedited.

As they did during the flu crisis last season, the FDA has also indicated that it may be willing to consider waiving other logistical and distribution requirements, including the need for a freezebox to store vaccine in frost-free freezers, in order to broaden the distribution of these additional doses. None of these expedited procedures will, of course, pose any added risk to the consumer or to the quality of the product. By producing up to 2 million doses for the healthy population between 5 and 49, we are freeing up 2 million doses of the injectable vaccine for use in the highest risk population, which could potentially save hundreds of lives.

After our initial very disappointing and sobering experience as a flu vaccine manufacturer, we spent several months earlier this year evaluating whether we should remain in the influenza vaccine business or whether we should cut our losses and get out after dealing with the costly and overwhelmingly difficult regulatory landscape to bring this new and effective vaccine to the market. Our partner with FluMist last year, Wyeth, a former manufacturer of the inactivated flu vaccine, also went through this same internal debate. In April, Wyeth opted to exit while MedImmune decided to stay in the business.

MedImmune's decision to stay in the flu business was based on a continuing belief that influenza is an extremely important disease and that FluMist is an important new addition in prevention, warranting our investment to become a meaningful contributor to the vaccine production in this country. Since taking over complete control of the future of FluMist, we have cut the price of the product from $46 a dose last year to a price as low as $16 a dose this year for the private market and negotiated even lower prices for government purchases. We are working with the CDC, VA and DOD, providing them the option to purchase a significant proportion of the additional product we are now working to deliver to the marketplace.

While we are here today because of an imminent and serious vaccine shortage, I want to emphasize the problem is much larger and transcends well beyond the season. As Speaker of the House Dennis Hastert stated on Wednesday, "there are only a handful of vaccine manufacturers left in the world. We know that our current production capabilities would not be able to handle a massive surge for vaccine products caused by a flu crisis. We need to take steps to address this situation before it becomes an even bigger problem."

Bigger? How much bigger does this problem need to become? How many more hearings, analyses, consultants, discussions and testimonies must there be before any action is taken? Already, King Pharmaceuticals, Wyeth, Parke-Davis and Merck have pulled out of the influenza vaccine business over the past few years. Why are they exiting? Two reasons.

First to participate in the influenza vaccine business requires enormous investment in clinical development, manufacturing facilities and regulatory requirements; and the return on the investment

is abysmal, given the low price received for the vaccine. On our part, MedImmune has invested $1 billion to bring FluMist to the market with what is a very narrow label and expects to invest $200 million more in an attempt to expand the indication to a broader U.S. population, an amount that you saw this morning from Dr. Fauci's presentation, which is greater than the NIH is expected to spend on FluMist over the next 3 years.

Second, the demand for influenza vaccine is inconsistent, such that when manufacturers increase capacity in anticipation of broader demand, interest often wanes and unused product is wasted. Demand is strongly influenced by policies set by the Federal authorities. Current influenza vaccine recommendations primarily target high-risk individuals. However, the burden of the influenza virus illness is significant in healthy persons who fall outside of these targeted age groups as well and in otherwise healthy unvaccinated school-aged children who serve as vectors for transmission of influenza to their families and to high-risk individuals with whom they have contact.

The vast majority of stakeholders in influenza prevention are reaching the same conclusion, that the recommended population for influenza vaccination must be expanded greatly, a movement that we all endorse. A universal recommendation that all Americans receive annual flu vaccine will drive the demand for routine annual vaccination and the development of sufficient infrastructure to develop the vaccine, which will in turn provide the impetus on the part of vaccine manufacturers to increase their production. This will ensure the capacity needed to produce even larger quantities of vaccine in the event of the emergence of a new pandemic strain.

Ironically, it is a situation like the one we are now faced with, where we are telling healthy individuals not to get vaccinated, which runs counter to the message public health authorities need to send to expand demand. History tells us that it will take several years before many healthy individuals again seek vaccination for flu.

What is it that MedImmune specifically recommend that the Federal Government do?

First, we believe that regulatory authorities should look at the available scientific and clinical data pertaining to FluMist and reconsider a broader role FluMist could play potentially within the context of public health given the benefits that we have demonstrated in clinical studies of this vaccine. This is particularly relevant to the 50 to 64-year-old high-risk group that will otherwise go unprotected this year.

Second, the government needs to find ways to incentivize companies to build manufacturing facilities in the United States. There is an increasing trend for U.S.-based companies to build manufacturing plants offshore in order to gain access to a well-trained pool of potential workers as well as significant tax advantages. With this trend comes the increased risk of the type of event we are currently experiencing. Companies will face regulatory decisions that may prevent product from entering the United States or, worse yet, in the event of a catastrophic event or the emergence of a new pandemic strain, the host country may embargo vaccine for use in its own borders.

Third, logistical and accounting issues need to be sorted out so that the Federal Government can stockpile additional product or even bulk vaccine, a relatively inexpensive step in the manufacturing process. Bulk material could be stored for up to 2 years or until a new influenza strain is introduced and could be filled at a defined schedule as needed.

Finally, the Federal Government should provide incentives for manufacturers to develop innovative production methods that could expand the capacity. They should make potential new vaccine strains available to the manufacturer sooner and eliminate the need for the FDA release for flu vaccine lots. All of these would result in earlier and greater product availability.

In conclusion, I would like to reiterate that MedImmune has manufacturing capacity to produce 20 million doses of influenza vaccine; and with the addition of our new $75 million state-of-the-art manufacturing facility currently being validated and modest changes in the works at our current facility, we will soon be able to produce 40 to 50 million doses of vaccine. In order to make production at these levels a viable option, we need the Federal Government to create sufficient support and demand to reduce regulatory hurdles and to place a far higher value upon influenza vaccination for all Americans.

Thank you for this opportunity to speak to you today.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Young follows:]

MedImmune Oral Testimony
Congressional Hearing on Government Reform, October 8, 2004

Good morning. It is a pleasure to be here this morning to address the Committee on this very important topic. My name is Dr. Jim Young, and I am the President of Research and Development at MedImmune, Inc., a biotechnology company headquartered in Gaithersburg, MD. As you may know, MedImmune is new to the influenza vaccine business having introduced a new type of flu vaccine this past year called FluMist, approved by the FDA for use in healthy individuals 5 to 49 years old. Unlike the other flu vaccines which are injected into the muscle, this vaccine is simply sprayed into the nose to protect against influenza.

MedImmune currently has the manufacturing capacity to produce 20 million doses of FluMist. This year, however, we produced only 2 million doses of bulk vaccine and before this week's events, had planned on filling and finishing only 1.1 million of those doses, which we did. That finished material, I am pleased to report, was released for distribution by the FDA yesterday.

I'm sure you're sitting there thinking, "With a capacity to produce 20

million doses of this innovative vaccine, why did we only fill only 1.1 million doses?" Quite simply, because the product

1) was approved with a very narrow indication by the FDA,
2) has been faced with significant confusion andeven misinformation propogated in the marketplace,
3) has not had strong support from the recommending authorities, and
4) was launched into a climate of overwhelming complacency and with a lack of awareness on the part of the public as to the severe illness and death that is associated with influenza.

It is these factors that account for an insufficient demand to justify increased production of FluMist.

Nearly eight months ago, I sat before this committee, testifying that close to 4 million of the 5 million FluMist doses manufactured last season would be destroyed at the end of the 2003-2004 influenza season, a season in which there was a vaccine shortage and 152 children died from flu. Thirty nine of those children actually were eligible to receive FluMist and could have received the vaccine, but didn't. The fact of the matter is that there were 4 million lost

vaccination opportunities with product we had available that went unused.

Consequently, as a result of last season's experience and based upon FluMist's existing license for the restricted population of healthy individuals age 5 to 49 years, MedImmune planned very limited production this season, somewhere between one and two million doses. This was a substantial about-face from our original intent when we decided to enter the influenza vaccine business nearly three years ago with the desire to increase the number of influenza manufacturers in the U.S. and work to fulfill the stated goals of public health officials to expand the number of U.S. citizens receiving influenza vaccination.

However, in response to the vaccine shortage announced this week, we have committed to filling the remaining bulk material we have in inventory starting today and expect to produce up to 1 million **additional** doses of FluMist for distribution. Under normal circumstances, getting these additional lots of FluMist approved and released by the FDA would likely take well into December. However,

we are in communication with the FDA and are hopeful that with their assistance, the timing of this release can be expedited. As they did during the flu crisis last season, the FDA has also indicated that it may be willing to consider waiving other logistical and distribution requirements, including the need for a freezebox to store vaccine in frost-free freezers, in order to broaden the distribution of these additional doses. None of these expedited procedures will, of course, pose any added risk to the consumer or to the quality of the product. By producing up to 2 million doses for the healthy population between 5 and 49, we are freeing up 2 million doses of the injectible vaccine for use in the highest risk population, which could potentially save hundreds of lives.

After our initial "very disappointing" and sobering experience as a flu vaccine manufacturer, we spent several months earlier this year evaluating whether we should remain in the influenza vaccine business, or whether we should "cut our losses and get out " after dealing with the costly and overwhelmingly difficult regulatory landscape to bring this new and effective vaccine to market. Our partner with FluMist last year, Wyeth, a former manufacturer of the

inactivated flu vaccine, also went through this same internal debate. In April, Wyeth opted to exit while MedImmune decided to stay in the business.

MedImmune's decision to stay in the flu business was based on our continuing belief that influenza is an extremely important disease, AND that FluMist is an important new advance in prevention, warranting our investment to become a meaningful contributor to vaccine production in this country. Since taking over complete control of the future of FluMist, we have cut the price of the product from $46 per dose last year to a price as low as $16 per dose this year for the private market and negotiated even lower prices for government purchases. We are currently working with the CDC, VA and DoD, providing them the option to purchase a significant proportion of the additional product we are now working to deliver to the marketplace.

While we are all here today because of an immediate and serious vaccine shortage, I want to emphasize that the problem is much

larger, and transcends well beyond this season. As Speaker of the House, Dennis Hastert stated on Wednesday, "There are only a handful of vaccine manufacturers left in the world. We know that our current production capabilities would not be able to handle a massive surge for vaccine products caused by a flu crisis. We need to take steps to address this situation before it becomes an even bigger problem."

Bigger? How much bigger does this problem need to become. How many more hearings, analyses, consultants, discussions, and testimonies must there be before any action is taken. Already, King Pharmaceuticals, Wyeth, Parke-Davis, and Merck have pulled out of the influenza vaccine business over the past few years.

So why are they exiting? Two reasons.

First, to participate in the influenza vaccine business requires enormous investment in clinical development, facilities and regulatory requirements and, currently, the return on the investment is abysmal given the low price received for the vaccine. On our part, MedImmune has already invested $1 billion to bring FluMist to the

market with what is a very narrow label and expects to invest $200 million more in an attempt to expand the indication to a broader U.S. population.

Second, the demand for influenza vaccine is inconsistent, such that when manufactures increase capacity in anticipation of broader demand, interest often wanes and un-used product is wasted. Demand is strongly influenced by policies set by federal health authorities. Current influenza vaccine recommendations primarily target high-risk individuals. However, the burden of influenza illness is significant in healthy persons who fall outside these targeted age groups as well, and in otherwise healthy unvaccinated school-age children who serve as vectors for transmission of influenza to their families and to high-risk individuals with whom they have contact.

The vast majority of stakeholders in influenza prevention are reaching the same conclusion: that the recommended population for influenza vaccination must be greatly expanded, a movement that we all endorse. A universal recommendation that all Americans receive annual flu vaccine will drive the demand for routine annual

vaccination and the development of sufficient infrastructure to deliver the vaccine, which will in turn, provide the impetus on the part of vaccine manufacturers to increase their production. This will also insure the capacity needed to produce even larger quantities of vaccine in the event of the emergence of a new pandemic strain. Ironically, it is a situation like the one we're now faced with, where we are telling healthy individuals NOT to get vaccinated, which runs counter to the message public health authorities need to send to EXPAND demand. And unfortunately, history tells us that it will take several years before many healthy individuals again seek vaccination for flu.

So what is it that MedImmune would specifically recommend the federal government do?

First, we believe that regulatory authorities should look again at the available scientific and clinical data pertaining to FluMist, and re-consider a broader role FluMist could potentially play within the context of public health given the benefits that have been

demonstrated in clinical studies of this vaccine.

Second, the government needs to find ways to incentivise companies to build manufacturing facilities in the U.S. There is an increasing trend for U.S.-based companies to build manufacturing plants offshore in order to gain access to a well trained pool of potential workers as well as significant tax advantages. With this trend, comes the increased risk of the type of event we are currently experiencing, companies will face regulatory decisions that may prevent product from entering the U.S., or worse yet, in the event of a catastrophic event or the emergence of a new pandemic strain, the host country may embargo vaccine for use within its own borders.

Third, logistical and accounting issues need to be sorted out so that the federal government can stockpile either additional product or even bulk vaccine, a relatively inexpensive step in the manufacturing process. Bulk material could be stored for up to 2 years or until a new influenza strain is introduced, and could be filled at a defined schedule as needed.

Finally, the federal government should provide incentives for manufacturers to develop innovative production methods that could expand capacity, make potential new vaccine strains available to manufacturers sooner and eliminate the need for the FDA release of flu vaccine lots. All of these would result in earlier and greater product availability.

In conclusion, I'd like to reiterate that MedImmune currently has the manufacturing capacity to produce 20 million doses of influenza vaccine and with the addition of our new $75 Million state-of the-art manufacturing facility currently being validated and modest changes in the works to our current fill/finish facility, we will soon be able to produce 40 to 50 million doses. However, in order to make production at these levels a viable option, we need the federal government to help create sufficient support and demand, to reduce regulatory hurdles and to place a far higher value upon influenza vaccination for all Americans.

Thank you again for this opportunity to speak to you today.

Chairman TOM DAVIS. Dr. Stroube.

Dr. STROUBE. Mr. Chairman, distinguished members of the committee, my name is Robert Stroube; and I'm the State health commissioner for the Commonwealth of Virginia and honored to be testifying before you today. I would like to thank the Chair and the committee for holding this hearing regarding the recent developments concerning the U.S. influenza vaccine supply.

The recent flu vaccine shortage is creating a serious challenge for public health. The present system of vaccine production and distribution is incapable of effectively responding to the current demand for the vaccine, let alone a large-scale flu outbreak or pandemic. It is imperative the Federal Government take steps now to improve our current flu vaccine production and distribution system.

In Virginia, the health department ordered about 110,000 doses of flu vaccine from Chiron, which we will not receive. This is almost all the flu vaccine that we typically provide to adults through 119 local health departments. Not having this vaccine will mean that many people, especially those at high risk for flu complications, will not be able to count on their local health department for a flu shot this year.

At this time, we expect only to receive about 11,000 doses of adult flu vaccine, but this is a drop in the bucket compared with the amount of flu vaccine that is needed for those people in our communities who are most vulnerable to serious complications from the flu. Any flu vaccine available from our local health departments will be provided to those people in the high-risk priority groups recommended by the Advisory Committee on Immunization Practices this past Tuesday.

The flu vaccine shortage hopefully will not impact the more than the 115,000 doses of flu vaccine we have ordered from Aventis for children in the Vaccines for Children program. This program is for underinsured children, Native American children and those on Medicaid. But the health department provides only a very small proportion of the flu vaccine that is provided to the public. Most vaccines are provided by the private sector.

The biggest difficulty is determining how much flu vaccine is available in the private sector within our State and how to advise the at-risk population on where to find any available vaccine. We do not have a way of tracking flu vaccine availability in the private sector. We do not have any legal authority to redirect flu vaccine in the private sector.

We are making every effort to encourage the medical community to follow the ACIP recommendations and prioritize the available supply for people in the priority groups identified. We have distributed information from the CDC to the health care community through our Health Alert Network. Over 54,000 health care providers were notified by e-mail or faxed Tuesday night and Wednesday.

In addition to our outreach to the medical community, we distributed a Statewide press release urging the prioritization of available flu vaccine, we have conducted numerous media interviews, and we have taken hundreds of phone calls from citizens. We are providing people the best information we have available regarding this developing situation.

This serious situation is compounded by the fact that we have gone to great lengths over the past few years to educate the people about the importance of getting their flu shot each year. We have not only encouraged people in the high-risk groups to get their flu shot, but more and more it has been encouraged for all people.

We had just launched our Statewide education efforts for this year—prior to receiving the unexpected news from Chiron. Our education efforts have now been undermined again due to this situation. For example, we had to cancel our annual "vaccinate and vote" campaign, which targets the vaccination of high-risk individuals on Election Day.

Six upcoming smallpox vaccination dispensing exercises for a bioterrorism preparedness program are now on hold because we were going to use flu vaccine to get volunteers to participate in these exercises.

This current situation follows similar problems we had last year when we ran out of flu vaccine at the height of the season. Last year, VDH, the Virginia Health Department, administered more than 160,000 of flu vaccine to the public, which is more than double the number of flu shots that we typically provide.

When we ran out of the flu vaccine last year, many high-risk patients went without vaccine, parents could not get young children vaccinated, and health care providers could not vaccinate their staff. Attempting to prioritize vaccine to high-risk patients was a local health department nightmare. In some cases, security was needed to maintain control of demanding patients.

Now Virginia and other States are faced with the difficulties of prioritizing a limited supply of flu vaccine again, even more limited than last year. We anticipate that many people will go unvaccinated this year.

As you know, only three companies are licensed in the United States to produce the vaccine. Chiron was expected to provide about half of the vaccine supply. Aventis is the other company that produced the flu vaccine for injection. The third company produces the live attenuated nasal flu vaccine, which is not targeted for the high-risk patients.

As I stated earlier this year when I testified before this committee, Congress needs to support the development a of a more reliable vaccine production and distribution process. The current year-long process is incapable of meeting increasing vaccine demands or timely adjustments to vaccine formulation. The Nation's influenza program must include a comprehensive and critical look at all aspects of the system, including production and distribution of vaccine.

The current situation over the past few years caused concern regarding our ability to address an influenza pandemic in the United States. Virginia has a pandemic flu response plan, but that plan cannot be effectively carried out without having an adequate supply of vaccines and antiviral medications. We must rely on the Federal Government to assure this.

In Virginia alone, we estimate that during an influenza pandemic there could be more 1.3 million outpatient visits, over 28,000 hospitalizations and over 6,200 deaths in a 12- week period. The

thought of these statistics alone are enough to make improving the flu vaccine production and distribution system a high priority.

Given the estimated 36,000 people that die each year in the United States due to flu, I believe addressing the flu vaccine production and distribution problem should be a high priority for Congress. Government must support improvements of the vaccine production process and consider ways to ensuring that enough flu vaccine is available.

Thank you for the opportunity to speak to you, and I will be glad to answer questions.

[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 October 8, 2004, 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 regarding the recent developments concerning the U.S. influenza vaccine supply.

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 was appointed by Governor Warner in 2001. I have served Virginia in virtually every leadership position within public health at the state and local level during my career of over 31 years.
I earned a Doctor of Medicine degree from the Medical College of Virginia, a Masters in Public Health from the 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.

The recent flu vaccine shortage is creating a serious challenge for public health. The present system of vaccine production and distribution is incapable of effectively responding to the current demand for the vaccine let alone a large scale flu outbreak or pandemic. It is imperative that the federal government take steps now to improve our current flu vaccine production and distribution system.

In Virginia, the health department ordered about 110,000 doses of flu vaccine from manufacturer Chiron, which we will not receive. This is almost all of the flu vaccine that we typically provide to adults through our 119 local health departments.
Not having this vaccine will mean that many people – especially those at high risk for flu complications – will not be able to count on their local health department for a flu shot this year.

At this time, we expect to only receive about 11,000 doses of adult flu vaccine. But this is just a drop in the bucket compared with the amount of flu vaccine that is needed for those people in our communities who are most vulnerable to serious complications from the flu.

Any flu vaccine available through our local health departments will be provided to those people who are in the high risk priority groups recommended by the Advisory Committee on Immunization Practices (ACIP) this past Tuesday.

The flu vaccine shortage hopefully will not impact the more than 115,000 doses of flu vaccine we have ordered from Aventis for children enrolled in the Vaccines for Children

(VFC) program. This program is for un-insured and under-insured children, Native American children, and those on Medicaid.

But the health department provides a very small proportion of the flu vaccine that is typically provided to the public. Most vaccine is provided by the private sector.

The biggest difficulty is determining how much flu vaccine is available in the private sector within our state and how to advise our at-risk populations on where to find any available vaccine. We do not have an instantaneous way of tracking flu vaccine availability in the private sector, and we do not have any legal authority to redirect flu vaccine in the private sector.

We are making every effort to encourage the medical community to follow the ACIP recommendations and prioritize the available supply for people in the priority groups identified. We have distributed information from the U.S. Centers for Disease Control and Prevention to the health care community through our Health Alert Network.

In addition to our outreach to the medical community, we distributed a statewide press release encouraging the prioritization of available flu vaccine, we have conducted numerous media interviews, and we have taken hundreds of phone calls from citizens. We are providing people the best information we have available regarding this developing situation.

This serious situation is compounded by the fact that we have gone to great lengths over the past few years to educate the public about the importance of getting their flu shot each year. We have not only encouraged people in the high risk groups to get their flu shot, but more and more it is being encouraged for all people.

We had just launched our statewide education efforts for this year – prior to receiving the unexpected news about Chiron. Our education efforts have now been undermined again due to this situation. For example, we had to cancel our annual "Vaccinate and Vote" campaign, which targets the vaccination of high risk individuals on Election Day.

And, six upcoming smallpox vaccination dispensing exercises for our bioterrorism preparedness program are now on hold because the flu vaccine was going to be provided to volunteers participating in those exercises.

This current situation follows similar problems we had last year when we ran out of flu vaccine at the height of the season. Last year, VDH administered more than 160,000 doses of flu vaccine to the public, which is more than double the number of flu shots than is typically provided through our local health departments. During a typical year the health department provides about 70,000 doses of flu vaccine.

When we ran out of the flu vaccine last year, many high-risk patients went without vaccine, parents could not get young children vaccinated, and healthcare providers could not vaccinate their staff. Attempting to prioritize vaccine to high-risk patients was a local health department nightmare. In some cases security was needed to maintain control of demanding patients.

Now Virginia and all the other states are faced with the difficulties of prioritizing a limited supply of flu vaccine again, even more limited than last year, and we can anticipate that many people will go unvaccinated this year.

As you know, only three companies are licensed in the U.S. to produce the flu vaccine. Chiron was expected to provide about half of the flu vaccine supply for the U.S. this year. Aventis is the only other company that produced the flu vaccine provided by injections. The third company produces the live attenuated nasal flu vaccine, which is not targeted for high-risk patients.

As I stated earlier this year when I testified before this committee, Congress needs to support the development of a more reliable vaccine production and distribution process. The current year-long process is incapable of meeting increasing vaccine demands or timely adjustments to vaccine formulation. The nation's influenza program must include a comprehensive and critical look at all aspects of the system including production and distribution of vaccine.

The current situation and our experience over the past few years cause concern regarding our ability to effectively address an influenza pandemic in the U.S. VDH has an influenza pandemic response plan, but that plan cannot be carried out without having an adequate supply of vaccines and anti-viral medications. We must rely on the federal government to assure this.

In Virginia alone, we estimate that during an influenza pandemic there could be more than 1.3 million outpatient visits, over 28,000 hospitalizations, and over 6,200 deaths in a 12 week period. The thought of these statistics alone are enough to make improving the flu vaccine production and distribution system a high priority.

It is time for the federal government to become more involved in the manufacturing process of the flu vaccine. We cannot get by with just two manufacturing companies providing the flu vaccine that is targeted for our high risk populations.

Given the estimated 36,000 people that die each year in the U.S. due to flu— I believe addressing the flu vaccine production and distribution problem should be a high priority for Congress.

Government must support improvements of the vaccine production process and consider ways of ensuring that enough flu vaccine is available.

Thank you for this opportunity to speak with you today. I would be pleased to answer any questions you may have.

Chairman TOM DAVIS. Well, thank you all.

I would ask unanimous consent to put in the record a letter from a Mr. Victor Schwartz talking about his concerns about product liability issues for a national vaccine strategy.

And Mr. Waxman wanted to put in the record a letter to Secretary Thompson signed by Evan Bayh and Rahm Emanuel.

Without objection, those will go into the record.

[The information referred to follows:]

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October 8, 2004

VIA ELECTRONIC MAIL

The Honorable Thomas M. Davis III
Member, U.S. House of Representatives
306 Cannon House Office Building
1st Street and Independence Avenue, S.E.
Washington, D.C. 20515

Re: PRODUCT LIABILITY ISSUES FOR A NATIONAL VACCINE STRATEGY

Dear Congressman Davis:

I was pleased to learn that you are holding emergency hearings today regarding the shortage of flu vaccine caused by the fact that a British manufacturer learned that its vaccine supply had become contaminated. For almost two decades, I have warned that our dependence on foreign manufacturers of vaccines could lead a health crisis in this country.

Not long ago, there were at least twelve domestic manufacturers of vaccines. Now, there are only two principal domestic manufacturers of vaccines. The flight of domestic manufacturers from vaccine production has been caused, in part, by a well-based concern regarding excessive liability exposure. In a nutshell, this is why.

An adverse health consequence may result following the administering of a vaccine. If such an event occurs, there is a distinct possibility that a plaintiff's lawyer will bring a product liability claim against the manufacturer, even if there is no actual causation between the vaccine and the harm. Unfortunately, there are courts in this country that will allow "junk science" experts to testify and opine about linkages that do not, in fact, exist.

Vaccines are generally administered to healthy people. For that reason, if an adverse result occurs, out-of-pocket damage awards can be in the millions. On top of those large awards are damages for pain and suffering, as well as other "noneconomic" damages. These may run as much as ten or twenty times the amount of out-of-pocket awards. These "noneconomic damage" awards have been on the rise in recent years.

Vaccine production is not, as you know, a highly profitable business. There often is one use per year for the vaccine, or even one use for a substantial number of years. In light of meager potential profits from such vaccines, one can readily understand how excessive liability exposure can lead potential domestic pharmaceutical manufacturers to say, "no thanks" to vaccine production.

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In the early 1980's, I worked with Democrat Rep. Waxman and Republican Members of the House on the National Childhood Vaccine Act. It has had some problems, but also has achieved the goals of assuring a supply of childhood vaccines. The key point about the Act is that in general, it took claims out of the tort liability system. It has certain "escape hatches" that may make it less than a perfect model for legislative action, but it is a possible starting point for adult vaccines.

My learned colleague, Jim Wood, of the Reed Smith law firm in Oakland, California, and I prepared a paper on the issue of a national vaccine liability strategy for the Chemical and Biological Arms Control Institute. I hope you might find it useful for you and Members of your Committee, as you work on this crucial issue. It is attached.

I stand ready to assist you and your staff in any way you deem appropriate.

Sincerely yours,

Victor E. Schwartz

Attachments

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Overland Park
San Francisco
Tampa
Washington, D.C.

Congress of the United States

Washington, DC 20515

October 7, 2004

Secretary Tommy Thompson
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Thompson:

Last influenza season, millions of Americans were forced to risk their health and well being because of a preventable vaccine shortage. This was unfortunate. However, what is even more alarming is that the Government's inaction has allowed history to repeat itself and our most vulnerable populations will be left unprotected once again. The Government has taken few steps forward in preparing our nation to combat the flu and address the 36,000 preventable deaths that occur annually.

This year, we introduced the Flu Protection Act, which was designed to address the influenza vaccine shortage in a comprehensive manner and break the vaccine shortage and delay cycles we have been experiencing for four out of the last six years. Unfortunately, some of the key recommendations in the Flu Protection Act went ignored and people are again left waiting in long lines with little hope of receiving the vaccine and protecting their loved one from a potentially deadly disease.

The recent initiative unveiled by the Centers for Disease Control to purchase and stockpile four and a half million doses of the influenza vaccine acknowledged that the government needs to play a role in ensuring a sufficient supply of the vaccine. This realization is commendable. However, much more needed to be done to make sure that all vulnerable populations were protected against influenza.

Under our proposed Flu Protection Act, the government would work with the CDC and vaccine manufacturers to estimate how many flu vaccines will be purchased each year. Currently there is an economic disincentive for manufacturers to produce an ample supply since each unused vaccine is a direct financial loss for their company. Understanding this dynamic, the federal government should create a guarantee-purchase supply program for the amount of vaccines necessary for each given flu season while educating the public on the need to be vaccinated. The guarantee-purchase supply program would only go into effect if the vaccine doses requested to be produced were not utilized by the end of the flu season by the marketplace. This method would provide manufacturers with an incentive to produce enough vaccines while only spending federal funds if the public becomes complacent and does not get vaccinated and would be a more fiscally responsible approach to current vaccine shortfall.

The Flu Protection Act also calls for greater flu education and outreach, a factor that is crucial in making sure that the Americans who most need the flu shot are prepared to get one. In addition, if the public is properly educated on the need for the vaccine, who should obtain the

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vaccine and when to be vaccinated, it is unlikely there will be a large quantity of unused doses at the end of each flu season for the government to consume.

As we have seen this year, we must also do more to decrease our reliance on only two vaccine manufacturers. The Flu Protection Act would have encouraged additional vaccine production in the United States by providing vaccine manufacturers incentives to either build or expand their manufacturing facilities in the U.S. Increasing the number of providers of the flu vaccine will increase our chances for having ample vaccine supply.

In addition to these efforts, we need to make efforts to research alternative influenza vaccines with a faster production time and explore ways to improve upon current vaccine manufacturing methods so that the necessary amount of vaccine is available at the beginning of the flu season when people could use it the most. The Flu Protection Act provides $100 million a year for such research efforts.

Finally, in the event of a shortage or a pandemic, the Government needs to develop a protocol to disseminate the vaccine to those who need it the most in an emergency and determine which strains to include in the vaccine with greater certainty. The Flu Protection Act would have required such a plan. In August of this year, the CDC indicated that approximately 2 million of Chiron's influenza vaccine doses would be unavailable for shipment due to contamination and that ongoing investigations would determine if their remaining supply would be released. During this time, the CDC should have developed a contingency plan and prepared public health officials in the event that the remaining 48 million of Chiron's doses were unusable. Instead, we find ourselves in the midst of another flu vaccine crisis and with no plan in place.

To address this immediate shortage, we recommend the Centers for Disease Control to quickly review any unreleased vaccine lots to determine if they can be used for this years flu season, prioritize those who need to be vaccinated through the shot first and determine recommendations for those who can be vaccinated through the FluMist. In addition, the government should take appropriate steps to ensure price gauging does not result as it has in the past during shortages, look for additional vaccine supply domestically and abroad and explore all other methods to manage the complications from the flu such as the use and availability of antivirals.

We have no appropriate excuse to offer Americans with children or older parents who find themselves waiting in line again for flu shots. If our Flu Protection Act had been implemented last year, we would have been a year ahead of where we are today. We cannot afford any additional delays and urge you to support the Flu Protection Act.

Sincerely,

Evan Bayh

Rahm Emanuel

Chairman TOM DAVIS. Let me start the questioning.

Dr. Young, on MedImmune, it just was called to my attention in terms of what NIH was telling some of their employees about the FluMist for some of their health care workers. For healthy people who don't fall into those vulnerable areas, FluMist is about all we are going to be able to get this year. What level of protection does that give, and if you are a health care worker or a vulnerable population, why isn't this used for them? Can you explain that?

Dr. YOUNG. Currently, because of the body of data we have from our clinical trials, supports the use in healthy 5 to 49 year olds. That is where the FDA approved it. We have done numerous studies in younger populations, older populations——

Chairman TOM DAVIS. Your 5 to 49-year-olds. Vulnerable population is 65 and over?

Dr. YOUNG. Absolutely.

Chairman TOM DAVIS. That leaves me out. What do you do if you are 55?

Dr. YOUNG. Although we have done studies——

Chairman TOM DAVIS. If you are a 55-year-old healthy guy where does that put you?

Dr. YOUNG. You know, I ask the same question. I am 51 years old, and I ask why should I not be able to receive FluMist when my 49-year-old peer can. I certainly don't believe that I am at any worse risk to receiving——

Chairman TOM DAVIS. This was just in clinical trials.

Dr. YOUNG. That is right.

Chairman TOM DAVIS. There is no evidence that it doesn't work. It is just that is where it has been——

Dr. YOUNG. Well, in fact, we have—our original clinical trial was in adults up to age 64. It is an interesting situation where, when we went to the Vaccine Advisory Panel of the FDA the first time, 4 years ago, they actually recommended approval for all adults up to age 64. In the meantime, 2 years later, 50 to 64-year-olds had become a recommended population for the vaccine. When the committee was asked again, should this be approved now for 50 to 64-year-olds, we were in a double jeopardy situation, and they said, well, we think it is safe, but we can't be sure that the efficacy has been demonstrated sufficiently to recommend approval.

We had actually gotten the reverse message from the FDA on that. They thought that we needed more efficacy data when, in fact, there is no—all of the evidence from the clinical trails suggests it is just as efficacious in that segment as in the lower population, adult population segment.

So I think we need to relook at that, particularly in a situation where last year we were recommending that 50 to 64-year-olds are a high risk population and yet now we are saying that they shouldn't get it, when in fact we may have a vaccine that could be useful in that population.

Chairman TOM DAVIS. Now, based on last year's sale, you produced a smaller supply of flu vaccines this year, is that right?

Dr. YOUNG. That is correct.

Chairman TOM DAVIS. Does the vaccine shortage this season—will that affect your decision next year? And is there any way you can cook up a larger batch this year or it is too late?

Dr. YOUNG. As I mentioned in my testimony, we actually had some additional unfilled product in inventory in freezers, which we are now thawing out and re—and filling to provide potentially another million doses of vaccine. But we can't ramp up de novo new additional supplies beyond that.

Whether it will influence us to produce more vaccine remains to be seen. We still have a lot of questions in the marketplace, a lot of confusion.

Just this morning you heard Dr. Gerberding report about the revised recommendations that came out 2 days ago suggesting that healthy health care workers and those who care for young, young children should be encouraged to use FluMist. While she was testifying to that, the NIH put out a memo to their employees saying they should not, in their hospitals, should not receive FluMist. So again adding to the confusion that the agencies are putting out different mixed messages out there to the constituencies.

Chairman TOM DAVIS. OK. Thank you.

Ms. Grant, you mentioned in your testimony that demand drives supply. What can the government do to help ensure that the demand for the annual flu vaccine is predictable? We do that for farmers. I mean, vaccine is pretty important.

Ms. GRANT. Well, I am going to start with a nonfinancial incentive first. That is to make sure that we are all pulling in the same direction in looking at the groups that aren't getting immunized. Only 67 percent of the seniors are getting immunized today, and yet we all know that is a recommendation. So that we can work with our agencies that care for Medicare patients, only 37 percent of our health care professionals in a year are getting immunized. They, obviously, are role models as well as needing to protect themselves. So we need to pull together to make clear year after year that we aren't anywhere near meeting the Healthy People 2010.

I think the other issue, a financial incentive that needs to continue to be discussed and reviewed, is you heard about the strategic stockpile this year. Certainly that has turned out to be a wise investment that CDC thought of planning for, having a few million extra doses; and that is something which I would encourage your committee to continue to look on favorably.

Now a little of a good thing goes a long way, and then we have to balance to make sure what the appropriate sizing of such an annual strategic stockpile would be so we don't risk throwing away excessive doses. But those two approaches would help drive demand, which will drive supply.

Chairman TOM DAVIS. Thank you.

Mr. Kanjorski.

Mr. KANJORSKI. Thank you, Mr. Chairman.

Mr. Chairman, I have the great honor and privilege of being the Member of Congress representing Aventis in the Poconos in Pennsylvania. I have had the occasion to be at the plant on numerous occasions where 1,700 of some of the most highly qualified people are working day and night to provide protection not only for the influenza but other necessary vaccines.

My impression, having been there and met with the officials of that organizations is that their first mission is to meet the needs of the American population and the world population to fight infec-

tious diseases such as influenza. It seems to me they have the capacity to do so.

They are frustrated, if I may say, that government has not participated in the best way to get that done. We talk about it. We have hearings on it. I think, as the Secretary referred and the other gentleman on the panel, that nothing seems to be accomplished.

It seems that the Congress has hearings when we find out a disaster such as this occurs, but after that we all go home. I dare say we won't have another hearing on vaccinations or vaccines until the next terrorist attack or other such pandemic occurs in the world, and we will all come in here, rub our hands, and say why didn't we all prepare for this, when all of the three witnesses today that are appearing at this panel, and the three earlier witnesses, are telling us out that there are things we can do to make sure that we smooth out the line for demand, that we anticipate future needs, that we anticipate pandemics and that we prepare to meet those challenges at relatively small cost.

I think I heard the figure of $100 million for a plant, and I think I have heard in the past maybe $1 billion of investment and other incentives to this industry would really bring us up to high speed to prepare for whatever we need at the highest technical response that science can give us and industry can give us.

I did a little calculation, and that was part of my antagonism toward the first panel. I am sure they are capable and doing the best they can. But what you are talking about, if it were $1 billion, it would cost us only 2 days of the cost of the Iraq war; and we are talking about the risk of 300 million Americans and 6 billion people in the world.

When you will look at the numbers in any regard and the lead time necessary to meet these challenges, the expenditures of 2 days of the Iraq war or a week of the Iraq war is miniscule. That money I think could be made available by the Congress, and probably there is a full intent to do so, except we have pretty terrible communication between the executive branch with a plan, the Congress with a response of priority, and then the people that are going to do the work, the private sector in this country and all around the world, that seem to be left out except when they run into a problem or we have a problem. Then we have this tremendous partnership that joins for these few days to soothe the American population so that everybody can go home and think that we are prepared. We are neither prepared for a world influenza epidemic, and we are certainly not prepared for a biological attack.

So, with all of this criticism, Mr. Chairman, it is not without a suggestion. I have enjoyed all of my visits to Aventis. I think they would entertain either this full committee or a representative portion of this committee to come up to the great Poconos Mountain areas for a day or two, show you what they do, show you what the industry does, show you the lack of coordination and cooperation between government and the industry and our various regulatory authorities and that we can walk away in 24 or 48 hours with an actual knowledge of what has to be done by this Congress and the executive branch of this government to really put a coordinated re-

sponse to the challenge of viral and bacterial infections in the United States. I highly recommend it.

Now I know I have a few minutes left.

Chairman TOM DAVIS. I will ask the staff to look at the that, too.

Mr. KANJORSKI. It is my invitation. Come on up there. You will enjoy it.

Chairman TOM DAVIS. It will certainly be better for me than the last time that I was in your district.

Mr. KANJORSKI. I agree with you, Mr. Chairman.

Mr. Chairman, Ms. Grant represents Aventis here. I just want to throw the question: What do you think the government has to do to help your company and other companies meet these challenges, not only of influenza but biological attack? What do we have to do? And lay it out and be candid with us.

Ms. GRANT. Well, thank you, Mr. Congressman; and we are equally honored to have you and your capable staff representing our employees and our district. So I thank you.

I would say we certainly welcome the committee's visit to the great State of Pennsylvania and the wonderful Poconos. You might want to consider doing it before the snow sets in, but—or after—but we would love to have you up there.

Congressman, I had mentioned five recommendations; and I will just reiterate two at this point.

First of all, it is the kind—a little kind of thing that I mentioned. And that is, for some reason, there are SEC accounting guidelines that just popped up in the last year or so which suddenly have created inconsistencies with the language that CDC has been using quite successfully with our and other companies for many decades to build strategic stockpiles. So it is like the old adage of, but for the nail in the horse's shoe, the battle was lost. So this little thing, which seems certainly within the purview of this committee, to perhaps talk about getting those two agencies together to see if we can't work that out.

The second issue, the very important issue you mentioned, planning for pandemic. CDC, through the National Vaccine Program Office, has just put out a draft plan for pandemic. We would strongly encourage this committee to think about the need to prepare now for the inevitable vaccine liability concerns and exposure that are going to emerge when any company in the world is asked to prepare a pandemic vaccine that by its very nature will not have had years of clinical trails and experiences.

What we are saying is we need to bring that issue to your attention. We need to work with you to make sure that we balance compensation and liability concerns so you are not disappointed when the companies point out that they just can't get in the business of working on the pandemic vaccine when we are in the middle of the pandemic.

So those are two of the five that I bring to your attention.

Chairman TOM DAVIS. Thank you very much, and thank you for what your company is doing.

Mr. Cooper, thanks for your patience.

Mr. COOPER. If we focus on the short-term concerns for a second. The earlier panel discussed the possibility of being able to halve the dose so that twice as many people could receive the vaccine or

the FluMist. What are the practical obstacles to making that happen, assuming that you got FDA approval for that?

Ms. GRANT. I am sorry, sir. As Dr. Fauci said, that is certainly something that—I am not sure it is a short-term solution. Because here we are in the midst of a season where we are already being advised by the public health authorities not to go the route of immunizing healthy individuals; and, as you heard, the trials done to date have been on healthy individuals. So while I believe my medical colleagues would suggest that there may be some promise in looking at that, it is probably too late this year to really think that is going to solve our problem.

I would be happy to ask my colleague, Dr. Johnson, to comment if he wishes.

Dr. YOUNG. If I can make a comment to that. I think the biggest concern is that there is concern now that the injectable vaccine doesn't work as well in the elderly as their immune system starts to decline with age. So the thought of halving a dose in a population which is currently thought to be suboptimally responding to the vaccine——

Mr. COOPER. So your product is for the healthy, 5 to 49, and could you halve the dose there?

Dr. YOUNG. Actually, half the dose would still fall in the specification for the vaccine.

Mr. COOPER. So you could do it?

Dr. YOUNG. The problem is that then you would have to adjust the shelf life to make it a much shorter half life so it doesn't fall below that spec over time. So unless the vaccine is used very quickly, that would be a problem.

Mr. COOPER. But FluMist could probably do it, if you got FDA approval?

Dr. YOUNG. Unfortunately, there is not a lot of data that supports being able to do that.

Mr. COOPER. I said if you got FDA approval.

Dr. YOUNG. Certainly.

Mr. COOPER. Second question. A number of jurisdictions across the country unfortunately ordered only from Chiron. What do we tell those jurisdictions that basically have no flu vaccine at all right now?

Ms. GRANT. As Dr. Gerberding said, literally Tuesday morning, as Blackberries were being worked at another hearing and the impact of this announcement became known, our company began to work with her staff to being to understand which States, particularly the public health sector, although it only buys about 10 percent of the vaccine, is and is not—does and does not have access.

As you heard, and I would like to reiterate, what we are working on together is to figure out where there is lack of coverage and then do the best we can. As she said, it won't be perfect, but the pledge is to try to make sure that we are able to provide some vaccines to all public health sectors.

Mr. COOPER. Let me put in a word for Nashville, TN, because it is my understanding that none of our hospitals in our city were able to get any vaccines. So it would be helpful there.

Third, for Aventis. When you sell the vaccine to a distributor, are there any safeguards against price gouging in the contract?

Ms. GRANT. OK. Well, in the case of a distributor, by their very nature, they intend to sell it on. So as far as our contract goes, we do not, per se, have controls over the price they charge.

I will say, however, Congressman, that as both an attorney and as a former health commissioner, I am well aware of the price—I think we should all be aware of the price-gouging laws that exist in every State and certainly our company would find that—any kind of price-gouging behavior absolutely outrageous and would encourage, if we hear from any customer or patient, to contact their local authorities to find out what their remedies are.

Mr. COOPER. How would you define price gouging? As a doubling of the price? What would it be?

Ms. GRANT. That is an interesting question. I really haven't thought about it to begin to volunteer a standard. But that might be one of those things that we would know when we see it.

Mr. COOPER. I think we are going to have a hard time reporting it unless we give them an idea of what the standard would be. If they don't know what they are going to report, you know, what is—what does the average vaccine sell for?

Ms. GRANT. Well, I will just say that our company has made very clear—our prices are known. It would be visible.

Mr. COOPER. What is the price?

Ms. GRANT. As was suggested, in general, it varies by the customer class and the type of vaccine. In general, this year it is between $8 and $10; and then the pediatric vaccine, the list price is about $12 a dose.

Mr. COOPER. So if customers were to see, $20, $25, that would be a doubling of the price; and that might count as gouging.

Ms. GRANT. A customer certainly might want to ask questions about that.

Mr. COOPER. There are a lot of other long-term concerns.

I appreciate everyone's testimony. I think you have given this panel and Congress a lot to think about; and hopefully we will be able to respond not only to this sort of problem but also a possibly larger problem, should bird flu or things like that come to the fore. Thank you very much.

Chairman TOM DAVIS. Thank you.

Mr. Van Hollen, thanks for your patience.

Mr. VAN HOLLEN. Thank you, Mr. Chairman. I also want to thank all of the witnesses for their testimony; and, Dr. Young, thank you for your testimony.

MedImmune is in my congressional district, Mr. Chairman, right here in Gaithersburg. So I think when we are planning that trip, Mr. Chairman, I just want to—we should make sure we stop in Gaithersburg, which is, of course, very close by here. I am sure that the company would be happy to have the committee visit.

Let me ask you, Dr. Young, or anybody else, but you in your testimony talked about the fact that there were a number of children last year who died of the flu who would have been eligible to receive FluMist. You were here I think for the testimony of Dr. Gerberding, and she was very reluctant to answer the question: What will be the direct health effect of this shortage that we are facing now in terms of the numbers of deaths and the number of

people hospitalized? And her answer was we can never predict the severity of the flu season and flu strain.

I understand that in terms of absolute numbers. But in terms of percentages, you know, given a particular flu season and the severity of that, do you have any estimate as to what this crisis is going to mean in terms of additional lives lost in this country?

Dr. YOUNG. I think it is very hard to come to a precise number, and it all depends on how well the available supplies of vaccine are deployed to the highest risk individuals.

Clearly, if we can continue to administer the available vaccine in that highest-risk elderly population, then clearly we can avoid a fair number of deaths, much like previous years.

Mr. VAN HOLLEN. Right.

Now, I guess the question—maybe this was asked earlier. But Aventis has obviously got contracts with certain providers already; and some of those, I assume, were providers who were going to be providing the product to people in the healthier range who would be eligible for FluMist. I guess the question is whether or not there is any discussions under way where we would redirect the Aventis product, which has been cleared for the broad age group, to the people at most severe risk and allow FluMist to be directed to those in the healthier age range.

Ms. GRANT. Well, I hope I gave the right figure about 33 million of our vaccine doses have already been distributed; and they certainly were, I am sure, sold to customers caring for all different populations.

You heard Dr. Gerberding say that, as we speak, our people are working with her people to figure out, certainly at the county level, where vaccine is. So I think we are always open—I mean, that will be, of course, a matter among the health providers at that level. The sheer scale—it would be unwise to promise too much because the sheer scale of the difference between the vaccine that we have produced and what under the best of circumstances can be available from FluMist won't solve the problem. But we will work together through CDC.

Mr. VAN HOLLEN. Let me ask you. You mentioned Dr. Gerberding and the fact that you are in discussions with some of your—the people you provided the product to and trying to figure out where it is and how we can get it to the most at need and risk populations. Has there been any reluctance on the part of Aventis to provide that information to public health officials at the county and State levels?

Ms. GRANT. I wouldn't characterize—I think the cooperation has been terrific. As I understand and in personally talking with her and in personally talking with our CEO who has been working with her, we are trying to do everything the best we can.

We are suggesting that there are some ways—just last year when we faced the late season surge demand and there was sort of the first instinct to, well, let's know where all of the vaccine is, having worked in the field for some 30 years our people knew that a lot of that vaccine had already been distributed. So that probably the first instinct should be let's ask people what they still have. Rather than trying to set up an enormously elaborate information system, sending things out, wondering why we are not hearing

back, just go out to people generally and say, if you have vaccine, please contact your local health officers. And that was actually rather successful.

So I don't think it is a question of reluctance. I think it is question of talking through practically what are you likely to get in the way of the best response to solve the problem. And that is as I understand where we are.

Mr. VAN HOLLEN. Good. Now I understand that with respect to the FluMist, because of the whole range of issues you discussed in your testimony, you didn't plan to produce more this year; and given the production times, it is just not feasible to do more than an additional million doses. Is that——

Dr. YOUNG. That is absolutely correct.

Mr. VAN HOLLEN. Dr. Fauci testified about some very, very important and good long-term options, but as we discussed the short-term options, I think your testimony is pretty clear. It is not so much in terms of our ability to generate more vaccine. It is a question of just using what we have and redistributing it.

Dr. YOUNG. Oh, yeah. If you look at the long-term planning that goes into supply requirements, it is years of planning. We have long-term 3-year, 4-year contracts with the egg producers to make sure that we have adequate supplies of substrate we need to grow the vaccine. Once we finish our campaign and stop making vaccine, the egg supply dries up; and, consequently, we can't go back and manufacture more product in a rapid response mode. So we have to really understand up front where the demand is going to be in order to ensure that we have adequate supplies on hand.

Mr. VAN HOLLEN. All right. Let me just ask one more.

In previous years, as I understand it, individuals in the 50 to 65-year range were also defined to be at high risk, is that right?

Dr. YOUNG. That is correct.

Mr. VAN HOLLEN. So when we get the list now of who is a high-risk group, it is really not based on a health decision. It is saying, here is the doses we have available, these are the people most at risk, but that those other individuals in this other age category, in terms of health analysis, they continue to be at risk as much this year as they were last year, right?

Dr. YOUNG. Absolutely. It is basically a triage system to say, with limited supply, who can we prioritize and ensure that we have the least—the greatest benefit for the amount of vaccine we have. And that is—it is a very difficult decision to have to say to someone, last year, you—we told you to get the vaccine. This year, we are telling you not to get the vaccine.

Mr. VAN HOLLEN. Thank you very much.

Chairman TOM DAVIS. OK. Any other questions?

Mr. VAN HOLLEN. No.

Chairman TOM DAVIS. Thank you all very much.

I know Ms. Blackburn is on her way over, so I am going to ask a couple of other questions as well.

Dr. Stroube, let me ask you: For those individuals who don't fall into the high-risk priority group for the flu vaccine, what precautions can they take to reduce their risks of contracting the flu?

Dr. STROUBE. Well, what we put out in—I was trying to find my press release so I can tell you exactly what we are telling people.

It is, basically, wash your hands if you have—anytime you think about it, anytime you have been with somebody or if you have a runny nose, to keep from spreading, to use good hygiene, to avoid—if you are sick with the flu, going in nursing homes, around people who are ill. Those are the type of recommendations we are making.

Chairman TOM DAVIS. Now, washing the hands, that is not—how does washing the hands help? Because your hand comes in contact with your face and everything else?

Dr. STROUBE. You rub your mouth and eyes, and then you have picked it up on your hands and you are transmitting it back to yourself.

Chairman TOM DAVIS. So washing your hands frequently would be one thing.

Dr. STROUBE. That is one thing. That is a traditional public health message for all kinds of things. But that is one of the things that we are stressing.

Chairman TOM DAVIS. What are we trying to do in Virginia since the British supply is now canceled for us? Are we going to try to work with the Center for Disease Control and Aventis and try to get some of that released for our vulnerable population?

Dr. STROUBE. Well, yesterday we had a video conferencing with all of our health directors all across the State and their staffs; and we are trying to find out what is going on from southwest Virginia, northern Virginia, the whole place, and come up with some consistent policies for the State. So we put a freeze yesterday on the vaccine we did have until we can sort out where it is and make sure it is equitably distributed.

Some of our local health departments got vaccine directly. Others didn't. So we want to try to do that. We want to come up with some knowledge of where the most needs are.

Yesterday, we were overcome, overwhelmed with nursing homes calling in and said they were relying on getting the vaccine from Chiron and don't have it. So we have to sort out who has vaccine, who needs it, and then figure out how we can match that up. And some will need persuasion, hopefully moving some of the vaccine that people have and using their good will to let us take it to other places on it.

We were actually hoping that we would be able to do more with the halving of the doses, but that doesn't look like it is going to be viable.

Chairman TOM DAVIS. How do private doctors get it? Do they get from the State or contract individually?

Dr. STROUBE. In Virginia, they contract directly with the distributors on it.

Chairman TOM DAVIS. Are you coordinating with them, too, to see what they have available, what doctors might——

Dr. STROUBE. Exactly. We sent out—like I was saying, 54,000 e-mails and faxes went out late Tuesday, early Wednesday to all of the health care providers. We have a law in Virginia now that requires that to provide their e-mail and fax to us, and we have that in a data base. We sent it out urging them to work with us, and we will be following up on that, trying to—at a local level, that will be passed off to our districts.

Chairman TOM DAVIS. Thanks. Let us know how we can help. Obviously, you learn from what has happened this year, and we just want—we don't want a reoccurrence, but we have to get through this year as well.

Mrs. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman; and I want to thank our panel for being here, all of the witnesses that have participated today.

In my State, in Tennessee, this is something that is important to us; and we are, of course, concerned about our supply, just as everyone else is. We have two suppliers, Chiron and—does about a third of the supply, and then Aventis does about two-thirds of the supply.

My question, Ms. Grant, is to you. You mentioned in your testimony, in your written statement, that demand drives the supply and what can the government do to help ensure that the demand for the annual flu vaccine is more predictable each year? Because one of the things that concerns me, and this is the reason that I asked the question of you, is it seems that so many times, regardless if we are looking at public health policy or we are looking at operational policy for governmental entities, whether it is the Federal, State or local entity, we are more reactive than proactive; and we fail to plan. We think in short-term segments and not long-term segments.

We know that you all have said—more than one of you have said in your written statements in your testimony that it takes from 5 to 7 years for a new company seeking to locate in the United States to be able to provide that vaccine. So, you know, I want you to, if you will, talk for just a moment about process and what we can do to do a better job with the predictable nature of what we would need each year.

Ms. GRANT. Well, as I mentioned in a couple of the recommendations, that it is very, very important that we all speak with the same language consistently, that despite the occasional setback, as we clearly are going to face this year which is frustrating to all of us, that we have to all agree that we are going to pull together to continue to recommend to the various risk groups the importance of being immunized.

And it is interesting, in Tennessee, I know that they are taking very seriously something that wasn't taken seriously a couple of years ago, and that is the importance of using standing orders when people are admitted to hospitals or nursing homes to make it very easy and routine. That is a process. It is a simple thing, in a sense. It is not so simple to execute it, but it is a simple thing to ensure that every single patient who is a resident of a nursing home or hospital year in year out is offered influenza vaccine.

There are millions of those patients, and that would have a profound affect on a certainty that demand—if all hospitals in all States we knew would do that, we would know how much more vaccine is likely to be utilized.

We talked about the health care workers, only 37 percent. If we had a common understanding that health care workers are ready, willing and able to—and interested in protecting themselves and their patients by being immunized.

So there are many individual things that we can do.

I mentioned the strategic reserve. Again, while the strategic reserve is not the total solution, the predictability of the government working with us collectively to think about what is the appropriate amount to guarantee that the government sector is interested in buying—we are not looking for that to be the total solution. It is a private market. It is working reasonably well. But those are a couple of very important things that we can start talking about.

Mrs. BLACKBURN. Thank you.

Dr. Young, I would like to hear from you and then Ms. Grant talking about, with a company who wants to locate, wants to create a flu vaccine and the 5 to 7-year window of time—which I think really is pretty optimistic if you are looking at it. But knowing the demand for vaccine is not going to be decreasing, it is going to increase, talk for a moment, if you will, about what you think that we should be looking at to shorten that window of time to create some efficiencies within what is a very heavily bureaucratic system which makes it very difficult for anyone who is doing R&D work or creating a vaccine to walk through that process. I would love to hear your thoughts on that.

Dr. YOUNG. It is a very complex issue, to say the least. Clearly, the vaccine business—the entire pharmaceutical business is highly regulated, as it well should be, to protect the safety of the public who receives these vaccines and drugs. So, clearly, very stringent standards have been established for current good manufacturing practices; and it is quite clear that it takes significant investments to meet those standards to design, construct, validate. We have to demonstrate that the process works reproducibly within certain parameters, time in and time out, to assure the quality of the product.

It is particularly significant when you start talking about biological products like this. It is not like chemical processes that are very easy to control and maintain strict control over the parameters of production. It is the manufacturing of biological products that become very labor intensive and testing intensive to ensure the high quality of that product.

So, unfortunately, there aren't really any easy shortcuts building a plant, designing a plant, and then validating and operating that plant. We have to put in some very strict standards to ensure the reproducibility, the safety and the potency of that product time in and time out; and, unfortunately, there aren't just any shortcuts to doing that.

Mrs. BLACKBURN. Ms. Grant.

Ms. GRANT. I would say certainly, as a company, we are used to planning 5, 10 years out. So while it is a long timeframe, the most important thing I would say for the government and this committee to think about right now are two or three things not to do. To tell our management and our shareholders in the world that we should continue to increase our capacity, which we want to do at Aventis, we have to make sure that the government is not going to chill our interests. So two things I would not do.

I would not think about what is sometimes described as the GOCO, or the government-operated facility. That is not what we

are looking for in the way of competition. We are looking for healthy private sector competition, and we will welcome that.

I think the second issue is the notion that we are sort of skirting around today, some of the taking issues. We would like to say that the first order of business is to really work collaboratively with the public sector to make sure that we get through tough situations and seasons without sort of jumping to more Draconian solutions.

It is always very welcome to have Congress work with State officials on environmental issues to make sure that, while we never compromise safety or other standards, that, nevertheless, that things—we work together and know that we want to get there in the next few years and work out those issues.

Mrs. BLACKBURN. Thank you. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Just a couple of last questions and we will let you go.

Ms. Grant, it is already October. Soon you are going to begin the process of developing and producing a new flu vaccine for next year. What does this do to avoid the shortages next year and the contingency plans, and we are not even sure that Chiron will be producing next year at this point. How do you factor that in?

Ms. GRANT. Well, certainly everyone in our company is very concerned about that type of issue; and I can only finish by repeating the pledge that we are taking into account all of the information in the environment, just as this year. We are seeing how we can optimize, maximize our production capability. This will certainly influence, as we hear more from the government over the next month or so, what we can do. We do have a certain maximum capacity. We are scraping up against that. But we are going to do everything possible to make sure we maximize.

Chairman TOM DAVIS. Easy for me to say, but then all of a sudden, if everybody else gets in the business and you are stuck holding 40 million shots, then it hits you financially. So isn't that part of the equation?

Ms. GRANT. It is a factor. And I just would say that is why we have to work together to make sure that we continue to increase the demand so that we always feel comfortable our ability to sell increased supply is justified by seeing the demand will be there.

Chairman TOM DAVIS. Well, we appreciate what you are doing. I am glad you are here. You are our saviors this year.

And, Dr. Young, that goes for your company as well. Same answer that I just talked about in terms of capacity for next year.

Dr. YOUNG. Absolutely. I mean, I think we have to look at the overall situation. Clearly, if more vaccine were available and the recommending bodies would be more proactive in trying to promote the use of the vaccine—just like this year. They have cut back on vaccine when it is—the recommendations in terms of who should get it, to prioritize who gets the vaccine in the event there is excess vaccine, they ought to be going in the other direction and saying, look, we have extra vaccine. We ought to be using it more broadly in kids. Only 10 percent of kids get vaccinated now. We ought to be pushing that in that event in order to spur more demand.

Chairman TOM DAVIS. 36,000 deaths, that is a lot of people that could have probably been—any of those been vaccinated? I mean,

these are the people who don't get vaccinated for the most part, right?

Ms. GRANT. It certainly is an issue. We knew last year that most of the children, sadly, the pediatric cases that resulted in death had not been vaccinated. So the public needs to understand that it is a very serious disease in the elderly and the young children and make sure they are immunized.

Chairman TOM DAVIS. Guys like me and Dr. Young, I guess we just keep washing our hands.

But thank you very much, both of you, for what you are doing. Dr. Stroube, thank you for your leadership at the State level. Let's work with you every way we can in the Commonwealth.

With that, the hearing is adjourned.

[Whereupon, at 1:35 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

LAW OFFICES

SHOOK, HARDY & BACON L.L.P.

MEMORANDUM

THE FEDERAL TORT CLAIMS ACT AND VACCINE LIABILITY PROTECTION

Under the Federal Tort Claims Act (FTCA),[1] federal employees are immune from liability for tort claims arising out of acts or omissions occurring within the scope of their employment. The FTCA establishes an exclusive remedy that makes the United States liable for the torts of its employees to the same extent that private employers are liable for the torts of their employees under the law of the state in which the act or omission occurred, with some exceptions.[2] Under the FTCA, the United States is not liable for punitive damages.[3] Claims must first go through an administrative process in the appropriate agency; if the claim is denied or the claimant disagrees with the compensation offered, the claimant may file a lawsuit.[4] Lawsuits are tried in federal district court without a jury. Attorney fees are limited to 25 percent of the judgment or 20 percent of the settlement[5] and the Government is not strictly liable. It also is immune from liability when it exercises a "discretionary function." This immunity, which has been construed rather broadly, covers public policy decisions.

As this memorandum will demonstrate, the FTCA has been utilized to protect entities other than the Federal Government when it was deemed in the national interest to do so. Perhaps the most relevant was the Swine Flu program instituted in 1996. Manufacturers or providers of Swine Flu vaccine were immunized from direct lawsuits, and the Federal Government acted as the defendant of record, utilizing the rules of the FTCA. There were two important exceptions under the program, the Government could be subject to strict liability and could not avail itself of the discretionary function exception. The FTCA recently amended this exception to provide protection to manufacturers and distributors under the Smallpox Vaccine program.[6]

Even more recently, the FTCA was utilized in the "Project Bioshield Act of 2004," S. 15. Project Bioshield provides the Secretary of Health and Human Services with authority to research and develop so-called "qualified countermeasures" in consultation with the National Institutes of Health.[7] Qualified countermeasures would include drugs, biological products, or devices deemed a priority for addressing events that could cause a public health emergency affecting national security or to treat or prevent harm that could result from such an event.[8] The

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1 28 U.S.C.A. §§ 1346, 2671 *et seq.*

2 *See id.* §§ 2672, 2680.

3 *See id.* § 2674. There is a narrow exception to accommodate an unusual quirk of Alabama wrongful death law. The exception provides that if a law of a state provides only for punitive damages, the United States may be held liable for compensatory damages.

4 *See id.* § 2675.

5 *See id.* § 2678.

6 *See* 42 U.S.C.A. § 233p.

7 *See* S. 15, 108th Cong., 2d Sess., § 2 (2004) (inserting § 42 U.S.C. § 319F-1(d)).

8 *Id.* (§ 42 U.S.C. § 319F-1(a)(2)).

Secretary would have authority to contract with experts or consultants with scientific or other professional qualifications to assist with the agency's research and development.[9] Any person carrying out such a contract, including an officer, employee, or governing board of that contractor, would be considered an employee of HHS for the purposes claims of personal injury or death resulting from the performance of the contract.[10] Thus, the FTCA would extend to these contractors in performing their research and development obligations. The Federal Government could then seek recovery from a contractor for claims paid if the injury resulted from the contractor's failure to carry out its contractual responsibilities, or stemmed from intentional, grossly negligent, or reckless conduct.[11]

There are other precedents for placing selected vaccine protections under the FTCA.[12] For example, under the Federally Supported Health Centers Assistance Act of 1995,[13] certain community health programs, their officers, and their physicians and other licensed or certified health care practitioners can claim FTCA protections. Congress justified its extension of the FTCA protections to these groups because of the substantial federal investment in these groups and the need to conserve taxpayer dollars for public health care.[14] In addition, although center physicians are neither hired nor supervised by the federal government, there is close federal supervision of the centers themselves in the form of clinical guidelines, funding and operational conditions, and quality assurance requirements. One could develop public policy arguments in selected circumstances to place vaccines under the FTCA.

In light of the substantial and serious problems facing vaccine manufacturers, it may be advisable to develop and support a proposal for legislation that builds on the Smallpox Vaccine legislation and the Project Bioshield Act of 2004.

Two different approaches could be taken. First, certain select vaccines could be afforded the same FTCA coverage as community health centers. Claims against the manufacturer could be subject to administrative review and tried only to a judge in federal court, where government attorneys would defend them. These claims would be subject to the Act's prohibitions against

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9 *Id.* (§ 42 U.S.C. § 319F-1(d)(1)).

10 *Id.* (§ 42 U.S.C. § 319F-1(d)(2)(A)).

11 *Id.* (§ 42 U.S.C. § 319F-1(d)(2)(C)).

12 Under the Swine Flu program, the FTCA applied except for the discretionary function exception and limits against strict liability. The Government could, in turn, sue suppliers if they engaged in grossly negligent or reckless behavior.

13 42 U.S.C. § 233(g).

14 The House Committee on Energy and Commerce favorably reported legislation bringing community health centers under the FTCA, explaining: "There is substantial evidence that community and migrant health centers are spending far more on medical malpractice insurance premiums that is justified by their actual claims experience, and there is reason to believe that this is the case with respect to health care for the homeless and public housing resident programs as well. Extending FTCA coverage to grantees (and organizational subcontractors) under these programs will enable them to redirect funds now spent on malpractice insurance premiums toward improving or expanding their services to their target populations." H.R. Rep. No. 102-823(II), at 6 (1992).

punitive damages and prejudgment interest and to its limits on attorney's fees. This approach is likely to be vigorously challenged by the organized trial bar, who will dislike the administrative review requirements, damages limitations, and fee caps. It could be challenged, however, by the Department of Justice, which has expressed concerns about the expansion of FTCA coverage and its attendant effect on the Department's funding and attorney workloads.

A second approach, while similarly likely to be opposed by the organized trial bar, may be more palatable to the Department of Justice, would still curb potential excessive liability while promoting the development of vaccines. Vaccines that are broadly needed in the federal interest could be given certain protections under the FTCA. These protections could vary based on the preferences of industry experts. At a minimum, these protections should include giving federal courts exclusive jurisdiction over the claims in order to minimize the "home town" effect of some state judges, and prohibiting punitive damages and prejudgment interest in order to control skyrocketing awards. Limiting punitive damages by bringing the vaccine industry under the FTCA may be more feasible politically than simply eliminating punitive damages or curbing pain and suffering damages, through legislation. That is because the argument could be made that, as with community health centers, Congress has the clear power to have more stringently regulated tort claims against vaccine manufacturers. Under the FTCA approach, it could be perceived that Congress chose the narrowest legislation to accomplish its goals.

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SYMPOSIUM: ISSUES IN TORT REFORM: National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?

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SUMMARY:
... Last year, Congress enacted legislation creating an innovative method of resolving claims for childhood vaccine injuries. ... After the no-fault proceedings, the claimant has the option of accepting the compensation awarded, if the injury were found to be vaccine-related, or bringing a civil action against the vaccine manufacturer in which several limitations on the manufacturer's tort liability would apply. ... If a person has been injured by a vaccine covered by the Act, a claim must first be brought through this no-fault compensation system before a tort lawsuit may be filed against a vaccine manufacturer. ... Based on these justifications for having a no-fault compensation system for vaccines, Congress set out to achieve two objectives: to provide an expeditious method of compensating children who are injured because of vaccines and to make liability for vaccine manufacturers more predictable so that the supply of vaccines in the United States will be adequate. ... The second objective, to make vaccine liability more predictable, will be

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accomplished only if the no-fault compensation program becomes the primary means of redress for vaccine-related injuries, meaning that the majority of claims that otherwise would be resolved in the tort system are resolved in the compensation system. ...

TEXT:

[*387] Last year, Congress enacted legislation creating an innovative method of resolving claims for childhood vaccine injuries. n1 It establishes a mandatory no-fault compensation system for persons injured through childhood vaccines. After the no-fault proceedings, the claimant has the option of accepting the compensation awarded, if the injury were found to be vaccine-related, or bringing a civil action against the vaccine manufacturer in which several limitations on the manufacturer's tort liability would apply. The legislation responded to two concerns: (1) liability for these injuries was causing United States manufacturers to stop producing vaccines, and (2) children injured by vaccines were often without a source of payment or compensation for their medical and rehabilitative needs, leading to greater resort to the tort system for some form of financial relief. n2

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n1 S. 1744, 99th Cong., 2d Sess. Title XXI, 132 CONG. REC. H11,597-606 (1986).

n2 See H.R. REP. No. 908, 99th Cong., 2d Sess., pt. 1, at 4-5, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6344-46 [Hereinafter HOUSE REPORT].

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Expanding tort liability and the tort system's impediment to product development have been concerns raised by manufacturers in other industries who are seeking reform in the product liability area through state and federal legislation. Efforts to enact a federal product liability bill have been ongoing since the late 1970s with legislation first introduced in the House of Representatives in 1980 by Rep. Richardson Preyer n3 and in the Senate in 1982 by Senator Robert W. Kasten. n4 The severity of the product liability problem may vary from industry to industry, but a common factor is the unpredictability of product liability rules which continually have been expanding in favor of the plaintiff. n5 Proponents of product liability reform argue that some of these expansions of liability have been unfair, and that the unpredictable nature of variable product liability rules makes it difficult to make reasonable actuarial assessments of future liability risks. n6

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n3 See H.R. 7921, 96th Cong., 2d Sess. (1980).

n4 See S. 2631, 97th Cong., 2d Sess. (1982).

n5 See S. Rep. No. 442, 99th Cong., 2d Sess. at 5-8 (1986).

n6 Hearings before the Subcommittee on Commerce, Consumer Protection, and Competitiveness of the House Energy and Commerce Committee, 100th Cong., 1st Sess. (1987) (Statement of V. Schwartz).

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The approach Congress took in the National Childhood Vaccine Injury Act of 1986 -- which on the one hand sets up a no-fault compensation system and on the [*388] other hand modifies the tort law rules for injured persons who choose not to accept compensation through that system -- could be viewed as either a panacea for the vaccine liability problem or as a precedent for an approach that Congress could take in addressing the broader product liability problem. This Article will explain that the dual compensation system/tort reform approach was a response to a unique situation with childhood vaccines, and that this type of approach would not work in a broad product liability bill.

Childhood Vaccine Crisis

The National Childhood Vaccine Injury Act addressed a crisis situation that existed for products that provide tremendous societal benefits. Vaccines to protect against serious and life-threatening diseases such as pertussis ("whooping cough"), diptheria, tetanus, measles, mumps, rubella, polio, and small pox, are, without doubt, vital products. It has been stated that "[v]accines have contributed more to public health in this country than any other medical product, device, or procedure." n7 Because vaccines contain biological material, however, they carry a risk of adverse effects. The Sabin polio vaccine, for example, is a live polio vaccine which contains a greatly weakened or attenuated polio virus. n8 Since it is administered orally and does not require boosters, it has replaced the Salk (injection) polio vaccine which is no longer manufactured in the United States. n9 There is an unavoidable risk with the Sabin vaccine, however, as it reproduces the weakened polio virus in the intestinal tract which in very rare cases is a virulent virus rather than the weakened Sabin virus. n10 When this occurs, the person who received the virus and persons coming in contact with that person may develop polio. Despite the risk of this unfortunate occurrence, society has benefitted from its dramatic decrease in the incidence of polio, a disease which killed or crippled hundreds of thousands of victims in the 19th and 20th centuries. In reporting the National Childhood Vaccine Injury Act, the House Committee on Energy and Commerce noted:

Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease. Billions of medical and health-related dollars have been saved by immunizations. And, through the development of vaccines to prevent childhood diseases, significant scientific progress has been made in the development of vaccines to prevent other types of diseases. In brief, the Nation's efforts to protect its children by preventing disease have been -- by every measure -- a success. n11

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n7 See P. Huber, Will the New Vaccine Statute Give a Shot in the Arm to Tort Reform?, Legal Times, Mar. 9, 1987, at 9, col. 1-3.

n8 See A. David, DTP: Drug Manufacturers' Liability in Vaccine-Related

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Injuries, *9 J. PROD. LIAB. 361, 376-77 (1986)*.

n9 The Salk vaccine contains an inactivated or killed polio virus.

n10 See A. David, supra note 8, at 376.

n11 See HOUSE REPORT, supra note 2, at 4, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6345.

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Recently, however, an increase in tort lawsuits for injuries associated with vaccines caused a number of United States vaccine manufacturers to withdraw from [*389] the market. n12 Faced with a dwindling vaccine supply and the imminent scarcity of a much-needed product, Congress stepped in. While some commentators argue that tort liability is a matter of state concern and, therefore, oppose federal legislation in this area, Congress recognized that the threat to the availability of childhood vaccines posed a national public health problem. n13

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n12 Id.

n13 Id. at 5, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6346. ("The availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities."; "The Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries.").

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In that regard, the most significant precedential value of the National Childhood Vaccine Injury Act is that it stands for the recognition that products liability is a matter of national concern. In a situation with one of the most severe liability problems and one of the greatest potential losses to society if those problems were not solved, a national solution was required. The House Energy and Commerce Committee noted:

The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine. Two States, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases. n14

Not all products may present the same societal benefits as childhood vaccines, and the loss of some other products might not pose the same national health hazards. Those may have been concerns that motivated Congress to develop a no-fault compensation system for this particular product. But the recognition

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that products liability is a matter of interstate commerce and, therefore, is the responsibility of the federal government does transcend generally among all products.

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n14 Id. at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348.

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Childhood Vaccine Compensation Program

The National Childhood Vaccine Injury Act of 1986 establishes a two-tiered system for obtaining compensation for injuries resulting from immunizations that state governments require children to receive as a condition of entry into school -- vaccines for polio, diphtheria-pertussis-tetanus (DPT), and measles-mumps-rubella (MMR). The first tier is a mandatory "no-fault" system under which compensation for specific injuries related to childhood immunizations, listed in the Vaccine Injury Table, is to be paid out of a Trust Fund established by the Act. The Trust Fund is to be financed with the proceeds of an excise tax imposed on each dose of the covered childhood vaccines. Funding for the program has not yet been authorized by Congress, and the Act is not effective until that time. n15

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n15 See S. Rich, Administration Attacks Vaccine Law, Wash. Post, March 6, 1987, at A6, col. 1.

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[*390] If a person has been injured by a vaccine covered by the Act, a claim must first be brought through this no-fault compensation system before a tort lawsuit may be filed against a vaccine manufacturer. The Act's objective is to provide a more speedy and more certain compensation alternative to the tort system, so that litigation is the last resort.

A claim for compensation is made by filing a petition with a United States district court. n16 The petition must contain a variety of materials necessary to make a finding as to whether compensation is to be made, including evidence that the person received a vaccine listed in the Vaccine Injury Table of the Act or contracted polio from a recipient of an oral polio vaccine, and that the person sustained or had significantly aggravated an injury listed in the Table and within the time periods specified in the Table. n17 The Secretary of Health and Human Services must be named as the Respondent to all petitions for compensation. No other persons may intervene or otherwise be made a party to the compensation proceeding. n18 The district court then is to designate a special master to assist in obtaining evidence, information, and testimony, and to conduct hearings and prepare proposed findings of fact and conclusions of law and submit these findings to the district court. n19 After the special master submits his findings of fact or conclusions of law, the district court determines whether to award compensation. n20 In making that determination, the only issue is whether the injury is vaccine-related. There need be no showing that a vaccine manufacturer was at fault.

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n16 S. 1744, supra note 1, at § 2111, 132 CONG. REC. H11,598-99 (1986).

n17 Id. at § 2111(c), 132 CONG. REC. H11,599.

n18 Id. at § 2112(b), 132 CONG. REC. H11,599.

n19 Id. at § 2112(c), 132 CONG. REC. H11,599.

n20 Id. at § 2112(d), 132 CONG. REC. H11,599.

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If the petitioner's injury is listed in the Table, and occurred within the time period set forth in the Table, there is a presumption that the injury was caused by the vaccine. n21 This presumption can be overcome by a preponderance of the evidence, submitted by the Secretary of Health and Human Services or a vaccine manufacturer, that a particular petitioner's injury is not vaccine-related. n22 Evidence that may be submitted to overcome the presumption includes proof of other infections, traumas or conditions, but does not include speculative or hypothetical matters or explanations. n23 Petitioners may also seek to prove that an injury not covered by the Table was caused by a vaccine. The entire proceeding, from date of filing through special master proceedings and court review, is to take place as expeditiously as possible and, in no case, should take more than one year. n24

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n21 Id. at § 2113(a), 132 CONG. REC. H11,599-600.

n22 Id.

n23 Id. at § 2113(b), 132 CONG. REC. H11,600; HOUSE REPORT, supra note 2, at 18, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6359.

n24 S. 1744, supra note 1, at § 2112(d), 132 CONG. REC. H11,599; HOUSE REPORT, supra note 2, at 17, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6358.

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If the district court determines that an injury is vaccine-related, it will award compensation to be paid from the Trust Fund established by the Act. n25 Compensation [*391] is made for actual, unreimbursable medical expenses, rehabilitation costs, and lost wages. n26 The award is to include an amount to provide for reasonable attorneys' fees and other costs incurred in proceedings on the petition. n27 The court may, in its discretion, make an award for attorneys' fees and costs even if it does not award compensation on a petition, if it determines that the action was brought in good faith and that there was a reasonable basis for the claim for which the action was brought. n28 In addition, the court may award compensation for pain and suffering up to

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decision must be filed in writing even if the court has refused to award compensation. If the petitioner fails to file a decision in writing within the 90-day period, he or she will be deemed to have accepted the court's judgment. n35

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n35 Id. at § 2121, 132 CONG. REC. H11,602.

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In sum, the compensation proceeding is relatively simple. There is no discovery, cross-examination, pleadings, or trial. The power of the special master to require evidence, submission of information, and require testimony, is intended to replace the usual rules of discovery in civil actions in federal courts. The only issues relevant to the compensation proceedings are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages. Congress structured the Act so as to encourage persons to take advantage of the compensation system by making it [*392] (1) mandatory, (2) not based on proving fault for a vaccine-related injury, (3) speedy, and (4) fair in terms of the amount of compensation.

As a trade-off for the certainty of no-fault compensation and as an added incentive to have less resort to the tort system, the Act modifies tort law for vaccine injury suits in several respects. Except to the extent that the Act has established a rule of law for such actions, tort actions for vaccine-related injuries will be governed by applicable state law. Thus, tort litigation under these modifications of law is the secondary system of recovery for vaccine injuries.

First, the Act adopts the principle contained in comment k of section 402A of the Restatement (Second) of Torts, that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects if its products are properly prepared and accompanied by adequate directions and warnings. n36 Under the Act, a vaccine is presumed to be accompanied by proper directions and warnings if the manufacturer demonstrates that the directions and warnings comply in all material respects with relevant federal law governing the approval and labeling of the vaccine. This presumption may be overcome if the claimant shows that the manufacturer engaged in fraudulent conduct or intentionally or unlawfully withheld information in obtaining pre-market approval for the vaccine from the Federal Food and Drug Administration, or if the claimant shows by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with Federal Food and Drug Administration requirements. The legislative history to the Act explains that the comment k principle was adopted for tort lawsuits because the Act's crafters believed that claims based on injuries involving unavoidable risks of vaccines should be resolved in the no-fault compensation system rather than in the tort system. The Committee Report notes:

Given the existence of the compensation system in this bill, the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared

or that it was accompanied by improper direction or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system. n37

If a person's vaccine-related injury is what would be considered an "unavoidable" risk of the vaccine, and the vaccine was properly prepared and accompanied by proper warnings, a tort claim should be defeated.

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n36 Id. at § 2122(b), 132 CONG. REC. H11,603.

n37 HOUSE REPORT, supra note 2, at 26, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6367.

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Second, vaccine manufacturers may not be held liable in tort lawsuits for their failure to provide warnings directly to the vaccine recipient, rather than physicians. n38 This provision overrules several court decisions that have held drug manufacturers liable for failure to provide direct warnings to the patient rather than to an intermediary such as a doctor, nurse, or pharmacist who can be expected to [*393] know about the product and its risks, and who is responsible for informing the patient. n39

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n38 S. 1744, supra note 1, at § 2122(c), 132 CONG. REC. H11,603.

n39 See, e.g., *Brooks v. Medtronic, Inc., 750 F.2d 1227 (4th Cir. 1984)* (Warnings associated with polio vaccine must be provided to patient); *Reyes v. Wyeth Laboratories, 498 F.2d 1264* (5th Cir.), cert. denied, *419 U.S. 1096 (1974)* (same rule); *Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968)* (same rule).

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Third, a vaccine manufacturer will be protected against punitive damages in a tort lawsuit if it shows that its product complied with applicable requirements under the Federal Food, Drug and Cosmetic Act and specified provisions of the Public Health Service Act. n40 The legislative history explains the rationale for this provision:

The Committee believes that punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved. Where a manufacturer has attempted in good faith to comply with a government standard -- even if the standard provides inadequate protection to the public -- the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the establishment of maintenance of the standard's inadequacy. n41

This protection against punitive damages will not apply if the manufacturer (1) engaged in fraud or intentional and wrongful withholding of information from the Secretary of Health and Human Services during any phase of a proceeding for approval of the vaccine, (2) intentionally or wrongfully withheld information

relating to the safety or efficacy of the vaccine after its approval, or (3) engaged in other criminal or illegal activity relating to the safety and effectiveness of the vaccine. In addition, trials will be divided into separate proceedings on liability, compensatory damages, and punitive damages, so that evidence on the extent of the claimants' injury or on actions of the defendant that allegedly justify punitive damages does not prejudice the findings as to causation and fault.

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n40 S. 1744, supra note 1, at § 2123, 132 CONG. REC. H11,603.

n41 See HOUSE REPORT, supra note 2, at 28-29, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6369-70.

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A Solution to the Vaccine Liability Problem?

The approach Congress took to address the children's vaccine liability problem, which creates a no-fault system as the primary method of compensation, is, undeniably, a response to a unique problem.

First, children's vaccines are unlike other products. Children are required by law in every state to be immunized in order to attend public school. The fact that state governments require children to undergo a risk in order to protect society as a whole, was seen by Congress as justification for development of a national fund to compensate children who are injured because of these risks. n42

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n42 See id. at 6, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6347.

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Second, unlike some other products, the incidence of serious injury with children's vaccines is very low. n43 Thus, a vaccine compensation system can be self-funding by adding a very small excise tax to the price of vaccines. n44 It would not be as easy to finance a compensation system for other products which have higher [*394] incidences of serious injury and, therefore, would require funding from outside sources, such as general revenues.

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n43 Id.

n44 As noted above, the funding mechanism for the vaccine compensation program has not been established.

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Third, the children's vaccine liability insurance situation was more widely felt than the liability crisis that exists with most other products. Most of

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the vaccine manufacturers in the United States have withdrawn from the market. n45 The loss of even one more manufacturer could mean that some children would be unable to receive vaccines, which would create a very serious public health problem. n46

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n45 See supra text accompanying note 14.

n46 See HOUSE REPORT, supra note 2, at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348. One can find a similar reduction in the number of sporting goods manufacturers, but one does not find as direct adverse health impacts. See 133 CONG. REC. S2,999 (March 11, 1987) (statement of Sen. Kasten).

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Based on these justifications for having a no-fault compensation system for vaccines, Congress set out to achieve two objectives: to provide an expeditious method of compensating children who are injured because of vaccines and to make liability for vaccine manufacturers more predictable so that the supply of vaccines in the United States will be adequate. n47 Assuming Congress sets the Act in operation by authorizing an excise tax to fund the compensation program, its success will be determined over time. At present, a few considerations lend to its prognosis.

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n47 See HOUSE REPORT, supra note 2, at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348.

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The first of Congress' objectives, to create an efficient method of providing adequate compensation for vaccine-injured persons, can be achieved only if the compensation proceedings are not abused. The overriding guideline of those proceedings is simplification. The burden will be on the district courts and the appointed special masters to administer the compensation program within these guidelines. Attempts by either side to interject discovery into these proceedings or to raise issues other than causation of the injury and the extent of damages, will defeat this objective.

The second objective, to make vaccine liability more predictable, will be accomplished only if the no-fault compensation program becomes the primary means of redress for vaccine-related injuries, meaning that the majority of claims that otherwise would be resolved in the tort system are resolved in the compensation system. Congress could have more greatly assured this result by making the no-fault compensation system the exclusive remedy for persons injured by vaccines. n48 Instead, Congress attempted to make the compensation program an appealing alternative to tort litigation and to reduce incentives for persons to choose tort suits as a means for resolving vaccine injury claims. It did so in several ways.

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n48 A report by the American Medical Association Ad Hoc Committee on Vaccine Injury Compensation explains that the goals of continued availability of vaccines, development of improved vaccines, and participation of health workers in vaccine programs will not be met unless a federal no-fault compensation system is the exclusive remedy of claimants and not merely an alternative to tort litigation. See M. Goldsmith, AMA Offers Recommendations for Vaccine Injury Compensation, 252 J. AM. MED. ASS'N 2937, 2939 (Dec. 7, 1984).

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First, the Act makes the filing of a petition in the no-fault compensation system mandatory before a tort lawsuit may be filed. In deciding whether to file a lawsuit, a petitioner who has been awarded compensation will weigh this assured and immediate recovery against the possibility of greater recovery at some time in the [*395] future if a tort lawsuit is successful. Second, the compensation provided for in the no-fault compensation program covers the petitioner's actual unreimbursable expenses and may compensate for pain and suffering. Third, the Act adopts three principles of tort law that, in the vaccine lawsuit context, may modify the rules that would otherwise apply in some states, making it more difficult for claimants to recover in a tort lawsuit. Despite these incentives for a claimant to accept a compensation award in the no-fault program system, it is uncertain whether more claims will be resolved through the program. Congress did not remove countervailing incentives that may favor tort litigation. For example, the prospect of a higher contingency fee may prompt claimants' attorneys to encourage claimants to reject the award and file a tort lawsuit. In light of the tort law modifications established by the Act, however, a realistic claimant's attorney would carefully consider the prospects of a successful tort lawsuit against the assurance of compensation already awarded. Furthermore, even though the tort law standards established by the Act follow general principles of tort law and will actually change the law in only some states, n49 judges may be less likely to find ways to expand tort liability for vaccine manufacturers given the existence of a no-fault compensation alternative. But these are considerations that may influence the course of individual claims, and it is difficult to forecast the outcome in the aggregate -- a point that creates doubt as to whether greater predictability for vaccine liability will be achieved.

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n49 The unavoidably unsafe principle, for example, is followed by most courts. See, e.g., *Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980).*

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Congress may have decided to retain the tort system for vaccine injury claims, at the expense of greater predictability, as a means of providing incentives for the manufacture of safe vaccines. For example, under the Act, vaccine manufacturers will be subject to liability in tort lawsuits if vaccines are not properly prepared or are not accompanied by adequate directions or warnings. It could be argued that under a no-fault compensation program, particularly where compensation derives from a general fund and is not linked to individual responsibility, expeditious and certain compensation is provided for

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at the expense of removing those incentives. The argument would be that the absence of a linkage between fault and payment for injuries removes incentives for vaccine manufacturers to act safely. Interestingly, representatives of professional consumer groups and trial attorneys have consistently opposed the establishment of fault standards of liability in federal products liability legislation proposed in Congress, on the theory that absolute liability is the greatest incentive for safety. n50 A fundamental principle of tort theory, however, is that placing liability on persons who act wrongfully creates incentives for safety. For this reason, it could be argued that an exclusive no-fault compensation system might not provide safety incentives.

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n50 See, e.g., S. 100, Product Liability Act: Hearing before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation, 99th Cong., 1st Sess. 77-85 (1985) (Statement of Gene Kimmelman, Legislative Director, Consumer Federation of America).

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In order to accomplish this objective within the framework of an exclusive no-fault compensation system, other methods of penalizing unsafe conduct and [*396] rewarding safe conduct could be developed. For example, instead of funding the program through an excise tax, some method could be developed for making assessments on vaccine manufacturers in accordance to the incidences of injuries related to their products.

A Window for the Future?

The structure of the no-fault compensation system for vaccine injuries signifies that this type of system may work, if at all, in very narrowly defined situations. The Act's no-fault system is designed for specified products and specific illnesses that will "trigger" compensation. Under the Table in the Act, it is relatively simple to determine whether a claimant's injury is vaccine-related.

Attempts to create broader compensation systems for product injuries have been made in Congress. In the 99th Congress, the Senate Commerce Committee considered a proposal to establish a compensation system for all products. n51 After months of evaluation of this proposal, including receipt of comments from professional consumer groups and representatives of manufacturers, all of whom were dissatisfied with the proposal, the Senate Commerce Committee gave up on this approach. n52 The fundamental problem with establishing a claims system to cover all products was trying to define the "trigger" for compensation. Since it is not practical or feasible to attempt to list every single product that currently is subject to tort liability, and to list every imaginable injury, illness, or disease that may be caused by all products, a broad products claims system would have to contain some alternative "trigger." The proposed Senate bill attempted to frame a "trigger" along the strictest lines of strict liability standards.

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n51 S. 1999, 99th Cong., 2d Sess. (1986).

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n52 See Product Liability Voluntary Claims and Uniform Standards Act: Hearings Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation, 99th Cong., 2d Sess. 104-148 (1986).

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The Senate Bill, S. 1999, required manufacturers to make payment of actual, unreimbursable economic losses ("net economic loss") if a product were "unreasonably dangerous" and a proximate cause of the claimant's harm while being used in a manner intended or anticipated by the manufacturer. n53 A manufacturer would not be required to pay the claim if the claimant was grossly negligent. n54 The Bill established a presumption that a product is "unreasonably dangerous," which the manufacturer could rebut by showing that the product's utility so outweighed the risk of harm that it was reasonable to produce it, or that the risk of harm was apparent or was a matter of common knowledge. n55 The Bill spelled out the warnings or instructions that must have been provided to rebut the presumption that the product was "unreasonably dangerous." n56 It also established a presumption of proximate cause in certain situations involving toxic harm. n57

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n53 S. 1999, supra note 51, at § 205(a) (1986).

n54 Id.

n55 Id. at § 205(b).

n56 Id. at § 205(b) and (c).

n57 Id. at § 205(d).

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[*397] Based on these guidelines, a manufacturer would have to determine whether a claim should be paid and notify the claimant. n58 If a claim were denied, the claimant would have the option of filing a civil action to obtain compensation for "net ecomonic loss" under the standards outlined above, or filing a tort lawsuit governed by the tort rules in Title III of the Act, which would restrict the liability of manufacturers in some respects.

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n58 Id. at § 206.

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Obviously, this "trigger" for payment of compensation in an "expedited products liability claims procedure" was very different from the Vaccine Injury Table which lists the products and related injuries that are compensable. The products liability "trigger" looked like a very detailed jury instruction in a products liability lawsuit.

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Given the complexity and subjective nature of the determination whether compensation should be paid under this expedited products liability claims procedure, it was not perceived as an appealing alternative to litigation. Representatives of both sides of the issue agreed that this approach would simply generate uncertainty and litigation over whether a particular product should give rise to compensation, and that it would not serve the goal of expeditiously providing compensation for injured persons.

After months of study, the Senate Commerce Committee abandoned the attempt to design a broad products compensation system and worked on procedures to foster settlement of products liability lawsuits. n59 The lesson learned from this exercise, however, is useful. An injury compensation system can serve the goal of expeditiously providing compensation only if the event which triggers payment is clearly defined and applicable on some objective basis. The National Childhood Vaccine Injury Act did this by listing vaccines and vaccine-related injuries in a Table in the Act. In workers' compensation, the triggering event is an injury "arising out of and in the course of the employment." n60 Unless a simple and objective "trigger" is developed for all types of product injuries, a broad-scale product compensation system is not achievable. Short of creating absolute liability for every injury in which a product was somehow involved, there would have to be a workable, objective guideline for determining whether a product defect caused the injury. Given the complexity of determining "defectiveness" -- as evidenced by the myriad of standards applied by courts -- it seems unlikely that this could be accomplished.

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n59 S. 2760, 99th Cong., 2d Sess. (1986).

n60 See generally A. LARSON, WORKMEN'S COMPENSATION § 6 (Desk ed. 1987).

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CONCLUSION

The National Childhood Vaccine Injury Act of 1986 is a unique response to the severe liability problems of a particular type of product. Whether the Act will actually be made operative by an authorization of funding for the compensation program and whether it is a successful resolution of those liability concerns remains to be seen. But two comments can be made on its precedential value.

[*398] First, by enacting this legislation Congress recognized its responsibility for major products liability problems. Congress has in the past acknowledged its interstate commerce responsibility for products by enacting legislation regulating product safety -- the Consumer Product Safety Act, n61 the Federal Food, Drug, and Cosmetic Act, n62 the National Traffic and Motor Vehicle Safety Act, n63 and so on -- but this step into products liability is a groundbreaker.

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n61 *15 U.S.C. § 2051* et seq. (1983).

n62 *21 U.S.C. § 301* et seq. (1983).

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n63 *15 U.S.C.* § *1381* et seq. (1983).

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Second, the approach to the vaccine liability problem is unlikely to be followed on a broader basis. This is true for several reasons. The mandatory nature of childhood immunizations and the ability to fund a compensation program without outside sources may have motivated Congress to take this approach. In addition, the inability to define an objective "trigger" would thwart development of a broad product-injury compensation program. The bottom line -- this particular approach to liability problems is unlikely to be a window for the future.

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Chemical and Biological Arms Control Institute

TO: CBACI - WORKING GROUP ON DEVELOPING A NATIONAL VACCINE STRATEGY MAP

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RE: Product Liability Issues for a National Vaccine Strategy

CBACI has launched a project "that is designed to develop a national vaccine strategy to reduce biological threats – both natural and deliberate."

The working group's agenda addresses a variety of issues that include establishing priorities for the development, manufacture and use of vaccines by the stakeholder communities; creating criteria for balancing risks, opportunity costs and trade offs between priorities; elaborating criteria for setting vaccine priorities; and identifying trade-offs that must be made in fashioning such a strategy.

This brief memorandum suggests that if a National Vaccine Strategy can be shaped it can just as readily be undone without adequate provisions for liability protections to identify the elements of a program to limit product liability. The memorandum summarizes a history of the

undoing of the vaccine industry by product liability cases, identifies past efforts to minimize liability concerns (with mixed results), and itemizes broad recommendations for critical elements of a successful liability protection scheme. The memorandum, in great part, draws upon the published legal literature on the topic and quotes liberally from it.

I

THE UNDOING OF THE VACCINE INDUSTRY BY PRODUCT LIABILITY

Without question, given the costs of development as well as the limited potential market, the vaccine business is a fragile one. Because of this market frailty, product liability lawsuits can have devastating effects. These effects include:

- "The possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical. Defendants cite a host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments. For example, according to defendant E.R. Squibb & Sons, Inc., Benedictin, the only anti-nauseant drug available for pregnant women, was withdrawn from sale in 1983 because the cost of insurance almost equaled the entire income from sale of the drug. Before it was withdrawn, the price of Benedictin increased by over 300 percent. (132 Chemical Week (June 12, 1983) p. 14.)

- "Drug manufacturers refused to supply a newly discovered vaccine for influenza on the ground that mass inoculation would subject them to enormous liability. The government therefore assumed the risk of lawsuits resulting from injuries caused by the vaccine. (Franklin & Mais, Tort Law and Mass Immunization Programs (1977) 65 Cal.L.Rev. 754, 769 et seq.; Feldman v. Lederle Laboratories (1983) 189 N.J.Super. 424, 460 A. 2d 203, 209.)

- "One producer of diphtheria-tetanus-pertussis vaccine withdrew from the market, giving as its reason "extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance." (Hearing Before Subcom. on Health and the Environment of House Com. on Energy and Commerce on Vaccine Injury Compensation, 98th Cong., 2d Sess. (Sept. 10, 1984) p. 295.) There are only two manufacturers of the vaccine remaining in the market, and the cost of each dose rose a hundred-fold from 11 cents in 1982 to $11.40 in 1986, $8 of which was for an insurance reserve. The price increase roughly paralleled an increase in the number of lawsuits from one in 1978 to 219 in 1985. (232 Science (June 13, 1986) p. 1339.)

- "Finally, a manufacturer was unable to market a new drug for the treatment of vision problems because it could not obtain adequate liability insurance

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at a reasonable cost. (N.Y. Times (Oct. 14, 1986) p. 10.)" [1]

• "The wholesale price of the vaccine against diphtheria, pertussis (whooping cough), and tetanus (referred to as the DPT vaccine) increased by over 6,000 percent from 1970 to 1987. [2, 3]

• Because of lawsuits and decrease demand due to adverse publicity, the sole manufacturer of a vaccine against Lyme disease withdrew the product from the market.[4]

• The Office of Technology Assessment has confirmed that while "vaccine can be an effective and cost-saving means of preventing disease, manufacturers of these drugs have been the subject of many liability cases" due to the fact that they are introduced into a healthy patient and have unavoidable side-effects and because many courts require warnings to be given directly to patients". It also noted "Legal staff at a firm engaged in R&D to develop a vaccine against HIV told OTA that liability was a significant consideration each time the company decided to continue this research. Furthermore, the firm's insurer was reluctant to provide any coverage for a potential product." [5]

• Two decades ago, before the adoption of the National Childhood Vaccine Injury Act of 1986, The Committee on Public-Private Sector Relations in Vaccine Innovation emphasized that "the common law tort system is not able to provide predictable, rapid and equitable compensation for vaccine-related injuries because each claim requires an extended costly and complex adjudication procedure that results in unpredictable outcomes." [6]

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[1] Brown v. Superior Court, 44 Cal.3d 1049, 1064-1065, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 421 (Cal. 1988)

[2] Manning, Richard L., *Changing Rules in Tort Law and The Market for Childhood Vaccines*, 37 J.L. & Econ. 247 (1994)

[3] "Hinman, [Alan R. Hinman, DPT Vaccine Litigation, 140 Amer. J. Dis. Child. 528 (1986); Alan R. Hinman, DPT Vaccine Litigation Update, 142 Amer. J. Dis. Child. 1275 (1988)] . . . provide[s] data on the lawsuit experience of the DPT vaccine from 1978 through 1987, a summary of which is [attached] in Table 3. As noted by the article, "This information was obtained directly from the three principal manufacturers over this time period, Connaught Laboratories, Lederle Laboratories, and Wyeth Laboratories, on the condition that specific details about each company and claim not be disclosed. These firms report no suits prior to 1978 and substantially increasing claims beginning in about 1982." [See Attached]

[4] *"The Complex End Of The Vaccine For Lyme Disease, Public Perception Of A Vaccine's Danger, Even If Wrong, Can Doom The Vaccine And Poses A Broader Threat To The Nation's Health,"* by Susan J. Landers, *AMNews* staff. April 22/29, 2002. http://www.ama-assn.org/amednews/2002/04/22/hlsa0422.htm

[5] Office of Technology Assessment, Pharmaceutical R & D: Costs, Risks and Rewards, Chapter 7, *"Product Liability and the Pharmaceutical Industry,"* 169 (1993)

[6] Institute of Medicine, Vaccine Supply and Innovation, 118 (1985). "The Committee recommended a compensation approach which would attempt to balance the need to compensate the rare injured victim and the public health goal or preventing the spread of harmful disease through vaccination." Earley, Joseph, *"Can*

II

ALTERNATIVES TO PRODUCT LIABILITY

Faced with the near extinction of a prescription product, government and industry have experimented with a variety of methods to attempt to minimize the impact of product liability. These efforts involve the swine flu vaccine, pediatric vaccines of these remedies, measures against bioterrorism, and vaccines to treat or cure the effects of the AIDs virus. While none has had the effect of reassuring the vaccine industry to reengage in the design of vaccines in a way seen decades ago, each does provide a lesson from which a product liability scheme can be extrapolated. This review evaluates each scheme with the recommendation of the Committee on Public-Private Sector Relations in Vaccine Innovation that a compensation approach which would attempt to balance the need to compensate the rare injured victim and the public health goal or preventing the spread of harmful disease through vaccination.[7]

A. SWINE FLU

In the face of the threat of the return of the virus that killed millions in 1918-1919. Congress enacted the Swine Flu Act in 1976.[8] The goal of the program was to vaccinate everyone in the country. With the insurance industry refusing to insure the manufacturers of the vaccine, Congress adopted the Act with these product liability features:

- Congress accepted responsibility for "personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it [under the Federal Tort Claims Act.][9]

Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis?", 30 Jurimetrics J. 351, 369(1990)

[7] *See* fn. 6.

[8] 1976 Pub. L. 94-380; 42 USC 247b(j)-(l)

[9] 42 U.S.C.A. 247b(k)(2)(A). The Federal Tort Claims Act is currently codified at 8 USCA § 1346(b), 1402(b); 2401(b) and § 2671-2680.

The elements of the Federal Tort Claims Act are:

- The federal government waives its sovereign immunity to allow civil suits arising from the negligence of its agents.
- A claim is initiated by the filing of an administrative claim with the appropriate agency. The claim is a precondition to filing a lawsuit.
- The remedy is an exclusive remedy. If the Act does not provide a remedy for a tort, the claim is barred.
- If a claim is rejected, a lawsuit must be filed in federal court.
- There is no right to a jury trial.
- Punitive damages are prohibited.

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- "The upshot . . .is that plaintiffs claiming harm from the flu program must sue the United States, which agrees to be bound by the law applicable to private persons in the particular states involved even if the liability is based on strict liability theories or the abuse of a discretionary function. The remedy against the United States is exclusive, and the case to be tried without a jury under the Tort Claims Act."[10]

"What killed the program, though, was the observation in early December that people given the swine flu vaccine had an increased risk of developing Guillain-Barre syndrome, a rare, usually reversible but occasionally fatal form of paralysis. Research showed that while the actual risk for Guillain-Barre was only about 1 in 1,000 among people who had received the vaccine, that was about seven times higher than for people who didn't get the shot.

"On December 16, the swine flu vaccine campaign was halted. About 45 million people had been immunized. The federal government eventually paid out $90 million in damages to people who developed Guillain-Barre. The total bill for the program was more than $400 million."[11]

B. NATIONAL VACCINE INJURY COMPENSATION PROGRAM[12]

In 1986, Congress passed the National Childhood Vaccine Injury Act (P. L.99-660), which established the National Vaccine Injury Compensation Program (VICP). 42 USCA § 201 et seq.[13]

1. OVERVIEW

"Congress created the VICP to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals thought to be injured by childhood vaccines. The VICP, which went into effect on October 1, 1988, is a no-fault alternative to the traditional tort system for resolving vaccine injury claims, whether the vaccine is administered in the public or private sector. The VICP covers all vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. The vaccines currently covered include diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT or Td), measles, mumps, rubella (MMR or any components),

- If the State where the claim arose has statutes limiting liability or imposing caps on non-economic damages, they may apply.

[10] Franklin, Marc. A., et al. "*Tort Law and Mass Immunization Programs: Lesson from the Polio and Flu Episodes*," 65 Cal. L.Rev. 754 (1977)

[11] Brown, David, "*A Shot in the Dark: Swine Flu's Vaccine Lessons*," Washington Post, May 27, 2002.

[12] From CDC's National Vaccine Program Office Vaccine Fact Sheets, www.hhs.gov/nvpo/factsheets/fs_tableIV_doc1.htm

[13] The legislation and its history can be found in *Congressional Quarterly Almanac 238* (Congressional Quarterly 1986).

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polio (OPV or IPV), hepatitis B, *haemophilus influenza* type b (Hib), varicella, rotavirus, and pneumococcal conjugate.

2. THE VACCINE INJURY TABLE

"There are three means of qualifying for compensation: 1) a petitioner must show that an injury listed on the Vaccine Injury Table occurred; 2) a petitioner must prove that the vaccine significantly aggravated a pre-existing condition; or 3) a petitioner must prove that the vaccine caused the condition.

"The Table lists specific injuries or conditions and the time frames in which they must occur after vaccine administration. The Table is a legal mechanism for defining complex medical conditions and allows a statutory "presumption of causation." However, if an adverse event is not listed on the Table, an individual may still file a claim but must prove that the vaccine did "in fact" cause the alleged injury. Compensation may not be awarded if the Court determines that the injury or death was due to an alternative cause unrelated to the vaccine, even if a Table injury is demonstrated.

3. FILING A CLAIM

"An individual claiming a vaccine-related injury or death files a petition for compensation with the Court, and are often represented by an attorney (which is not a requirement). The Secretary of HHS is named as the Respondent. For injuries or deaths resulting from a vaccine administered on or after October 1, 1988, the following restrictions apply:

- In the case of an injury, the claim must be filed within 36 months after the first symptoms appeared. The effects of the injury must have lasted at least 6 months after the vaccine administration, or the injury must have resulted in inpatient hospitalization and surgical intervention.

- In the case of a death, the claim must be filed within 24 months of the death, and within 48 months after the onset of the vaccine-related injury from which the death occurred.

"An HHS physician reviews each petition to determine whether it meets the medical criteria for compensation. This recommendation is provided to the Court through a Respondent's report filed by the DOJ. An attorney presents the HHS position from the DOJ in hearings before a "special master" who makes the decision for compensation under the VICP. A special master is an attorney appointed by the judges of the Court. Decisions may be appealed to the Court, then to the Federal Circuit Court of Appeals, and eventually to the U.S. Supreme Court.

"If a case is found eligible for compensation, the amount of the award is usually negotiated between the DOJ and the petitioner's attorneys. If the attorneys can't agree, the case is scheduled for a hearing for the special master to assess the amount of compensation.

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Compensable claims, and even most claims found to be non-compensable, are awarded reimbursement for attorney's fees and costs.

"A petitioner may file a claim in civil court against the vaccine company and/or the vaccine administrator only after first filing a claim under the VICP and then rejecting the decision of the Court."

4. EFFECTS

"The statute helped to stabilize the pediatric vaccine market, but supply problems persist, and many experts in the field continue to debate different mechanisms for reducing the threat of future shortages."[14]

5. CRITICISMS AND LIMITATIONS

While the VICP has had the effect of stabilizing the pediatric vaccine market, it has provided limited protection against tort claims based upon the allegation that thimerasol is associated with autism.[15]

Further, a claimant has a right to accept or reject the VICP award. If the award is rejected, the claimant can sue in tort in state court subjecting the manufacturer to the costs of litigation. One author has recommended that this be modified to permit state tort claims only for manufacturing defects.[16] "Still, full preemption would provide here most organizations and procedural benefits, completely streamlining compensation for vaccine injuries."[17]

C. SAFETY ACT[18]

In November 2002, President Bush signed the Homeland Security Act, Public Law 107-296, creating a new cabinet-level Department of Homeland Security. The Homeland Security Act includes the "Support Anti-Terrorism by Fostering Effective Technologies Act of 2002" – the so-called Safety Act. Under the Safety Act, the Secretary of DHS can designate certain products as "qualified anti-terrorism technology." To be designated as qualified anti-terrorism technology, the drug, diagnostic, vaccine, or medical product must have "the *specific* purpose of preventing, detecting, identifying, deterring, or limiting the harm from acts of terrorism." (Emphasis added.)

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[14] Lars Noah, *Triage In The Nation's Medicine Cabinet: The Puzzling Scarcity Of Vaccines And Other Drugs*, 54 S.C.L. Rev. 741 to 54 S.C.L. Rev. 741 (2002). Footnotes deleted.

[15] *See* e.g., www.momsonmissionforautism.com; www.vaccineinjury.org

[16] Levine, Jaclyn, Levine, Shoshana, *The National Vaccine Injury Compensation Program: Can It Still Protect An Essential Technology?*," 4 BOJSTL 9 (1998).

[17] *Id.* at 74.

[18] In part from "*From Smallpox Vaccine Injury and Law Guide*", 19 May 2003. By Edward P. Richards, JD, MPH, and Katharine C. Rathbun, MD, MPH, www.biotech.law.lsu.edu/blaw/bt/smallpox/svlaw.htm#risksx

What is not clear is whether the designated products have to be dedicated solely for treatment against acts of terrorism or if they can include products that have a multi-purpose application.

To be designated the product must meet seven criteria that include efficacy as well as whether there are scientific studies showing the ability of the product to reduce the risk of harm.

If the product is designated it may qualify for three liability protections: a limitation of damages along with exclusive federal court jurisdiction; a rebuttable presumption that the government contract defense applies; and a cap on liability in an amount equal to its insurance coverage. Punitive damages are prohibited.

Whether the government can indemnify the provider of the qualified product is unresolved.

Further:

> "The Act uses a strategy for legal immunity that has been used in other laws, including the immunity provisions for federally qualified community health centers.

. . . .

> "Deeming covered persons to be employees of the Public Health Service means that any claims for their negligence must be filed against the Federal government under the Federal Tort Claims Act (FTCA). . . . The Federal Government is substituted for the defendant in such cases, which provides nearly complete legal protection for the hospital or individual who is the real subject of the claim. Under the Department of Justice's opinion, . . . this provision should provide complete immunity for tort claims against health care workers and their institutions."

To-date it does not appear that a vaccine has received a designation.[19] An example of what happens to a vaccine program is seen in the Smallpox Vaccination Program announced

[19] The first approvals were on June 18, 2004. None of the approvals were for vaccines or other biologics. Those that were approved include: Lockheed Martin Corporation: Risk Assessment Platform – June 18, 2004 – The Risk Assessment Platform (RAP) is a data-mining knowledge management tool leveraging commercial data and subject matter expertise to provide authentications and risk assessment information to its operators by employing tailored algorithms and rules responsive to specific application requirements to aid the decision-making process. This designation/certification expires on June 18, 2009.

Michael Stapleton Associates: SmartTech System and Explosion Detection Services. June 18, 2004 – Michael Stapleton Associates offers both the SmartTech System, a two-way high-speed video and audio system designed to allow off-site bomb technicians to review x-ray screening of items for explosives and hazardous

by the President on December 13, 2002. The goal of the program was to vaccinate a core of the population who could provide support in case of a bioterror attack.[20] The program failed to obtain the public's support.

Apart from its possible partisanship, the Democratic Members of the House Select Committee of Homeland Security, January 2001, noted these failures in the report, "A Biodefense Failure: The National Smallpox Vaccination Program One Year Later,":

"Three key failures are responsible for the continuation of this serious gap in biodefense:

- Sufficient resources were not allocated nor requested in time for public health agencies to properly implement the program, leaving state and local agencies without the funding to manage vaccinations without cutting other health services.
- An adequate compensation plan to compensate volunteers who may suffer side effects from the vaccine was not in place when vaccinations began.
- Healthcare workers, first responders, and the public-at-large are not persuaded that smallpox is a serious threat that warrants participation in a limited vaccination program."

The report continues:

"*Reason 2: An Adequate Compensation Plan Was Not Provided*

"The provision of adequate compensation to those volunteers suffering side effects from vaccination is a critical element to a successful smallpox preparedness program. A strong compensation program sends a message to volunteers that their participation and willingness to accept a small risk of serious injury for the public good is appreciated and necessary for homeland security. It also affects the personal calculation of risk that each healthcare worker makes when deciding whether to volunteer. Even with adequate screening, serious adverse reactions to the vaccine can and do occur. Although fears that some fatal heart attacks were caused by the vaccine

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materials, and explosives detection services that include canine explosive detection teams. This designation/certification expires on June 18, 2009.

Northrop Grumman Security Systems, LLC: Biological Detection System. June 18, 2004 – The Biological Detection System is designed to screen mail for the presence of anthrax spores as it is processed on automated mail sorting equipment in mailrooms. This designation/certification expires on June 18, 2009.

Teledyne Brown Engineering, Inc.: Mobile Fluid Jet Access System. June 18, 2004 – The Mobile Fluid Jet Access System is a remotely operated, ultra-high pressure water jet cutting system designed to facilitate access to and aid in the neutralization of explosive devices. This designation/certification expires on June 18, 2009.

[20] "Protecting Americans: Smallpox Vaccination Program,"

www.bt.cdc.gov/agent/smallpox/vaccination_programstatement.osp

now appear unfounded, [21] 49 serious reactions have been reported to CDC, the predicted rate of about 0.1 percent.[22] In addition to the rare side effects, more common reactions, including temporary fatigue, nausea, and other mild illnesses can cost a worker lost wages, injury time, or other benefits. Moreover, because of the nature of the vaccine, the vaccinated worker risks sickening others with whom he or she comes in contact (such as family members). All of these possible occurrences may be considered by a potential volunteer and lead to a refusal to be vaccinated. The availability of compensation is more likely to make volunteers willing to take these risks.

"Unfortunately, the Administration did not properly manage the critical issue of compensation. While the 2002 Homeland Security Act provided liability protection to those manufacturing and administering the vaccine, no clear remedy existed at the time of the initiation of the campaign for those who were injured by the vaccine without negligence.[23] Instead, Administration officials expected individual workers' compensation plans to provide compensation.[24] But this assumption was not consistent with advice from public health officials, lawyers, and unions, all of whom pointed out that, with the highly variable coverage and quality of insurance plans, the Administration's approach would be a recipe for confusion and rejection by potential volunteers and their employers.[25]

"Again, Congress had to act to develop and pass a compensation plan, the Smallpox Emergency Personnel Protection Act of 2003.[26] By then, warnings of adverse reactions and reports of three deaths linked to the vaccine had already contributed to a growing reluctance among health workers to participate. By the time the Administration established a system to provide compensation eight months later,[27] the vaccination program was stalled."

Project Bioshield, passed by both houses and signed by President Bush on July 20, 2004, establishes a program to spend $5.6 billion over 10 years to have the private sector

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[21] Steve Mitchell, "*Study: Smallpox Shots Not Linked to Deaths*," *United Press International*, October 2, 2003.

[22] Centers for Disease Control and Prevention, *Smallpox Vaccination Adverse Events Report*, http://www.cdc.gov/od/oc/media/spadverse.htm.

[23] Congressional Research Service, *Homeland Security Act of 2002: Tort Liability Provisions*, RL 31649, July 22, 2003.

[24] Tommy Thompson, *HHS Teleconference on Smallpox Policy*, December 14, 2002, http://www.cdc.gov/od/oc/media/transcripts/t021214.htm

[25] (a) National Association of City and County Health Officials, "National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers," Press Release, March 7, 2003, www.haccho.org/press66.cfm; visited November 20, 2003; (b) Congressional Research Service, *Smallpox Vaccine Injury Compensation*, RL 31960, June 13, 2003, by Susan Thaul; (c) AFL-CIO, *State and Federal Smallpox Compensation*, http://www.aflcio.org/yourjobeconomy/safety/smallpoxcomp.cfm; (d) Meg Fletcher, "Vaccine Raises Claim Issues," *Business Insurance*, January 13, 2003, 1.

[26] Public Law 108-20.

[27] "*Interim Final Rule: Smallpox Vaccine Injury Compensation Program: Smallpox Administrative Implementation*," *Federal Register*, December 16, 2003, 68(241):70080-70106.

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develop vaccines and treatments using bioterror objects. Funds have been appropriated but the act fails to provide adequate liability protections. Critics of Project Bioshield state that its compensation provisions for those who have unexpected side effects from untested vaccines or antibodies are ineffective.[28] On March 11, 2003, Senator Gregg, chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee, introduced a bill that included Project Bioshield and more controversial items related to establishing a smallpox vaccination compensation program. The latter provisions were faced with strong Democratic opposition in part due to liability protections to manufacturers of thimerosal. As such, Senator Gregg agreed to remove the smallpox vaccination compensation provisions from the bill. The revised bill was subsequently renamed The Project Bioshield Act of 2003.[29] [30]

D. BLOOD SHIELD LAWS

As is the case with vaccines, but for very different reasons, the consumer base for blood products is very small. Because of this small base all fifty sates and the District of Columbia have adopted Blood Shield Laws that prohibit the application of strict product liability for injuries associated with blood therapies.

> With a very small consumer base over which to spread costs, the imposition of strict liability would pose a serious threat to the availability of factor concentrate due to increased cost or reduced production--a potentially deadly situation to people who rely on blood products to survive. As the Washington Supreme Court recently explained: "It would be unrealistic to expect such a small number of hemophiliacs to be able efficiently to spread the costs associated with liability insurance . . . . The end result for factor concentrate would be that the product would not be available to those who need it." (Footnote omitted.) [31]

One scholar has recommended an administrative compensation scheme that would permit product liability claims against identified manufacturers whose products infected an individual with a virus while providing an administrative remedy to recover medical expenses, lost income and a fixed sum for pain and suffering for those who cannot identify the responsible manufacturer. The fund would be based on what amounts to a tax based on industry sales. [32]

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[28] Project Bioshield, washingtonpost.com, May 24, 2004 at A22.

[29] http://democrats.senate.gov/dpc/dpc-doc.cfm?doc_name=lb-108-2-139 (May 17, 2004).

[30] "U.S. officials are hoping that Project BioShield will yield enough new-generation anthrax vaccine to dose 25 million people. Federal health officials also hope that the $5.6 billion program will provide antidotes for botulism and anthrax, a safer smallpox vaccine and a long-awaited children's version of an antiradiation pill. The program received bipartisan support in Congress. It passed the House on a 414-2 vote July 15. The discovery of sarin gas in a roadside bomb in Iraq and ricin and anthrax attacks against the Capitol spurred the Senate to pass it 99-0 in May." Wall Street Journal, July 21, 2004

[31] Klein, Andrew R. *"A Legislative Alternative to 'No Cause' Liability in Blood Products Litigation,"* 12 Yale J. on Reg. 107, 118 (1995)

[32] Id.

E. CALIFORNIA AIDS VACCINE VICTIMS COMPENSATION FUND

"Recognizing the experience of childhood vaccine manufacturers, the California legislature enacted a statute in 1986 to provide an incentive for vaccine manufacturers to develop and produce a vaccine for the AIDS virus.[33], [34] In addition, this statute established a

[33] California Health and Safety Code Section 199.45, §§ 199.50 to 199.52. Repealed by Stats. 1995, c. 415 (S.B.1360), § 22; footnotes omitted. The law is currently codified at California Health and Safety Code Section 121270

[34] The Legislature's findings might also be applied to the efforts by the CBACI Task Force:
121250.

> The Legislature finds and declares all of the following: (a) The rapidly spreading AIDS epidemic poses an unprecedented major public health crisis in California, and threatens, in one way or another, the life and health of every Californian. (b) The best hope of stemming the spread of the AIDS virus among the general public is the development of an AIDS vaccine to develop an immunity to exposure. (c) No vaccine has yet been fully developed, tested, or approved for AIDS. An effective vaccine, especially when directed at high-risk groups of unexposed persons, will virtually eliminate the risk of contracting AIDS, just as the risk of contracting polio and smallpox have been virtually eliminated by earlier vaccine development, production, and use among the general public. (d) Private industry today has the capability of conducting the vaccine research, biological research, immunology, and genetic engineering of appropriate viral components needed to formulate, develop, produce, and test an AIDS vaccine. Whenever these and other appropriate expertise cannot be found within a single company, the formation of multiinstitutional research groups should be encouraged and prioritized, as it is in the public interest to encourage efforts toward vaccine production. (e) It is of the highest importance and in the public interest to maximize public protection by developing an AIDS vaccine and by establishing high levels of immunization, initially among high-risk populations. (f) The continuous spread of AIDS and especially the threat of infection spreading among population groups previously considered low-risk demands that the highest of priorities be given to the development of a universal immunoprophylaxis. (g) The use of vaccines to control the spread of infectious pathogens is recognized as one of the genuinely decisive technologies of modern medicine. Recent advances in pharmaceutical technology combined with better understanding of the immune process offer the hope of an AIDS vaccine that is effective, safe, relatively inexpensive, and relatively easy to administer. (h) Utilization of this new science may be forestalled, however, by problems that have recently deterred the development of vaccines by traditional means. These problems must be resolved before the full public health benefits of new approaches to vaccine development can be fully and expeditiously realized. (i) The marketplace conditions facing vaccine manufacturers and developers today have changed considerably over the past 30 years. Private manufacturers and developers of vaccines cannot be forced to produce vaccines, and may choose, under the free enterprise system, not to produce them if marketplace conditions are unfavorable. (j) Certain market conditions are slowing and threatening to halt the development of an AIDS vaccine. Any delay in the discovery, testing, approval, and production of the vaccine because of these secondary considerations may cost tens of thousands of human lives annually, unnecessary pain and suffering for hundreds of thousands of infected Americans, and billions of dollars in medical costs and in lost productivity. (k) Resource constraints in the public and private sectors and the time required to bring vaccines to market presently limit investments in vaccines [sic] research and development. Although universities constitute a significant resource in AIDS research in particular and vaccines research in general, university funding limitations and conflicting research priorities make reliance on the resources and expertise of the private pharmaceutical industry a necessary supplement to public funding of AIDS research. (l) There has been a decrease in the willingness of pharmaceutical companies to become involved in vaccine research, development, and manufacturing because of uncertain profitability and perceived and actual marketplace risks and disincentives. (m) It is clearly in the public interest to provide appropriate and necessary incentives toward the timely development and production of an effective and safe AIDS vaccine. (n) The development of an AIDS vaccine provides an exceptionally important benefit,

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fund to compensate those injured by use of an approved vaccine. Although this program is modeled after the National Vaccine Program, there are some significant differences.

"The California act is designed with the specific goal of developing an effective AIDS vaccine. To this end, the legislation takes a two- step approach. First, it guarantees a market for any FDA approved vaccine. Second, the law attempts to limit litigation costs manufacturers may face by compensating those injured by the vaccine. Under the program, an injured party receives compensation of up to $550,000 for personal injuries, lost income, and pain and suffering. The compensation fund is to be maintained by a surcharge of no more than $10 on each dose of vaccine dispensed in California. The compensation fund is subrogated to any claim an injured party receiving compensation is otherwise entitled to assert. The fund may also seek indemnity for compensation it provides from third parties found to be liable for injuries resulting from use of an AIDS vaccine.

"The most obvious difference between the California Act and the National Vaccine Program is that an injured party can seek recovery concurrently from both the compensation fund and the vaccine manufacturer. Unlike the National Vaccine Program which effectively acts as an insurance fund, the California plan provides for victims' compensation through both an insurance mechanism and recovery in tort. The apparent rationale of the California scheme is to ensure that injured parties have a quick method of compensation for any injuries sustained while allowing the injured party to seek additional compensation directly from the vaccine manufacturer.

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making its availability highly desirable. However, certain conditions may preclude that development, including the following: (1) There is a high cost for capital expenditures for vaccine development (estimated to be from ten million dollars ($10,000,000) to thirty million dollars ($30,000,000)). Testing costs of clinical trials (twenty million dollars ($20,000,000) per vaccine, by some estimates) are particularly burdensome, especially for smaller firms. (2) There is an uncertain market demand for a vaccine once development costs have been invested and FDA marketing approval has been secured. (o) Without state intervention to assure minimal profitability of an AIDS vaccine, inadequate incentives may exist for the private sector to commit resources and expertise to the accelerated development of an AIDS vaccine. (p) In light of the dangers inherent in the AIDS epidemic to the general public of California, it is crucial that to the extent possible any serious obstacles to the development of a vaccine be removed. (q) Because an AIDS vaccine provides an exceptionally important public benefit, it is in the public interest to take uncommon action to facilitate the development and production of a vaccine. (r) It is as well in the public interest to assure fair compensation, if necessary at public expense, to any innocent victim who may be injured by an AIDS vaccine, as a part of implementing the socially beneficial policy of establishing high levels of AIDS immunization. (s) In light of the high incidence of AIDS amongst Californians, the California Legislature must lead our country into the 20th century in this effort. (t) It is therefore fitting and proper that the State of California enact uncommon and exceptional legislation in order to prevent the further spread of the AIDS epidemic.

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"Although the effectiveness of the California plan cannot be assessed until an AIDS vaccine has been manufactured and marketed, the plan offers some insight into development of a comprehensive AIDS vaccination policy."[35]

The law was enacted in anticipation of new development of a vaccine for the treatment of AIDS. It did not identify injuries or side that would be compensated other than to provide:

> (3) "Damages for personal injuries," means the direct medical costs for the care and treatment of injuries to any person, including a person entitled to recover damages under Section 377 of the Code of Civil Procedure, proximately caused by an AIDS vaccine, the loss of earnings caused by the injuries, and the amount necessary, but not to exceed five hundred fifty thousand dollars ($550,000), to compensate for noneconomic losses, including pain and suffering caused by the injuries. Cal. H&S Code § 121270(b)(3).

A task force[36] was created with the charge to make recommendations about the following:

> (1) The process by which victims are to be compensated through the fund.
>
> (2) The procedures by which the fund will operate and the governance of the fund.
>
> (3) The method by which manufacturers are to pay into the fund and the amount of that payment.
>
> (4) The procedural relationship between a potential victim's claim through the fund and a court claim made against the manufacturer.
>
> (5) Other issues deemed appropriate by the task force.

To the extent the law permitted a choice in remedy, it ignored the tragic history of subjecting vaccines to the tort system. [37]

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[35] Smith, H. William, Case Western Reserve Law Review, "*Vaccinating Aids Vaccine Manufacturers Against Product Liability*," 42 CWRLR 207 (1992)

[36] 14 members of the task force included "10 members appointed by the Governor, of which two shall be from a list provided by the California Trial Lawyers Association, one from the department, the Director of Finance, one unspecified member, and one attorney with experience and expertise in products liability and negligence defense work, two representing recognized groups that represent victims of vaccine induced injuries or AIDS victims, or both, and two representing manufacturers actively engaged in developing an AIDS vaccine. In addition four Members of the Legislature or their designees shall be appointed to the task force, two of which shall be appointed by the Speaker of the Assembly and two of which shall be appointed by the Senate Rules Committee." Cal. Health & Safety Code § 121270 (n)

[37] The law is currently codified at California Health and Safety Code Section 121270

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III

SUGGESTED REMEDIES

A. THE FEDERAL TORT CLAIMS ACT AND VACCINE LIABILITY PROTECTION

Under the Federal Tort Claims Act (FTCA),[38] federal employees are immune from liability for tort claims arising out of acts or omissions occurring within the scope of their employment. The FTCA establishes an exclusive remedy that makes the United States liable for the torts of its employees to the same extent that private employers are liable for the torts of their employees under the law of the state in which the act or omission occurred, with some exceptions.[39] Under the FTCA, the United States is not liable for punitive damages.[40] Claims must first go through an administrative process in the appropriate agency; if the claim is denied or the claimant disagrees with the compensation offered, the claimant may file a lawsuit.[41] Lawsuits are tried in federal district court without a jury. Attorney fees are limited to 25 percent of the judgment or 20 percent of the settlement[42] and the Government is not strictly liable. It also is immune from liability when it exercises a "discretionary function." This immunity, which has been construed rather broadly, covers public policy decisions.

As this memorandum will demonstrate, the FTCA has been utilized to protect entities other than the Federal Government when it was deemed in the national interest to do so. Perhaps the most relevant was the Swine Flu program instituted in 1996. Manufacturers or providers of Swine Flu vaccine were immunized from direct lawsuits, and the Federal Government acted as the defendant of record, utilizing the rules of the FTCA. There were two important exceptions under the program, the Government could be subject to strict liability and could not avail itself of the discretionary function exception. The FTCA recently amended this exception to provide protection to manufacturers and distributors under the Smallpox Vaccine program.[43]

Even more recently, the FTCA was utilized in the "Project Bioshield Act of 2004," S. 15. Project Bioshield provides the Secretary of Health and Human Services with authority to research and develop so-called "qualified countermeasures" in consultation with the National

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[38] 28 U.S.C.A. §§ 1346, 2671 *et seq.*

[39] *See id.* §§ 2672, 2680.

[40] *See id.* § 2674. There is a narrow exception to accommodate an unusual quirk of Alabama wrongful death law. The exception provides that if a law of a state provides only for punitive damages, the United States may be held liable for compensatory damages.

[41] *See id.* § 2675.

[42] *See id.* § 2678.

[43] *See* 42 U.S.C.A. § 233p.

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Institutes of Health.[44] Qualified countermeasures would include drugs, biological products, or devices deemed a priority for addressing events that could cause a public health emergency affecting national security or to treat or prevent harm that could result from such an event.[45] The Secretary would have authority to contract with experts or consultants with scientific or other professional qualifications to assist with the agency's research and development.[46] Any person carrying out such a contract, including an officer, employee, or governing board of that contractor, would be considered an employee of HHS for the purposes claims of personal injury or death resulting from the performance of the contract.[47] Thus, the FTCA would extend to these contractors in performing their research and development obligations. The Federal Government could then seek recovery from a contractor for claims paid if the injury resulted from the contractor's failure to carry out its contractual responsibilities, or stemmed from intentional, grossly negligent, or reckless conduct.[48]

There are other precedents for placing selected vaccine protections under the FTCA.[49] For example, under the Federally Supported Health Centers Assistance Act of 1995,[50] certain community health programs, their officers, and their physicians and other licensed or certified health care practitioners can claim FTCA protections. Congress justified its extension of the FTCA protections to these groups because of the substantial federal investment in these groups and the need to conserve taxpayer dollars for public health care.[51] In addition, although center physicians are neither hired nor supervised by the federal government, there is close federal supervision of the centers themselves in the form of clinical guidelines, funding and operational conditions, and quality assurance requirements. One could develop public policy arguments in selected circumstances to place vaccines under the FTCA.

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[44] *See* S. 15, 108th Cong., 2d Sess., § 2 (2004) (inserting § 42 U.S.C. § 319F-1(d)).

[45] *Id.* (§ 42 U.S.C. § 319F-1(a)(2)).

[46] *Id.* (§ 42 U.S.C. § 319F-1(d)(1)).

[47] *Id.* (§ 42 U.S.C. § 319F-1(d)(2)(A)).

[48] *Id.* (§ 42 U.S.C. § 319F-1(d)(2)(C)).

[49] Under the Swine Flu program, the FTCA applied except for the discretionary function exception and limits against strict liability. The Government could, in turn, sue suppliers if they engaged in grossly negligent or reckless behavior.

[50] 42 U.S.C. § 233(g).

[51] The House Committee on Energy and Commerce favorably reported legislation bringing community health centers under the FTCA, explaining: "There is substantial evidence that community and migrant health centers are spending far more on medical malpractice insurance premiums that is justified by their actual claims experience, and there is reason to believe that this is the case with respect to health care for the homeless and public housing resident programs as well. Extending FTCA coverage to grantees (and organizational subcontractors) under these programs will enable them to redirect funds now spent on malpractice insurance premiums toward improving or expanding their services to their target populations." H.R. Rep. No. 102-823(II), at 6 (1992).

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In light of the substantial and serious problems facing vaccine manufacturers, it may be advisable to develop and support a proposal for legislation that builds on the Smallpox Vaccine legislation and the Project Bioshield Act of 2004.

Two different approaches could be taken. First, certain select vaccines could be afforded the same FTCA coverage as community health centers. Claims against the manufacturer could be subject to administrative review and tried only to a judge in federal court, where government attorneys would defend them. These claims would be subject to the Act's prohibitions against punitive damages and prejudgment interest and to its limits on attorney's fees. This approach is likely to be vigorously challenged by the organized trial bar, who will dislike the administrative review requirements, damages limitations, and fee caps. It could be challenged, however, by the Department of Justice, which has expressed concerns about the expansion of FTCA coverage and its attendant effect on the Department's funding and attorney workloads.

A second approach, while similarly likely to be opposed by the organized trial bar, may be more palatable to the Department of Justice, would still curb potential excessive liability while promoting the development of vaccines. Vaccines that are broadly needed in the federal interest could be given certain protections under the FTCA. These protections could vary based on the preferences of industry experts. At a minimum, these protections should include giving federal courts exclusive jurisdiction over the claims in order to minimize the "home town" effect of some state judges, and prohibiting punitive damages and prejudgment interest in order to control skyrocketing awards. Limiting punitive damages by bringing the vaccine industry under the FTCA may be more feasible politically than simply eliminating punitive damages or curbing pain and suffering damages, through legislation. That is because the argument could be made that, as with community health centers, Congress has the clear power to have more stringently regulated tort claims against vaccine manufacturers. Under the FTCA approach, it could be perceived that Congress chose the narrowest legislation to accomplish its goals.

B. ELEMENTS OF A SUCCESSFUL COMPENSATION SCHEME

If vaccine manufacturers cannot be brought under the Federal Tort Claims Act (similar to what was done for Swine Flu)[52], a successful compensation scheme would have most or all of these elements.

1. Create a national standard of liability and compensation that preempts the product liability laws of the state.

[52] The benefits are that there is no strict product liability, no exposure to punitive damages, and tried to a court, not a jury; variations include having the manufacturer accept the benefits of the Act while paying for any liability and handling its own defense.

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2. The national fund is created from a combined tax on vaccine manufacturers, purchasers and attorney fees from awards.[53]

3. The national fund is the sole source for compensation of vaccine injuries.

4. As part of a national vaccine compensation program of risks that are known, a special master would be created who determines the amount of compensation (based upon an existing table of injuries) that would include past unreimbursed as well as future medical expenses, lost earnings, damages for pain and summering with a cap of $250,000 and reasonable attorneys' fees and costs. If the patient has died there is a cap of $250,000.

5. The injuries entitled to compensation must be clearly defined and a mechanism for adding newly discovered injuries should be recognized. The California AIDS Vaccine Victims Compensation Fund provides a model for the addition of injuries as they become associated with a vaccine.

6. Proof of the vaccination must be offered within a specified time period from date of manifestation of injury.

7. If there is proof of vaccination as well as proof of a compensable injury there is a presumption that the vaccine was the cause of the injury.

8. If proof of either fails, the patient bears the burden of proving that the vaccine was the cause of the specific harm.

9. If state tort claims are permitted in any way at all, there is a presumption that a warning on a vaccine is adequate and the claim for a failure to warn is preempted if FDA has approved the warning; such a presumption can be overcome only with proof by clear and convincing evidence.

10. If state tort claims are permitted, there should be preemption in the absence of fraud or intentional misrepresentation that must be established by clear and convincing evidence including evidence that there was reliance upon the misrepresentation.

11. If state tort claims are permitted in any way at all, the FDA Regulatory compliance defense should be adopted.[54]

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[53] The VICP was originally funded by a risk-based excise tax that was determined by evaluating the risk the specific vaccine posed for an injury. In essence, the higher the risk, the higher the tax. When the fund ended up with more money than it spent the system was changed to a flat-tax of $.75 per component of a vaccine. One proposal for future vaccines is to "impose a flat tax on every does of vaccine produced and couple it with a risk-based rebate. By incorporating risk into the rebate, the VICP can use retrospective 'hard' data based n actual injuries attributable to specific manufacturers." Levine, Jaclyn Shoshana, *"The National Vaccine Injury Compensation Program: Can it still Protect an Essential Technology?"*, 4 B.U.J.Sci.& Tech. L. 9, 70 (1998)

12. If state tort claims are permitted, and if manufacturer petitions to have a warning to a vaccine added and rejected by FDA no liability if adverse event from failure to warn.[55]

13. If state tort claims are permitted, punitive damages cannot be recovered.

C. OTHER STRATEGIES FOR THE FUTURE[56]

"In response to the latest round of vaccine shortages, interested parties have begun serious efforts to find solutions to the problem. First, the FDA needs to facilitate rather than impede the production of critical pharmaceuticals. The agency now does a better job of getting essential drugs to the market, but it needs to help keep them on the market as well. **When it initially licenses products, the FDA gives priority to reviewing drugs and biologics intended for the treatment of life-threatening conditions for which effective therapies do not yet exist; it needs to do the same when it inspects facilities and resolves disputes involving GMP requirements. At the very least, the FDA must demonstrate additional flexibility in case of a serious supply shortage.**

"Second, cost-containment strategies need to give way to some mechanism for paying a premium for critical pharmaceutical products or at least providing their manufacturers with generous tax incentives. [There are] other oft-mentioned solutions to the scarcity problem, in roughly descending order of merit: insulating manufacturers from tort liability, stockpiling supplies, and nationalizing part of the industry.

1. REMOVING THE LIABILITY CLOUD

. . . .

"One solution would replace tort liability with alternatives modeled on workers' compensation programs. . . . Congress enacted the National Childhood Vaccine Injury Act in response to fears of critical vaccine shortages and dramatic price increases. Manufacturers of listed vaccines must pay an excise tax to fund an administrative compensation system, and the legislation adds procedural and substantive barriers that are designed to discourage the filing of tort claims. This mechanism appears to have succeeded in stabilizing prices and stemming further exit from the market, though recent litigation involving vaccines or injuries not explicitly covered by the program has shaken some of the confidence that manufacturers have had about the extent of their protection from liability. Some commentators have proposed similar compensation systems for other types of drug

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[54] Noah, Lars, " *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability,"* in Symposium, "Regulatory Compliance as a Defense to Products Liability, 88 Geo.L.J. 2147 (2000):

[55] *"Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense"*, 24 Seton Hall L Rev 1437(1994).

[56] Noah, Lars, *Triage In The Nation's Medicine Cabinet: The Puzzling Scarcity Of Vaccines And Other Drugs*: 54 S.C. L. Rev. 741 to 54 S.C.L.Rev. 741 (2002). Footnotes deleted.

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products, or, as happened in the case of the swine flu vaccine, **the federal government could agree to indemnify manufacturers who supply products used in a mass immunization campaign**.

"**A less cumbersome but equally controversial reform would give pharmaceutical manufacturers the benefit of a regulatory compliance defense.** A couple of states have enacted legislation designed to limit tort claims against pharmaceutical products.

. . . .

"In response to fears of an emerging shortage of raw materials needed to make life-saving medical devices, Congress enacted the Biomaterials Access Assurance Act of 1998. **Under this statute, a biomaterial supplier that neither manufactured nor sold the allegedly defective implant would face tort liability only if it 'failed to meet applicable contractual requirements or specifications'** when it furnished raw materials or component parts. When named in a lawsuit as a co-defendant, the biomaterials supplier receives certain procedural benefits, including protection from sweeping discovery requests and an opportunity to seek an expedited dismissal with prejudice or summary judgment if the plaintiff cannot establish that the supplier also made or sold the implant or furnished nonconforming biomaterials. It remains to be seen whether this legislation adequately reassures biomaterials suppliers, but the law provides still another model for responding to concerns that unpredictable tort litigation will cause additional shortages of critical pharmaceuticals in the future."

IV

CONCLUSION

Professor Noah provides a succinct summary of the issue as well as a possible solution.

"For a variety of reasons, shortages of vaccines and other critical pharmaceutical products have increased in the last few years. Pressures emanating from regulatory agencies, courts, and insurers have conspired to make this line of the pharmaceutical business less than attractive. The FDA's implementation of GMP requirements, especially those governing the production of vaccines and other biologics, have created compliance difficulties for manufacturers; the threat of tort liability continues to drive some drug companies from particular markets; and cost-containment pressures resulting from bulk government purchases or declining levels of insurance reimbursement have eroded profit margins. Under these conditions, the pharmaceutical industry's focus on blockbuster drugs for lifestyle uses or chronic health conditions should come as no great surprise.

"This is a multi-faceted problem that does not admit of any single or simple solution, but the government should not respond in ways that further weaken market incentives. Instead, it should try to encourage private manufacturers to continue supplying critical pharmaceutical products. A number of steps would help improve the business climate: more **flexible regulation of manufacturing facilities, greater protection from the vagaries of tort liability, and the avoidance of excessive cost controls. In addition, the government should bolster its emergency stockpiles, but it must take care to avoid suggestions that the public sector should take over the entire operation,** because then we really would have only a single supplier that would risk many of the same shortcomings that government-run monopolies have encountered in other fields."[57]

[57] Lars Noah, *Triage In The Nation's Medicine Cabinet: The Puzzling Scarcity Of Vaccines And Other Drugs*, 54 S.C.L. Rev. 741 (2002). Footnotes deleted.

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NUMBER OF FIRMS IN VACCINE MARKETS

Year			Live Virus	Live Virus	Live Virus	Live Virus
	DPT	DT	Polio	Measles	Mumps	Rubella
1950	1	10				
1951	9	10				
1952	1	10				
1953	1	10				
1954	1	9				
1955	9	8				
1956	9	7				
1957	8	7				
1958	7	7				
1959	7	7				
1960	7	7				
1961	7	7				
1962	7	7				
1963	7	7				
1964	8	8	3	1		
1965	8	6	3	4		
1966	7	7	3	6		
1967	7	7	3	6		
1968	6	6	3	7		
1969	6	6	3	7	1	
1970	6	6	3	7	1	2
1971	6	6	3	5	1	4
1972	6	6	3	5	1	4
1973	6	6	3	5	1	4
1974	5	6	3	4	1	2
1975	4	4	2	3	1	2

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Year			Live Virus	Live Virus	Live Virus	Live Virus
	DPT	DT	Polio	Measles	Mumps	Rubella
1976	5	6	2	3	1	2
1977	5	5	2	2	1	2
1978	5	5	1	2	1	1
1979	6	6	1	2	1	1
1980	4	5	1	2	1	1
1981	4	4	1	1	1	1
1982	3	4	1	1	1	1
1983	3	4	1	1	1	1
1984	4	4	1	1	1	1
1985	2	5	1	1	1	1
1986	1	5	1	1	1	1
1987	2	6	1	1	1	1
1988	2	6	1	1	1	1
1989	2	5	1	1	1	1

NOTE.--For each year, the entries in the table are the number of firms listing each vaccine for sale in various issues of either the Drug Topics Red Book or the American Druggist Blue Book. DPT refers to the diphtheria, pertussis, and tetanus vaccine and DT to the diphtheria and tetanus vaccine. Excerpt from: 37 J.L. & Econ. 247, *253

These data provide a useful basis for this study because among the childhood vaccines, DPT has been the target of the most product liability litigation and has attracted the most public attention. In addition, the effects of liability costs on its price are almost perfectly transparent due to its relationship to the DT vaccine.

SOURCE.--The entries in this table are reported in Alan R. Hinman, DPT Vaccine Litigation, 140 Amer. J. Dis. Child. 528 (1986); and Alan R. Hinman, DPT Vaccine Litigation Update, 142 Amer. J. Dis. Child. 1275 (1988).

NOTE.--The lawsuit data were provided to Hinman by the corporations involved in the litigation, namely, Connaught Laboratories, Lederle Laboratories, and Wyeth Laboratories, on the condition that specific

Excerpt from: Richard L. Manning, *Changing Rules in Tort Law and The Market for Childhood Vaccines*, 37 J.L. & Econ. 247, 258 (2004)

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