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THE SMALLPOX VACCINATION PLAN: CHALLENGES AND NEXT STEPS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

EXAMINING THE FEDERAL ROLE AND ITS IMPLEMENTATION OF A NATIONAL SMALLPOX VACCINATION PROGRAM, FOCUSING ON PREVENTION AND PREPAREDNESS STRATEGIES

JANUARY 30, 2003

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THE SMALLPOX VACCINATION PLAN: CHALLENGES AND NEXT STEPS

THURSDAY, JANUARY 30, 2003

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:00 a.m., in room SD–430, Dirksen Senate Office Building, Senator [chairman of the committee] presiding.

Present: Senators Gregg, Frist, DeWine, Kennedy, Dodd, Mikulski, Jeffords, Reed, and Clinton.

OPENING STATEMENT OF SENATOR GREGG

The CHAIRMAN. Good morning, everybody. I understand Senator Kennedy is at the Estrada hearing of the Judiciary, so he may or may not be arriving later. I know a number of other members are coming but since everybody is here, I thought we could start a little early, which is a nice way to begin.

Today we are taking on the issue of how we address the smallpox vaccination question for our society. This has become a critical question of healthcare and of national protection. I view this obviously as an issue of national security.

The way I see it, and I have spent a considerable amount of time on this even before we had the problems that we are confronting today, is that if we are able as a society to put ourselves in a position of being ready for a smallpox attack, the likelihood of it occurring will be significantly less. It would be unlikely that the terrorists would use the smallpox virus against us if they knew that the damage that they were going to cause was going to be dramatically reduced because a large number of Americans had been immunized and were not going to be impacted by their attack. So I think it is one of these situations where if we are able to prepare properly, we will never have the event.

On the other hand, if we do not prepare properly, the event is a possibility. We know that our enemies, the people who have already struck at us and harmed us, would use this weapon if they had it. We regrettably are not sure who does have it by now and we therefore need to prepare ourselves.

I congratulate the administration for its aggressive initiative in this area and it is nice to have today before us the two leaders in the administration on this issue.

I think there are three issues which I would like this hearing to focus on. No. 1 is how we deal with vaccinating the general public.

No. 2 is how we deal specifically with vaccinating children. And number three is how we deal with the very, I think, important issue of compensation. I do not believe we can get people to participate in a general vaccination program or even in a targeted vaccination program unless we have set up a structure so that, in those rare instances where there is harm caused as a result of the vaccine, people understand that they are going to be able to receive at least pecuniary protection. So that becomes a major element of this question.

Just for the record, when other members decide to be here the way we are going to proceed in this committee is that we are going to have opening statements by myself and Senator Kennedy and should the majority leader, and I am assuming the majority leader will be here, he will obviously be granted the opportunity for an opening statement. Then we are going to go to five-minute questioning periods and the order of questioning will be determined by the order of arrival.

[The prepared statements of Senators Gregg, Enzi, and Mikulski follow:]

PREPARED STATEMENT OF SENATOR GREGG

I would like to thank all of our witnesses for taking the time to come here today to discuss the implementation of the Administration's smallpox vaccination plan.

While smallpox no longer occurs naturally, some in the intelligence community are concerned that countries like Iraq and North Korea may possess samples of the virus. Highly contagious and easily dispersed in the air, smallpox virus can be a deadly weapon in terrorist hands.

Congress and the Administration have responded to this potential threat by purchasing 300 million doses of smallpox vaccine and by developing a plan to protect the American people against such an attack.

In accordance with this plan, the smallpox vaccine would be offered to 500,000 health care workers, expand to 10 million emergency responders, and extend to the rest of the population as early as 2004.

As a strong advocate for making the smallpox vaccine available to the general public, I think the plan was thoughtful and on the mark. Americans, after consulting with their doctors, should be allowed to make voluntary, informed decisions to receive the vaccine for themselves and their families.

The more people who are vaccinated against smallpox, the lower the rate of transmission of the disease, and the greater likelihood that such an outbreak could be contained. Also, the fewer people who are susceptible to the disease, the less likely an enemy is to use it against us.

Health care worker vaccinations began on Friday, January 24. The National Institute for Allergy and Infectious Diseases, the CDC, and its state and local partners should be commended for planning the pre-event smallpox vaccination program and for helping it become operational so quickly.

As with any comprehensive program rolled out under such exigent circumstances, there are some questions and concerns.

These areas include logistics; provider education and training, including screening for contraindications and treating adverse reactions; and preventing the vaccine's inadvertent transmission.

There has also been no pediatric testing of the smallpox vaccine—only on adults. Most adults don't want the vaccine for themselves, so much as to protect their children. Children are not small adults, and we need to make sure that our stocks of smallpox vaccine are safe and effective for children—notwithstanding recent positive testing in adults.

I am also sympathetic to the concerns of our health care and emergency workers who volunteer to be vaccinated. They will be on the front line in responding to any smallpox attack, and we must ensure that their health and safety is protected, and that persons who suffer serious adverse reactions to the vaccine have appropriate recourse.

While some have called for a new federal "no fault" workers' compensation program to cover smallpox-vaccine related injuries, we need to remember that states already have such systems already in place.

Vaccinated workers are not the only group of people who could be injured; co-workers, family members, patients, and others could become infected inadvertently. These persons could not file a claim under any state workers' compensation program.

I'm looking forward to hearing our witnesses on this issue, and will continue to work with the Administration, my friends across the aisle—and especially our health care and emergency workers—to address this important issue.

We need to ensure that the children and families of these workers are protected.

Finally, we need to know what Congress must do to ensure an adequate supply of smallpox vaccine, the development of a safer smallpox vaccine, and the development of vaccines to address other biological threats.

In light of these issues, some have urged that the smallpox vaccination program be delayed. I strongly disagree. Considering the potential threat to our nation posed be a smallpox attack, we must continue to move forward.

Even the Institute of Medicine (IOM), which was charged by the CDC to provide advice on how best to implement the program, does not recommend that it be delayed. In his testimony before the Labor, HHS Appropriations Subcommittee yesterday, the Chair of the IOM's Committee on Smallpox Vaccination Program Implementation, Dr. Brian Strom, made this point clear.

. . . by recommending that CDC "proceed cautiously," the [IOM] committee never implied that CDC was proceeding too quickly or without due caution, as has been somewhat misstated in some of the press reports on the committee's recommendations. The committee did not recommend that the vaccination program be delayed or slowed down. The committee only encouraged CDC to facilitate local implementation at the pace that safety would allow. CDC has acknowledged that these are its intentions, and the committee believes that CDC will proceed accordingly.

That is the purpose of today's hearing: To ensure that the smallpox vaccination plan continues to proceed safely and efficiently. I look forward to hearing from our witnesses.

PREPARED STATEMENT OF SENATOR ENZI

Thank you Mr. Chairman. On December 13, 2002 the President announced a plan to better protect Americans against the threat of a smallpox attack by hostile groups or governments. The Administration's smallpox vaccination program is an important tool in our fight against bioterrorism. While there is no reason to believe that smallpox presents an imminent threat, the deliberate release of the smallpox disease is now considered a possibility. Now is the time to take precautions to deal with this dangerous possibility.

The Administration has carefully considered the risks of a smallpox attack as well as the risks of the smallpox vaccine. Their plan represents a targeted, prioritized response to both risks. The program recommends vaccination for those civilians who would be most critical in responding to a smallpox outbreak.

Approximately 500,000 health care and public health workers will be asked to volunteer for the vaccine during Phase I of the program. This initial group includes health care workers who would treat smallpox cases and public health response teams who investigate initial smallpox cases and implement control measures. Up to 10 million health care workers and first responders subsequently will be offered the vaccine on a voluntary basis during Phase II. Pre-attack vaccination of these health care workers and first responders will allow them to better protect the American public in the event of a smallpox attack. These health care workers and first responders will be at the front-line of our battle against bioterrorism. We must see that they are properly armed.

Yet the armor—the smallpox vaccine—carries its own risks and side effects. In the past, about 1,000 people for every million people vaccinated for the first time experienced serious, but not life-threatening. reactions. Rarely. people have experienced potentially life-threatening reactions. Based on past experience, The CDC estimates that between 1 and 2 people per million people vaccinated will die as a result of the life-threatening reactions to the vaccine. Because the vaccine contains the live vaccinia virus, the vaccinated individual can also potentially infect others.

Careful screening, education, and training on the administration of the vaccine will help to minimize complications and secondary exposure. I am very interested in hearing our witnesses discuss effective screening, education and training measures. I am very proud to have been an original cosponsor of the Needlestick Safety and Prevention Act, which was enacted to significantly reduce the risk that health care workers will contract a bloodborne disease in the course of their work. I am very interested in hearing our witnesses discuss the needles used to give the smallpox vaccine and ensuring its safe administration.

I'm interested in hearing more about how the CDC and NIH are preparing for the possibility of a smallpox attack—both initially if our first response if not sufficient. Contemplating these scenarios is chilling, but very necessary if we are to be prepared for any eventuality.

While proper screening, education and training can reduce complications and secondary exposer, they cannot entirely eliminate vaccine risks. Concerns about liability for adverse reactions may inhibit manufacturers from making the vaccine. Liability concerns may also inhibit health care entities and health care professionals from administering, the vaccine. Concerns about compensation for adverse reactions may inhibit health care workers from getting the vaccine.

The Administration's smallpox vaccine program is dependent on the voluntary participation of manufacturers, administrators, health care workers and first responders. We must appropriately address these liability and compensation concerns to ensure that the Administration's program is successful.

Section 304 of the Homeland Security Act was enacted to allay liability concerns so as to encourage the manufacture and administration of vaccines. Section 304 designates manufacturers and health care entities and workers who administer the vaccine to be federal employees for purposes of administering the vaccine. The Federal Tort Claims Act (FTCA) makes federal employees immune from liability for torts committed within the scope of their employment. The federal government would then assume tort liability for smallpox vaccine related injuries and deaths pursuant to the FTCA. The FTCA does not permit jury trials or punitive damages. Furthermore, an individual most prove negligence in order to recover under the FTCA.

The Department of Health and Human Services has issued guidance on Section 304. However, questions remain about liability and compensation for vaccine-related injuries and illnesses. Some have argued that the liability protection afforded by Section 304 is not adequate. Others have argued that the compensation afforded by Section 304 is not adequate. Successful implementation of the Smallpox Vaccine Plan requires satisfaction of these seemingly inconsistent goals First, we must clarify what Section 304 does—and does not—do.

We need answers to the following questions:

Who and what activities fall under the liability shield of Section 304?

Does Section 304 preclude recovery, under state workers' compensation laws?

If not, will state worker's compensation cover vaccine-related injuries and Illnesses?

Are there individuals who could sustain vaccine-related injuries, either directly or indirectly, with no recourse for compensation?

These answers are needed to identify gaps in the compensation structure for vaccine-related injuries. Once these gaps are identified, we can discuss appropriate measures to fill them.

However, we must be careful to maintain the integrity of state workers' compensation systems. State workers' compensation laws provide a "no-fault" remedy for work-related injuries and illnesses. In exchange, workers' compensation damages are limited and are the exclusive remedy against an employer. A new federal workers' compensation system upsets the delicate balance created by state workers' compensations systems and usurps state autonomy in this area.

I look forward to hearing from our witnesses about the challenges and next steps for the smallpox vaccination program. I look forward to working with my Colleagues and the Administration to address these challenges so that we may take an important step in our fight against bioterrorism.

Thank you Mr. Chairman.

PREPARED STATEMENT OF SENATOR MIKULSKI

Thank you for holding this hearing, Chairman Gregg. I look forward to hearing from the experts about their concerns with the Administration's smallpox vaccination plan.

I have serious concerns that the Administration is rushing into this plan, without taking care of doctors and nurses on the front lines, and without plans to communicate with the public and health care professionals in the event of a smallpox attack.

Vaccine safety is critical. Brave doctors and nurses on the front line are volunteering for a smallpox vaccine. They put themselves and their families at risk to protect our country in a smallpox attack. We owe it to them to make sure they can get medical care if they need it, their families will be able taken care of if they are injured, and they will not be sued for treating their patients.

There are serious problems with this plan. The federal government has done a poor job communicating with the public and health professionals. One in five nurses surveyed last week did not know that vaccination given within a few days of exposure will prevent smallpox. This is unacceptable.

Let's take lessons learned from the anthrax attacks that killed two Marylanders. The government must speak with one voice about the risks and benefits of the vaccine. The Institute of Medicine (IOM) agrees. IOM recommended that the federal government designate one person, a scientist like Dr. Fauci or Dr. Gerberding, to be the national spokesperson on smallpox.

The federal government must have a plan to communicate with the public, medical professionals, and public health officials. Who coordinates with governors? What happens when a case of smallpox is diagnosed? Quarantine? Vaccinations? There must be clear answers to these questions.

Vaccinations have begun. I am concerned that the Administration has rushed vaccination with out enough attention to vaccine safety. How safe is safe? Who set the standard for safe? Are safer vaccines in the pipeline?

There is no compensation to the families for nurses or doctors who are seriously injured or die from this vaccine. There is no guarantee that first responders can get medical care if they get sick. Doctors and nurses are not getting vaccinated for personal protection. They are getting vaccinated to protect the public. The federal government must protect the protectors.

Questions about liability have not been resolved. Unless hospitals, doctors, and nurses are protected from lawsuits, this plan will fail.

States and hospitals are bearing these costs without any help from the federal government. The costs to implement this plan will be staggering. States will spend about $85 per vaccination at a time when states are already strapped for cash. States will have

to cut back on other bioterrorism improvements like building better labs and hiring extra disease detectives.

Hospitals are being asked to bear much of this burden. Johns Hopkins in Maryland will reassign immunized doctors and nurses so they don't treat patients for a couple of weeks to make sure patients do not get sick. These staffing reassignments will be especially hard on hospitals because of the nursing shortage.

I am looking forward to hearing from our witnesses today, especially Dr. Gerberding and Dr. Fauci. There are many questions that must be answered before this country is adequately prepared for smallpox.

The CHAIRMAN. At this time I would like to hear from the representatives from the government, Dr. Fauci and Dr. Gerberding. We will begin with Dr. Gerberding.

STATEMENTS OF JULIE L. GERBERDING, M.D., M.P.H, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA; AND ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, BETHESDA, MD

Dr. GERBERDING. Good morning and thank you very much for having this opportunity to update you on the current status of the smallpox vaccination implementation program.

As you know, smallpox is a devastating, disfiguring and a deadly disease. This disease has a mortality rate of 30 percent. Fortunately, we were able to eradicate it, at least the natural disease, but we know that there are countries and/or entities that have the smallpox virus and could use it for purposes of a biological attack on the United States. We do not know the quantitative risk of an attack but we know it is not zero and we need to prepare to protect the American people should that occur.

In December President Bush announced the policy for immunization of Americans against smallpox. He was very specific in his policy. The recommendation was that we protect the military troops and that we protect those civilians who would be in a position to respond to initial cases of smallpox and protect the country in emergency situations, and that would include emergency medical service workers, healthcare providers, and others who would be part of our overall emergency response team. The highest priority in this is to protect the smallpox preparedness teams, which are the public health workers and the clinicians who would take care of the very first cases of smallpox.

We have plans in place and let me just show you on the next graphic the progress that has been made over a relatively short time frame. In November no States had approved plans for mass vaccination of the American public and no States had plans for immunization of smallpox response teams or emergency personnel. By this month, all States have approved plans for how they would in emergencies immunize their citizens and all States have plans for how they would immunize the smallpox response teams. So we have made considerable progress very fast in terms of our planning.

Let me explain to you on the next graphic how we will roll out this immunization program. The States receive $918 million in sup-

plemental resources for terrorism preparedness and response. By June of this past year they had received the entire allocation. In December, as I mentioned, the president announced his policy and in January, specifically last Friday on January 24, the first stage initiated civilian vaccination of emergency response teams.

As of today, 22 States and two counties have received 127,200 doses of smallpox vaccine. Thirty-eight States and two counties have requested a total of 205,700 doses of vaccine. So the States have, I think, made a heroic effort to become prepared and are initiating right now vaccination primarily of the vaccinators who will staff the vaccine clinics but over the next several weeks we anticipate that these efforts will be scaling up and ultimately expanding to achieve a level of preparedness that will allow us to initiate a wider vaccine campaign should we need to in case of an emergency.

It is important to respect at this point that the president specifically did not recommend vaccination of the general public at this point but charged us to make vaccine available to those who insist on having it in an orderly fashion over the next several months. And I remind you that although Secretary Thompson has been able to ensure that we have a dose of smallpox vaccine if we need it in an emergency for every man, woman and child in America, right now we do not have licensed vaccine sufficient in quantity or supply to immunize beyond the groups that I have already mentioned that were included in the president's initial recommendations.

So we have, I think, stepped up and scaled up our efforts but I wanted to also explain what would happen if we had a case or a suspect case of smallpox today because I think our capacity to respond to this has significantly improved over the last several months.

If we had a case today two things would happen. First of all, laboratory samples would quickly be sent to the Laboratory Response Network and to CDC so that we could confirm it was a case and at the same time, individuals would be getting on an airplane from CDC carrying this kit, which contains 1,500 doses of vaccine, and they would initiate the initial round of vaccine around the suspect case to take the earliest step possible to prevent spread to others.

So I think we have exercised this plan through multiple false alarms and we appreciate that the most important component of detection really is identification of the first case early enough to initiate this level of response, but our preparedness has continued to improve regularly over the last several weeks. Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Gerberding may be found in additional material.]

The CHAIRMAN. Dr. Fauci?

Dr. FAUCI. Thank you very much, Mr. Chairman, for calling this hearing, for giving me the opportunity to testify before you. I am just going to spend a few minutes talking about the vaccine that is being used in the program announced by the president and executed by the CDC, talk a little bit about the toxicities.

Dr. Gerberding told you quite well that this is a very serious disease with a 30 percent mortality, with no treatment. However, what is important is that we have a very, very effective vaccine

and that vaccine, as you know, historically has been responsible for eradicating smallpox in the United States and worldwide.

The vaccine that we are using in the currently implemented program is called Dryvax. It is, in fact, a vaccine that you and I got when we were children and that, in fact, was used in the United States and a version of this, different modifications, throughout the world. It is greater than 95 percent effective.

However, we know historically, particularly from the 1968 cohort data, that for every million individuals vaccinated there will be between 14 and 52 life-threatening adverse events and between 49 and 935 nonlife-threatening serious events with one to two deaths. This has been in primary vaccinees. An important point, as we know, that if you were previously vaccinated the chance of your getting an adverse event is considerably less than among primary vaccinees.

What do we do when we do get an adverse event? The time-honored approach is to administer a substance called Vaccinia Immune Globulin, which is derived from the plasma of people who have been formerly vaccinated. Currently we have enough Vaccinia Immune Globulin or VIG to take care of the projected adverse events that we might expect in the program that is being implemented now through the CDC. By this summer we will have enough VIG to cover the projected adverse events were we to vaccinate 300 million people, which we have no intention of doing, only in the event of an attack.

Also, there are experimental approaches like Cidofovir, which is an antiviral drug, that is now in our stockpile to use to complement the VIG if, in fact, the VIG fails.

We are also pursuing something we feel is very important from a research standpoint, is to develop a vaccine with considerably less toxicities. One of these, called Modified Vaccinia Ankara, is actually a vaccine that has been used successfully in Germany for a couple of decades during their smallpox vaccine program. It is clearly quite a safe vaccine. It is an attenuated vaccinia virus. What we do not know for sure is its efficacy in epidemic conditions. We are pursuing this aggressively together with other attenuated forms and hopefully within the next couple of years we will have a considerable amount of this were we ever to need it.

Let me spend the next just minute or so talking to you about the broader approach that we are taking in the effort of research to counter the microbes that we might be met with in the future, including smallpox but also anthrax, botulism, and others. We have a research program anchored in our strategic plan and a research agenda to cover both Category A and B agents and we talked to you about the Category A and B agents, the top six in the Category A, and then a larger number of B and C agents.

That program is anchored on the classical NIH approach of basic research but with a new paradigm, a paradigm of taking that research and accelerating the translation of that research into identifiable products in the form of vaccines, therapeutics and diagnostics, with the clear collaboration of industry, and that is what the president was referring to in one of the points he made in the State of the Union Address when he referred to Project Bio-

Shield, which would be a major incentive, one component of it, for industry to get involved.

And finally, in this last slide I want to emphasize that the ultimate goal or vision is to develop universal or wide-ranging antibiotics, antimicrobials, antivirals that can be used against all classes of biological pathogens, to develop new platforms for vaccine development and other countermeasures, to modulate the immune system that we might bolster up capability when we do not know exactly what the microbe is, and also to develop molecularly based diagnostics.

At the end of the day we believe this will have two major accomplishments. One will be that it would effectively defend us against the microbes of bioterror. But also, since bioterror agents are really emerging and reemerging diseases that resemble very much the naturally occurring diseases, so that what we learn for biodefense will have important implications for decades and decades to come in our approach toward emerging and reemerging diseases.

Thank you very much, Mr. Chairman. I would be happy to answer questions.

The CHAIRMAN. Thank you, Doctor.

[The prepared statement of Dr. Fauci may be found in additional material.]

The CHAIRMAN. Let us assume that any outbreak of smallpox anywhere in the world is a terrorist attack. That is a reasonable assumption since the disease has been eradicated. So is it not also reasonable to assume that if there is an attack, it is not going to occur at one place? It is going to have been planned. It will be a multiphased attack. It will involve maybe who knows how many people that have been infected traveling on what would be very populated areas, either public transportation or going to public events. Since smallpox is such a huge threat because it can be spread so easily, it would be quickly disseminated amongst large numbers of people and moved about the country and possibly about the world, depending on where the attacks occurred.

So I think is it not unreasonable to presume that we are not simply going to have a single outbreak; that if an attack occurs, that we are going to have dramatic multiple outbreaks, and that they will be spread out across large areas, large population centers, and be very hard to contain? Is that not a reasonable assumption?

Dr. FAUCI. Quite a reasonable assumption. There could be all of the above. There could be minor moderate or there could be multifocal. One would think logically that if there is a bioterrorist-led attack with smallpox, that it would be something that would have maximum effectiveness in impact, negative impact on us. So whether it happens or not, we absolutely need to be prepared for it.

The other important point that you alluded to, Mr. Chairman, that is really quite critical to the whole preparedness effort is that our experience over decades and decades has been against naturally occurring smallpox. We do not have any experience of what would happen, for example, on an aerosolized multifocal attack throughout the United States and otherwise, and that is the reason why, as Dr. Gerberding mentioned, we have to have that core of preparedness.

The CHAIRMAN. Which leads me to the second question. Why do we presume that vaccinating a small percentage of the population would allow us to effectively deal with an attack, which would be focussed on the general population and would be moving extremely quickly? Is it not inevitable that if we are going to keep this attack from occurring that the general population has to have been protected before the event occurs?

Dr. GERBERDING. I think that what we are trying to do here is balance protection of the general population ahead of an attack with what we know to be very harmful consequences of this vaccine. And what we have said right now is that it is absolutely necessary that we have the preparedness capacity to initiate a mass vaccine program if we needed to.

Initially the recommendations from our experts were that the number of people who needed prevent immunization was quite small. That number has grown over time as we have begun to appreciate that we need to have this level of preparedness in every community for the reasons that you, I think, correctly outlined.

But it is also important to appreciate that while this is a devastating disease, it is not as infectious as people imagine. It is actually not very efficiently spread compared to something like measles or influenza. Most, although not all, but most of the transmission occurs after people are quite ill and when people are ill, their home and the risk that they present for spread is primarily to their household contacts.

There are a few people who disseminate before they are in that stage. These are the coughing people or people with very profound presentations of the illness. But the experience with the people who eradicated this infection over the last several decades is that you can contain the infection through an incredibly aggressive immunization program if you have the army of people available to go out and do that level of vaccination.

If there is an aerosol exposure to this virus in the country there are people who will not be safe from the first exposure to smallpox. We know that. That is an honest statement. But once we have identified that there is an exposure, we will be able to protect most people by implementing an immunization program. And as we have more licensed vaccine and more capacity to immunize safely larger groups of people, we will need to look again at whether our initial recommendation should be expanded.

The CHAIRMAN. Do we have the capacity to identify an aerosol exposure outside of having people get very sick?

Dr. GERBERDING. As you probably have heard, recently there has been deployment of technology that is in the expansion phase right now that allows detection of microbes in the air. This is a project that EPA is doing in conjunction with CDC, HHS and others to detect the organism before it could have a chance to cause disease. This capacity is evolving. We look forward to improvements in the technology over time but we are aiming to be able to detect aerosols before they cause disease in the human population.

The CHAIRMAN. But we do not have that capacity relative to smallpox right now, do we?

Dr. GERBERDING. We have a limited capacity to do that right now for smallpox.

The CHAIRMAN. Limited. How limited?

Dr. GERBERDING. Well, I feel a little uncomfortable about discussing exactly where these systems are deployed right now but I would be happy to get back to you for the record with what we know about it and we can confer with our colleagues from EPA.

The CHAIRMAN. OK.

Dr. Fauci, you mentioned the other vaccine initiatives which you are pursuing under this BioShield that was announced Tuesday evening. You listed the six Category A or you mentioned that there are six Category A. Maybe you could identify what those six are and what the status is on each one relative to our capacity to protect the society.

Dr. FAUCI. I would be happy to, Mr. Chairman. The six are smallpox, anthrax, botulism toxin, tularemia, plague, and the hemorrhagic fevers, particularly Ebola.

We are discussing smallpox. You know quite well where we are now with smallpox. The only additional thing is what I alluded to, is that we do not want to stop here. We want to go to the next generation of much safer attenuated smallpox. That would fit under one of the BioShield concepts of being able to let industry know that were they to get involved with us in making the investment to try and develop a safer form of a vaccinia smallpox vaccine, that we would essentially assure that that would be purchased even if we had to stockpile it.

Anthrax, we have a couple of contracts that are now directed at developing a safer, better, more effective and easy to use anthrax. The current anthrax vaccine is based on taking the supernatant or the material in a culture from the growing anthrax microbes and using that as the vaccine. It requires six immunizations over 18 months. It is not a convenient way to make someone protected by vaccination. We are working right now on a recombinant what we call protective antigen referred to as RPA, which is the next generation of anthrax vaccine, and we hope within a shorter period of time, within a period of a year to two, to have sufficient quantities of that to essentially replace what we are having now with the first generation of anthrax.

Botulism toxin, the approach to botulism toxin is fundamentally to develop anti-toxin against it. We have limited supplies of a horse-derived anti-toxin that has been used for the naturally occurring botulism, usually in children, which when children usually from contaminated from food get botulism toxin poisoning, they wind up going into respiratory difficulty because it paralyzes the muscles' ability to actually breathe. That is one of the more devastating effects of this particular microbe and its toxin.

We are processing rapidly the stores of horse anti-toxin that we have now that has to be converted from crude gross sera into the anti-toxin in its more concentrated form. That is going to take a considerable period of time. That is another thing we need to accelerate.

The next generation is to make what we call a monoclonal antibody or a very specific antibody that is generally tailored and manufactured in an animal but can be converted to a humanized form. Once we succeed in that Mr. Chairman, we could stockpile an unlimited quantity of that.

We have Ebola, one of the hemorrhagic fevers, we have very good news with Ebola in that we have developed at the NIH and others are also involved in this, an Ebola vaccine that has been tested in a monkey model and has protected essentially 100 percent of a group of a dozen or more monkeys that were deliberately challenge with Ebola intraperitoneally, and we are going into phase one trials now in humans in calendar year 2003.

The other two—plague. Plague is a variation disease. We have antibiotics that are good against plague. We do not have a very good vaccine against plague. We used to have one. It is now at the point where it is getting on clinical hold with the FDA, so we will have to develop a better one than that.

And then also tularemia, we have good antibiotics against it but we need to get a better vaccine. So those are the——

The CHAIRMAN. Are you doing anything in the chemical area, such as with VX gas?

Dr. FAUCI. Not directly, but there are certain aspects of chemical and radiation that the NIH will do vis a vis certain types of effects on the nervous system, etc, but we are not directly specifically doing research. The CDC has a program. Also, the Department of Defense also has a program on that and we are collaborating with them.

The CHAIRMAN. I want to come back to that but, as I said in my opening statement, whenever we have the good fortune to be joined by the majority leader, since we are fortunate enough to have him on the committee, it is going to be the new established tradition of this committee to recognize the majority leader when he does arrive and give him the opportunity to make any statements or ask any questions.

OPENING STATEMENT OF SENATOR FRIST

Senator FRIST. Thank you, Mr. Chairman and I thank both of you for being with us today for an issue that is close to my heart and one that I have had the opportunity of working with both of you over the last several years.

I want to welcome both of you formally to the committee and thank the chairman for holding this very important meeting. Let me just make three quick points and then I ask some questions.

First of all, I think that it is absolutely critical that we support President Bush's plan to vaccinate healthcare workers, public health officials, and first responders. The range of reasons is clear. From 10 to as many as 14 countries have developed offensive biological weapons programs; Therefore, it is imperative that we have individuals who are going to be first called if something happens right now vaccinated. Who are the American people going to turn to if a child comes home with smallpox? It is going to be those first responders and public health officials.

It is also incumbent upon us to give the American people an opportunity to make an informed decision about being vaccinated with a licensed vaccine. This policy introduces the challenges that have been addressed and will continue to be addressed.

I say this because 3 or 4 years ago we would have been talking about this as a pure public health initiative. Now, this preparation is apart of national security.

The second point that we must address through legislation is liability concerns. Two months ago, the president acknowledged this concern. We have to address the fears that one may not be compensated if injured from the smallpox vaccination—a barrier to immunization. I think the smallpox compensations concerns must be addressed by the U.S. Senate, and the House and the entire Congress.

My third point is that this process is part of a long-term strategy. This process began with the public health initiatives that have gone on for many years. It has been accentuated by the bioterrorist threats that we in this building and in Washington, DC have seen in a very real way. We must increase our knowledge of the use of biological weapons and microorganisms as weapons of mass destruction.

In that long-term strategy, we have to look once again at the liability issues and compensation measures for the future countermeasures. It comes down to improved communications, improved surveillance, improved infrastructure, and in improved capacity-building.

I wanted to make those three points and then I will fall back in line for questions here shortly, but once again I want to thank both of you for being with us.

The CHAIRMAN. Well, I did State that the tradition was going to be that you could also ask questions.

Senator FRIST. No, that is fine.

The CHAIRMAN. OK, then we will go to Senator Reed.

Senator REED. Thank you very much, Mr. Chairman. Thank you for holding the hearing. Thank you, Dr. Gerberding and Dr. Fauci.

Three critical issues and the leader illustrated many of them—safety, cost and compensation. And Dr. Fauci, you talked a great deal about the safety but let me for a moment talk about cost.

The State health departments now are challenged to engage this program. They also have on-going responsibilities for the vaccination, immunization in my children. In my State about $250,000 they are committed to in a tough budget time.

I wonder if there is any thought, Dr. Gerberding or Dr. Fauci, to help out the States with this program directly with aid and assistance.

Dr. GERBERDING. Thank you. When we distributed the $918 million to the State and local health governments in June we had specific capacities that they were expected to accomplish with that allocation. Some of those capacities included developing an infrastructure that would allow delivery of products in national pharmaceutical stockpile, such as vaccine, but we did not include a specific smallpox vaccine program in those expectations.

Since that time obviously we recognize we need to have this program get implemented as safely and as expeditiously as we can. The States are doing this, in part, with the infrastructure support that we have given them. We will be making another allocation of $918 million in August, assuming the budget evolves as predicted. And we have some infrastructure capacity because of the immunization programs that you have already mentioned. And, of course, the vaccine itself is free.

But there are gaps in what the States have now and what is needed to actually implement this program. We do not know exactly what those gaps are. We have never done this before and it is very difficult to predict a priori what is actually needed.

There have been all kinds of analyses done to look at this, some of them from an economic framework where you are factoring all the direct and indirect costs like gasoline to get to the clinic, and so on and so forth. But another way of looking at it is the way I think most people doing budget look at it, and that is what is actually needed to fill the gap between what you have and what you are going to have to spend to make the program work.

When we looked at our own economic assessment and then tried to identify the gaps in what we are giving people and what they need to do the program, we estimated that per person on average across the country, the gap would be somewhere between $10 and $15 and we picked $13 for planning purposes but we recognize as we go forward we are going to have to be looking at that very carefully and that is not going to be the same in all jurisdictions. In part there is an economy of scale, so as you immunize more and more people, the cost per person you vaccinate will become less and less. In some places where the immunization programs are spread out, the gap may be greater.

And, as I said, the bottom line is we recognize there is a gap. We do not know how it is. Right now we are focussing on looking for how we can provide somewhere around $13 per person who is immunized.

Senator REED. Given that gap, are you also going to look closely at the maintenance of effort on other vaccine programs, immunization programs, so that we do not have the situation where the States are literally robbing Peter to pay Paul?

Dr. GERBERDING. Absolutely. We are very concerned about the overall situation of public health at the State and local level. This is, as Senator Frist mentioned, a system that has suffered from long-term neglect and the investments that we are making right now are helping but we are dealing with a very fragile public health system and we are concerned that all of the efforts that we are putting into terrorism preparedness right now must serve a duel function. We must make sure that these investments also support on-going public health issues, such as vaccination of children or long-term imperatives that are part of our overall mission.

Senator REED. Let me ask a question with regard to compensation. Is CDC or anyone looking at the relationship between workers compensation programs in the various States and someone contracting, a healthcare worker, for example, contracting a side effect based on the vaccination? And also the private insurance coverage for a situation like this, is that being thought through carefully?

Dr. GERBERDING. We believe that we must make sure that the people who participate in this program have appropriate and fair compensation if they are injured as a result of it and we will do whatever we can to make this program successful in that light.

We have been working with the Association of State and Territorial Health Officers to assess what is the current status of compensation programs and it varies very much from State to State. It also varies from facility to facility or employer to employer.

Many people do have good coverage. Some people do not. And many people are concerned that they could fall through the cracks of compensation.

So we are very concerned about this and we are obviously trying to learn as much as we can about what gaps exist in this program so that we can identify options for filling them.

Senator REED. Mr. Chairman, I have one additional question, if I may?

The CHAIRMAN. Go ahead.

Senator REED. My understanding is that the reporting of adverse events is a relatively passive system. It requires someone to take the initiative to report it. With respect to the safety considerations, are you looking at a more active monitoring of immunizations and adverse reactions, something more than you have at the moment? And maybe Dr. Fauci, you can comment on that. I would assume you want to validate those statistics of two deaths in a million, etc.

Dr. GERBERDING. We have several ways of monitoring side effects in this program and trying to do this as safely as possible really is our overriding priority. We have a mechanism; as people come into the vaccine clinics they are enrolled in a confidential secure system that operates into a database through the Internet. So we will know on a regular basis, basically a daily basis, who is participating in the vaccine program.

Once you are in the program, it is necessary to come back to have your vaccine site checked to make sure that it was effective and that you did develop the pustule there that indicates you are protected. So when people come back for that seven-day time point, it is the perfect opportunity to actively determine whether or not they have experienced any side effect or any complication. This is particularly important for the more common and less serious side effects.

In addition to that, some States are doing a more proactive survey of individuals and we have a mechanism in hospitals for healthcare workers that is being developed at CDC right now so that when the infection control nurse or the infection control staff check the arms of the healthcare workers who have been vaccinated on a daily basis, they can put that information into a data system that monitors that yes, the vaccine site is fine, there is no spread, there is no threat to patients, and the dressing is appropriate, and so forth.

Finally, for the serious complications, the life-threatening complications that Dr. Fauci mentioned, we have the control over the release of the VIG, the antidote. So in order for people to receive the antidote, CDC and our colleagues have to know about it, and that is a perfect trigger for us to go and investigate, evaluate, learn something, decide whether the complication truly is vaccine-related or not.

And all of this information is regularly presented to our Data Safety Monitoring Board, which meets for the first time tomorrow, and that is a group of experts who will be monitoring the safety of the program as we go forward to try to make sure that we are doing everything we need to be doing at CDC to protect our volunteers, as well as the patients that they may be taking care of.

Senator REED. Do you have a comment, Doctor?

Dr. FAUCI. Yes, just a small complementary comment, Senator. The information that we will be getting from the program that Dr. Gerberding just described will really be very important because the data that I showed on my slides is over three decades old. It comes from the 1968 cohort. And although things are similar, they are not really exactly the same. The data I showed you were in primary vaccinees. At least half of the people who will be coming into the program for the smallpox response teams and the emergency first responders, at least half of those will have already been vaccinated. So the incidence of toxicities in those individuals will be considerably lesser.

On the other hand, as people say appropriately, in the year 2002 there are more people that would have immunosuppressive or contraindicating conditions. Even though we will be aggressively when someone comes in to volunteer, asking them do you have a transplant, are you on glucocorticoids, do you have eczema or atopic dermatitis, we do not know when those factors balance where the 2002 numbers are going to fall in. So that is the reason why what Dr. Gerberding is saying is critical and important.

I might also add from a historical standpoint the fact that the CDC controls the Vaccinia Immune Globulin, as Dr. Gerberding mentioned, is a good indication of how many people will actually need it. If you go back 20 some odd years, the CDC controlled the administration of Pentamidine for pneumocystis carinii pneumonia and it was that monitoring of how many people were asking for Pentamidine that was one of the big kick-offs and the red flags that we were dealing with the very incipient phase of the HIV epidemic.

Senator REED. Thank you, Doctor.

Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Frist?

Senator FRIST. Thank you, Mr. Chairman.

Dr. Fauci, Congress provided liability protection to the smallpox vaccine manufacturers and administrators in the Homeland Security Act. When we drafted that legislation, we did it specifically for the smallpox vaccine. Your list of bioterrorists agents includes tularemia, smallpox, anthrax, Ebola, the other hemorrhagic viral fevers, plague. Recognizing that each of those agents have had bioweapons programs designed around them—which most people do not realize—leads me to think that something further than just smallpox vaccine should have this liability coverage. Otherwise, every time an agent is used, whether it is anthrax here on Capitol Hill and New York and Florida or tularemia, or plaque or Ebola, we are going to have come back and legislate each and every time. That is not very appealing to me as a legislator. We need to address the piecemeal liability issue, and I would like for you to comment on that.

The second issue from my opening statement that I want you to explore a little bit further is the overall infrastructure of our vaccine manufacturing base. The very present risk of increased liability exposure when there is such a low rate of return to those same manufacturers. Government is not in the business of manufacturing a broad range of vaccines, nor should we be, nor are we capable of really doing that. At the same time, when you have huge liability risk and the potential of being literally put out of business, pru-

dent companies, even if it is in the national interest, are not going to be focussing their business on this critical issues.

Since the 1970s when I started medical school, we have seen a constant decline in the number of vaccine manufacturers from say, 12 or 14. I would argue that such a decline in the manufacturing base is due to liability concerns. We now have four manufacturers in the world making vaccines and only two that are actually American companies today that make the licensed vaccines.

At the same time, every year, I or Senator Gregg or one of us must go to the floor and comment on the fact that we have childhood vaccine shortages. But if we have shortages with childhood vaccines which are being used, it is clearly going to be difficult for companies to develop vaccines for the increasing threat or risk that we have with these agents that we have not really thought very much about, including botulism toxin. As we sit here, we know that Saddam Hussein has over 6,000 liters of botulism toxin, the most powerful poison in the world.

We do not have the vaccine infrastructure to develop new bioterrorism vaccines today, no matter how good the science is at the NIH. We have an obligation to lower the barriers that prevent the development of a vaccine infrastructure. I would argue much of the infrastructure is disappearing due to a lack of a market or a guaranteed market, coupled with this huge liability. This is where public health again becomes part of the national security problem.

Could you comment on how you see that playing out? The problem is crystal clear to me and it is crystal clear to you, but how you see this vaccine infrastructure, national security risk and liability playing out?

Dr. FAUCI. You said it very well, Senator, and we really appreciate the leadership that you and your colleagues have shown with the Homeland Security taking care of the liability. But as you so appropriately pointed out, that is one microbe and we are talking about the big picture of vaccines.

Just very briefly, the infrastructure and the lack of incentive for companies to either stay in the vaccine field or what we hope, to come into the vaccine field because we have so many new challenges with biodefense, is exactly what you said. The infrastructure has diminished at the same time as they have gotten out of the field and there is a concern about liability.

Addressing the infrastructure component, that was one of the issues that we described to you a couple of days ago vis a vis the BioShield and getting an incentive so that at the end of the day they would know that when they are getting ready to go to their board of trustees or their stockholders and say we have a good idea, we have some funding from the NIH, we have some collaborations with the CDC, but we want to go forward, but we do not have any guarantee that anybody is going to use this. That is one of the three-pronged components that the president announced the other night about Project BioShield.

We would say we would have a guaranteed assurance that if you do get involved and build that infrastructure, that there will be a purchase of that material even if we do not ever use it and we stockpile it. That addresses building up the infrastructure and the confidence of industry that if they work with the Federal Govern-

ment there will be something there not only that they will not lose money on it but they could get a modest profit out of that.

Senator FRIST. Did you comment on Bioshield in your opening statement?

Dr. FAUCI. I just alluded to it briefly.

Senator FRIST. I don't know if Bioshield was mentioned or a sentence in the State of the Union or not, but for me, this initiative really caught my attention. And the size of it was how much? $6 billion. And that is——

Dr. FAUCI. It is less the size of the amount than it is what is described as—and you know very well but sometimes the general public does not quite understand what it is—it is a permanent and indefinite appropriation authority where the authority exists that when the secretary of HHS and the secretary of DHS come to the realization that we really do need a product, the president can then have a finding to say we really need to do that. So we could draw out of this mandated authority to be able to actually put however much money one needs to do that purchase.

Now clearly the liability issue is a complex issue. It was addressed specifically for smallpox. For some but not all of the products and the biodefense countermeasures that we are talking about, since the Federal Government will essentially be the sole purchaser of several but not all of those, that could fall and would fall under the Federal Tort Claims Act that would cover that component of the liability.

But I agree with you there are gaps there that we need to address and we would be very happy to work together with you in addressing them.

Senator FRIST. Thank you, Mr. Chairman.

The CHAIRMAN. This is a huge issue and we do have to get on it quickly because we are simply not going to get the vaccine industry back up unless we do something in the areas liability and compensation.

Senator Mikulski?

Senator MIKULSKI. Thank you, Senator Gregg.

Senator Frist, I am just so glad that you have found the time to be able to—usually majority leaders are not. So good to have you here.

To Dr. Gerberding and Dr. Fauci, welcome. Doctor, I do not know you as well as I know Dr. Fauci but look forward to getting better acquainted.

Right now I think there is great fear about smallpox. I think there is fear about an attack on the United States and being exposed to smallpox but I also think there is now a lot of fear around the vaccine to prevent one getting smallpox and the fear centers on either dying or having some type of grim chronic condition—paralysis, blindness, things that as physicians, you could even share with us.

I want to pick up then on the liability because part of my overall questions will be how do we contain the fear, even if there is an attack?

Regarding the liability issue, if a nurse or an emergency medical person, first responder, gets the vaccine and they get sick where the consequences particularly are chronic, number one, who pays

for their medical care? And number two, who would, say with blindness, then pay for on-going compensation? Would the Federal Government pay for that? Who pays for that, for their medical care and, of course, their own lost income?

Dr. GERBERDING. Right now the existing mechanism is that we are relying on the workers compensation programs that exist through the State or the employer and whatever private insurance the individual has. Some of these programs are comprehensive; some are not.

Senator MIKULSKI. Well, how can we move to uniformity? Because if we go to your private health insurance, many have the exclusion related to an attack of war and smallpox, we are not talking about an accidental exposure. This is war where we would be exposed to smallpox. So therefore we would be in litigation over will the insurance company pay? So that seems flawed.

Workman's compensation is uneven around our country because there are 50 different State programs. Have you looked at all 50 and would all 50 cover this particular situation?

Dr. GERBERDING. Right now I have information from 34 States. We do not have the information back from all 50. Part of it is a State issue but in addition, there are differences in how employers within each State provide coverage. Some are self-insured and some are not.

Senator MIKULSKI. Doctor, would it make your job easier, because I have noticed a very tepid response to even the voluntary request. In Connecticut only four doctors showed up and these are very informed people, far more informed than dealing with the general public.

Do you feel that a national program, tightly written, targeted—we are not talking big loopholes or big lawyer fees or whatever—do you think that that would get more compliance and more rapid compliance?

Dr. GERBERDING. Senator, I believe that we need to do whatever it takes to remove the barriers to this program. We must have the preparedness capacity that we need to protect people. I am not sure I understand what all the barriers are and you have mentioned compensation as being one; I think fear is another.

Senator MIKULSKI. Doctor, we need to understand the barriers and we need to understand them quickly. In other words, if you have a tepid response, and I think you would agree it has been tepid in terms of who is willing to get the vaccines now. You do not have thousands of people saying I want it because I am ready to serve America, but I am going to be protected myself. We are talking about very dedicated people—nurses, doctors, emergency people. Hasn't the response been tepid?

Dr. GERBERDING. Actually I was able to say earlier in my testimony that so far, the States have requested—we have delivered 127,000 doses at the States' request, so the States are expecting to immunize that number of people. What the rate of immunization will be remains to be seen.

What we know is happening right now is that just the vaccinators are getting vaccinated so that they will be prepared to immunize everyone else. I do not think we are going to know for

sure how many people are stepping up to the plate and when until the program progresses.

Senator MIKULSKI. That is up till today. You have only heard from 34 States if their workman's compensation would cover what we would call medical personnel and of those 34 States, would they cover both medical treatment and income compensation?

Dr. GERBERDING. Of the 34 States that I have information on, one State has said it would not.

Senator MIKULSKI. So 33 said it would?

Dr. GERBERDING. That there would be at least partial coverage, and most are checking to get a comprehensive decision from their attorney general.

Senator MIKULSKI. You know, if there is blindness or paralysis, partial coverage does not cover it.

Dr. GERBERDING. I understand.

Senator MIKULSKI. So what would we do about the other part?

Dr. GERBERDING. This is the concern that I share with you. There are gaps and we have to find ways to address those gaps.

Senator MIKULSKI. Well, I know that my time is just. Just a follow-on.

If a patient gets sick because of they were exposed to a nurse or a doctor who has taken the vaccine but inadvertently causes one of their patients or someone being carried in an ambulance to get smallpox, what is the compensation for the patient?

Dr. GERBERDING. Right now the compensation program is not available for contacts of people who have been vaccinated and are exposed.

Senator MIKULSKI. So we have a big job ahead of us. Thank you.

The CHAIRMAN. Senator Jeffords?

Senator JEFFORDS. Dr. Gerberding, what were the elements in choosing which States and counties would receive these initial doses of vaccine?

Dr. GERBERDING. What happened was CDC issued guidance for States to develop their plans and as the plans were submitted this past January, they were reviewed according to the completeness of the various elements. As they were approved, then States were given permission to request the doses of vaccine that they needed to initiate their program.

As of today all States have approved plans. In one State, and I forget which one it is, there is some minor contingency that has to be cleared up before we could release vaccine. But the vaccine will be made available to every State when they request it.

Senator JEFFORDS. I know that Vermont was selected. What did that mean?

Dr. GERBERDING. It means that the State of Vermont contacted CDC and said please ship us vaccine; we are ready to go.

Senator JEFFORDS. Again what is the plan for evaluating the implementation of the smallpox program in the initial stage?

Dr. GERBERDING. I am sorry; I missed your question.

Senator JEFFORDS. For evaluation of implementation of the smallpox program, what is the plan?

Dr. GERBERDING. The plan is quite comprehensive. In addition to monitoring the safety and the mechanisms that I described earlier, which include following people who have chosen to be vaccinated

and using another system for identifying people with severe effects, several States are working on a program to contact the people who could have been vaccinated but chose not to be, to understand why they chose not to be included in the program and are we aware of all the barriers to participation?

Senator JEFFORDS. Dr. Fauci, yesterday you mentioned that we need to be prepared against genetic manipulation of some of these bacteria and viruses that could be used in a terrorist attack. I am concerned that there could be potentially unlimited variations of these bacteria or viruses. Could you elaborate on these issues and how we can be prepared?

Dr. FAUCI. Yes, Senator. That is an excellent question that we continually struggle with.

The kinds of genetic manipulations fall into two broad categories. One is much easier to do than the other. The easy one for anyone to do would be to genetically mutate the microbe so that it resists or avoids the currently used antibiotics against it. The approach to that would be, and that is part of our strategic plan, is to have at least two and generally three alternatives antibiotics or antivirals that act at different parts of the replication or metabolic cycle of a microbe so that if it is changed in one way, you will have an alternative antimicrobial against it. We have a broad plan to do that.

The anchor of that plan is to essentially sequence, the same way we have sequenced the human genome, to get the full sequences of virtually every microbe that could be a potential bioterror, the microbes on our various Category A, B, and C agents. That is one approach.

The other approach is a little bit more—in fact, a lot more difficult for anybody to do, is to manipulate the microbe so that it avoids or counteracts the effect of a vaccine. So if, for example, someone were to take a smallpox and genetically manipulate it so that if it gets into you it would mute or dampen your body's ability to respond appropriately even if you were not vaccinated, that falls under the category of enhancers of the immune system so that when you develop a vaccine, you develop a vaccine that so induces a specific response against the microbe that it would overcome even the genetic manipulation to try and weaken the body's immune system.

So those are the two strategies. As you say, there are infinite possibilities of being able to mutate. However, only a few of those would have an impact of being able to still maintain the capability of the microbe to infect and hurt you because some mutations actually put the microbe out of business.

Senator JEFFORDS. During the recent mad cow disease scare in Europe there was a great deal of concern about prions and what role they played in the disease. These are not bacteria or viruses, I believe.

Dr. FAUCI. No, they are not.

Senator JEFFORDS. Can you tell us more about these? And do we need to be concerned about them in our fight against bioterrorism?

Dr. FAUCI. We have a lesser concern about the prions, which are a protein that actually can self-replicate itself. That is, as you alluded to correctly, a protein that is responsible for animal diseases and there is a version of it in humans, ovarian Jakob Creutzfeldt

disease it is called, a big word that does not mean much except that that is the name of the disease.

We are doing research on prion disease at the NIH. We are doing it in other parts of the Federal research enterprise. It is fundamentally not under the auspices of what we would consider a high probability bioterror event. Just by the very nature of what it is, I mean if somebody wants to in a bioterror way attack our agricultural system with animals in the sense of inserting into our animal stock something that would cause economic difficulty, as opposed to hurting people, but nonetheless this is something that we do have research on, but it is not in the big, broad umbrella of a high priority biodefense.

Senator JEFFORDS. Thank you.

Dr. FAUCI. You are welcome.

The CHAIRMAN. Senator Clinton?

Senator CLINTON. Thank you, Mr. Chairman, and thank you for calling this important hearing. I think there are obviously going to be a lot of unanswered and maybe at this point in time unanswerable questions in the face of these new challenges.

I greatly appreciate the work that both CDC and NIH are doing to develop an adequate supply of medications for those who might have side effects, who suffer injuries, lost work time, and other consequences as a result of the vaccinations. And I do believe we need some kind of system to ensure that they are taken care of and compensated.

I cannot help but add that of course if we had a universal healthcare system this would not be as big a concern, but we are going to continue to patch away at the old broken system and it is just going to get creakier and creakier and squeakier and squeakier and leakier and leakier and I think that the threat of terrorism, combined with advances in the knowledge of the human genome which are going to tell us that we are all vulnerable and susceptible to something, should prove to be a spur to our dealing with this issue on a much broader level. But in the meantime I hope that we will take seriously the challenges of providing adequate compensation.

I have had a different but related experience with respect to the World Trade Center health effects on the workers and volunteers most directly involved. We did, with bipartisan support, set up a program at Mount Sinai to begin to screen those people and we had our first report of the outcomes of those screenings and we have very high percentages, in some cases 50 percent to 80 percent, of decreased pulmonary and respiratory capacity, adult-onset asthma, and many other issues. And some of the people who were construction workers, utility workers, etc. do not have adequate insurance and do not have the capacity to either be screened or taken care of. So I just think this has to be put into a broader context.

And from my perspective there is another related issue which we have heard about in the news, which is that if we underfund this massive vaccination effort, then State and local public health departments will be picking up the costs and some are already saying that they cannot continue their other work, the routine immunizations and other kinds of public health work, as well.

So I am very much looking forward to working with the chairman and Majority Leader Frist, along with Senators Kennedy, Mikulski, Durbin and myself and our colleagues in the House to try to come up with a package of legislation that does address these very legitimate issues.

If I may, Dr. Fauci, I know that there is not anyone who knows more and has worked harder on the HIV/AIDS challenge and it is clear that we now have not just with HIV/AIDS but with other conditions, including eczema in our population, a lot of immunosuppressed people, people who are more vulnerable to the side effects, and this is a concern that we all have because of not only those directly vaccinated but the potential contagion effect.

What will the impact of these immunodeficiencies have on the number of injuries, deaths and side effects, as best as you are able to extrapolate?

Dr. FAUCI. Thank you for that question, Senator Clinton. It depends on the immunodeficiency. For example, if someone has a transplantation, they have a kidney or a lung or a pancreas or what have you, it is very clear and easy that they know they have it, so they would be immediately excluded from any pre-event vaccination program. Obviously if there is a massive attack, we would be vaccinating them if they came into contact with a person, but we make sure we have a lot of Vaccinia Immune Globulin around.

We would have to do, and that is part of the program, serious questioning to go through the list—eczema, atopic dermatitis. Are you on glucocorticoids? Are you taking steroids for anything? Do you have an immune-suppressed disease that is being treated, like lupus or rheumatoid arthritis? Do you have cancer chemotherapy? All of those kinds of things.

There are other things that obviously are of concern, is HIV. We need to question people, is there any possibility that you may be at risk for HIV, and if you are, to clearly go and get an HIV test. HIV is one of the immunosuppressive diseases that we have and if someone is far advanced in HIV, then just inadvertently, without knowing it, if they get vaccinated they could be in trouble.

So that is the reason why it is very clear in a vaccination program, which is why a pre-event program where you have the time to go through those multiple menus of contraindications would be very helpful in averting vast majority of inadvertent vaccinations for someone who would have a contraindication. So we share your concern.

Senator CLINTON. Thank you.

Dr. Gerberding, I recognize that there are studies of smallpox vaccine safety in children currently in progress in Cincinnati and Los Angeles; is that right?

Dr. GERBERDING. I would have to defer to Dr. Fauci on that.

Senator CLINTON. Is that right, Dr. Fauci?

Dr. FAUCI. The studies are not going on, Senator. As part of the vaccine program for the dilutional study of the Dryvax, which is now the product that is being used in its undiluted form in the program that Dr. Gerberding described, in the dilutional study, if we were going to widely use diluted Dryvax, you have three general components of people. Those who have been previously vaccinated, that study is done. Those who have never been vaccinated before,

that study was done. The third component was in children but when the clinical trial to determine if it actually was still immunogenic in children, was there any specific unexpected toxicities in children, even though you would not predict it because that is exactly the vaccine that you and I got when we were children, but nonetheless we needed to do the clinical trial.

When the clinical trial went before the IRB the Cincinnati group felt that it was a reasonable approach; let us do it. The UCLA group said you know, we cannot determine on the basis of the codes that guide you as to whether or not you can do research in children whether the risk/benefit ratio for a child, given the current threat, we just cannot make that determination as to whether or not we should go ahead with the trial.

So what they did is that they sent it back to the secretary and there is a code of regulation that says they need to do that. The secretary then took the problem, sent it before the Office of Human Research Protection. They had a public comment period. Many of the comments came in with concern that for children, particularly infants, since they have a greater incidence of serious effects, that they felt that it should not go on.

In the meantime it became clear that we were not going to be using Dryvax on children anyway because the program would be excluding children because it would be for health workers, first responders, etc. For that reason the clinical trial in children with Dryvax has now been called off and we are not going to do a clinical trial in children for this particular product.

Senator CLINTON. Thank you.

The CHAIRMAN. Thank you, Senator.

I would like to keep this going but I know you folks have to get back and actually take care of America, so we are going to let you go, but this issue of what we do with children is critical. The compensation issue, also absolutely critical. And Senator Frist, as our majority leader and doctor, has put forth some really excellent ideas in the area of vaccines generally and how we are going to try to get our whole vaccine industry backup, which would include provisions on compensation and liability.

So we will pursue those at a later date with you, but we are definitely going to be moving on that. I quite honestly hope we move on Senator Frist's ideas fairly quickly. So we thank you very much for your time. We appreciate it and keep up the good work.

If we can get the next panel to step forward?

Our next panel, and we appreciate their participation, represents a variety of folks who are on the front lines of this issue, coming from various walks of life and who have substantive interest in and concerns about how we proceed with the smallpox vaccination process.

I would ask that you submit your formal statements and if you could keep your general comments concise and to the point so that we could get right into the questions, that would be very helpful.

Let me begin. We will go from right to left from my side because on the right is a gentleman from New Hampshire who I have known for many years. He is a good friend, a neighbor, and somebody who is a specialist of the first order in managing hospitals. So let us begin with you, Bill.

STATEMENTS OF WILLIAM J. SCHULER, CEO, PORTSMOUTH REGIONAL HOSPITAL ON BEHALF OF THE FEDERATION OF AMERICAN HOSPITALS, PORTSMOUTH, NH; WILLIAM J. BICKNELL, M.D., M.P.H., BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH, BOSTON, MA; JON ABRAMSON, M.D. ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS, WASHINGTON, DC; MARTHA BAKER, R.N., CO-CHAIR, SERVICE EMPLOYEES INTERNATIONAL UNION (SEIU) NURSING ALLIANCE, WASHINGTON, DC; AND KIM BUSH, PRESIDENT, VACCINES DIVISION, BAXTER HEALTHCARE CORPORATION, WASHINGTON, DC

Mr. SCHULER. Good morning. I am William Schuler, president and CEO of Portsmouth Regional Hospital, of HCA, Hospital Corporation of America, and our trade association. I would like to thank Chairman Gregg, Ranking Member Kennedy and others on the Senate Health and Education, Labor and Pensions Committee for providing me this opportunity to discuss the smallpox vaccination plan from the perspective of a community hospital.

Portsmouth Hospital, our trade association, the Federal of American Hospitals, fully support the administration's decision to provide voluntary smallpox vaccinations to healthcare workers. We particularly applaud the chairman, ranking member and other members of the committee for their continued advocacy of the voluntary vaccinations. There seems to be widespread recognition that the proper implementation safeguards will produce an environment where our Nation's hospitals can provide the safest care and work setting for our patients, our employees, and our families. By vaccinating these core caregivers, we enable them to step forward with the assurance of their own immunity to provide this vital care.

Portsmouth's role in the vaccinations. While we applaud the direction in which we are heading, hospitals are concerned that much of the responsibilities for implementing the vaccination plan appear to be filtering to the hospital level. In my testimony I will highlight the critical issues facing a community hospital, how we are handling them, and where we feel guidance and assistance is needed.

First, it may be helpful to describe the stages of the pre-event vaccination initiative from a hospital perspective. I will refer to three stages. Stage one is the vaccination of the smallpox response teams and front-line healthcare workers. This stage is currently under way. In stage two, vaccinations will be offered to all healthcare workers, EMS, first responders, fire-fighters and police. Stage three, the vaccinations will be offered to the general public.

At Portsmouth we arrived at a core group of 40 providers for stage one. We began our efforts to recruit volunteers in November, with the physicians first being invited to a classroom-style presentation by the chief of staff, infectious disease physicians, myself and others. Approximately 25 physicians volunteered immediately. A similar presentation was offered the following week to hospital nursing and ancillary staff; an additional 30 clinicians were added to the volunteer roster.

Ultimately the 40 volunteers were chosen because they had been previously vaccinated against smallpox, screened for contraindications, and provided with additional educational resources. In March

we anticipate these volunteers will visit area clinics at staggered intervals to receive the vaccination.

Now allow me to touch on some of the concerns with the implementation plan. As the vaccination process proceeds to stages two and three, Portsmouth faces increasing medical and staffing challenges. According to a study by the CDC, 36 percent of adults receiving vaccine for the first time will likely be sufficiently ill to miss work, school, or recreational activities or have trouble sleeping. Nationwide, this amount of absenteeism, superimposed on winter illness and critical nursing-wide shortages, will surely exacerbate an already tenuous staffing shortage.

To ensure the support of normal hospital operations, we must follow staggered vaccination schedules. We anticipate up to 10 employees may require time off. We should be able to cover this level of absenteeism without impacting patient care. In future stages, however, additional staff members are vaccinated and these staffing issues become of major significance.

According to CDC guidelines, hospital responsibilities include not only education, screening for contraindications, identification of volunteers but also daily vaccination site assessment and the evolution of takes. This means that the hospitals must provide daily staffing for a 21-day vaccinee site assessment clinic. In stage one we should be able to absorb the financial staffing burden. However, it might be a burden not so easily managed in the future.

Furthermore, in stage two the logistics for staffing education, site care, assessment and recordkeeping will certainly require Federal and State support. They are not activities that a local community hospital can easily absorb. Consideration for extra funding to the State public health departments would enable them to play a much greater role than we have seen to date and will ease the vaccination-related staffing issues expected to be shouldered by the hospitals.

Community healthcare systems will be severely stressed in stage three. Using the published rates of vaccine-related complications, the 50,000 vaccinees in our service area could lead to 5,000 office visits and up to 500 hospital admissions, an untenable demand for a medical community with a 200-bed hospital like ours. We will need a system where specialists would help with the evaluation of the more severe vaccine reactions, discussing and coordinating home care for all but the most ill. This system has been discussed at the State level and is yet to be developed. Mass vaccinations will create a volume of ill patients that in most communities will be unprecedented and profoundly difficult to manage.

With regard to communication and planning, I will tell you that the communication between the State OEM and the local emergency personnel has been suboptimal. In the early stages local emergency personnel, fire and police were not adequately informed of the CDC vaccination plans or the responsibilities for such a plan. Initially, hospital and community representatives' responsibilities were to be quite limited. As the planning stage unfolded, responsibilities originally assigned to the OEM were given to both hospitals and the community.

We have communicate this issue to State leaders and have learned that New Hampshire OEM, like many other States, has

not received additional funding from FEMA. At a time when State and municipal budgets are also stressed, there is an understandable reluctance to take on additional responsibilities without funding. In short, the State's OEM is relying too heavily on staffing resources at the local hospital level for planning and implementation. In order to strengthen the overall postevent, the State OEM requires additional funding, staffing and other resources.

We appreciate the recent classification of section 304 of the Homeland Security Act that appears to resolve many of the liability concerns. However, further clarification on liability may be needed in the scope of employment issues.

Specifically it is not clear if the current guideline provides protection for vaccinated person who inadvertently and outside of the scope of one's employment spread the infection caused by a smallpox vaccine outside the participating hospital. We look forward to working with Congress and the administration to achieve full protection intended under section 304.

It is vitally important that the healthcare workers are protected from personal expense and loss of wages as a result of adverse reactions to voluntary vaccination and we hope that this will occur.

Finally, in a time of national emergency requiring implementation of mass immunizations, healthcare resources will be severely strained. It is in these limited circumstances that certain aspects of the healthcare laws and regulations may not be in the best interest of patients and healthcare workers in our hospital. I have laid out an example in my testimony in response to anthrax exposures occurring in Florida, New York, Washington, DC. and other States.

As you know, EMTALA requires hospitals to provide medical screening to all patients requesting medical treatment. In the event of mass vaccination potential smallpox exposures, hospital emergency departments could be overwhelmed by the worried well. Any hospital following the recommendations of the State health department, as outlined in our testimony would have to be subject to potential liability under EMTALA.

In addition, when hospitals are coping with mass vaccination clinics and potential complications generated, the completion of the usual hospital forms, such as notices of HIPAA privacy rights and advanced beneficiary notices, may not be possible or practical. We hope that the committee will consider how to mitigate the consequences of these regulatory dilemmas in a time of national crisis.

In closing, I would like to commend the committee for its commitment to the safety and well-being of the first responders and their families. Portsmouth Regional Hospital and the federation look forward to working with the committee to implement the administration's voluntary smallpox vaccination plan. Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Mr. Schuler may be found in additional material.]

The CHAIRMAN. Dr. Bicknell?

Dr. BICKNELL. It is an honor and pleasure to be here this morning, Mr. Chairman and members of the committee. I am going to touch on certain high points of my written testimony.

I am a physician with a public health degree. I was commissioner of public health in Massachusetts at one time. I sit currently on the

Massachusetts Statewide Smallpox Work Group. Most recently I have been a proponent of careful selective, progressive and ultimately widespread pre-exposure vaccinations as the best way to protect the Nation against the threat of a bioterrorist attack using smallpox as a weapon. And even though Dr. Gerberding and Dr. Fauci are not here, I think they and the Nation have made tremendous strides in the last year in this area.

National security, economics, and economic disruption, medicine, public health, and labor-management issues often get confused as we discuss smallpox. This is complicated by serious misunderstanding of the facts, confusion of fact and opinion, and finally, there is honest disagreement about what is right and what is not right. And, of course, as we have heard earlier, this is all in the context of all the other bioterrorist threats.

I want to touch on six points and then if there is time, elaborate later. The president's three-phase plan is extremely sound. Implementation today, I feel, is seriously flawed. Finishing phase two is an urgent national priority, particularly given the course of world events. Until phase two is done, we are not protected. And I would say that although there is wide recognition in this room about national security issues, in the public health and medical community the concern that Senator Frist expressed just has not hit home. That message has to get out that this is a national security issue; it is not just a medical or public health issue.

We have all the gadgetry, tools and manpower to do this. What we do not have is the organizational structures. They are not yet in place.

There is dangerous misinformation about key aspects of smallpox transmission and control. This needs to be corrected. Let me give you a couple of examples. I would take exception to what Dr. Gerberding said that mostly you are sick and you go home. And I would distinguish between Dr. Gerberding, who I think we would all agree is not a terrorist, and if she got sick she would go home, but I could be a terrorist. I had to present to my university president, who is known as somewhat of a bear, and I had a fever of 103.5. I presented. If I am a motivated terrorist I will get up and walk around. And, in fact, as you become infectious it is not visible. You start to feel better. There is no obvious rash and you are highly infectious.

We have to plan for a worst-case event, not what happened in the smallpox years of eradication when we had high levels of population immunity, not very mobile populations, and nobody was a terrorist. They were just plain old people getting sick. This is a very different State of affairs.

Now let us talk about some of the risks of vaccination. I think there is misinterpretation and misinformation out there. I do not want to give the sense that smallpox vaccination is like a sugar cube but let us look at it with care. We are talking about adults, not kids at the moment. I understand your issue of kids and I will get to that in a moment.

If you look at the historical data, U.S. military since World War II, 1963 data, around 14 million people. 1968 data, 14 million people, Israeli military experience, Israeli civilian experience, U.S. civilian experience since the 1980s, I believe you will find that there

are two adult deaths. Both of these people were in 1968 and would have been screened out. One had aplastic anemia, one leukemia. In 1968 we had nine deaths; seven were in children, a 16-year-old girl, and a 62-year-old woman. We are not vaccinating children at the moment and we are planning to carefully screen. We would not have vaccinated the two people who did die.

What is happening with the U.S. military as of this moment? As of January 25, over 2,000 military hospital workers have been vaccinated, including staff at Walter Reed, which has a hematology oncology ward, transplant unit, a neonatal intensive care unit, all where you do not want accidental spread. It has not happened. Vaccinated workers continue caring for patients using the semi-permeable membrane dressing—I have some here—long sleeves and scrupulous hand-washing.

The semi-permeable membrane dressing makes an already rare event—114 cases of transmission to other people happened in 1968 after 14 million vaccinations. You do not do kids, drop that by 70 to 90 percent. You add this dressing; that reduces it by 90 to 95 percent. This is a controllable thing.

What has happened in the military? The success rate of vaccination has been for people who are first-time vaccinees, 97 percent successful, revaccinees 99 percent.

What about sick leave? Four percent of first-time vaccinees take a day or two off. One and a half percent of revaccinees take a day or two off. Complications have been minor and are occurring at the levels that have been historically expected.

Full data on the military are classified in terms of numbers—I do not know them; CDC and FDA do—but I have been told that those numbers are getting very large and the rates of complications, side effects and time off in the larger number of troops approximates that that is happening in the 2,000 health workers.

So I think we need to put the risk of adult vaccination in perspective. It would be absurd to promise but it would not be surprising to find out when phase two is done and we have done 10 million, we might have zero, one or two deaths, not the hundreds of deaths that we are thinking of. So I think we need to get that very much in perspective.

CDC needs a clear, concise, strategic statement that articulates the president's plan and establishes a rationale and framework for implementation. It is just not clear now to people out there. And then within that document there need to be simple, and I would emphasize simple, pre- and postexposure guidelines. They are not simple now. They are too complex and if we had to act now we would have chaos, confusion and casualties. We need to be prepared to move in a big hurry and this requires not just advanced planning but the elegance that comes from simplicity.

Finally, I think we may have made some fundamental mistakes in assessing what public health and the public health system is all about. I am working with Ken Bloem, who you may know. He has led major teaching hospitals in Chicago, Palo Alto and Washington and we feel the public health system is by its very nature and culture not an emergency response system and never has been. We may need a different structure, perhaps an integrated Federal-State incident command structure with emergency medical services

and the acute medical care system taking the lead role for mitigating the adverse events of a bioterrorism attack. And in this conceptualization, public health, particularly laboratories and epidemiologic intelligence, play a supportive but not a directive role.

The side effects of children I think need to be put in perspective. I have a two-and-a-half-year-old grandson and he is at the center of my life but I do not think we should vaccinate him yet. The reasoning goes like this. The bad complications and deaths and a lot of the less bad ones mostly are in kids under 10. The worst one, encephalitis, is really bad, hits kids under 10 in this country—our data is very clear on that—mostly under 10, almost exclusively. Most of the deaths almost exclusively under 10. There is no treatment for this. It is rare but about 25 to 30 percent die and another 10 or 15 percent have permanent brain damage.

Children are the ones who get accidentally infected with each other. It is rubbing up in a sandbox. We are not doing kids; that eliminates that.

Complications are common of the less severe kind—one in 9,000, one in 10,000. That means there is going to be a complication in virtually every city in town.

Post-attack you can isolate kids. If we have phase two completed and a mechanism in place that we can vaccinate in schools and churches and gymnasiums rapidly, we can protect children very rapidly and avoid the complications they will experience by preexposure attack.

The four-day window, we have heard a great deal about the four-day window. That is a myth. It does not exist. If you are vaccinated within 4 days you may get less severe illness; there is no evidence you can prevent it. And that is all over the place; that is just wrong.

The visible rash. Let me just read you something. Happened in 1913. "One person with smallpox arrived in the country and traveled by train. In the initial phase of the disease nobody noticed the rash on his face. Almost everyone who traveled with him from Queensborough to Manchester got smallpox—the ticket collector and those who went on to Stallybridge." Something like 100 people being infected from a single case, and this was not a terrorist. Suppose you were a terrorist; you could do a better job.

Most doctors, if they are properly trained, will be able to quickly identify a case. That is wrong. That can never, ever happen. Smallpox does not look like much until day three or four and it will be missed and then there will be overdiagnosis. This is another compelling argument for getting the president's plan done, at least through phase two and I would hope phase three, and I would like to extend it, move from it is okay if you are adult to it is urged if you are an adult.

Ring vaccination. There is tremendous evidence that ring vaccination, as proposed until very recently—it came off the website over the weekend, guideline B—ring vaccination many thoughtful people feel, as it has been proposed, will not work. What will work is vaccinating with a little kit the friends and neighbors of the first case, gear up for local mass vaccination, vaccinate in the area locally. If there is a second case in another geographic area move to

national mass vaccination. That will work and that will only work if we finish phase two and have 10 million done.

In conclusion, I would say this. We are potentially prepared but we are not there yet. And until the plan is done through phase two, we will not be there.

Finally, as with the interstate highway program and the space program, I think the BioShield initiative is going to have all kinds of other unintended positive benefits and I think these hearings are a great first step along the way and I would be pleased to answer questions. Thank you very much.

The CHAIRMAN. Thank you, Doctor.

[The prepared statement of Dr. Bicknell may be found in additional material.]

The CHAIRMAN. Dr. Abramson?

Dr. ABRAMSON. Good morning, Mr. Chairman and members of the committee. I am Jon Abramson. I am chair of the Department of Pediatrics at Wake Forest University School of Medicine. I am here today in my role as chair of the Committee on Infectious Disease for the American Academy of Pediatrics. I appreciate the opportunity to participate in the hearing on the smallpox vaccination program.

This committee has asked us to respond to three very important questions. We provided written testimony and our own policy from the American Academy of Pediatrics that you can read. Today I will focus my remarks on the questions concerning implementation of the president's smallpox vaccination plana and what needs to be done to ensure that the plan maximizes protection afforded to children. During the allotted time I will cover three main points.

The American Academy of Pediatrics' recommendations are based on the information provided to us by the government that the risk of smallpox, though not zero, is small. Should the risk assessment change, then our answers to these questions may change.

No. 2, voluntary vaccination of the general public is the least scientifically defensible policy, no matter what the level of risk a smallpox attack.

No. 3, the safety and effectiveness of the various smallpox vaccines, particularly the recently developing tissue culture-derived vaccine, needs to be studied in children.

The American Academy of Pediatrics believes that the general public, particularly children, should not be offered the smallpox vaccine at this time. This recommendation is based on weighing the relative high rate of serious adverse events, including death, caused by the smallpox vaccine versus the low risk of a smallpox attack. Infants and children are particularly vulnerable to the complications caused by the smallpox vaccine because of their high incidence of atopic dermatitis and of immune deficiencies that have not yet manifested or been diagnosed.

Currently the AAP favors a ring vaccination policy that includes a plan for rapid distribution of smallpox vaccine and development of strategies for urgent vaccination of large numbers of the population, rather than a voluntary or mass vaccination program. However, if the risk of attack was felt to be high or an attack occurred, then a recommendation to vaccinate everyone except those with high-risk contraindications would make sense.

Unfortunately, the concept of a pre-event voluntary vaccination for the public, while appealing on the surface, makes the least sense from a public health and scientific standpoint and in actuality is a misnomer. Under a voluntary vaccination scenario, children whose parents did not want them to get the vaccine would accidentally be inoculated by those who did receive the vaccine.

It is important to point out that before 1972 when smallpox vaccine was routinely given to everyone who did not have a known contraindication, approximately 25 percent of those who developed serious side effects were those unintentionally inoculated with the vaccine. While the use of semi-permeable dressings can reduce the risk of spread of the vaccine virus, these dressings are unlikely to be practical for large-scale vaccination because they are expensive, cause allergic reactions in some people, and compliance with their use will vary greatly. Thus, many unintentionally vaccinated children could end up with adverse consequences from the vaccine, some of which would be very serious, including death.

To answer the question about what needs to be done to ensure that children are eligible to receive the smallpox vaccine, I need to point out that recent studies have shown that the currently available licensed 30-year-old Dryvax vaccine can effectively be administered to adults. However, no pertinent recent clinical trial has been done or will be done to ascertain if this is true for children.

Furthermore, the new culture-derived vaccine currently being developed has never been tested in adults or children. We are aware of planned studies of adults of this new vaccine but know of no such planned studies in children. Children are not little adults and their distinct physiologic responses must be studied before large numbers of children are exposed to the vaccine.

Both the American Academy of Pediatrics and the Advisory Committee on Immunization Practices of the CDC have clearly stated these studies need to be done in children. Congress in 1998 passed the Food and Drug Administration Modernization Act to make sure that children would no longer have to receive drugs that had not previously undergone testing to assure safety and effectiveness in children.

As a pediatrician and a father, I cannot imagine that we are willing to potentially use the smallpox vaccine in greater than 70 million children and not know that it will be safe and effective in preventing disease. Nor can I imagine if a smallpox attack did occur that we are willing to let millions of children be part of an emergency experiment.

The enormous cost of the smallpox vaccination program will also have an impact on the health of children. Public health officials have indicated that the vaccination plan will divert public health funds from other programs, such as routine childhood immunization and dental clinics or worse yet, may close public health facilities altogether to accommodate the cost of the smallpox initiative. The AAP strongly urges Congress to ensure that these other vital public health programs that protect against on-going and preventable diseases are not sacrificed for a currently nonexistent disease; that is, smallpox.

We are looking forward to continuing this dialogue with you to assure that the appropriate research, therapeutic provisions, and

policies are in place to protect children against the threat of biologic, chemical and nuclear attack while continuing the programs that are needed to maintain the health of our children.

Thank you and I would be happy to answer any questions.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Abramson may be found in additional material.]

The CHAIRMAN. Ms. Baker?

Ms. BAKER. Good morning, Chairman Gregg, Ranking Member Senator Kennedy and other committee members.

My name is Martha Baker. I am a registered nurse at Jackson Memorial Hospital in Miami, FL, one of the largest public hospitals in this country, and I am a national co-chair of the Service Employees International Union Nurse Alliance.

As a trauma nurse I work on the front lines of medicine, providing every patient who comes through the door with the best care possible. If a smallpox outbreak occurs I want to do no less for someone suffering from that terrible disease. If there is a bioterrorism threat, healthcare workers like me want to be ready to respond.

Unfortunately, the administration's smallpox vaccination plan lacks important safeguards and a lot of healthcare workers are hesitant to roll up our sleeves and put the health of our patients, our loved ones, and ourselves at risk without better support.

The prestigious Institute of Medicine has suggested better safeguards. The American Public Health Association has called for compensation for vaccine victims, liability protection, and adequate resources to safely implement the plan. The National Association of County and City Health Officials say the lack of adequate funding for this program is diverting resources away from their efforts to make sure we are prepared for other bioterroristic threats.

The USA Today reported last week that more than 80 hospitals have opted out of the smallpox program. In Connecticut, as someone mentioned earlier, where the program was launched on January 24, only four healthcare workers showed up for vaccines after workers' concerns about the plan were unanswered. Out of 10,000 employees at my hospital, 49 people have volunteered, and that is before screening has taken place.

Everyone agrees that this is a risky vaccine. Past experience and recent studies have shown that out of every million people, up to one-third may experience flu-like symptoms and need to miss few days of work. A thousand may have serious reactions, 14 to 52 will have life-threatening complications, and as many as one or two may possibly die. One of the ER docs I work with had a life-threatening reaction to the smallpox vaccine when she was a child; she got the encephalitis. So it is important to everyone to remember that these statistics are not just numbers. If we vaccinate 500,000 healthcare workers, one of us may be expected to die.

Healthcare workers across America are wrestling with the known risks of the vaccine while knowing that the administration's program does not adequately protect us and our patients. The Homeland Security Act protects the drug companies that produce the vaccine and the hospitals who administer it from liability but if someone gets sick as a result of the vaccine, they will be lucky to

get a get well card from our elected leaders. I think we can do better than that and I hope you do, too.

First, we need better screening to try and limit adverse reactions from ever happening. For example, pregnancy and HIV are two contraindications for this vaccine that can be easily identified but the current civilian program does not provide for that testing. By contrast, servicemen and women who are candidates for the smallpox vaccine are being offered those tests free of charge.

Second, as the Institute of Medicine has recommended, we need a more proactive approach to monitoring those vaccinated—their patients, their coworkers, their household members—to make sure we catch and provide medical treatment for any adverse events as early as possible and so other workers and the public as we go into phase two can learn from our experiences. The passive CDC surveillance plan will not be effective enough.

Better screening and surveillance will reduce the cost of providing medical treatment and covering lost wages for people who are harmed by this vaccine, which is our third concern. People with more serious adverse reactions will need a fair compensation program that is easily accessible, recognizes the no-fault likelihood of injury, and covers the cost of medical care and lost income. The Childhood Vaccine Injury Compensation Fund provides a good model as a common-sense program that works.

Workers compensation programs will not provide an adequate safety net. Many states won't cover workers because the vaccine is voluntary. It will not provide any protection at all for patients or family members. Even those who are eligible may not get all of their medical expenses covered and are likely, after perhaps a couple of years of fighting, to receive only a percentage of their usual earnings.

Other concerns include protecting workers who choose not to get vaccinated from discrimination, providing adequate resources for State and local health departments so they can implement a safe plan, and getting the FDA to license sheathed bifurcated needles to deliver the vaccine safely and consistently with the Needle Stick Safety and Prevention Act. I actually have those safe and unsafe needles here.

We are pleased that Chairman Gregg and Majority Leader Frist and Senator Kennedy have agreed to work together on legislation that could address many of our issues. We had hoped that we would not be asked to volunteer for this vaccine until better safeguards were already in place but now that vaccinations have started, we urgently need Congress to pass and fund legislation that closes the gaps that several of us have referred to and put forth the very safest plan possible.

On behalf of the Nation's largest healthcare union I am grateful for this opportunity to express the concerns of the front-line healthcare workers. Thank you.

The CHAIRMAN. Thank you very much.

[The prepared statement of Ms. Baker may be found in additional material.]

The CHAIRMAN. Mr. Bush?

Mr. BUSH. Mr. Chairman, members of the committee, thank you for the opportunity to speak today about the smallpox vaccines and about the threat of bioterrorism.

I am Kim Bush and I am the president of Baxter BioScience Vaccines, a subsidiary of Baxter International. Baxter is a U.S.-based global healthcare company that provides critical therapies for people with life-threatening conditions.

Today Baxter has five licensed vaccines worldwide in a broad pipeline with more than a dozen vaccines at various stages of development. Baxter, in conjunction with Acambis, is playing a major role in the production of 155 million doses of smallpox vaccine for the U.S. government.

The development of a new vaccine from discovery to final licensed product may take as many as 10 years or more. In the case of our current smallpox effort, this innovative public-private partnership has been able to dramatically compress the time frame to meet the national security needs. This is possible because the FDA, other government agencies and manufacturers truly did decide that producing a new smallpox vaccine was not and could not be business as usual.

Mr. Chairman, the willingness or the ability of the private sector to become engaged are not barriers to the development of biodefense vaccines. Indeed, I believe the new BioShield legislation may become an excellent accelerator to that engagement.

Baxter, like a number of other companies, can meet many of today's biodefense needs, like those identified in the president's State of the Union Address. The question is under what conditions and with what incentives can these capabilities be optimized? And let me share with you some issues associated with that question.

Every healthcare company, like Baxter, must make some very difficult choices relative to which R&D projects to fund. Often vaccines emerge as a less appealing choice because other medical or pharmaceutical products have longer term, more predictable market potential. Also, growing concerns about intellectual property protection, very serious liability issues, and the cost of meeting regulatory requirements and compliance must be considered.

Making vaccines, which involves production from living organisms, is a costly, difficult, and very complex process. In addition, a vaccine that will be stockpiled and used only in an emergency is not likely by itself to create a sustainable business model. The realities of highly unpredictable needs, shifts in government policy and funding, and changes in perceived threats make matters even more challenging.

In light of this, it is critical that the Nation's biodefense priorities be more clearly stated so that industry can adapt and respond more effectively. At the same time, we would like to see the government proactively bring together the skills and the expertise of the vaccine industry necessary to assure the security of the American public.

Enhancement of the procurement system would be beneficial. Highly regulated procurement systems that work very well under normal circumstances do not necessarily provide incentives or easy to manage processes for manufacturers to provide vaccines to the U.S. government efficiently.

In addition, consideration might be given to enhancing the regulatory system such that it deals with the abnormal and the unpredictable as effectively as it did with the smallpox situation. The FDA deserves enormous credit for already initiating this process, as exemplified by some of its newest clinical trial rules.

Mr. Chairman, Baxter believes that liability exposure is one of the most serious impediments to new biodefense vaccine development. There is no liability protection for vaccine manufacturers beyond the Homeland Security legislation for smallpox. In addition, as has already been discussed, there is no comprehensive mechanism to provide compensation to persons who may suffer an injury.

Another important need is continued adequate intellectual property protection here and abroad. We would like to work with Congress and the administration to seek ways to assist developing nations in improving access to healthcare technologies but without undermining the strong intellectual property protections that are the engine that drives discovery.

The vaccine industry needs to be healthy and vibrant. We must address the challenges of rising development costs, downward pricing pressure, the high cost of regulatory approval and compliance, and the constant threat of predatory lawsuits. In recent years we have seen vaccine shortages and a continued decline in the number of vaccine manufacturers. Today in the U.S., as was mentioned earlier, there are only four major manufacturers and to our knowledge, to our knowledge, there are no stand-alone manufacturers of licensed vaccines and I think this demonstrates how difficult it is to build a sustainable business enterprise solely on a vaccine portfolio.

In closing, we have the following recommendations for the government. First, establish and clearly communicate the Nation's biodefense priorities and time lines. Second, establish an in-depth working knowledge of industry capabilities to align those capabilities more effectively with national interest. There was a mention earlier of infrastructure. It might surprise you there is probably more in place than you may be aware of. Third, enhance the procurement process to embrace fast decision-making for critical biodefense contracts. Fourth, use the Homeland Security Act as a template for expanding manufacturer product liability coverage. And finally, provide incentives that promote a healthy vaccine industry by adapting existing programs to take into account the very unique and complex nature of vaccine development and manufacturing.

As a manufacturer committed to assisting in this effort, we would be pleased to work with this committee, others in Congress and the relevant government agencies to ensure that vaccine development for biodefense truly is seen as not being business as usual.

We certainly appreciate the opportunity to share our views with you here today. Thank you.

The CHAIRMAN. Thank you, Mr. Bush.

[The prepared statement of Mr. Bush may be found in additional material.]

The CHAIRMAN. This question is directed to Ms. Baker but I would be interested in anybody else's response to this. This compensation issue—compensation and liability, which go hand in hand in my opinion—is obviously at the core of getting a vaccine

industry up and running and getting vaccines back in the marketplace and getting people to take advantage of the vaccines once they are there.

I understand that what you are basically saying is that you want a no-fault system where people would get recovery for loss of wages and medical costs. Is that what you think is needed so that a person, once they have shown through whatever trusts has been set up, following State workers comp or a VIC fund model, once the person has been identified as having an illness which is directly related to the vaccine, that that person would then have the right under a no-fault process to receive compensation that would cover loss of medical costs and loss of income at a reasonable rate?

Ms. BAKER. Yes. Healthcare workers, like I said, we work where we work because we are glad to step up to the plate and help with whatever emergencies are happening. And we actually surveyed our members. They are nearly 100 percent ready to do it. It is when they start looking and getting the facts that it becomes a scary process.

We want the screening obviously to happen. That is an important part. That will eliminate the high——

The CHAIRMAN. We all understand the screening.

Ms. BAKER. So the screening and the monitoring and the compensation for loss of wages and medical care, obviously. And workers comp is a battle.

The CHAIRMAN. Right, I understand. What I am more interested in, is if we are thinking of how we would set up a system, I see workman's comp as a template but I am trying to get the parameters of what the recovery should be. If we are talking medical costs and loss of compensation, some percentage, as long as the illness is proved to have been caused by the smallpox vaccine, that seems to me to be a reasonable template. In exchange for that, you limit liability, obviously.

You said, Bill, that there are a number of regulatory events out there that still stand in the way of you doing this that are just not consistent with this type of a national security issue. Could you name a few of those?

Mr. SCHULER. I have referred to EMTALA and HIPAA in terms of in a time of crisis if stage three comes out and there is massive vaccination, hospitals are going to have to move very quickly to pass along information and to sometimes redirect patients so they can get adequate care. And I think during this defined period of crisis it would be very important for the healthcare workers to be somewhat shielded from violating these acts in an effort to take care of patients.

The CHAIRMAN. I do not know whether we have given the secretary of HHS or the president the right to waive those regulatory events in the case of a national emergency, declared national emergency or not, but I think that is worth checking into and I appreciate your bringing it to our attention. We will check into it.

It was interesting to hear Dr. Abramson and Dr. Bicknell, who are about as far apart as you can get on the issue of whether this is a threat. We are not going to resolve that in the minute that I have left for my questions but clearly that is an underlying concern, Dr. Abramson taking the position that the threat is not high

enough to justify the exercise and Dr. Bicknell taking just the opposite position, that the threat is high enough to justify a great deal, and that gets to a public policy issue which we are not going to resolve now but I do want to note that this is an issue.

Senator Kennedy?

Senator KENNEDY. Thank you very much, Mr. Chairman. I apologize that I was not here for the earlier part of the hearing. We were down at the Judiciary Committee with some nominees.

Now as I understand it, there has been a very slow process where the States have been signing on for the administration's program. I understand now that, I guess, California, Connecticut, and Vermont have started. New Jersey intends to start either tomorrow or in the next couple of days, Massachusetts mid-February, but it is very slow-going. And even in Connecticut I think Ms. Baker had indicated the small number of people that—it might have started but it extraordinarily limited in its coverage.

And I think Senator Gregg has pointed to one of the real problems and challenges, and that is what kind of risks are we facing or ask people to take and what can they do about it? As I understand now, most of the private insurers will not compensate the workers if they take it and have an adverse reaction, but that has been the position of most of the private insurance companies. So you have an option about suing the government, and that is not a very satisfactory situation.

So basically people look into it and they are talking about the kinds of risks that you have talked about, Ms. Baker, and there is still a lot of questions that are out there and it seems to me it was suggested at least in the questioning of our chairman that unless we are going to develop some kind of compensation fund that is going to help meet the needs of people, as you have described it, we are just not going to get it done.

In my own State, Cooley Dickinson Hospital in Western Massachusetts—the only reason I keep remembering it is because it is where I landed after my plane crashed and it probably saved my life—they have indicated that they will not participate under the present system. When I heard about that I asked my staff to look up other hospitals and there is a score of hospitals, more than 80 hospitals in 22 States—Medical College of Virginia, Richmond, Vanderbilt University, Children's Hospital, Philadelphia, Grady Memorial in Atlanta. All across the country the list goes on, included in the record.

So it seems to me that whatever we are going to do, we have to get this up and going, is what I am hearing from our panel. They have talked about different other features.

Do most of you believe that that is fairly essential before we are going to get a real active program in place? Ms. Baker? I will hear the panel quickly and then I have just one or two other questions I would like to hear from the panel on.

Ms. BAKER. Right, the risks can probably be debated, as Dr. Bicknell said. We have history to rely on only at this point, perhaps, but that alone is a risky enough decision to make. To think that you are going to step up and do something that you will have no safety net is another serious risk. And I think if that one can be eliminated and safely taken care of, and I do not know why hos-

pitals would want to participate if they are going to just take on a huge burden.

Our hospital, Jackson Memorial, has agreed to pay 7 days, 100 percent AD time on the front end if someone is sick, but then it puts you in the predicament of after that, workers comp kicks in at 66 percent, so it is still a problem that there is not adequate compensation. That certainly has to make the person, whether it is the hospital or the healthcare worker, more willing to participate if there are some safety nets in place financially.

Senator KENNEDY. Others want to make a brief comment?

Dr. ABRAMSON. The only other point I want to make is that though I think the controls in the hospital setting will be good, if we accidentally inoculate one of our patients, that patient has no recourse and that has a sense of unfairness to it.

Senator KENNEDY. And the pressures hospitals generally are under at this time in terms of the cutbacks, the additional kinds of pressures that they are under.

Very quickly, Mr. Bush, are you, in terms of the production of the smallpox vaccine, are you on time? Is Acambis on time and on budget?

Mr. BUSH. Yes, we are making very good progress.

Senator KENNEDY. I was interested to hear Dr. Abramson and Dr. Bicknell and I want to welcome Dr. Bicknell from Massachusetts, Boston University. When you talked about your higher-ups I know just what you were talking about. No one else did but Dr. Silber is a good friend of mine, a supporter and a great guy but he—I understood what you were saying.

Let me just quickly because our time is moving about, both of you support giving out the vaccine to the public, anyone that wants it. We get asked about that. Just very quickly I would ask maybe the panel that and then my time is already up.

Dr. ABRAMSON. We are not in favor of giving it out to the public for the reasons I stated. I am particularly concerned that daycare is a whole different scenario than it was 30 years ago. If we have adults, even if we just do adults, those adults are taking care of our children in daycare. I think the chances of cross-inoculation, the worker to the child, is substantial and these parents have not volunteered their children to be inoculated.

So in a low-risk situation, which is what we have been told as I sit on the Advisory Committee on Immunization Practices—we have been told the risk is not zero but small—under that scenario we are not in favor.

Dr. BICKNELL. I would like to say a couple of things. I think the threat issue is an important one and it seems to me that the determination of threat is not something that physicians can do, public health people can do. That is a national determination. And if the threat is nontrivial, then the question becomes what to do.

I would agree completely with Dr. Abramson that I think pre-event, pre-attack vaccinating children is not merited. I think the point about daycare is a very good one. I think that could be handled. I do, though, think once we have the data—we will have an enormous amount of data. We have military data now. In a few months we will have lots of data. We will go to 10 million. We will really know the risks of transmission.

The transmission, 114 contacts from 14 million people vaccinated. I think if daycare is a threat area, let us segregate, plan about that, make sure that people do use the dressing, urge maybe that daycare do not participate, whatever it may be. But the more vaccination of adults that is done before the fact, the easier it is to control afterwards. There is absolutely no doubt about that.

And in adults I think the historical data shows and I think we will find as the data emerges from the military and others that we are dealing with a vaccine that is not going to be killing adults the way that we have been hearing about or even having the serious adverse events.

So I would urge after we get phase two, make it widely available to the adult population with appropriate protections. And if people are working and living with high-risk people, hey, do not do those.

Senator KENNEDY. I would just give others who want to make a comment a brief comment.

Mr. SCHULER. I think is important also to get through at least phase two and then provide the public with the choice in terms of whether they can proceed or not.

The CHAIRMAN. Does anybody else want to comment on Senator Kennedy's question?

Senator KENNEDY. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Dodd?

Senator DODD. Thank you very much, Mr. Chairman. I apologize, as well, for not being down at the outset of the hearing and let me thank all of you for being here. We are having a hearing down the hall with the deputy secretary of State and the United States ambassador to the United Nations on the Iraq issue, so it is a not unrelated subject matter obviously as we start talking about weapons of mass destruction and how we respond to them here. So at one end of the hall here we are talking about the threats and the other end of the hall here we are talking about how we respond to them, at least from a medical standpoint.

Just an observation or so. One is obviously when you have a hearing like this and we are talking about Connecticut being the first State, obviously we had a lot of news back in the State about the reactions from healthcare workers and Ms. Baker, you are correct; we had a very small number of people, a lot of comments about the risks being posed. That in and of itself, I sort of regret that was the case. On the one hand I applaud it because it was obviously warning people about some things, but I worry about this kind of information as we have hearings such as this and people do not distinguish at various phases of this and we end up having the negative impact of a lot of people walking away from something they should probably do at some point, at least adults, anyway, beyond the healthcare workers and the first responders, and so forth.

So it is going to be important that we get in front of this issue as quickly as we can so that we can start to ease the natural concerns people would have about subjecting themselves voluntarily to a medical procedure which could raise medical risks for them. So it is going to be very, very important that our discussions and our debates and the legislation that the chairman and Senator Kennedy and Senator Frist are talking about can have an early hearing, Mr. Chairman, and an early discussion and debate so we can

start offering some positive information to the public generally about the direction we are heading in. That is the first point I wanted to make.

I note in my prepared remarks, Mr. Chairman, about the Vaccine Injury Compensation Program that we have already used for children injured by childhood vaccines that we put in place. It might not be a bad idea to look at that as a model for this program, as well. Do you want to comment on that? When I get to the questions I would be interested in what the panel might think, particularly you, Dr. Abramson, Dr. Bicknell, about whether or not if you are familiar with that program, whether or not something like that would be worthwhile.

The question I would like to get to, and I am sorry that I was not here for Dr. Fauci, who raised some of these concerns, but in his testimony he mentioned the difficulty that individuals with compromised immune systems and others, such as children, pregnant women, and the elderly would face in the event of a bioterror event involving smallpox. He also mentioned that a helpful development of medicine, such as Vaccinia Immune Globulin if I am pronouncing that correctly—VIG is a lot easier—could greatly reduce the risk of complications for these individuals. And I want to know if you might comment, Dr. Abramson particularly, on that point.

And recent studies have shown obviously that currently available licensed Dryvax, if that is how you pronounce that, vaccine can be safely and effectively administered to adults. However, no recent pertinent clinical trials have been or will be done using this 30-year-old frozen vaccine to ascertain whether this is true for children.

Senator DeWine and I authored legislation dealing with the pediatric clinical trials and testing, which I presume you are familiar with, Dr. Abramson, and maybe others on the panel are, as well, which has done some remarkably good work in a relatively short period of time. So we are interested in having more testing being done.

I heard your response obviously to the issue of whether or not childcare workers and so forth ought to be vaccinated with the dangers of cross-contamination and I support your point entirely. But I also would like to get some sense out of this that we are heading in a direction where as we develop these vaccines, develop them in the diluted versions of them potentially that would have the same beneficial impact on those who are receiving them, that we would not exclude children. In the past they have recommended that children under the age of three—I think that was the age, or one—was it one? That was, I thought, more of a question that at least early on was more of a process question than a health question. Obviously that may be different.

I wonder if you might generally comment on those particular issues—the VIG possibility and whether or not we can get to a point relatively quickly where we can produce products here that would be safe for the general population with obviously some risks involved, and whether or not this program we have adopted for children where trials are being used as a way of protecting them from the potential implications would work here, as well.

Dr. ABRAMSON. I think you good points, Senator Dodd, and let me try to comment on them.

The Vaccinia Immune Globulin, VIG, is effective. We hope to have enough doses in another year or so that we could handle all the complications if we had to immunize the Nation. But it is not effective, unfortunately, against the encephalitis. So that is the one complication for which VIG does not work.

The American Academy of Pediatrics is very concerned that these studies are not being done in children; so the decision was made not to do the Dryvax dilutional studies in children. What would happen if we had an attack tomorrow? Well, the problem is that we do not have enough Dryvax to give out to the Nation and we would have to start diluting it and we wouldn't know what we were doing and that is of great concern to us.

I also am unaware—I have talked to Acambis and maybe Mr. Bush can clarify this, but when I last talked to them there were clear studies that would be done of the new vaccine which should hopefully be safer. The technology in doing it clearly should make it safer. There were studies planned in adults; there were no studies planned in children.

We have to get away—that was the whole point of the FDAMA Act—get way from thinking that we can use these drugs and vaccines in children and not study them. It is just not a safe thing to do. We have many instances of where something works fine in adults and does not work fine in children.

Senator DODD. You do support, I presume, the rulemaking authority we have sought here to require that products be tested for children?

Dr. ABRAMSON. That is a whole debate that is going on right now and you know what has happened in the courts, of course. I think I will let Mr. Bush——

Mr. BUSH. Yeah, let me clarify a couple of things. You commented on the Dryvax. The Dryvax is in limited quantity. That was the older generation vaccine. That is being used now, my understanding, and when that is done, the new generation, the next generation product that is currently going into the national pharmaceutical stockpile will begin to be used.

That product is made in a new generation cell technology that makes for a much purer vaccine. You could debate how much safer that makes a vaccine and I think there are three critical components. One is the way it is made, the purity. The strain that is selected. In this case the strain was selected from the New York City Board of Health strain. However, it was clonally adapted so that this strain is a little bit less virulent than what we have seen in the past.

In addition, to the doctor's point, we need to make sure that we do clinical trials on this. The only true indicator of safety, not the only true but the best indicator will be the clinical trials. Phase one is already done. Phase two is in progress. Phase three is already under design with the FDA and Dr. Manath with Acambis would have to speak to design for the pediatric trials.

Senator DODD. Well, are you going to do that? Is that part of the deal?

Mr. BUSH. That is part of the whole development contract.

Senator DODD. The children will be? There are going to be trials done for children?

Mr. BUSH. That I cannot answer for sure. That is why I say I would have to defer to the medical director at Acambis. He is driving that.

The CHAIRMAN. Well, I think it was Dr. Fauci's point earlier that they decided not to do the Dryvax because they knew it was going to be replaced by the Acambis product, but when they got the Acambis product they were going to do childhood testing.

Mr. BUSH. Yes, we can clarify that. We can get back to you and clarify that for the record. I honestly do not have that information.

Senator DODD. I would appreciate that. In fact, I would like the answer but more importantly, I would like you to tell them we would like them to do it.

Mr. BUSH. OK. I will share that information.

Senator DODD. Any other quick comment on—sorry, go ahead.

Dr. BICKNELL. I think Dr. Fauci said that if we went nationwide because of an attack we will have enough Vaccinia Immune Globulin on hand by mid-year of this year, so we are really, really close on that.

Senator DODD. Just a quick comment on the—what did I call it again? The program we established, Mr. Chairman, the VICP, childhood vaccine, the Vaccine Injury Compensation Program. That is a model for some of the discussion that has gone on already.

Dr. ABRAMSON. I think the American Academy of Pediatrics thinks that would be a very good model for compensating people who were injured by vaccines, the whole concept of everybody putting themselves at a little bit of risk for the public good and if something does happen like when we were using oral polio and you had vaccine-related paralysis, then somebody would be compensated for that is a very good model.

Senator DODD. Any disagreement with that conclusion?

Mr. BUSH. No, I was just going to comment on that. I think part of the issue is a technical issue around whether the product is licensed or not and, as you know, that program is set up now for licensed vaccines being used in children.

The issue you have right now when Dryvax runs out until the new generation vaccine is licensed by the FDA, which will be 2005, you basically will not have a licensed vaccine available to the public even if they wanted it. And once it is licensed, then you could get a prescription or request from a physician to have that done.

But in a sense, what the government would do is tax itself because the government has prescribed use of that vaccine, so it would need to fund that. But it is certainly a model to look at as we go down the road.

Senator DODD. Anything else?

Dr. BICKNELL. This raises a very interesting point if I read it correctly, that if there were an attack tomorrow or the next day and we would, in fact, dip into the Acambis stock that has been produced already and is barely going into phase three trials, a lot of people could be very nervous about taking it because it would be kind of a very early investigational new drug and compensation would not cover.

So that would be a very important loophole to plug. It is an unlikely event but we could very well be faced with having to use a vaccine that is still in kind of the middle stages of development and we would certainly not want to have liability issues out there at that moment when we have an attack in progress.

Senator DODD. Good point.

Mr. BUSH. I would just like to echo that point. It is very, very important. And all the way from the manufacturers to the practitioners, that is a real issue.

Senator DODD. Absolutely.

Mr. BUSH. We really do not have a choice in that the old, old vaccine, some of the material that has been around and is being kept in case we had a massive attack today, is unlicensed very old, some of it made 30, 40, 50 years ago, may still be viable, probably could be used. The Dryvax has a good record, has been tested, but is in limited quantity, is not made any longer.

And then you will be into next generation cell culture vaccine and there is a possibility if something happened, this product—Dryvax, the licensed product—would be gone and for a year or a year and a half you would have to use an IND unlicensed product and that is why we as a manufacturer continue to bring up the issue of liability, and the clinical trial part of this is very, very important as we move forward.

Dr. BICKNELL. There could easily be a window before phase three is done when there is lots of Acambis about but it is really not——

Mr. BUSH. But let me make one other comment, too, and this is with permission of Dr. Manath from Acambis, that the trials have gone well. There have been no unexpected situations, nothing that they did not expect to see, nothing unusual. It just takes time to work through these clinical trials because we do have to do it in the proper way under FDA guidance, working very closely with them. They have been outstanding in support of the process but it will take some time to do that.

But again this is a vaccine that is being made different but in terms of its strain is very close to the Dryvax strain, so we would not expect a lot of differences in this.

Senator DODD. Well, it raises the issue—I do not know whether we ought to be talking about some set of procedures for the FDA, sort of an aside approach, to be looked at in these potential emergency situations, on a different track when the situations warrant it, such as this case is, to be looking at maybe an expedited process or something else. It is something you have to be careful about so it does not become the mainstream, but if you had cases like this, it seems to me it is in our interest to have some sort of an expedited procedural process that would allow for some procedures to occur here that offer some protections.

Mr. BUSH. Yes, and let me say again I would like to reiterate even though I am not personally involved in the trials, I do know that the FDA, CDC and the agencies have been extremely supportive of the process.

Senator DODD. Yes, we know that.

Mr. Chairman, thank you.

The CHAIRMAN. Thank you, and I thank the panel. One of the purposes of this hearing was to begin to have some discussion on

the issue of liability. I do think Section 304 of the Homeland Security Act addresses a lot of what we have just discussed right here, but we will have to check on that.

In addition, independent of what we may hope, the fact is that the people who appear to know what they are talking about tell us the threat is out there and so we have to get ready for it and we have to deal with it and this panel has been very helpful in giving us some ideas on how to do that, as was the prior panel, and we appreciate your taking time to help us out.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF JULIE L. GERBERDING, M.D.

Good morning, Mr. Chairman and members of the Committee.

I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR).

Thank you for the opportunity to testify today about the efforts underway to assure the nation is prepared in the event of an attack using smallpox virus as a weapon.

THE DISEASE

Smallpox is a serious, contagious, and sometimes fatal infectious disease. There is no specific treatment for smallpox disease. Prevention strategies involve vaccination of exposed or potentially exposed individuals. Smallpox outbreaks have occurred from time to time for thousands of years, but the disease was eradicated after a successful worldwide vaccination program. The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977.

Regardless of the mode, magnitude or duration of any terrorist attack, smallpox would be expected to spread from person to person following its introduction. Much is known about the natural transmission of smallpox. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects, such as bedding or clothing. Rarely, smallpox has been spread by virus carried in the air in enclosed settings, such as buildings, buses, and trains. Humans are the only natural hosts of variola, the virus that causes smallpox. Smallpox is not known to be transmitted by insects or animals.

THE VACCINE

The smallpox vaccine is the only way to prevent smallpox. The vaccine is made from a virus called vaccinia, which is another "pox"-type virus related to smallpox virus. The vaccine helps the body develop immunity to smallpox. It was successfully used to eradicate smallpox from the human population. We have had a lot of experience with the smallpox vaccine and know it is very effective: it was used to eradicate smallpox from the world. It is safe in most people, but in some people it is associated with life-threatening adverse events. This risk of serious adverse events has made it more difficult to find the right balance between preparedness and not placing people at risk unnecessarily.

Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eliminated in the United States. Vaccination was stopped because the risk of the vaccine was felt to outweigh the risk from the disease.

Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals annually who work with smallpox and similar viruses in a research setting.

The stockpiling of smallpox vaccine was an important priority before September 11, 2001, and smallpox vaccine was already in production at that time. The events of the fall of 2001 heightened concern that terrorists may have access to the virus and attempt to use it against the American public. In response to these events, the Department of Health and Human Services (HHS) increased its order for vaccine, accelerated production, and began working to develop a detailed plan for the public health response to an outbreak of smallpox. The United States currently has sufficient quantities of the vaccine for every single person in the country in an emergency situation.

SMALLPOX RESPONSE PLANNING

A single report of a smallpox case in the United States will require an aggressive outbreak control effort to contain spread of the disease. In partnership with State and Local Health authorities, DHHS/CDC is in the process of establishing a smallpox preparedness and response program that: Enhances community awareness and clinician expertise about smallpox disease and smallpox vaccination through education and training; Performs disease surveillance and laboratory analysis to rapidly detect a single case of smallpox and any subsequent cases; Implements public health interventions, based on careful consideration of epidemiology and mode of transmission of smallpox, in the safest possible manner; Provides vaccination and follow-up service, on a voluntary basis, immediately to those individuals who respond to

a smallpox emergency (including, but not limited to, those who will treat the victims, provide security, vaccinate the population, and perform disease case investigations), then, based on knowledge gained, expand the program to include those responders who would be occupationally at risk during a smallpox outbreak; Provides for the capability to rapidly vaccinate a greater number of responders or the entire population should a case occur or threat levels of a possible smallpox terrorist attack increase.

Response to an Attack

States need to be prepared to rapidly implement aggressive smallpox containment activities, including the ability to vaccinate their entire populations. On October 28, 2002, CDC issued post-event smallpox planning guidance to the 50 states; the District of Columbia; the commonwealths of Puerto Rico and the Northern Marianas Islands; American Samoa; Guam; the U.S. Virgin Islands; the republics of Palau and the Marshall Islands; the Federated States of Micronesia; and the nation's three largest municipalities (New York, Chicago and Los Angeles County). To date, all 62 jurisdictions have developed plans that are undergoing review by CDC.

In addition, we are also working collaboratively with other nations (Canada, France, Germany, Italy, Japan, Mexico, and the U.K.) in the Global Health Security Action Group (GHSAG) to provide a coordinated and collaborative response to a bioterror event. In particular, we are working closely with Canada and Mexico, as a smallpox outbreak in either could necessitate a rapid response in the U.S.

INCREASING PREPAREDNESS PRIOR TO AN ATTACK

President's Plan

On December 13, 2002, President Bush announced a plan to better protect the American people against the threat of smallpox attacks by hostile groups or governments. This announcement is a vital step in ensuring that we are prepared to respond to a single reported case of smallpox. The President's decision will provide the public health and emergency response system with a cadre of vaccinated individuals who would respond in the event of outbreak of smallpox. The President's announcement identified the need for the public health system to provide smallpox vaccine to the following:

Smallpox Response Teams

HHS has been working with state and local governments to form volunteer state and local Smallpox Response Teams that can provide critical services to their fellow Americans in the event of a smallpox attack. To ensure that Smallpox Response Teams can mobilize immediately in an emergency, health care workers and other critical personnel are being asked to volunteer to receive the smallpox vaccine. Pre-attack vaccination of Smallpox Response Teams will allow them, in the event of a smallpox attack, to immediately administer the vaccine to others and care for victims. In the initial phase of vaccination, vaccine will be offered to core members of public health and health care response teams. Then vaccination will expand to include health care workers and others who may be first responders.

Department of Defense and State Department Personnel

The President also announced that the Department of Defense (DOD) will vaccinate certain military and civilian personnel who are or may be deployed in high threat areas. Some United States personnel assigned to certain overseas embassies will also be offered vaccination.

Members of the General Public

The federal government is not recommending that members of the general public be vaccinated at this time. The government has no information that a smallpox attack is imminent, and there are significant side effects and risks associated with the vaccine. HHS is in the process of establishing an orderly process to make unlicensed vaccine available to those adult members of the general public without medical contraindications who want to be vaccinated either in 2003, with an unlicensed vaccine, or in 2004, with a licensed vaccine. A member of the general public may also be eligible to volunteer for an on-going clinical trial for next generation vaccines.

IMPLEMENTATION OF SMALLPOX PREPAREDNESS PLANS

On November 22, 2002, CDC asked states how they intend to vaccinate individuals most likely to respond to a smallpox attack. CDC requested pre-attack plans that contain information on the number of people comprising each Smallpox Response Team, information on where vaccines would be administered, the number of health care facilities identified to participate, and the number of clinics needed to

support this effort. States were also asked to address vaccine logistics and security, vaccine safety monitoring, training and education, data management, and communications in their plans.

Status of State Pre-Attack Vaccination Plans

States have worked diligently to develop plans to vaccinate and have begun implementing them. My oral testimony will address the current status of their implementation.

The plans indicate that approximately 450,000 public health and healthcare personnel may be offered the smallpox vaccine. Vaccination is voluntary and eligible individuals will make their own decisions as to whether or not to receive the vaccine. There are no negative ramifications employment ramifications for anyone who chooses not to be vaccinated. About 1,500 clinics around the nation will be set up to deliver the vaccine to those who choose to receive it. In addition, state health officials have identified over 3,300 health care facilities that will participate in the program.

DISTRIBUTING VACCINE TO THE STATES

The National Pharmaceutical Stockpile (NPS) Program ensures the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. The NPS Program stands ready for immediate deployment to any U.S. location in the event of a terrorist attack using a biological toxin, chemical or radiological agent directed against a civilian population at the request of the locality.

The week of January 20, 2003, CDC delivered kits with enough vaccine and needles for 21,600 public health and healthcare workers to Connecticut, Nebraska, Vermont and Los Angeles County. As of January 22, 2003, 20 states (including 1 county) requested nearly 100,000 doses of vaccine. These were the first shipment of vaccine to state and local governments under the President's plan to protect the American people from an intentional release of the smallpox virus. Under the program, smallpox vaccine is being offered to those most likely to respond to a potential outbreak of the disease. Each state notifies CDC when it is ready to receive its shipment of smallpox vaccine to begin pre-event vaccination of public health and healthcare workers. Once CDC receives a request for smallpox vaccine from a state, the order is forwarded to the National Pharmaceutical Stockpile for processing and shipment. CDC is providing smallpox handling instructions, cold chain management guidance, and all appropriate documentation. CDC will deliver Dryvax smallpox vaccine, packaged and shipped in increments as small as one vial (100 doses). CDC will validate all delivery information prior to shipment and will release vaccine after validation of temperature monitoring information.

TRAINING AND EDUCATION

Because smallpox vaccine has not been used routinely in the United States since the early 1970s, many of today's healthcare providers are not familiar with the disease, the vaccine, or the vaccine's potential side effects. This makes training of those administering and those receiving the vaccine necessary to ensure that this program is implemented as safely as possible. Anyone considering vaccination must receive information on conditions that are contraindications to vaccination (e.g., certain skin conditions, compromised immune systems, pregnancy, allergies to components of the vaccine, or household contacts with a condition listed above). CDC has held 19 training and education sessions on smallpox that reached an estimated 800,000 clinicians, members of the public health workforce, and members of the general population. Training has been conducted in classrooms, via satellite, over the Internet, through videotaped sessions and CD-ROM, and over the telephone. Thirty different training products, in a wide variety of media formats, currently are available.

Training for Response Team Members

Training and education for Smallpox Response Team members will be critical. In order to prepare for their participation in a smallpox response effort, all Smallpox Response Team vaccination candidates will be asked to watch a video distributed by CDC and will receive a packet of information describing the purpose of the national smallpox preparedness program. The response team members will receive general information about smallpox disease and the vaccine, including pre- and post-vaccination worksheets to provide instructions for anticipating and monitoring any potential side effects, as well as fact sheets on various methods of treatment for side effects resulting from vaccination. Prior to vaccination, each vaccine recipient will be required to fill out a patient medical history and consent form to confirm

the absence of contraindications and to confirm the patient's consent in receiving the vaccine.

Training for Clinicians

Clinicians must be able to detect the first symptoms of a potential case of smallpox. During vaccination of response team members, clinicians will be an important resource for volunteers who are making a decision about whether or not they want to accept the smallpox vaccine. CDC has an ongoing initiative to educate clinicians about smallpox, done in conjunction with experts from a variety of medical professional organizations, including the Infectious Disease Society of America, the American Academy of Dermatology, the American College of Emergency Medicine (within a consortium of other emergency clinician organizations), and several primary care organizations. We are planning to help these organizations repackage information from CDC, and distribute it to their constituents in the format most appropriate for their members. In addition, CDC has established ongoing communication with 66 professional organizations that represent front-line clinicians to determine the smallpox training and education needs of their members. Within the next month, CDC is planning a national mail-out of critical clinician information to the nation's hospital and clinical community through each state's licensing board. In addition, we anticipate hundreds of thousands of clinicians will participate in CDC's upcoming Public Health Training Network program on "Clinical Management of Adverse Events Following Smallpox Vaccination: A National Training Initiative" scheduled for February 4, 2003. To supplement this extensive campaign to educate clinicians, CDC is also utilizing its normal means of getting information to clinicians, including the Health Alert Network, the secure Epi-X program, and the Morbidity and Mortality Weekly Report (MMWR). CDC has also contracted to establish a 24-hour-a-day, 7-day-a-week hotline for clinicians to call with questions about smallpox vaccinations.

Training for Laboratorians

CDC is providing smallpox training for laboratorians, including detailed instructions on the differentiation of smallpox from other rashes. On January 29, 2003, CDC will broadcast nationally a training program entitled, "Smallpox and Vaccinia Laboratory Testing: A National Training Initiative." The program presents detailed information, specific to those who perform testing and those who use laboratory services, such as physicians, nurses, epidemiologists, and state medical officers. They will also be given specific information on the laboratory role in diagnosing adverse events associated with smallpox vaccination. In addition, CDC has developed "Agents of Bioterrorism: A Guide for Clinical Laboratories," which includes information for clinical laboratorians about handling specimens suspected of containing smallpox. This guide will be distributed to the state public health laboratories within the next two weeks. The state public health laboratories can customize the guide with state-specific information and deliver it to the clinical laboratories in their area.

Education for the Public and the Media

CDC has, and will continue to use, weekly (and as warranted) media briefings, media advisories, access to smallpox vaccine experts, and public information materials to create awareness of the smallpox vaccination recommendations, the purpose of the recommendations, and the risks associated with smallpox vaccine. In addition, CDC is using its website to provide easy access to a wide range of smallpox education materials, including materials designed specifically to meet the needs of different audiences such as members of the public, health care providers, people for whom smallpox vaccination is recommended, and state and local health departments. We have been, and will continue to work with, state and local health departments and other partners to help ensure our messages and materials are visible and readily available. CDC also operates a 24-hour-a-day, 7-day-a-week public information hotline that is accessible in English and Spanish.

PREVENTING, DIAGNOSING, TREATING, AND MONITORING ADVERSE EVENTS

Ensuring that we can implement this program as safely as possible has been central to our planning. The first part of this effort is to carefully educate and screen those considering vaccination. We have had a great deal of experience with this vaccine and have information on who is at risk of serious adverse events (e.g., those who have certain skin conditions, have compromised immune systems, are pregnant, have allergies to components of the vaccine, or have a member of their household with a condition listed above). Second, we will, with state and local health departments and the healthcare community, ensure that we diagnose, manage, and treat

adverse events promptly and correctly. Third, we will very carefully monitor adverse events to ensure that we know of any unexpected patterns or types of adverse events on a real-time basis and can quickly modify the program to decrease the risk of adverse events if necessary. Included in this effort is education about what to expect after vaccination, when to be concerned about an adverse event, and where to go for help.

The Smallpox Vaccine Adverse Events Monitoring and Response System will monitor the occurrence of clinically significant, especially serious, adverse events (AEs). It will also serve to identify any unexpected adverse events. This process will help to build state capacity for assessment of adverse events.

Diagnosing and Treating Adverse Events

CDC will provide technical assistance to state health departments, including screening to identify and exclude persons with contraindications and help in implementing proper clinical procedures. There will be a designated telephone hotline for state health departments. CDC will monitor state tracking of clinically significant AEs. CDC will also inform states of any adverse event reports transmitted directly to CDC.

Efforts are underway to work with healthcare providers to assure they are educated about the smallpox vaccination program and smallpox vaccine AEs. This includes recognizing possible AEs and managing and treating any AEs among their patients. Standard algorithms are under development to assist physicians in proper identification and treatment of these patients.

Vaccinia Immune Globulin (VIG) is a product used to treat certain serious adverse reactions caused by smallpox vaccine. Sufficient quantities of VIG are available now to treat all anticipated adverse events resulting from the current vaccination program. New VIG is being produced and delivered to the National Pharmaceutical Stockpile for distribution, if needed, as the vaccination program expands. An effort is underway to produce new lots that will meet the standards for intravenous immune globulin. Cidofovir is a drug used to treat viral infections in persons with HIV/AIDS. It may be helpful in treating vaccinia reactions in cases where VIG does not work.

The state will inform CDC of VIG and/or Cidofovir requests. A CDC clinical team will then assess the request with the state and treating physician. CDC Drug Services and the National Pharmaceutical Stockpile will coordinate release of VIG and Cidofovir. The treating physician will then designated as a co-investigator on the Investigational New Drug (IND) protocol.

Reporting

CDC is working with the states to develop an active surveillance system to detect serious adverse events following smallpox vaccine. CDC intends to implement recommendations that all health care workers have their vaccination sites monitored in the hospital daily, which will contribute information on serious illnesses that occur in all vaccinees. In addition, CDC will use the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system administered by CDC and the Food and Drug Administration (FDA), to monitor smallpox AEs. The data collected through VAERS will be analyzed to identify any new or rare vaccine side effects, increases in rates of known side effects, associations with specific vaccine lots, or patient risk factors.

Post-vaccination Surveillance

Post-vaccination surveillance will be conducted for people receiving the smallpox vaccine. This surveillance will assist in determining the rates of common AEs, assessing impact on time lost from work, and evaluating vaccinee satisfaction with the immunization program. This will be done by telephone survey 10 and 21 days post-vaccination.

Data and Safety Monitoring Board

CDC has established a Data and Safety Monitoring Board to provide advice to the CDC and program managers on selected aspects of pre-event smallpox vaccination program implementation.

The committee will review reported adverse events to determine whether rates of serious events are within expected limits; whether recommendations for screening out persons with contraindications are being properly observed; whether adverse events following vaccination are causally or only coincidentally linked to vaccination; and whether the adverse events experienced necessitate a substantial change in the way the program is run.

IOM COMMITTEE

Through the Institute of Medicine's (IOM) Committee on Smallpox Vaccination Program Implementation, the IOM is providing advice to the CDC and program managers on selected aspects of pre-event smallpox vaccination program implementation. The IOM Committee released its first report on January 17, 2003.

The committee is making recommendations to CDC and state and local vaccine program managers to improve: CDC guidance designed to identify potential vaccine recipients at high risk of vaccine adverse events and complications; CDC measures to ensure the early recognition, evaluation, and appropriate treatment of adverse events and complications of smallpox vaccination; CDC plans for collecting and analyzing data on vaccine immunogenicity, adverse events, complications, and vaccine coverage; the informed consent process for vaccine recipients; professional education and training materials; communication plans for public health and medical professionals and the public; state smallpox vaccination implementation plans; and the achievement of overall goals of the smallpox vaccination program (e.g., vaccine coverage rate, equity of access, adverse reaction rates, etc.).

CONCLUSION

Assuring the nation is prepared in the event of an attack by a hostile group or government is one of the highest priorities for the administration. HHS and CDC are dedicated to assisting the states in increasing smallpox preparedness. We greatly appreciate all the work the states and local jurisdictions have done to develop plans and begin to implement them. We look forward to continuing to support states' efforts to protect the American people.

Thank you for the opportunity to testify before you today on this important public health issue. I would be happy to answer any of your questions.

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

Mr. Chairman and Members of the Committee, thank you for inviting me here today to discuss the implementation of the President's smallpox vaccination plan, which is intended to protect the American people against the threat of a smallpox attack. Because of the long-standing expertise of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) in biomedical research on emerging and reemerging infectious diseases, including smallpox and other potential bioterror agents, the Institute has been designated by President Bush to play a leading role in the nation's fight against bioterrorism. As Director of the NIAID, I am committed to bringing all of our research expertise to bear on the full implementation of this important effort.

SMALLPOX VACCINE IMPLEMENTION PLAN

On December 13, 2002, the President announced a plan to prepare and protect the American people against the threat of a possible smallpox attack by hostile groups or governments. Under the plan, the Department of Health and Human Services (DHHS), through the Centers for Disease Control and Prevention (CDC), will work with state and local governments to form volunteer "Smallpox Response Teams" who can provide critical services to their fellow Americans in the event of a smallpox attack. To ensure that these teams can mobilize and perform effectively in an emergency, it is recommended that health care workers and other critical personnel volunteer to receive the smallpox vaccine. The President also announced that the Department of Defense will vaccinate certain military and civilian personnel who are or may be deployed in high threat areas. Some U.S. personnel assigned to certain overseas embassies also will be offered vaccination. It should be noted that the Federal government is not recommending vaccination for the general public at this time.

SMALLPOX THE DISEASE

Smallpox is a serious, contagious, and sometimes fatal disease. The symptoms of smallpox infection appear approximately 12 to 14 days (range: 7 to 17 days) following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2-3 days. The rash starts with flat red lesions (a "maculopapular" rash) all beginning at the same time. These lesions become pus-filled and begin to crust, forming scabs that separate and fall off after about 3-4 weeks. Individuals are generally infectious to others from the time period immediately prior to the eruption of the maculopapular rash until the time of the shedding of scabs, but are most infectious

during the first 7 to 10 days of rash. The mortality of smallpox infection is approximately 30 percent, although mortality is likely to be much higher in those with compromised immunity, such as individuals with HIV infection and those receiving cancer therapies or drugs to prevent the rejection of transplanted organs. Smallpox patients who recover frequently have disfiguring scars over large areas of their body, especially their face; some are left blind. There is no licensed treatment for smallpox disease, and the only known prevention is vaccination.

A massive vaccination program led by the World Health Organization (WHO) eradicated all known smallpox disease from the world in the late 1970's, a resounding success story for vaccination and public health. The last case of smallpox in the U.S.A. was in 1949, and use of the vaccine in this country was discontinued in 1972. In 1980, WHO recommended that all countries stop vaccinating for smallpox. At the present time, small quantities of smallpox virus are stored in two secure facilities in the United States and Russia explicitly for research purposes, but it is believed that unrecognized stores of smallpox virus exist elsewhere in the world.

Prior to its eradication, smallpox was considered one of the most devastating infectious diseases known to mankind. Today, with the real possibility that smallpox may be used as an agent of bioterrorism, it may be once again poised to threaten public health worldwide.

SMALLPOX THE VACCINE

The "Smallpox Response Teams" and "first responders" identified in the President's Smallpox Vaccination Plan will receive FDA-licensed Dryvax smallpox vaccine in the undiluted form. This vaccine was made by Wyeth Laboratories and approximately 15 million doses have been in storage since 1982, when the company stopped making the vaccine. Historically, Dryvax smallpox vaccine has proven to be 95% effective in preventing smallpox infection. In unvaccinated people exposed to smallpox, the vaccine can lessen the severity of, or even prevent, illness if given within 3 days after exposure.

The vaccine is freeze-dried, live vaccinia virus, a poxvirus related to smallpox virus it is not a dead virus like many other vaccines. The vaccine is delivered in an unusual way, using a technique called scarification whereby the material is pricked into the skin using a two-pronged needle. Successful vaccination is measured by the development of a clear-cut pustule 6-8 days after vaccination. This is known as a "take." The blister dries up and a scab begins to form, and by the third week the scab falls off, leaving a scar. The immunization site remains contagious for vaccinia until the scab dries up completely and falls off. For that reason, the vaccination site must be cared for carefully to prevent the virus from spreading. Approximately one week after vaccination, many people experience fever, malaise, myalgia, soreness at the vaccination site, and swelling of the lymph nodes in the area of the vaccine, particularly under the arms.

In order to determine whether the existing supply of Dryvax vaccine (15 million doses) retained its potency and could even be diluted to expand the stock, a series of clinical trials were performed. In this regard, NIAID conducted a study on adults who had not been previously vaccinated to determine whether Dryvax could be diluted effectively to make more doses of this smallpox vaccine available. This clinical trial showed that the existing U.S. supply of smallpox vaccine was still very potent in its undiluted form and could be diluted five-fold and retain its potency, effectively expanding the number of doses of smallpox vaccine in the United States to 75 million. A report describing these findings appeared in the April 25, 2002, issue of The New England Journal of Medicine. The Dryvax vaccine also is being studied by NIAID in previously vaccinated populations to determine whether any residual immunity exists from earlier vaccinations.

In addition to Dryvax, NIAID is sponsoring clinical trials of another vaccine against smallpox developed by Aventis Pasteur. Eighty million doses of Aventis Pasteur's smallpox vaccine, a different formulation of the vaccinia smallpox vaccine, have been in storage for 40 years. NIAID-supported studies performed through its Vaccine Treatment and Evaluation Units will determine the safety and preliminary efficacy of various concentrations of Aventis Pasteur's smallpox vaccine in adults. To further ensure adequate supplies of smallpox vaccine, DHHS has contracted with Acambis, Inc. to produce a cell culture based smallpox vaccine for licensure.

SMALLPOX VACCINE RESEARCH CHALLENGES AND OPPORTUNITIES

While the Dryvax smallpox vaccine is currently the most effective weapon against a possible smallpox attack, it still poses risks, even in healthy populations. Fortunately, most individuals experience only mild symptoms. However, serious reactions to smallpox vaccination are well documented in studies dating back to the 1960s

when smallpox vaccination was routine in the United States. Those data indicate that, for every 1 million people vaccinated, there are 14 to 52 life-threatening adverse events such as post-vaccinial encephalitis with 1 to 2 deaths. In addition, there are 49 to 935 serious, but not life-threatening events. Moreover, because smallpox vaccination ceased in the U.S. more than 25 years ago, there is limited experience with this vaccine in the era of HIV infection, organ transplantation, and immunosuppressive therapy.

The protection of all populations, including immunocompromised individuals, pregnant women, and children is the next critical important step in addressing the smallpox threat. NIAID is carefully examining alternatives to Dryvax including modified vaccinia Ankara (MVA), which may be a viable "second generation" smallpox vaccine for individuals at high risk of complications from the current Dryvax smallpox vaccine.

Several of the complications of smallpox vaccination can be treated with Vaccinia Immune Globulin (VIG), which is derived from the plasma of volunteers who previously have received a smallpox vaccination. DHHS currently has more than enough VIG to cover the adverse events that are projected to be associated with vaccinating the smallpox response teams and first responders under the President's smallpox vaccination plan. Furthermore, the CDC has contracted for additional supplies of VIG to ensure an adequate stockpile of this product by this summer to cover the severe adverse events that might be expected for over 300 million vaccinees.

Assessments of MVA vaccine candidates in multiple animal models, including immunosuppressed animals, are providing important data on the safety and efficacy of the vaccine. In addition, historical data from people who received an MVA vaccine in Germany in the 1970's adds to the body of scientific data. Importantly, the clinical trials conducted in Germany at the time included children, who are known to be at risk for adverse events associated with the conventional vaccinia-based vaccine. MVA vaccine also has been tested recently as an experimental vaccine vector for the delivery of other vaccine candidates, including HIV and cancer vaccines. These studies suggest that the vaccine may be safe in immunocompromised individuals.

In late 2002, the NIAID issued a Request for Proposals (RFPs) intended to provide resources for the initial development of MVA vaccine candidates. NIAID intends to issue a second RFP during the summer of 2003, entitled "Production and Acquisition of MVA Vaccine." The objective of the second RFP will be to manufacture, formulate, fill and finish, and test, in accordance with current Good Manufacturing Processes (cGMP) regulations, up to 30 million doses of MVA vaccine to constitute the U.S. government's stockpile for emergency use under Investigational New Drug (IND) status and to provide a licensure plan to include the conduct of expanded human safety studies required for licensure and the conduct of pivotal animal protection studies. A third contract solicitation for the acquisition of a licensed product is being planned for 2005, under the auspices of the CDC.

In addition, the NIAID Vaccine Research Center on the NIH campus in Bethesda, MD, is conducting a clinical trial to determine the safety of MVA and to compare the immunogenicity of MVA and Dryvax. This study is being conducted in healthy volunteers who have not been previously immunized with vaccinia; a future trial with vaccinia-experienced subjects is being planned. NIAID also is looking ahead to develop "third" generation smallpox vaccines, including recombinant protein vaccines.

NIAID is also evaluating drugs for use against smallpox virus. NIAID-supported scientists have developed a form of the antiviral drug cidofovir that can be administered orally. Injectable cidofovir already has been approved by the Food and Drug Administration (FDA) for treating CMV retinitis in individuals with HIV/AIDS and has shown activity against smallpox and related viruses in laboratory and animal studies. Preliminary data from these experiments suggest that cidofovir may be helpful in controlling the progression of serious vaccinia-related complications. To illuminate this issue, NIAID worked last year with colleagues at the CDC, the FDA and the Department of Defense (DoD) to develop an Investigational New Drug application to evaluate cidofovir in the treatment of smallpox. NIAID continues to explore the development of additional therapeutic interventions against smallpox and other potential bioterror agents.

BIODEFENSE RESEARCH

Smallpox is only one of a number of potential bioterror threats to our nation. In 2002, NIAID convened two Blue Ribbon Panels to provide objective scientific advice on NIAID's biodefense research activities involving smallpox as well as other potential agents of bioterror. As a result of these deliberations, the Institute has devel-

oped two research agendas: one focuses on the CDC's Category A agents, which include smallpox, while the second focuses on NIAID's Category B and C Priority Pathogens. Guided by the recommendations outlined in these agendas, NIAID developed a total of 52 biodefense initiatives to stimulate research in Fiscal Years 2002 and 2003; 36 are new initiatives and 16 are significant expansions. During this same time period, NIAID has seen a 30 percent increase in the number of grant applications; the vast majority of these are in response to our biodefense initiatives.

In Fiscal Year 2002, several NIAID initiatives encouraged industry partnerships and focused on the development of new diagnostics, vaccines and therapeutics for CDC Category A agents. These types of research initiatives have been well received. As a result, NIAID has expanded and reissued many of these collaborative efforts in Fiscal Year 2003, and plans to do the same in Fiscal Year 2004. In addition, the new initiatives will be broadened to address NIAID's Category B and C Priority Pathogens.

A number of significant advances in understanding, treating and preventing potential agents of bioterror have already been realized. For example, NIAID-supported scientists determined how anthrax toxin gains entry into a cell and demonstrated how the toxin can be effectively blocked from entering the cell, suggesting that the development of specific anthrax toxin-blocking compounds could be a viable approach to treating anthrax disease. Furthermore, intramural researchers at NIAID's Vaccine Research Center are working on the development and pre-clinical testing of an Ebola vaccine, while others have discovered a single gene mutation in the plague bacterium, Yersinia pestis, which may have been responsible for the emergence of the "Black Death" in the 14th century.

NIAID also has expanded genomic sequencing of potential agents of bioterrorism, including anthrax and plague, and has recently awarded contracts to two companies designed to spur development of a new anthrax vaccine. Similarly, the Institute has new initiatives planned to encourage development of vaccines against plague and therapeutic strategies against Botulinum toxin.

In Fiscal Year 2003, NIAID will establish a nationwide network of Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research and pursue an initiative to design, build, and renovate a system of Regional and National Biocontainment Laboratories to serve as national resources for biodefense research and product development. These facilities will include a small number of Biosafety Level-4 (BSL-4) laboratories, the level of containment necessary to study highly pathogenic organisms.

CONCLUSION

The threat of resurgent smallpox is real and its potential is devastating; however, the President's Plan moves us in the right direction to address this threat head-on. We will continue to work closely with the Administration, including our colleagues within HHS, to fully implement the President's smallpox vaccine action plan. In addition, NIAID will continue to bolster our biodefense research efforts, which span basic, clinical and product development research, and infrastructure development. With a strong research base and talented investigators throughout the country, we fully expect that NIAID's research programs will provide the elements essential to enhance significantly our nation's defenses against the threat of bioterrorism.

Thank you for the opportunity to testify. I will be happy to answer any questions.

PREPARED STATEMENT OF WILLIAM SCHULER

Good morning, I am William Schuler, President and CEO of Portsmouth Regional Hospital, of HCA, Hospital Corporation of America. I would like to take this opportunity to thank Chairman Gregg, Ranking Member Kennedy, and others on the Senate Health, Education, Labor and Pensions Committee for providing me this opportunity to discuss with you the implications and concerns raised by the Federal Government's smallpox vaccination plan from the perspective of a community hospital.

Portsmouth, HCA and our trade association, The Federation of American Hospitals, fully support the Administration's decision to provide voluntary smallpox vaccinations for healthcare workers. We particularly applaud the Chairman, the Ranking Member and others on the Committee for their continued advocacy of voluntary vaccinations. There seems to be widespread recognition that proper implementation and safeguards will produce an environment where our nation's hospitals can provide the safest patient care and work setting for our patients, our employees and their families.

We believe that advanced voluntary vaccinations will provide the best protection to our providers in an identified smallpox outbreak, and will strengthen the ability of nurses, doctors and others throughout the nation to deliver the care that would

be needed-care that would likely stretch for weeks and months following a smallpox epidemic. By vaccinating these core caregivers, we enable them to step forward with the assurance of their own immunity to provide this vital care.

PORTSMOUTH'S ROLE IN VACCINATIONS

Portsmouth Regional Hospital, a 209-bed full service facility, is the seventh largest hospital in New Hampshire. In 1998, we served as one of the four facilities in the country chosen by the US Department of Justice to participate in Operation TOPOFF, a nationwide exercise to test healthcare preparation for mass casualties.

Under the President's smallpox vaccination plan, the Department of Health and Human Services (HHS) will work with state and local governments to form volunteer Smallpox response teams comprised of healthcare workers and first responders. Understandably, much of the efforts have filtered to the hospital level. As I describe how this vaccination plan is proceeding, I will highlight the critical issues facing a community hospital, how we are handling them, and where we feel further guidance and assistance is needed. These issues include: 1) Staffing; 2) Treatment of vaccine-related adverse effects; 3) Communication, Planning and Funding; 4) Liability and Compensation; and 5) Regulatory Requirements.

Allow me to begin by describing the stages of the vaccination initiative:

PRE-EVENT PREPARATIONS

Stage I

Step 1—One "pilot" clinic that will consist of a very small group of clinical individuals from two hospitals in the central region of the state, as well as five to seven members of the Public Health department vaccination team. (Imminent)

Step 2—Five or six vaccination clinics at sites that have not yet been designated. Approximately forty core, prescreened healthcare workers from Portsmouth Regional Hospital will be vaccinated at this time, twenty nurses and twenty physicians. (March)

Stage II

Vaccinations will be offered to all healthcare workers, EMS, First Responders, including Firefighters and Police. We are not aware of any policy or guidance from any level of government on this step or how many workers will be vaccinated. (End of summer if plan progresses)

Stage III

Vaccinations will be offered to General Public. Public would, at that time, receive vaccine from their primary care providers.

POST-EVENT PREPARATIONS

Community Clinics—A collaborative effort led by the state Office of Emergency Management (OEM), facilitated by a community team of Fire, Police, State Department of Health and Human Services employees, and hospital representatives. This team is charged with the formulation of a workable plan in which vaccination of an entire community, consisting of fifty to one hundred thousand people in our catchment area could be achieved in ten days following a smallpox outbreak in the United States.

At Portsmouth Regional Hospital, recruitment of volunteer physicians and clinical staff, including nurses, radiology technologists, respiratory therapists, and others began in our facility in mid-November, 2002. Physicians were the first to be invited to a classroom-style presentation by the Chief of Staff, Infectious Disease Physician, Infection Control Practitioner, Emergency Room Medical Director and myself. The physicians assumed the leadership role in the development and implementation of the voluntary vaccination plan. Educational booklets and volunteer rosters were distributed to the 150 physician attendees. Approximately twenty-five physicians volunteered immediately. A similar presentation was offered the following week to hospital nursing and ancillary staff, as well as staff from physician offices, local nursing homes and visiting nurse associations. An additional thirty clinicians were added to the volunteer roster. From our volunteer roster, we arrived at a core group of forty providers for Stage I vaccination, all from the hospital's Inpatient and Emergency Department staff. These volunteers were chosen because they had previously been vaccinated against smallpox, screened for contraindications and provided with additional educational resources. In March, we anticipate that this core staff will visit area clinics at staggered intervals to receive the vaccination.

STAFFING

As the smallpox vaccination process proceeds into Stages II and III, Portsmouth faces increasing medical and staffing challenges. According to a study recently reported on by the CDC, 36% of adults receiving the vaccine for the first time will likely be sufficiently ill to miss work, school, or recreational activities or have trouble sleeping. Nationwide, this amount of absenteeism, superimposed on winter illnesses and a critical nationwide nursing shortage, will surely exacerbate an already tenuous staffing shortage. Provisions must be allowed for staggered vaccination schedules of clinical staff to ensure support of normal hospital operations. Although our core team of forty staff has all previously received the smallpox vaccine without complications, we anticipate that approximately ten employees may require some time away from their duties. At this stage, we should be able to cover this level of absenteeism without impacting patient care. However, in future stages, as additional staff members are vaccinated, including those who have not had the vaccine before, these staffing issues will become of major significance.

According to the CDC guidelines, hospital responsibilities include not only program education, screening for contraindications, and identification of healthcare workers to be offered vaccine, but also daily vaccination site assessment and management, and evaluation of 'takes'. Such site assessment means that hospitals must provide daily staffing for a twenty-one day vaccine site assessment clinic. At this stage of vaccinations (Stage I) at Portsmouth, we would likely be able to absorb the financial and staffing burden. However, such a burden might not be so easily managed in a much larger hospital with a much larger pool of vaccinees.

Furthermore, in a Stage II setting, when a greater number of healthcare workers, EMT's, firefighters and police are vaccinated, the logistics for staffing, education, site care, assessment and record keeping will require state and federal support. They are not activities that a local community hospital can absorb with existing staffing. Consideration for extra funding to State Public Health departments would enable them to play a much greater role than we have seen to date in education, screening and post-vaccination site care, and will ease the vaccination-related staffing issues which are currently expected to be shouldered by the hospitals.

TREATMENT OF VACCINE-RELATED ADVERSE EFFECTS

If and when mass vaccination (Stage III) within the community occurs, it is important to recognize that community health care systems will be severely stressed. Using published rates of vaccine related complications, the 50,000 vaccinees in our designated service area could potentially lead to 5,000 office visits and up to 500 hospital admissions—an untenable demand for a medical community and a 200 bed hospital like our own. We anticipate the need to coordinate a system where specialists would help in the evaluation of the more severe vaccine reactions, discussing and coordinating homecare for all but the most ill. This system has been discussed at a State level in theory only, but has yet to be developed. We will hardly be unique in this regard. Mass vaccination will create a volume of ill patients that in most communities will be unprecedented and profoundly difficult to manage.

COMMUNICATION, PLANNING AND FUNDING

Major issues remain regarding communication and division of labor. Communication between the State OEM and local emergency personnel has been sub-optimal. In the early stages of Community Clinic planning, local emergency personnel (fire and police) were not adequately informed about the CDC vaccination plans, or their responsibilities in such a plan. Initially, hospital and community responsibilities were stated to be quite limited. As planning unfolded, responsibilities originally assigned to the OEM were given to the hospital and community.

We have communicated this issue to State leaders, and have learned that the New Hampshire OEM, like many other states in the country, has received no additional funding from FEMA. The New Hampshire OEM remains funded only through the Bioterrorism Grant and the New Hampshire Department of Health and Human Services. At a time when state and municipal budgets are already stressed, there is an understandable reluctance to take on additional responsibilities without funding. Furthermore, as is happening nationwide, New Hampshire is looking for millions of dollars in cuts from the Department of Health and Human Services in order to balance the State's budget. As a result, the state's OEM is relying too heavily on the staffing resources at a local hospital level for planning and initiation. In order to strengthen overall post-event planning, the State OEM requires additional funding, staffing, and resources.

LIABILITY AND COMPENSATION

We, as a nation, must ensure that healthcare workers are protected from personal expense and lost wages as a result of adverse reaction to voluntary vaccination. Initially, hospitals and affiliated organizations, such as physician offices, had significant concerns about their protection from liability in the case of adverse outcomes from vaccination, or the rare, yet potentially devastating, inadvertent spread of the vaccinia virus to other healthcare workers or patients. We understand and appreciate the recent clarification of Section 304 of the Homeland Security Act that appears to have resolved many of these liability concerns. The guidance clarified that a hospital participating in the vaccination program is a covered entity, regardless of where its smallpox response team is vaccinated. The declaration goes a step forward by clarifying that all members of a participating hospital's team are covered, whether employees or not, such as non-employed medical staff.

However, further clarification of liability may be needed on the "scope of employment" issue. Specifically, it is not clear if the current guidance provides protection for vaccinated persons who inadvertently, and outside of the scope of one's employment, spread the infection caused by the smallpox vaccine outside the participating hospital. We look forward to working with the Congress and the Administration to achieve the full protection intended under Section 304.

Significant concerns also remain regarding first party compensation claims for health care workers and first responders. The only avenue to address compensation as a result of illness, under current law, would be through State Workers' Compensation Law, which provides coverage after three days of vaccine-related absence. However, since the vaccination is voluntary, and not a condition of employment, it remains unclear whether this would be an option for our employees. Furthermore, our hospital does not feel that our volunteer health care workers should be asked to absorb the first three days of absence from their own sick leave banks, nor should hospitals be responsible for payment of this sick time directly. In addition, not all private practice physicians subscribe to workers' compensation. Therefore, we would suggest that Congress develop an additional fund, similar to the National Vaccine Injury Compensation Program, to ensure that no volunteer health care worker goes without compensation due to smallpox vaccine-related complications. Providing such compensation would help us significantly in the recruitment of additional health care workers.

REGULATORY REQUIREMENTS

Finally, in a time of national emergency requiring the implementation of mass immunizations, health care resources will be severely strained. In these limited circumstances, certain aspects of current healthcare laws and regulations may not be in the best interest of the patients and health care workers in our hospitals.

For example, in response to anthrax exposures occurring in Florida, New York, Washington, D.C. and other states, some state departments of health issued directives regarding the handling of patients who feared they had been exposed to anthrax or other biological agents. One hospital was instructed to put a sign outside of the emergency department directing patients to an alternative site. In another instance, a state health department told asymptomatic patients who feared anthrax exposure that they did not need medical screening until laboratory results from source letters or packages were received. As you know, EMTALA requires hospitals to provide medical screening to all patients requesting medical treatment. In the event of mass vaccinations or potential smallpox exposures, hospital emergency departments could be overwhelmed by the "worried well." Any hospital following the recommendations in the two examples above would have been subject to potential liability under EMTALA.

In addition, when hospitals are coping with mass vaccination clinics and the potential complications generated, the completion of the usual complement of hospital forms such as notices of HIPAA privacy rights and Advance Beneficiary Notices may not be possible or practical. We hope that the committee will consider how to mitigate the consequences of these regulatory dilemmas in a time of national crisis.

CONCLUSION

In closing, I would like to commend the Committee for its commitment to the safety and well being of first responders and their families. Portsmouth Regional Hospital, HCA and the Federation of American Hospitals look forward to working with the Committee to implement the Administration's voluntary smallpox vaccination plan.

I would like to emphasize four key points—first, as the immunization program progresses to Stage II and Stage III, staffing shortages are likely to become particularly acute. Extra funding to State Public Health departments would enable them to play a much greater role than has been seen to date in education, screening and post-vaccination site care, and will ease the vaccination-related staffing issues which are currently expected to be shouldered by the hospitals. Second, further clarification on hospital liability as it pertains to "scope of employment" issues may be necessary. Third, Congress should consider developing an additional fund, similar to the National Vaccine Injury Compensation Program, to ensure that all volunteer health care workers have access to compensation in the event of smallpox vaccine-related complications. Fourth, although not the primary focus of today's hearing, Congress may want to review the consequences, in limited national emergency circumstances, of regulatory issues such as EMTALA and completion of the paperwork requirements for HIPAA and Advanced Beneficiary Notices.

Thank you for providing me this opportunity to testify. I will be happy to answer any questions the Committee may have.

PREPARED STATEMENT OF WILLIAM J. BICKNELL, M.D.

Mr. Chairman, members of the committee, colleagues and guests, it is an honor to be invited to testify before the Health, Education, Labor and Pensions Committee. My name is William J. Bicknell, I am a physician with a public health degree, have served as Commissioner of Public Health in Massachusetts, am Board Certified in Public Health and Preventive Medicine and have been a Professor of Public Health and International Health at Boston University's Schools of Public Health and Medicine for over 20 years. Most recently I have been a proponent of careful, selective, progressive and, ultimately, widespread, pre-exposure vaccination as the best way to protect the nation against the threat of a bioterrorist attack using smallpox as a weapon.

Issues of national security, economics and economic disruption, medicine, public health, and labor/management issues often get confused as we discuss smallpox. This is complicated by misunderstanding of the facts, confusion of fact and opinion and, finally, honest disagreements as to the correct course of action. And, as we consider smallpox, it is important to remember that it is just one of a number of bioterrorist threats.

CONTEXT

First let me provide some context. Smallpox (Variola) is very contagious with a 30% overall fatality rate in persons who have not been vaccinated. 60% to 80% of survivors are disfigured. There is no treatment. It is a terrible disease and an excellent weapon. The threat is widely believed to be real but cannot be quantified. However, as the consequences of a terrorist release of smallpox on an unprepared nation have the potential to be devastating, preparation is essential.

Many of us were vaccinated years ago. This decreases the likelihood of vaccine complications and may provide some very limited immunity to smallpox. From a personal or public health perspective the only significant benefit of vaccination 10 or more years ago is a further reduction in the already low rate of vaccine complications in adults. More about this shortly. The important point is anyone who has been vaccinated over 10 years ago cannot count on being protected from smallpox.

The nation is far better prepared today for a smallpox attack than it was even a few months ago. The three phase plan announced by the President in December is prudent and makes excellent sense. A tremendous amount has been accomplished and Drs. Fauci and Gerberding deserve to be congratulated for their leadership and excellent work. We now have sufficient vaccine to protect everyone and Vaccinia Immune Globulin (VIG) to treat the treatable complications of vaccination. The President's policy, as announced in December, if it is fully and well implemented and if we move rapidly with no discernable pause from Phase I to Phase II, will give us the ability to rapidly control a terrorist generated outbreak of smallpox. But we are not yet ready. Before addressing the remaining issues and problems, I would like to summarize some facts about smallpox vaccination.

VACCINATION—SOME FACTS

Smallpox was eradicated in the 1970s after many years of great effort. At that time the immunity level of the general population was very high and most people in Africa and Asia were far less mobile than our population today. Today's American population is substantially non-immune and highly mobile. No one has any experience in dealing with an outbreak of smallpox in this very different and dangerous

context. The unquantifiable but real risk of attack and our highly mobile and substantially non-immune population requires us to plan for a worst-case scenario, not a desirable or not too bad scenario. Managing less is easier. However, terrorists can do their job well. We know this. Planning for less than a worst case could be disastrous.

As we consider the possibility of attack, we must think beyond the tragedy of deaths and disfigurement and recognize the consequences of substantially shutting down commercial activity for weeks or more. In addition to domestic disruption, it would be reasonable for other countries to ban all arrivals from and departures to the United States. If panic, civil unrest and martial law were to ensue, the adverse consequences to the United States will be immense, horrible and incalculable. My most fundamental message to the Committee is we must rapidly complete Phase I and, without pause and with contemporaneous evaluation of Phase I results, move rapidly and without delay into Phase II of the President's plan. In my judgment, basic protection of the nation will not be sufficient until Phase II is completed.

As Dr. Henderson, former director of the worldwide smallpox eradication program, said in 1999: "One can only speculate on the probable rapidity of spread of the smallpox virus in a population where no one younger than 25 [now 30] years of age has ever been vaccinated and older persons have little remaining residual immunity."

Does vaccination work? Yes, it is very effective and prevents smallpox. Dr. Henderson and his colleagues demonstrated this dramatically with great benefit to mankind.

The vaccine (vaccinia virus): We have enough for everyone living in the United States. The new Acambis product is expected to have a similar risk profile to the "old" recently relicensed Dryvax product. Newer vaccines that may be safer are still 2 or more years away. Drs. Fuci, Gerberding and Monath know far more about this than I. They too are far more qualified than I to comment upon the likelihood and risks of genetically engineered smallpox variants.

How safe is the vaccine? 14,168,000 persons were vaccinated in 1968, with 9 deaths, 7 of them in children. The 2 deaths in persons over 10 were a teen (age 16) with aplastic anemia and an adult (age 62) with leukemia. Using today's guidelines we would not vaccinate any children, and we would screen out and not vaccinate the teen and the adult. Deaths in children and sick adults can be expected not to occur today. In 1968 there were 114 cases of accidental vaccination of others with 1 death (a child). Mostly these were child-to-child transmissions (70%) and the balance (26%), with 2 or 3 exceptions, were between parent/grandparent and child. There is substantial historical evidence of safety in adults from the US military since World War II, the Israeli Military in the early to mid 1990s, and the recent Israeli civilian experience, There have been no reports of vaccine related deaths.

However, we do not have to rely entirely on historical data or recent Israeli experience. As of January 27, over 2000 military hospital workers have been vaccinated, including staff at Walter Reed. This very sophisticated, modern hospital has a hematology/oncology ward, transplant unit and neonatal intensive care unit. These are all areas where you would not want to accidentally spread vaccinia virus from recently vaccinated workers to patients. This has not happened. Vaccinated health care workers continued caring for patients using semi-permeable membrane dressings, long sleeves, and scrupulous hand washing. The semi-permeable membrane dressing reduces the shedding of vaccinia virus from the vaccination site into the environment by 95% to 99%. In addition, patient contact with recently vaccinated workers was minimized in the hematology/oncology ward, transplant unit and neonatal intensive care unit.

Primary or first-time vaccinees receive 3 jabs of the special bifurcated needle and 97% have a successful vaccination or take rate. Persons who had been vaccinated years ago (revaccinees) receive 15 jabs and have a 99% take rate. Sick leave day(s) off are taken by 4% of primary and 1.5% of revaccinees. Almost all sick leave has been 1 to 2 days off with 1 day being the most common. The military use the semi-permeable dressing for hospital workers but not for troops who use a band-aid. This is consistent with the CDC guidelines. Complications have been minor and are occurring at the expected rates.

Full data on our military are still classified as to numbers but CDC and FDA have this information and, in terms of complications and absenteeism, there is nothing to suggest anything much different from the above.

It is very important to remember that many of the military are first-time vaccinees, a group at higher risk of vaccine complications than revaccinees, and similar to a well screened group of civilian health workers. In only a few weeks we will have recent hard, current data on serous complications, minor complications and absenteeism. However, everything to date suggests that the widely reported

fears of some health workers either for themselves, their fmailies or for their patients are not well founded.

As our recent experience with adult first-time vaccinees is somewhat limited, the plan to vaccinate 500,000 military and 500,00 civilian first responders will expand our experience base and, I believe, put to rest many fears. We are observing and evaluating as we go. We can contemporaneously, without pausing, adjust policy if the risks are greater than expected. Otherwise, we can and should rapidly move to 10,000,000 in Phase II, continue collecting data, recalibrate if needed, and finally make vaccination available to the general adult public. Anything less than completing Phase II is half-built protection. If a hospital, city or state chooses to do less, it is at higher risk, becomes a preferred target and weakens national defense.

It is worth remembering that those at greatest risk of vaccine complications are also at greatest risk of dying from smallpox. Thus, the more we do careful screening, education and vaccination pre-attack, the more the most vulnerable among us will be protected.

CHILDREN & SMALLPOX VACCINATION

Fatality rates from smallpox in children can approach 50%. Children are one of our most cherished assets. Gareth, my 2 and 1/2 year old grandson is certainly at the center of my life. So why not vaccinate children now, before an attack? The reasoning goes like this:

1—The worst complications and the most deaths from vaccination, including deaths in otherwise healthy children, occur in children under 10.

2—Arguably the worst complication—Post Vaccinal Encephalitis (PVE)—cannot be predicted and cannot be treated. This is rare and occurs most commonly in young children (15 of 16 cases in 1968). In 1968, 4,900,000 children under 10 were vaccinated for the first time, only 15 got PVE (0.0003%), but 4 died (26%) and 4 had complications including brain damage and paralysis of the arms and legs.

3—Children are most likely to be accidentally infected or accidentally vaccinated by others. In 1968, with a total of 14,168,000 vaccinations (39% primary vaccinees) there were only 114 reported cases of accidental vaccination of others with 90 of these cases (79%) occurring in children. Children are most commonly infected by another child (70% of cases) or by an adult caregiver. 96% of the cases where one person accidentally vaccinated another were either child-to-child or between caregiver and child. Only one occurred in a hospital setting where a recently vaccinated nurse cared for a child with active eczema. This is also a good example of why it makes sense to use the semi-permeable membrane dressing and schedule recently vaccinated staff not to care for patients, such as eczema and immune disorder patients, at high risk of accidental immunization.

4—Complications in children, ranging from mostly minor to, very rarely, severe, are quite common. For a mother often any complication is seen as severe, even though in the grand scheme of things it may be inconsequential. My own son had a smallpox vaccination complication in the 1960s, I don't remember it, his mother does! Based on 1968 data, children under 1 can expect to experience 1 complication for every 8,900 vaccinated, for children from 1 through 9 years of age the expected complications would be about 1 in 12,000. This is a lot of complications even though the vast majority would not be severe.

5—Post-attack, children are far easier to isolate than adults. In a smallpox emergency we would say stay home until your local vaccination point is ready in somewhere between 1 and 5 days. Hopefully, this will be closer to 2 or 3 days. Then children will be rapidly vaccinated and protected before they are infected. The benefits of vaccination would now greatly exceed the risks.

6—The more adults that are vaccinated pre-attack, the less likely it is there will be widespread transmission and transmission to children post-attack. In my judgment, this is a good reason to modify Phase III of the President's plan and move from allowing adults in the general public to be vaccinated to encouraging adults to be vaccinated.

What would I do for my family? I want the adults vaccinated or revaccinated so long as they had no contraindications. I'd say no for any children under 10. And I would want a tested and proven mechanism in place for rapid post-attack vaccination of every remaining unvaccinated adult and all children so that smallpox deaths would be reduced to a minimum (In a post attack scenario there are very few contraindications to vaccination.). In my judgment this approach offers the best protection with the least risk, pre- and post-attack, for children, adults and the nation.

A NOTE ABOUT MODELS

There are many mathematical simulations or models of a smallpox attack extant. They are confusing to many. However, it is my understanding, with the possible exception of one model, that, when the assumptions are well understood and corrections are made so that the populations being considered are comparable, the results from various models are remarkably similar and favor the President's plan. If and as further modeling takes place and is used to inform policy and to test the feasibility of alternative program structures at the federal and state levels, it is vital that models be reality based and comprehensible with clear and explicit assumptions. The work of Ed Kaplan (Yale), Larry Wein (Stanford) and David Craft (MIT) is exemplary and their expertise represents a real national resource in this area.

JURISDICTIONAL ISSUES

These are non-trivial. The Homeland Security Act may have eliminated these concerns at the federal level, but perhaps not. At the state and local levels, jurisdictional issues remain. A colleague (Ken Bloem—He has led several leading academic medical center hospitals across the country) and I have been working on a concept that recognizes the unique problems in coordinating a response to bioterrorism events in the United States. Our constitutional division of responsibilities between the federal government and the states is only one complication. There are overlapping agency jurisdictions at the federal, state and local levels and we have a highly unusual blend of private and public organizations whose activities must be coordinated.

We are considering an approach that would use an incident command structure with incident commanders who may not be traditional public health professionals, but would simultaneously be federal and state employees reporting directly to the governor of a state and to a deputy or under-secretary in Homeland Security. These issues are not the subject of this hearing but they are of vital importance and I mention them only to highlight their importance. We now have all the material things needed to control a smallpox attack. It is time to imaginatively and realistically address the organizational and human issues that are essential for an effective response.

LIABILITY

I will not address liability as great progress has been made in this area and others are far more expert than I.

SERIOUS MYTHS & MISCONCEPTIONS

1—The smallpox vaccine is so dangerous it should not be used before an actual case of smallpox occurs—WRONG.

There are differences of opinion. However, the historical data and current experience demonstrate that with careful screening, the use of the semi-permeable membrane dressing and limiting vaccination to healthy adults, the risks of severe vaccine complications and particularly deaths can be reduced to extremely low levels. These levels are far below the levels of many avoidable risks we all accept on a daily basis and far lower than what many health professionals are anticipating.

It is essential to distinguish between vaccine side effects in children under 10 and all others as well as between first-time vaccines and repeat vaccinees. Children under 10 are at highest risk, repeat adult vaccinees are at lowest risk. Deaths in healthy adults, whether previously vaccinated or not, can be expected to be extremely low.

2—A contagious smallpox patient is always visibly sick with a rash so there is no risk to health workers if a person infected with smallpox is not obviously sick with a rash—WRONG.

CORRECT—Transmission can occur without a visible rash, with the person not feeling well but not so sick as to preclude travel and walking around.

3—Vaccinating within a 2, 3 or 4-day window after exposure may/will prevent disease—WRONG.

CORRECT—Vaccination within 5 days of exposure may prevent death, and probably results in less serious disease (lower fatality rate), but there is little to no evidence that vaccination after exposure prevents disease.

4—If doctors are just properly trained they will be able to quickly identify the first case or two of smallpox—WRONG.

First case(s) will be diagnosed late: Smallpox doesn't look like much until day 3 or 4. Confirming may take another day or two. Once the first case is confirmed, there will be over-diagnosis. No amount of training can prevent this. As rapid diagnosis cannot be assured, and it would not be surprising if it took longer than 3 or

4 days, this is an additional compelling reason for rapidly completing Phase II of the President's plan.

5—Identifying individual cases, tracing contacts with targeted vaccination of contacts, isolation and quarantine (Often called "Ring Vaccination") is the preferred strategy to contain a smallpox attack—WRONG.

In any serious terrorism scenario, this will not work. See the comparison of post-attack ring vaccination and immediate mass vaccination by Kaplan, et al. With ring vaccination, we can also anticipate failure of quarantine, serious disruption of commerce and quite possibly civil unrest. As the first case or two are identified and obvious case contacts are vaccinated, we should simultaneously ramp up for local mass vaccination in the area of the first case(s) and be ready for more widespread national mass vaccination if a case occurs in a second geographic area.

All of the above have substantial implications for planning pre- and post-attack national control strategies.

I submit as part of my written testimony a recent article by Dr. Ken James and myself that carefully reviews and considers many of the issues I have been raising during this hearing. It proposes a framework not only for the US but also for other countries to consider as they, too, face the possibility of smallpox. I also include a recent article by Warren Kaplan, Esq. that, although using Massachusetts as an example, takes a national perspective on federal and state legal issues as they impinge upon mounting an effective response to the bioterrorism threat.

THE PREFERRED NATIONAL STRATEGY

1—Pre-Attack: Implement the President's plan in a timely manner with real-time evaluation of Phase I results as we move immediately to Phase II. There is no argument for delay and protection is not adequate until Phase II is complete. I would more actively encourage vaccination of the general population once first responders have been vaccinated. This will decrease post-attack transmission, decrease panic and make post-attack control much easier. I would also consider using the semi-permeable membrane dressing for everyone who is vaccinated not just hospital workers. Why not decrease the risk of accidental vaccination to the lowest possible levels?

2—Post-Attack: With one or two cases in the nation, I recommend: A) in the area where the first case(s) occur immediately vaccinate obvious contacts and simultaneously initiate mass vaccination; B) mobilize for national mass vaccination; and C) move to national mass vaccination if there are any cases in a new geographic area.
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REMAINING PROBLEMS

Clear, concise, accurate information to the public and to the medical and public health community is needed. This is getting better but further improvement is essential. Open, honest, direct and forthright communication including acknowledging uncertainty and errors are essential to gain and maintain the trust of the public in government.

Although we have all the material to control an outbreak of smallpox, administratively, we are far from ready. Mass vaccination tomorrow would be chaotic. Who is in charge and who should do what are often not clear. Plans should emphasize simple methods and procedures that recognize we will be vaccinating in a big hurry. To do this well requires not just advance planning, but the elegance that comes from simplicity.

Finally, the public health system is, by its nature and culture, not an emergency response system and never has been. We need to consider an integrated federal-state incident command structure with Emergency Medical Services and the acute care system taking the lead role for mitigating the adverse health impact of any bioterrorism event. In this conceptualization, public health, particularly laboratories and epidemiologic intelligence, would play an essential supportive, but not directive, role.

Of the utmost importance, if smallpox or some other bioterrorist threat becomes a reality, we must be certain our plans will work. Therefore, we must move to rapidly complete Phase II of the President's plan, and whatever our ultimate organizational structure, we must realistically and regularly test our post-attack plans.

CONCLUSION

This is a terrorist threat we have anticipated and can largely prevent. The nation has made tremendous strides in the past 16 months. The President's plan is sound, takes the teeth out of the smallpox weapon and decreases the smallpox risk for us

and the rest of the world. But we must keep moving. We can simultaneously be prudent, avoid needless risk and move ahead rapidly.

Putting the President's smallpox control plan into effect is but one step in a long and arduous journey on the road to improved national protection against a variety of bioterrorist threats.

Finally, as was the case with the interstate highway program and the space program, I believe we can look forward to many positive and unanticipated benefits to our bioterrorism preparedness initiatives.

Thank you for offering me the opportunity to testify. I welcome questions.

PREPARED STATEMENT OF JON ABRAMSON, M.D.

Good morning, Mr. Chairman and members of the Committee, I am Jon Abramson, MD Chair, Wake Forest University Physicians, Physician-in-Chief, Brenner Children's Hospital and Weston M. Kelsey Professor and Chair of Pediatrics at Wake Forest. I am also the Chair of the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP). The AAP is an organization of 57,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. On behalf of the Academy, I would like to thank you for the opportunity to present this statement.

In December, the AAP applauded President Bush's announcement that the government did not recommend routine smallpox immunizations for the general public. At the same time, we urged the government to do all it could do to examine the needs of children.

This Committee has asked the AAP to respond to three very important questions about the President's smallpox vaccination plan. Everything that I say today in response to these questions is based on the information that the government has provided about the risk of a smallpox attack (i.e., the risk while not zero, is very small). Should the risk assessment change, then our answers to these questions might well be different.

What is the best approach for implementing the Administration's plan to make smallpox vaccine available to the general public?

The AAP has carefully analyzed this question and we believe that the general public, particularly children, should not be offered the smallpox vaccine at this time. This recommendation is based on weighing the relatively high rate of serious adverse events, including death, caused by the smallpox vaccine versus the low risk of a smallpox attack.

During any general public smallpox vaccination campaign infants and children would be particularly vulnerable to complications of vaccination for the following reasons:

1) High prevalence of atopic dermatitis.

2) Immune deficiencies that have not yet manifested or been diagnosed in the infant (e.g., primary immune deficiency) or child (e.g., HIV-infected children who have a delayed presentation).

3) Greater risk in infants of serious complications due to the smallpox vaccine.

4) Greater risk of unintended inoculation (e.g., self-inoculation of an eye, cross-inoculation between children in a child care center, some of whom will have contraindications to smallpox vaccination such as atopic dermatitis).

Currently, the AAP favors a ring-vaccination policy that includes a plan for rapid distribution of smallpox vaccine and development of strategies for urgent vaccination of large numbers of the population rather than a voluntary or mass vaccination program. However, if the risk of an attack was felt to be high or if an attack occurred, then a recommendation to vaccinate everyone, except those with high risk specific contraindications (e.g., a patient who recently received a bone marrow transplant), would make sense. Unfortunately, the concept of a pre-event voluntary vaccination program for the public, while appealing on the surface, makes the least sense from a scientific and public health standpoint.

Some have proposed that vaccination of the general public will decrease the spread of smallpox in the event of an attack. However, those of us in the public health community know that voluntary vaccination programs (without incentives) have not yielded vaccination rates at levels high enough to prevent outbreaks of disease. It is very unlikely that vaccination rates for smallpox will exceed the rates needed to prevent outbreaks and, therefore, this particular argument for vaccination of the general public is not based on sound, known public health principles. Ring vaccination is an effective method for containing this disease, if it occurs, while minimizing risks.

The words voluntary vaccination is a misnomer. Under a voluntary vaccination program scenario many infants, children and adults, who did not want to get the smallpox vaccine, would accidentally be inoculated by those who did receive the vaccine. It is important to point out that before 1972 when smallpox vaccine was routinely given to everyone who did not have a known contraindication, 25% of those who developed serious side effects were those unintentionally inoculated with the vaccine. Moreover, although the use of semi-permeable dressings can reduce the risk of spread of the vaccine virus, these dressings are unlikely to be practical for large-scale vaccinations because they are expensive, cause allergic reactions in some people and compliance with their proper use will vary. Thus, many children whose parents did not wish for them to get the vaccine could end up with adverse consequences from the vaccine, some of which would be very serious - including death.

What more needs to be done to deal with liability and compensation concerns?

To answer this question I speak not only from the viewpoint of the AAP, but also as the Chair of the Wake Forest University School of Medicine physicians group. Over the past few months our medical center has struggled with trying to come up with a smallpox vaccination program that would allow us to implement President Bush's request that we immunize a group of healthcare workers at various hospitals to care for children or adults who are exposed to or develop smallpox. There are a number of troublesome issues that arise from this request including concerns about liability and compensation.

Recent statements from the administration have clarified that the federal government's intent is to assume liability risk for physicians and hospitals that participate in this program. However, this does not provide injury compensation for patients or household contacts that are accidentally inoculated. This is very problematic. For example, if I as part of the healthcare team suffer a serious adverse event, I am covered by the workmen's compensation program. However, if I accidentally inoculate one of my children at home or a patient I am caring for in the hospital and they develop a serious side effect they are not covered. We urge Congress to correct this problem by enacting a "no fault" mechanism, similar to the successful National Childhood Vaccine Injury Compensation Program, to compensate those injured directly or indirectly by the smallpox vaccine. Furthermore, it is important that those receiving the smallpox vaccine be adequately informed about the risks associated with the vaccine including issues surrounding liability and compensation.

What needs to be done to ensure that children are eligible to receive the smallpox vaccine?

Recent studies have shown that the currently available licensed Dryvax vaccine can be safely and effectively administered to adults. However, no recent pertinent clinical trials have been or will be done using this 30-year-old frozen vaccine to ascertain whether this is true for children. Furthermore, the new tissue culture-derived vaccine that is currently being developed has never been tested in adults or children. We are aware of planned studies in adults for this new vaccine, but know of no such planned evaluation of the vaccine in children.

Surveillance studies done prior to 1970 when undiluted Dryvax vaccine was routinely used suggest that children have a higher incidence of adverse effects from the vaccine than adults do. Children are not 'little adults', and their distinct physiological responses must be studied before being exposed to the vaccine. Both the Committee on Infectious Diseases of the AAP and the Advisory Committee on Immunization Practices (ACIP) of the CDC have clearly stated that these studies need to be done in children similar to the testing that is done for other childhood vaccines.

In 1998, Congress passed the Food and Drug Administration Modernization Act (FDAMA) to make sure that children would no longer be subjected to receiving drugs that had not previously undergone testing to assure safety and effectiveness in children at various ages. Are we really willing to make and potentially use millions of doses of smallpox vaccine to prevent smallpox in children and not know if it will be safe and effective in preventing the disease? If a smallpox attack did occur are we really willing to let millions of children be part of an emergency experiment? The AAP and ACIP have clearly stated that these studies should be done and we hope that Congress will assure that they are. The AAP strongly recommends that Congress take immediate action to assure that they are.

The National Association of County and City Health Officials, have estimated that the total cost of the vaccination program, including purchase of the vaccine, training personnel, screening potential vaccine recipients, and data collection, could be as much as $1 billion. Local health officials have indicated that the vaccination plan will divert public health funds from other health programs including childhood immunization clinics and control of tuberculosis and pertussis. The AAP strongly urges Congress to ensure that these other vital public health programs that are needed

to protect against ongoing and preventable diseases are not sacrificed to protect the population against a potential, but currently non-existent disease (i.e., smallpox).

The American Academy of Pediatrics is eager to work with Congress and the Administration to assure that the appropriate research, therapeutic provisions and policies are in place to protect children against the threat of a biologic, chemical or nuclear attack, while continuing the programs needed to maintain the health of our children. Thank you for your consideration and I would be happy to engage in a dialogue and answer any questions that you have.

PREPARED STATEMENT OF MARTHA BAKER

Good morning Committee Chairman Gregg Ranking, Member Kennedy and other Members of the Senate HELP Committee.

My name is Martha Baker. I have been a registered nurse for 23 years. I work in the Trauma Intensive Care Unit of Jackson Memorial Hospital in Miami, Florida, and I'm a national leader of the 1.5 million member Service Employees International Union, the largest health care union in the country. I am also president of SEIU Local 1991 and cochair of the SEIU Nurse Alliance, which is made up of 110,000 nurses across the country. In addition to nurses, our union represents doctors, laboratory technicians, EMTs, orderlies, dietary workers, laundry workers, environmental services workers, and other occupations within the health care sector. Many of these employees work in occupations that would likely be defined as "first responders" in the event of a smallpox attack.

As a trauma nurse, I deal with emergencies every day and work on the frontlines of medicine, providing every patient that comes through the door with the best care possible. If a smallpox outbreak occurred, I'd want to do no less for someone suffering from that terrible disease. That's why—if there is a bioterrorism threat—it makes sense that health workers should take steps now so we're ready to respond. Unfortunately, problems with the Bush Administration's smallpox vaccination plan are making a lot of nurses like me hesitant to roll up our sleeves and put the health of our patients, our loved ones, and ourselves on the line.

Dr. Fauci and Dr. Gerberding, have already discussed the scientific details of this vaccine. Suffice it to say, everyone agrees that this is a very dangerous human vaccine. When the vaccine was routinely being administered up until 1972, for every 1 million vaccinated, 1,000 people suffered serious side effects, 14-52 people suffered life-threatening complications and one or two died.

The question we face today is whether our elected leaders in Washington could be doing more to make sure the vaccine program is safe and effective. The prestigious Institute of Medicine says better safeguards are needed. The American Public Health Association has called for compensation for vaccine victims, liability protection, and adequate resources to safely implement the plan.

Many hospitals across the country are speaking with their feet. The USA Today reported last week that more than 80 hospitals have decided to opt out of the program. The majority of states have not yet ordered the vaccine. And in Connecticut, only four doctors showed up to get vaccines after nurses' concerns about the plan went unanswered.

I'd like to talk about the issues workers and management at my hospital faced when we tried to figure out how to safely implement this plan.

First, everyone wanted to be sure we weren't doing anything to put our patients at risk.

Jackson Memorial is one of the largest public hospital in the country. On any given day, we care for hundreds of patients. Some are pregnant women, newborn infants, and children. Many of them are battling cancer or are HIV positive. If I or anyone in my household has these conditions, the Centers for Disease Control and Prevention says I shouldn't take the vaccine. So how can we be sure our patients are 100 percent safe in the care of nurses, doctors, or other caregivers who get vaccinated? In June, the Advisory Committee on Immunization Practices (ACIP) recommended against direct patient care for about three weeks. In October, the same panel said patient care is safe. While the medical experts debate the issue, the nurses I work with just want to know—Am I going to infect someone in my care?

Nurses, doctors, and management at our hospital decided that any volunteer who could accidentally expose vulnerable patients to the virus in the vaccine should be put on administrative leave until they were no longer shedding the live virus in the vaccine.

In our hospital—as in just about every hospital across the country—understaffing is a constant issue. Too few nurses are already under pressure to provide quality care to patients who are sicker than ever before. Recent studies suggest that the

smallpox vaccine will make up to 1 in 3 nurses too sick to work for a few days—and those are just the people with normal reactions.

Staff at our hospital will be vaccinated in stages, so we don't create a staffing crisis that compromises care. And if workers at our hospital get sick for a few days as a result of the vaccine, management has agreed to treat it as an on-the-job injury so they won't face any loss of income.

Next, we thought about our own health and the health of our families.

The Washington Post reported last week on a survey that showed how little nurses know about smallpox and the vaccine. I can tell you from my own experience that it's true. So we knew we had to make sure everyone is provided with good information by holding training sessions on work time so they can make an informed decision. We're also going to closely monitor people who are vaccinated and make that information is available as we go along so other workers can benefit from our experience. The lack of proper surveillance and reporting is a critical missing piece of President Bush's vaccination plan. It would be a shame if the 10 million "first responders" who are set to get vaccinated after health care workers don't have access to the knowledge we gain during the first phase of this plan. This is why we support the Institute of Medicine recommendations for "active" monitoring of those vaccinated, and not the "passive" monitoring CDC currently recommends.

Many health workers being asked to volunteer for this vaccine are women who have children at home, are pregnant, or could be pregnant. Latex allergies and other skin disorders are more common among health care workers. And certainly advanced treatments mean many people, including nurses and other health workers, are living with cancer, HIV, or other disorders that put them at a higher risk of adverse reactions from the smallpox vaccine.

Our hospital is providing free and confidential testing for any volunteers who want to be sure they aren't pregnant or infected with HIV before they volunteer for this vaccine. Our service men and women in the military who are candidates for the vaccine are being offered such protection, but as of yet, the federal government has not agreed to pay for such tests for civilian health worker volunteers, Spending a relatively small amount on preventative testing can reduce the cost of any compensation fund, as adverse effects are less likely if people at high risk are identified and screened out. Not everyone will need testing but there must be mandatory screening with free voluntary testing where such follow-up is indicated. Not only must testing be confidential, but smallpox responders must be protected against any discrimination or retaliation on the job if they refuse to be vaccinated.

Most nurses are used to vaccinations. We see how sick people get at this time of year and counsel our patients about getting their flu shots. Health care workers fought for access to the Hepatitis B vaccine. So in a way, getting another vaccination is all in a day's work. And since the average age of nurses is 47, many of us got a smallpox vaccine when we were children.

But there's a reason why our country stopped vaccinating children against smallpox. The risks outweighed the benefits. People were getting sick and a few were dying from the vaccine. A doctor I work with had one of the life-threatening reactions to the vaccine that everyone is talking about—she got encephalitis when she was vaccinated as a child.

The situation is potentially much more precarious today. Back in 1972, few people lived with weakened immune systems, and less than 5 percent had eczema; both groups that are now considered high risk and should not be exposed to the vaccine. Today, it is estimated that between 30 million and 50 million Americans fit a high-risk category. This includes people who are receiving chemotherapy, have had organ transplants, are pregnant or are planning to become pregnant, have allergies to some antibiotics or latex, are taking high doses of steroids, have, or have ever had eczema (now estimated at up to 22 percent of the population), or are infected with the AIDS virus.

The risks of this vaccine are real. Health care workers around the country are asking: What if me or one of my patients or one of my children is one of the unlucky few who gets sick?

Unfortunately, there is no good answer to that question. This is why careful screening and free, confidential testing—as well as active, on-going medical surveillance of vaccine volunteers and their patients, co-workers, and household members—is essential. Health care workers and those close to them must have immediate access to free medical treatment if needed. If serious reactions occur, countermeasures must be in place to perhaps prevent a life threatening response, including the immediate availability of Vaccinia Immune Globulin (VIG).

The Homeland Security Act protects the drug companies who produced the vaccine and the hospitals who administer it from liability. If workers, their patients, or their family members get sick as a result of the vaccine, they'll be lucky if they

receive a "get well" card from our elected leaders. I think we can do better than that—and I hope you do, too.

Nurses at my hospital had a voice in how our smallpox vaccination plan will be implemented because we have a union. But most health care workers aren't so lucky. Without action by Congress, the safety of this plan for workers and our patients will depend a lot on where you live and which hospital you work in.

Even our hospital hasn't been able to answer the question of what will happen if one of us, or one of our patients, or someone we live with gets really sick from this vaccine. At Jackson Memorial we are fortunate since our employer has agreed to pay for up to seven days of administrative leave for those of us who have less severe reactions. But what happens after that is an unknown. Where can health care workers or others suffering injury or illness from the vaccine or exposure to the vaccine turn to for coverage of medical care and lost wages.

State and federal workers' compensation programs do not provide an adequate safety net. We have already heard that some state workers' compensation programs won't cover us and others won't do enough. Some workers' compensation programs may not cover the claims of workers who have adverse reactions because they have voluntarily agreed to be vaccinated. Some state workers' compensation laws do not require coverage for all workers. Since workers' compensation only applies to injuries that are work-related, it won't provide any protection for patients or family members who could be at risk.

Even where applicable, workers will not be fully compensated. Most workers' compensation programs replace only two-thirds of workers' earnings. There are also limits on the maximum weekly benefits, which means that more highly paid health care workers cannot receive anything approaching adequate replacement of their lost income. In addition, there are caps on medical care, posing a particular problem for workers who suffer a severe side effect. Clearly, for most civilian responders and others who become ill from exposure to the vaccine, the workers' compensation program will not be there for us.

So where do we turn for coverage of our medical costs and lost wages if we become ill from the vaccine—either directly or indirectly? Since health care and emergency workers are being asked to step forward to help protect our nation against a possible smallpox attack, we believe the federal government has a responsibility to make sure that no one vaccinated or harmed as a result of the vaccinia virus has to worry about paying for medical treatment or recovering lost wages. In the case of more severe adverse reactions, there must be a fair compensation program that is easily accessible, recognizes the no-fault likelihood of injury, and covers the cost of medical care and lost income.

If smallpox is a threat, then we need to prepare for it in a way that doesn't make the problem worse. It has been SEIU's view that the national smallpox program should not proceed until all necessary protections and safeguards are in place. But now that vaccinations have started, Congress urgently needs to pass and fund legislation that closes the gaps in the Administration's smallpox plan that could put everyone at risk.

THE NEED FOR FEDERAL LEGISLATION

This is why SEIU and other unions representing health care and emergency workers have developed a legislative proposal that speaks to the safeguards that we believe must be in place in order to carry out a successful, safe smallpox responder program. I have attached the full proposal, but briefly we believe a safe, effective smallpox program must include the following:

Sufficient federal funding to allow all states through state and local public health agencies, in cooperation with hospitals and other health care entities, to have the needed resources to carry out and coordinate all aspects of a comprehensive smallpox program. States should not have to siphon funds now being used to strengthen state and local public health infrastructure to fund the smallpox program. States must ensure there are the following:

1. Mandatory education that is available prior to vaccination for all potential smallpox responders, their household members, and co-workers who may be exposed to the vaccinia virus.

2. Mandatory Medical Screening and voluntary testing program that provides free and confidential screening and testing for pregnancy. HIV, and other conditions that could put volunteers at high risk of side effects. Workers who choose not to receive the vaccine should not face discrimination or retaliation on the job.

3. Medical Surveillance and Treatment of volunteers, patients, co-workers. and household members for any adverse effects of the vaccine. Treatment must be available at no cost to those suffering adverse reactions to the vaccine as well as protec-

tions to ensure no lost wages or benefits if they are required to take time off from work. A federal compensation program must available for those suffering from more serious adverse reactions. For those responders or others who have no health insurance, there must be some provision, such as temporary Medicaid coverage to ensure that treatment costs are covered. In addition, the Institute of Medicine has recommended a much stronger system of reporting adverse reactions tot he vaccine.

Compliance with the Needlestick Safety and Prevention Act of 2000. Only the safest and most effective bifurcated needles should be used to administer the only smallpox vaccine. A sheathed bifurcated needle is available for the smallpox vaccine. We urge that the FDA expeditiously expand their current license for safer bifurcated needles so that they can be used as part of this national smallpox program and included as part of vaccine kit.

A National Smallpox Vaccine Injury Compensation Program. This program would cover costs for medical care, lost wages, and pain and suffering for those who face more severe reactions to the vaccine or as a result of exposure to the vaccinia virus. We already have a model for this in the childhood vaccine injury compensation act, which is a no-fault, easily accessible compensation program.

CONCLUSION

SEIU, along with the other health care unions, are very pleased that Chairman Gregg, Majority Leader Frist and Senator Kennedy have agreed to work together in crafting legislation that we believe will meet many of these points raised above. We look forward to working with you to assure our nation's smallpox program includes the protections that health care workers, emergency workers, patients, and household members need and deserve. Given that smallpox vaccinations have already begun, we hope that you will move quickly to introduce legislation and to appropriate the necessary funds to make it a reality. On behalf of SEIU, we are grateful for this opportunity to express the concerns of frontline health care responders. Thank you.

PREPARED STATEMENT OF BAXTER HEALTHCARE CORPORATION

Mr. Chairman, members of the Committee, thank you for the opportunity to speak today about smallpox vaccine and the threat of bioterrorism.

I am Kim Bush, President of Baxter Bioscience Vaccines. Baxter International Inc. is a global health care company that, through its subsidiaries, provides critical therapies for people with life-threatening conditions. Baxter's Bioscience, Medication Delivery and Renal products and services are used to treat patients with some of the most challenging medical conditions including cancer, hemophilia, immune deficiencies, infectious diseases, kidney disease and trauma. With 2002 sales of over $8 billion, and approximately 48,000 team members in 110 countries, Baxter is a global leader in developing innovative medical therapies that improve the quality of life for people around the world.

Baxter has a total of five licensed vaccines worldwide, and a broad pipeline of vaccines with more than a dozen vaccines at all stages of development from pre-clinical to pre-launch, including influenza and various meningococcal combination conjugates. Baxter's NeisVac-C meningococcal vaccine was approved in the U.K. in 2000 and is now licensed in 29 countries. Our newest next generation influenza vaccine has been approved for Phase III clinical trials this year in the U.S.

Baxter Healthcare Corporation, in conjunction with Acambis Inc., is participating in the production of 155 million doses of smallpox vaccine for the U.S. Government.

Mr. Chairman, I would like to make the point that what has happened in the case of the smallpox vaccine partnership between Baxter/Acambis is extraordinary to the point of being unprecedented. As you may be aware, although smallpox vaccine has been around for many years, the process used by Baxter and Acambis—growing the vaccinia virus in cell culture—is entirely new insofar as large-scale production is concerned.

Under optimal circumstances, the development of a new vaccine from the beginning through product delivery to the ultimate end user is a process that may take 10 years and in some cases has taken much longer. In the case of our current smallpox effort, however, through an innovative public-private partnership, this time frame has been dramatically shortened and compressed so that the needs of national security can and have been met. At the same time, neither product quality nor the need to demonstrate safety and effectiveness in clinical trials is being compromised. That is a remarkable feat made possible because the FDA and all of the other government agencies along with the manufacturers decided this was not "business as usual." I am not sure many Americans know or appreciate the long hours, weeks of intensive and exhaustive fact-finding, and all the other hard work and col-

laboration that went into this contracting process. If they did, I am sure they would be very proud—as I am—of what our civil service and political leadership can accomplish in partnership with the private sector when an urgent need arises. It took only 58 days to complete the decision making process to award a $400 million contract. That is unprecedented!

At the same time, we believe there are some lessons from this experience and we appreciate this opportunity to share with you some thoughts and ideas based on our experience as to how the country can enhance its ability to prepare for and respond to other bioterrorism threats. It is unfortunate that a disease that scientists and health care workers throughout the world devoted decades to eradicating may now be a bioterrorist threat. We therefore must use whatever scientific and medical tools at our disposal to defend against the unthinkable.

We believe a number of issues need to be considered and resolved if we are to have a truly meaningful and productive public-private partnership in defending against bioterrorism. I can assure you that the barriers are not in the willingness or ability of the private sector to become engaged.

For example, Baxter currently has the capability to make vaccines for numerous bioterrorism threats. Now—today—we have the technical ability to produce and deliver vaccines for smallpox (2nd generation and next generation/MVA), as well as vaccines that utilize recombinant, cell culture and conjugate technology and can protect against a variety of both viral and bacterial diseases. We can respond to pandemic threats including influenza, with our proprietary cell culture based production technology that eliminates the need for egg-dependent growth platforms and decreases the risk of adverse reactions. Beyond that, another 5 to 10 vaccines are possible if we select the right partners. In short, Mr. Chairman, Baxter, like a number of other companies, is technically able to meet many of the country's vaccine needs. The questions are under what conditions and with what incentives can these capabilities be optimized and what are the factors working against them? Let me share with you some of the issues we and industry are dealing with.

UNCERTAINTY OF MARKET CONDITIONS FOR ANTI-BIOTERRORISM PRODUCTS

Inside a company such as Baxter, proposals to fund vaccine projects must compete against each other as well as against non-vaccine projects for R&D dollars. To put it simply, when you do the math, vaccines often come out as a less appealing choice for investment than other medical or pharmaceutical products. If you add to this the current and growing attacks on intellectual property protection, particularly as it pertains to health needs of developing countries—along with liability issues facing the industry and the costs of meeting regulatory requirements—it's not hard to understand why vaccines are viewed by some in less and less favorable terms as an investment priority.

New vaccine development decisions are risky in and of themselves. Bioterrorism products present even more difficult challenges because such products, especially if they are vaccines, may represent one-time-only opportunities and the market is extremely unpredictable. Certainly a product that is to be stockpiled and used only in case of emergency is not one that can by itself create a sustainable business model or warrant a huge R&D expenditure. That is even more true when we factor in the reality that shifts in government policy or perceived threats could change priorities and funding initiatives overnight. Today's urgent need may become tomorrow's minor concern, or vice versa.

Beyond that, for a manufacturer of vaccines that often take months to move through the production process, scheduling and anticipating needs are critically important. Also, just as for up-front decisions regarding product research and development, expensive manufacturing and production funding priorities and resource allocation decisions also take place in an environment of competing and sometimes conflicting demands.

Against this backdrop, it is critical that needs be clearly stated. This is not always the case for government needs. Numerous different agencies have responsibility to foster research related to bioterrorism. That is a good thing and, indeed, there is a lot going on. However, from the perspective of industry their activities are not always coordinated or visible. Sometimes the procurement process lacks transparency—RFPs are issued and announcement dates come and go, sometimes without good communication as to the reasons for delay or what the issues are. Highly regulated procurement systems that work well under normal circumstances and are set up to procure standard material goods or to support small business R&D, do not necessarily provide incentives for large, capable manufacturers of complex biopharmaceuticals—nor are these standard procurement practices necessarily the fast-

est way to get products, especially biopharmaceuticals, into the hands of the U.S. government.

Another factor adding to the risk is our awareness of the fact that, in some cases, what the government is willing or able to pay for a product may be determined according to the appropriations available, not the value of the product to be purchased or the cost structure of the manufacturer. Hence, when investment decisions for R&D programs or manufacturing are being made by vaccine producers, we must consider the possibility that the government agencies may be bound by artificial limits in terms of determining what constitutes a fair price for the final product.

To create improved incentives to invest in new bioterrorism vaccines, it would be very helpful to hear a clearer and more coordinate message from the federal government as to the definition of its needs.

Mr. Chairman, I would also like the Committee to be aware that the vaccine industry today is somewhat splintered in the sense that—on the one hand you have a small number of large integrated manufacturers—and, on the other, a host of small companies including some small start-ups, that have really focused on a particular niche or technical capability. From our standpoint, it would seem very beneficial to the government to gain a greater understanding of the strengths of all these different companies, and put together a comprehensive composite picture of how all of these companies might be used in varying partnerships or consortia to bring forth the best possible result in the shortest possible time.

Currently, the way the system works, the government will issue an RFP and ultimately award the work to one prime contractor. It may very well be that alternative processes might foster partnerships and collaborations between companies with strengths that complement each other. I can say from our own Baxter experience that our partnership with Acambis in producing smallpox vaccine has been optimal for the government and certainly has worked well for our two companies. Yet, that partnership came about only through a series of events and pre-existing relationships that would not normally occur and were almost serendipitous. We think the government could be much more proactive in terms of acquiring a broader knowledge of the industry's capabilities and using that knowledge to foster public-private partnerships. This could more readily harness the diverse talents and capabilities of the private sector to achieve the best possible results in the shortest possible time.

Accordingly, Mr. Chairman, we recommend that all of the government agencies that are involved in biodefense preparation develop a process for working in a more collaborative fashion to establish and communicate clear national research and development targets, thoroughly educate themselves on the capabilities of the industry, foster partnerships among different companies, and establish an RFP process that has an overriding goal of getting the best product in the shortest possible time. That is what occurred in the case of the smallpox contract with truly remarkable results and we think that process can be replicated for other bioterrorism research initiatives.

IMPACT OF REGULATION

The current regulatory system for drugs and biologics was established around the concept of assuring that the American people have safe and effective medicines to treat or prevent the wide range of medical conditions that can afflict people in a normal lifetime. Biologic products such as vaccines, because they are made from living organisms and are generally injected into healthy people, are subject to particular scrutiny under our existing regulatory setup—and justifiably so.

The question I raise today, however, is whether a regulatory system that works well and is set up to deal principally with conventional and often predictable health needs is positioned to deal with the abnormal and the unpredictable. Can it be better adapted to expedite the availability of medicines to counter organisms that have been weaponized or are highly exotic and almost never encountered during normal times? Certainly, in the case of the smallpox contract, we have seen that the regulatory system can quickly adapt when faced with an issue of overriding national interest.

The FDA has also moved forward in giving the vaccine industry better guidance in the critical area of designing clinical trials for products to protect against bioterrorism threats. The FDA and the industry agree that, because of ethical and safety concerns, Phase III efficacy trials are not possible in the case of vaccines, therapeutics or drugs to treat bioterrorism agents if such trials would require challenging human subjects with a deadly organism or highly toxic substance. Accordingly, the FDA has been developing alternative testing methods to be used when human studies are not feasible—because the product being tested is intended to deal with chem-

ical, biological, radiological, or nuclear substances. The FDA deserves enormous credit for undertaking this initiative, which was underway even before September 11, 2001. This new rule that was made final on May 30, 2002, should provide industry with clear guidance on how to construct clinical trials.

There are still some issues remaining for which regulatory solutions remain elusive. Let me give you one example. Tick-borne encephalitis (TBE) is a viral infection of the central nervous system that can lead to a number of serious neurological problems and in a small number of cases, death. TBE is common in Europe, Eastern Europe and East Asia. It currently is not known to exist in the United States. Some bioterrorism experts have expressed concern that this virus could be weaponized, and there is also interest on the part of the U.S. Army in having a vaccine to protect troops that might be stationed in places where TBE is prevalent.

Baxter has a vaccine for TBE that has been approved and marketed in Europe for many years. It would be preferable if the U.S. Army uses that vaccine for our troops to have FDA approval. For that to happen, however, Baxter would have to invest millions of dollars to conduct large and lengthy clinical trials to gain U.S. regulatory approval of a vaccine already licensed in Europe. Baxter might make such an investment if there was a high probability of having a U.S. purchaser but, otherwise, it would not make sense to seek U.S. licensing of a vaccine to prevent a disease that does not exist in the U.S. and for which there is no medical need.

Mr. Chairman, we are very encouraged by the steps taken so far by the FDA to assist industry in moving forward with anti-bioterrorism research projects, and we are hopeful the agency will build upon this process to identify and address additional needs as they become apparent. We do hope to find ways to address issues such as with the TBE vaccine that, because of unusual circumstances, falls outside of the range of solutions that can be sought within the usual regulatory process. We recommend that there be better collaboration between international agencies that might help eliminate duplication of regulatory efforts and harmonize high standards for licensing quality products.

ISSUES RELATING TO LIABILITY AND RISK MANAGEMENT

Mr. Chairman, Baxter believes that liability exposure is one of the most serious impediments to new vaccine development, especially in the area of preparing for a bioterrorist threat. This is because, unlike the situation with childhood vaccines, there is no comprehensive regime in place today designed to provide rapid and predictable compensation to persons who may have suffered a vaccine-related injury from bioterrorism vaccines.

As you may be aware, when Baxter and Acambis first entered into the contract with HHS to produce smallpox vaccine, the indemnification protection that was made available to us was a hastily cobbled together extension of a 1950s Executive Order—originally developed for Department of Defense contractors. Under this system, should our smallpox vaccine be used and result in adverse patient reactions, Baxter and Acambis would have to go through the lengthy, costly and difficult process of defending all lawsuits brought against us, and pay all claims until our insurance was exhausted. Then, and only then, would the government step in and take responsibility for the claims. This system exposes a manufacturer to tremendous legal costs and creates enormous difficulties in negotiating an insurance portfolio with private insurers, not to mention the uncertainty of how the government might exercise its discretion in indemnifying claims.

This system is less than optimal and provides a strong disincentive to get involved in future vaccine contracting even assuming that the Executive Order could protect companies contracting for vaccines other than smallpox.

The language included in the Homeland Security Bill relating specifically to smallpox is a significant improvement over the Executive Order. Under that legislation, if HHS makes the appropriate declaration concerning the need to immunize all or some of the public against smallpox, then the government will, in effect, stand in the shoes of the manufacturer for purposes of defending lawsuits and paying claims.

The system set up in the Homeland Security bill makes far more sense and we recommend that it be extended to all bioterrorism vaccine development programs undertaken by the government. We believe that, if a vaccine is developed and manufactured at the request of the government to specifications set forth by the government, and is delivered to the government to be used only when, where and how the government specifies, and given only to those individuals that the government determines should get the vaccine, then the government should bear the responsibility in paying the claims of those who have experienced injury or adverse reactions.

We strongly urge Congress to look at the smallpox liability language in the Homeland Security bill as a template for handling liability issues for future bioterrorism vaccine development.

INTELLECTUAL PROPERTY PROTECTION

Another point I would like to touch on is the need to continue to assure adequate intellectual property protection. In combination with adequate market opportunities, patents are the means by which manufacturers can recover the cost of development and fund future research projects. As I had previously mentioned, it usually takes 10 years to bring a vaccine to the marketplace. Thus, upon entry into the market following regulatory approval, most vaccines only have less than ten years of remaining patent protection. Manufacturers rely on this relatively short period of protected sales to recoup the considerable costs of research, development, and clinical trials. In recent years, especially with respect to diseases affecting developing countries, we have seen an effort to require compulsory licensing or otherwise undermine patent protection as a way of making medications affordable for those nations, many of which are poor. I should add that, in many instances, developing nations are also in tropical regions, and many of the targets of both conventional vaccine research and bioterrorism preparation are on diseases of tropical origin.

As a company strongly committed to improving access to healthcare, Baxter understands the laudable goals of those who want to make medications more available to developing nations. At the same time, we need to recognize that the vaccine industry cannot afford to develop products for the diseases affecting those areas, including diseases that can be weaponized, if it cannot rely upon strong protections for the inventions and know-how that create those products.

As the U.S. continues the process of developing a trade agenda for the WTO and related negotiations, we strongly urge Congress and the Administration to seek ways to assist the poorer nations in improving access to health care technologies without undermining the strong intellectual property protections that are, in the final analysis, the engine that drives discovery of those technologies in the first place.

CREATING A SOLID BASE FOR THE VACCINE INDUSTRY

Finally, Mr. Chairman, if the vaccine industry is to make a meaningful contribution to the defense against bioterrorism, the industry must be healthy and vibrant. That is not universally the case today. To the contrary, rising development costs, downward pricing pressure, high costs of regulatory approval and compliance, and the constant threat of predatory lawsuits have combined with the inherent difficulties of manufacturing vaccines to create a situation where the industry is having trouble meeting the country's basic needs for regular childhood and seasonal vaccines—let alone meeting the country's needs on an emergency basis for innovative vaccines to combat bioterrorism threats.

Unlike mass-produced pills and tablets, which are synthesized from chemicals according to a standard recipe and are manufactured in a highly mechanized and predictable fashion, vaccines are produced from living organisms—including viruses and bacteria and cell cultures and other living systems. Despite the best efforts of vaccine manufacturers, there can often occur a great deal of variation and unpredictability in the way these organisms grow and behave. In some cases these organisms are cloned or are the result of recombinant DNA technology. The process of making a vaccine from beginning to end can take many months, with many opportunities for unexpected and unwanted variations to occur. Building facilities to mass-produce vaccines requires investments of hundreds of millions of dollars. In other words, making vaccines is a costly, lengthy, difficult and a complex process.

In recent years we have seen shortages of vaccines that guard against measles, mumps, rubella, pneumonia, meningitis, diphtheria, tetanus, pertussis, chicken pox and adult influenza. We have witnessed a constant decline in the number of vaccine manufacturers—for U.S. licensed vaccines, there were 26 different manufacturers in 1967. Today in the U.S. there are only four major manufacturers. To our knowledge there are no stand-alone manufacturers of licensed vaccines in the U.S. which demonstrates how difficult it is to build a sustainable business enterprise solely on a vaccine portfolio.

Mr. Chairman, shortages and contraction are not indicators of an industry in the best of health. If America wants to build a dynamic biomedical infrastructure to serve as a bulwark against bioterrorism, we cannot do so on a fragile foundation.

The market for vaccines today, both in the U.S. and around the world, is one that is focused on, if not obsessed with, getting the lowest possible prices. Given the financial issues facing many governments and the problems facing many developing

countries, that's not hard to understand. But what we must also understand is that the natural and inevitable result of downward pricing pressure is that many vaccines have now become low margin products and, as such, have the ability to contribute only marginally to the funding of future research and development for vaccine initiatives.

We have developed an attitude as a country that vaccines should be cheap, readily accessible and treated as an entitlement. Vaccines have done such an effective job for so many years, there has been a tendency to take them for granted, and there is a general lack of appreciation in the public of how difficult it is to produce vaccines and of the complex and formidable regulatory environment that faces these products. We recognize clearly the need to ensure consumer safety with vaccine products, especially as in many cases these products are given to individuals who are not yet ill. However, the overall attitude towards emerging vaccines for bioterrorism threats cannot be "business as usual" or these products will never be available. As one manufacturer capable of and committed to assisting in this effort, we would be pleased to work with this committee, others in Congress, the FDA, and other relevant agencies to determine the best ways to re-tool this process to expedite the development and availability of essential vaccines.

CONCLUSION AND RECOMMENDATIONS

In closing, we believe that government can take a number of steps to improve the investment climate and willingness of private companies to make a greater commitment to research on bioterrorism vaccines and drugs.

We are hopeful that industry can gain a clearer picture of the government's needs and develop a collaborative process to meet those needs. To assist in that process, we strongly encourage government agencies involved in biodefense to establish and communicate clear national research and development targets, and work to better understand and coordinate the capabilities of the private sector to achieve those targets. We also hope that the contracting process will be structured in a way that reflects the urgency of the situation, and has the overriding objective of getting the best product in the shortest possible time, at a cost which is reasonable to both the government and the contractor. Obviously, the FDA must be a full partner in that process so that it can think about and address issues that would not normally be raised in the process of approving drugs and biologics for more conventional uses. International regulatory harmonization of high standards would be especially useful.

With respect to liability and risk management, we hope Congress will look closely at the smallpox liability language in the Homeland Security bill as a template for handling liability issues for future bioterrorism vaccine development. This is critical because we expect that many of the new vaccines that will be developed as part of this effort will—unlike the smallpox vaccine—have no previous history and therefore will raise much more speculative questions of liability than is the case with smallpox. Getting private insurance we expect will be next to impossible, so some different mechanism must be in place.

Finally, Mr. Chairman, we hope that future policy in the area of vaccines will reflect an understanding of the difficulties and complexity of the vaccine manufacturing process, the need for strong intellectual property protection, and the enormous financial investment and risks created for the industry due to liability issues and regulatory compliance. The overall facts and data concerning the vaccine industry in the U.S. do not paint a picture of a completely healthy industry. To the contrary, there are some fairly serious warning signs based on the overall contraction of the industry and the shortages of recent years.

We appreciate this opportunity to share our views with the Committee and would be happy to answer any questions you might have.

STATEMENT OF PATRICK M. LIBBEY

On behalf of the National Association of County and City Health Officials (NACCHO), I thank you for the opportunity to provide initial comments on the national smallpox vaccination program from the perspective of local public health agencies. This program has multiple practical complexities. We expect that new questions and concerns will continue to arise as states and localities gain experience. We look forward to working with the Committee on a continuous basis to identify new issues and lessons learned as implementation proceeds.

NACCHO represents the nation's nearly 3000 local public health agencies. Many will be involved in planning and implementing smallpox vaccination in their communities, particularly as the program extends into its second phase of vaccinating up to ten million first responders, as the President has announced. This program

has serious and far-reaching implications for local public health practice. Our message, based on the classic admonition, "First, do no harm," is straightforward. It is, "Slow down and stay small."

We all must respect the sense of urgency conveyed by the President. However, we also believe that, in light of the President's statement that there is no imminent risk of a smallpox outbreak, we owe it to our communities to proceed carefully and take the time to evaluate Our vaccination activities as we go. We must also understand and document clearly the consequences of the necessary diversion of resources from other critical public health work to smallpox vaccination.

Localities Need More Assistance and Flexibility in Implementing Smallpox Vaccination

Planning is well underway for the initial phase of vaccinating 500,000 volunteer medical and public health response teams. Local public health agencies that will play a role in this phase are encountering many questions. Among these are the presence or absence of liability protection for entities engaged in vaccination and the availability of compensation for vaccinated persons who lose work time or incur medical care costs as a consequence. The Homeland Security Act and state workers' compensation laws do not adequately address these concerns, which remain substantial barriers.

Local public health agencies also need consistent guidance in several areas. They need accurate, uniform guidelines for clinical practice. They need guidance for communicating with potential vaccinees. They need guidance for communicating with their communities, particularly in explaining the program as the President has established it and in explaining the particular course of action that their state has adopted. It is appropriate and expected that state plans for initial vaccinations will vary, but it is essential that local public health officials be able to explain why the types and numbers of people who will be asked to volunteer for vaccination vary markedly among the states.

It is also essential that the federal government take the time to evaluate the initial experience of vaccination. This should include: monitoring side effects; identifying unexpected logistical barriers to vaccination; consulting more thoroughly with the next larger cohort to be vaccinated; and instituting measures for quality assurance. CDC has undertaken a training program that relies on distance-based training and a "train the trainer" model for administering vaccinations. It is essential to evaluate the effectiveness of that training, so that there is greater assurance that vaccines are administered and "takes" are evaluated properly. We do not believe it will be appropriate for any community to move forward with vaccinating a larger population until we have identified what training methods are effective and implemented them to prepare the larger number of vaccinators that will be required.

Implementation of Vaccination of Up to Ten Million First Responders Will Take More Time and Resources Than are Now Planned

The logistics for vaccinating the first 500,000 volunteers nationally remain incomplete, but we are confident that states and localities can master them. However, those same plans and logistics will not work when the objective expands by a factor of 20 to encompass up to ten million first responders. The broader program cannot be successful unless we take the time not only to apply the lessons learned in the first phase of the program, but also to tackle significantly greater logistical problems. We have only begun to identify the potential issues. These include: Who will provide vaccinations and how will they be indemnified? How do we get vaccine to a larger group of vaccinators and assure its proper storage, handling and administration? How do we train vaccinators? How do we ensure that emergency and routine first responders can be vaccinated without disrupting essential community services? Local public health agencies have long experience in mounting immunization programs, but the unique characteristics of the smallpox vaccine raise a host of new questions. We must take the time to answer them before we can expect to launch an effective vaccination program.

We also need to assess the costs of such a program. We know that they will be great. States and localities already are diverting significant resources to smallpox vaccination and there is no endpoint in sight. We are greatly concerned about two effects of such a diversion. First, staff hired through the state and local grants for bioterrorism preparedness cannot also pursue the other important preparedness activities that are now underway. We already see these activities slowing or halting in many locations. A disproportionate amount of resources may be spent on smallpox vaccination for an indefinite time, at the expense of other bioterrorism and emergency preparedness programs.

Second, the magnitude of a program to vaccinate ten million persons, and possibly also other members of the general public, will drain general public health resources at an alarming rate for an unknown period of time. In some jurisdictions, new staff have been hired with federal bioterrorism preparedness funds because they have the skills to improve public health capacities in the five focus areas of the cooperative agreements, including epidemiology, communication, and the application of information technology. These staff cannot readily be transferred into smallpox vaccination, which requires a different set of competencies. In many other jurisdictions, existing staff has taken on the additional job of preparing for bioterrorism. In either case, it is inevitable that existing staff in maternal and child health, immunization, or other clinical programs will be diverted even more into smallpox vaccination. This will further disrupt essential community services. We recommend a more measured, thoughtful implementation, whereby the capacity for smallpox vaccination is incorporated more gradually into routine public health practice. We cannot afford to exact a sudden, dramatic toll on routine disease. prevention and health promotion activities.

The Scope of Smallpox Vaccination Should be Limited

We have grave reservations about offering smallpox vaccination on demand to members of the general public, in the absence of a heightened threat assessment. Smallpox vaccine is inherently less safe than immunizations we advocate and offer routinely. We are greatly concerned about both inflicting harm unnecessarily and compromising our effectiveness in routine immunizations. Adverse reactions to smallpox vaccine will be well publicized and we would expect such publicity to have a chilling effect on both childhood and adult immunization efforts. Our best chance to minimize this effect is to limit explicitly the use of smallpox vaccine, thereby distinguishing it from routine immunizations, and to ratchet up our ongoing public education about the relative risks and benefits of routine childhood and adult immunization.

For all these reasons, we urge a slower, measured approach to smallpox vaccination. We urge that the program be kept at minimal levels and grow only as rapidly as threat assessment demands, so as not to disrupt other basic community health protections or cause unnecessary harm.

RESPONSE TO QUESTIONS OF SENATOR GREGG FROM WILLIAM SCHULER

Question 1. In your statement, you cite hospital staffing as a real concern as the smallpox vaccination program moves into the second and third phases. What are your thoughts as to how or what needs to be done to address this issue?

Answer 1. In a Stage 2 clinic, where all healthcare providers and first responders are vaccinated, the number of absences could be devastating. Offering the vaccine to only 20% of the staff at a time, in five clinics at staggered three week intervals should allow for a number of vaccine related absences which would not likely debilitate hospital operations.

The number of patients with adverse reactions from a Stage 3 clinic would overwhelm hospital resources. Triage of all but the most acute vaccinia adverse reactions in an offsite facility would help to eliminate congestion in emergency rooms. Provisions for staffing and resources to provide home care or care in a dormitory-type setting for all but the most acutely ill would alleviate unprecedented volume of inpatient bed needs.

Question 2. Communication between federal, state and local agencies is imperative to making this vaccination program a success. In your view, have communications between your hospital and the relevant federal, state, and local agencies been sufficiently adequate? As we continue to move forward with the plan, do you have any ideas on how communications could be improved?

Answer 2. As mentioned in the testimony, early in the planning process, communications and guidance to local authorities (fire, police) was extremely limited. With the progression of time, this communication has improved and responsibilities delineated to a workable level. A Federal oversight program in the development of community post-event vaccination Clinic Response Team would have facilitated a quicker start, and would have eliminated some, if not all of the initial confusion. As we move further into planning and closer to a finished, workable plan, it is clear that hospital representatives in a community planning group could benefit from a state or Federal level group board meeting in order to bring share relevant and timely information at the community level planning meetings.

Question 3. In the absence of knowing whether or not your health care workers would be covered by dew Hampshire's workers' compensation program, you urged that a federal "no fault" program be created to compensate workers for smallpox

vaccine-related injuries. It is my understanding that the State of New Hampshire has recently said that it would, in fact, cover all smallpox vaccine-related adverse events. As such, do you still believe such a federal compensation program is necessary—at least with respect to health care workers already covered under the state's program?

Answer 3. A Federal baseline for coverage would allow for, and facilitate, uniformity between states. In New Hampshire, we are very fortunate to have lawmakers who recognize the importance of protection to the front line volunteers. It is unlikely that all states will follow New Hampshire's lead. Given complexity of smallpox vaccination program (e.g., multi-state transport of vaccine, multi-agency directives. CDC, State Departments of Health, healthcare organization ownership beyond state of administration) a federal program would be appropriate. The Federal program could be developed to offer coverage of all participants (self-employed physicians, non-employed volunteers, others) and those who develop vaccine-related illness including co-workers, spouse/household members, etc.

RESPONSE TO QUESTIONS OF SENATOR GREGG FROM BILL BICKNELL, M.D.

Question 1. Though we are focusing much of today's efforts on implementing the current three-phase vaccination plan, what do you believe needs to be done to strengthen our public health care system in order to be able to adequately respond to a smallpox outbreak?

(See also my answer to Question 5 below)

1. All states should either have a diagnostic laboratory that can rapidly identify smallpox or have an arrangement with a laboratory in a nearby state.
2. Vaccine for post attack use should be pre-positioned at the state level with the national stockpile used to replenish supplies as post-attack vaccination gets underway. A clever terrorist will assure multiple infections in many different geographic areas across the country. For those who choose not to get vaccinated pre-attack, as well as for children (see below), getting the vaccine as close to their arms as possible for very rapid use post-attack is just common sense.
3. Plans for post-attack vaccination should be sufficiently detailed that each person or family group knows where they are to report for vaccination. Far more and far smaller vaccination clinics will need to be planned if we are to vaccinate the entire country in 5 to 10 days post-attack. This means a town like mine. Marshfield, with a population of about 25,000, needs 3 to 5 sites such as public school gyms and places of worship Volunteers need to be identified and trained to staff and operate these vaccination sites and occasional trial runs need to done to test the system and work out the kinks.
4. Distribution to local clinics from state stockpiles can be done by state and local police.
5. So long as we complete Phase II of the President's plan and, I would hope move from being, permissive to encouraging the adult population to be vaccinated in Phase III, little more than the above needs to be done. There will be very few cases of actual smallpox because we will have quickly halted transmission by implementing widespread mass vaccination in all geographic areas where there is disease. I would strongly recommend, as soon as there is smallpox in two different geographic areas, the nation more immediately to vaccinating the entire country.
6. Consideration could be given to converting old armory's and other large spaces, possible recently closed hospitals, to temporary low intensity, hospital/nursing care facilities. Frankly, for smallpox, I don't think this will be needed and staffing would be very difficult and Would have to come in large part from already short-staffed acute-care hospitals. If there is a smallpox event. I foresee rapid discharge of hospital patients and stopping admissions of all but the most urgent cases. This will free up large numbers of staffed beds with trained personnel who have access to laboratory and other support services needed to take care of the ill.
7. As the state epidemiologists and their staffs are likely to be called upon to help interpret data in any bioterrorism event, they need to be trained in a very different kind of data analysis and interpretation. Specifically, they need to learn how to deal with very incomplete, fragmentary and conflicting data in the context of no option for wait and see. This is absolutely antithetical to the mind set and culture of most everyone in public health, epidemiologists included. Whether or not such an approach would be accepted and would work is an open question. However, although there are certainly exceptions, many of the current breed of epidemiologists in public health agencies and in academia are simply not equipped to deal with the realities of imminent death, limited data and the need for immediate decisions.

8. The national smallpox post-attack plan (Guide B, Vaccination Guidelines for State and Local Health Agencies) was removed from the CDC website on Monday January 26. I leave emailed to you a separate long communication about this that I sent to CDC on February 19. States have made their post-attack plans according to the guidelines which have been withdrawn and now states and local authorities are without published national guidance in case of an attack. This needs to be corrected rather urgently. At present, what would happen after a smallpox attack is not at all clear.

It is my sense, without hard data, that this is not just a CDC problem. Rather it may be compounded by and reflect poor communications between HHS and CDC. Effective communication with the public before, and particularly after, a bioterrorism event requires near seamless, collegial relationships characterized by mutual trust and respect between the leadership and key staff of HHS, CDC and doubtless HSA. Almost certainly staff is limited in every agency and everyone has too much to do. Bioterrorism, including smallpox, is a dynamic threat, If an attack comes, it will likely be different from what we have anticipated. Therefore, easy, open and fast internal communications will be essential to effectively marshalling and coordinating the best possible national response. But it is my understanding that, whatever the public posture, the day-to-day communications between HHS and CDC may not be what they should be. Now is the time for building a culture of teamwork, collegiality, mutual trust and respect. Whether in Washington or Atlanta the players need to invest time in pulling together with a real emphasis on clarity, simplicity and realistic expectations. Finally, an effective response to an attack is further complicated by a common federal problem, lack of realization that it is the states and medical providers within the states that are the implementers. Today, the states and providers are not marching well to a confused drummer, nor will they in the future.

Question 2. What are your thoughts on testing the smallpox vaccine for safety and efficacy in children?

I believe the current vaccine (DRYVAX) has been adequately tested in children and there is no need to test it further. It was used in millions of children and we know the side effects and we also know it is effective and there is nothing to suggest that children's immune response today is different from what it was 30 or more years ago.

New vaccines, and the only relevant products at this moment are the two Acambis vaccines which are slightly different from each other, should undergo Phase I and Phase II trials in children. Although I am not an expert immunologist, I believe with Phase I and II trials in children and Phase I, II and III trials in adults we would have sufficient data to license for use in children in a post-attack situation.

If use in children was to be permitted pre-attack, then Phase III trials in children would be appropriate.

Question 3. Once the new Barter-Acambis vaccine has been FDA-licensed and manufactured in sufficient amounts, do you believe that it should be made available to children? If not, why?

Assuming the risk profile is very similar to DRYVAX, and there is little reason to think otherwise, I would be very hesitant about making the vaccine available for use in children under 10. It is in this age group that very severe reactions and deaths, though rare, are most likely to occur. As children can be readily isolated and rapidly vaccinated post-attack, so long as we have Phase II of the President's pre-attack plan fully in place. I feel the nation's younger children are well protected without being immunized pre-attack. This underscores the importance of fully completing Phase II of the President's pre-attack plan.

Another reason not to vaccinate young children is 70% of the cases of accidental vaccination of others comes from child to child contact. Accidental vaccinations will happen to children without regard to their or their parents wishes and some of these children are likely to have contraindications to vaccination. Reactions in those accidentally vaccinated can be very serious. In 1968, when 14,168,000 persons of all ages were vaccinated, the nation experienced 50 very serious reactions and one death in persons under 10 years old that were accidentally vaccinated by contact with another deliberately vaccinated person.

On balance, I'd be in favor of lowering the age of permissive vaccination in Phase III of the President's plan to 10. I would be very hesitant to go lower based on the information available to me at this moment.

Vaccinating children before an attack poses particularly difficult questions. The risks of vaccination are definitely greater in children than adults. This will almost certainly be true but not easily proven with the new Acambis products. The risk of death from smallpox is greater in younger children. The ease of isolating children prior to vaccination in a post-attack scenario is easier for children than for adults.

The risk of attack is unknown, non-trivial and certainly greater than zero. Children under 10 face a heightened risk of very serious and sometimes lethal complications. For some of these complications, there is no treatment. Taken together, these factors make widespread vaccination of children before an attack very problematic. In children, if there is a good post-event vaccination plan in place for every community, the risk of vaccination need only be taken if there is an actual attack. After an attack the vaccine risk is far outweighed by the risk of death from smallpox.

In my written testimony (the relevant part is pasted just below) I review the arguments for not vaccinating children under 10 with DRYVAX and I suspect we will find the Acambis products to have a similar risk profile in adults. To get any idea of the serious risks in children of the new Acambis products would require huge numbers, tantamount to widespread vaccination. If we complete Phase II of the President's plan, we are in a position to rapidly vaccinate children after an attack and minimize deaths from smallpox and not unnecessarily expose children to an untreatable, often lethal, vaccine complication (Post Vaccinal Encephalitis) as well as other serious and also sometimes fatal complications.

FROM MY WRITTEN TESTIMONY—CHILDREN AND SMALLPOX VACCINATION

Fatality rates from smallpox in children can approach 50%. Children are one of our most cherished assets. Gareth, my 2½ year old grandson is certainly at the center of my life. So why not vaccinate children now, before an attack? The reasoning goes like this:

1. The worst complications and the most deaths from vaccination, including deaths in otherwise healthy children, occur in children under 10.

2. Arguably the worst complication—Post Vaccinal Encephalitis (PVE)—cannot be predicted and cannot be treated. This is rare and occurs most commonly in young children (15 of 16 cases in 1968). In 1968, 4,900,000 children under 10 were vaccinated for the first time, only 15 got PVE (0.0003%), but 4 died (26%) and 4 had complications including brain damage and paralysis of the arms and legs.

3. Children are most likely to be accidentally infected or accidentally vaccinated by others. In 1968, with a total of 14,168,000 vaccinations (39% primary vaccinees) there were only 114 reported cases of accidental vaccination of others with 90 of these cases (79%) occurring in children. Children are most commonly infected by another child (70% of cases) or by an adult caregiver. 96% of the cases where one person accidentally vaccinated another were either child-to-child or between caregiver and child. Only one occurred in a hospital setting where a recently vaccinated nurse cared for a child with active eczema. This is also a good example of why it makes sense to use the semipermeable membrane dressing and schedule recently vaccinated staff not to care for patients, such as eczema and immune disorder patients, at high risk of accidental immunization.

4. Complications in children, ranging from mostly minor to, very rarely, severe, are quite common. For a mother often any complication is seen as severe, even though in the grand scheme of things it may be inconsequential. My own son had a smallpox vaccination complication in the 1960s, I don't remember it, his mother does! Based on 1968 data, children under I can expect to experience 1 complication for every 8,900 vaccinated, for children from 1 through 9 years of age the expected complications would be about 1 in 12,000. This is a lot of complications even though the vast majority would not be severe.

5. Post-attack, children are far easier to isolate than adults. In a smallpox emergency we would say stay home until your local vaccination point is ready in somewhere between 1 and 5 days. Hopefully, this will be closer to 2 or 3 days. Then children will be rapidly vaccinated and protected before they are infected. The benefits of vaccination would now greatly exceed the risks.

6. The more adults that are vaccinated pre-attack, the less likely it is there will be widespread transmission and transmission to children post-attack. In my judgment, this is a good reason to modify Phase III of the President's plan and move from allowing adults in the general public to be vaccinated to encouraging adults to be vaccinated.

What would I do for my family? I want the adults vaccinated or revaccinated so long as they had no contraindications. I'd say no for any children under 10. And I would want a tested and proven mechanism in place for rapid post-attack vaccination of every remaining unvaccinated adult and all children so that smallpox deaths would be reduced to a minimum (In a post attack scenario there are very few contraindications to vaccination.). In my judgment, this approach offers the best protection with the least risk, pre- and post-attack, for children, adults and the nation.

Question 4. What are your thoughts about using an adverse event tracking or reporting system to gain more data or information on the frequency, and types of adverse events and our experiences dealing with those events?

I think adverse event reporting is a good idea. However, what we really need to know are the severe adverse events. I would define severe as anything requiring hospitalization or that results in death. The lesser events are of academic but not really of public policy interest or relevance. I think the DOD is doing an excellent job of rapidly tracking analyzing and publicizing adverse events. We should learn from the DOD.

Question 5. In your written statement you suggest, "that it is time to imaginatively and realistically address the organizational and human issues that are essential for an effective response." Could you expand upon these thoughts and offer a few specific recommendations for its to consider?

Ken Bloem and I have given this question a great deal of thought. Public Health by experience, tradition and culture is not an emergency service. Almost nothing is done in real time, with limited, conflicting and ambiguous data. Public Health collects, analyses and plans for the next event. It seeks consensus and works across and within very diverse communities with many different points of view. Building consensus and avoiding risk is at the heart of today's public health culture. This is not wrong but it is antithetical to mounting and managing a response to bioterrorism where rapid action, on limited data, that does not respect individual rights, is likely to be essential. I had personal experience with this when I managed a bioterrorism-like event in Massachusetts in the 1970s suing the state emergency powers and would be pleased to provide more details, specifics and lessons learned.

Ken and I feel that the public heath apparatus should be supportive but not have a primary role in bioterrorism response. Support from the pubic health laboratories and almost certainly the state epidemiologists will be desirable. However, overall management should not rest within public health. Primary responsibility for responding to the publics needs will and should rest with the acute care delivery system particularly hospitals and larger clinics. Rather than have event management in the hands of pubic health, we feel each state should have trained and designated incident commanders for bioterrorism. The incident commander would be both a state and a federal employee for purposes of the incident and report directly to the governor of the state and the appropriate under-secretary in the Department of Homeland Security. The incident commander could be a non-physician appropriately trained or a physician with a strong background in both management and emergencies. In some jurisdictions the incident commander could be a public health professional. Dual federal-state reporting and employment finesses the problem of constitutional authority and largely avoids the need to amend many state emergency power laws. This approach uses what pubic health has to offer in an appropriate and reasonable way. It avoids asking public heath to do a job that it is not suited to do by organizational structure, culture, tradition and temperament. It is as simple as not using a screw driver to hammer a nail.

Mr. Bloem and I are preparing an article for publication on this approach and will go into the legal, political, technical and managerial implications in some detail. As we complete this article, we will be pleased to share this with you and discuss with interested committee members and staff.

Question 6. Today, few physicians are properly trained to recognize and quickly identify smallpox—what recommendations do you have, considering the practical and financial limitations, to better prepare our health care providers for this task?

Your question suggests that physicians can be trained to quickly recognize smallpox. Unfortunately this is not the case. I would do no more than is being done. Early detection of smallpox by training physicians is just not going to happen. This is a necessary consequence that flows from how smallpox disease manifests itself, not blindness, ignorance or resistance on the part of physicians and other health workers. Perhaps the most common presenting complaint of patients to the medical community is feeling lousy with a fever. That's smallpox and many, many other things too. A few days later a very non-specific and unimpressive bump or lump will show up on the face or shoulders or arms. These bumps do not look like smallpox. They look like a bump or two that even the most discerning diagnostician might at most note but is very unlikely to call smallpox. 24 to 48 hours later, after about 4 or 5 days of being infectious, the patient is likely to be recognized as possibly having smallpox.

It is reasonable to have posters in outpatient departments and emergency rooms. It is a good idea for the prevention, control, recognition and management of smallpox to be part of medical school and residency training curricula. Beyond that, don't waste your time or money.

Many thanks for giving me the opportunity to answer these questions.

Please feel free to contact me at any time about smallpox or related issues.

RESPONSE TO QUESTIONS OF SENATOR GREGG FROM JON ABRAMSON

Question 1. Children are not small adults, shouldn't we make sure that the smallpox vaccine supple is safe and effective for children, regardless of the positive results obtained through adult testing?

Question 2. What can and should be done to ensure that our stocks of smallpox vaccine can be used safely and effectively in children?

Answer. Because these two questions are closely aligned we are collectively responding to the questions as presented.

The AAP would concur that the smallpox vaccine supply should be made safe and effective for children regardless of the positive results obtained through adult testing. As stated in the AAP's testimony and smallpox vaccine policy statement——

> [c]hildren are not "little adults", and their distinct physiological responses must be studied before being exposed to the vaccine. Both the AAP and the Advisory Committee on Immunization Practices (ACIP) of the CDC have clearly stated that these studies need to be done in children similar to the testing that is done for other childhood vaccines.

We can not predict how soon a smallpox attack might occur and therefore whether the tissue-derived smallpox vaccine currently under development will be available when needed. Thus, we need to ensure that the diluted Dryvax smallpox vaccine is also tested for safety and effectiveness in children at the same time that the Acambis vaccine is also studied in children. Moreover, these clinical trials in children should not wait for the completion of the adult clinical trials.

Question 3. In your written statement you bring attention to the issues of smallpox vaccine-related adverse events in infants and children and recommend that they should not be offered the vaccine at this time. You also cite several medical conditions (HIV, primary immune deficiency) that may not be fully manifested in the young infant. How would we deal with these issues should the country need to employ a ring-vaccination program? For example, under those urgent conditions time may not be available to perform HIV or other screening tests.

Answer. Under pre-event circumstances we do not believe children should be vaccinated for the reasons already described in our testimony and smallpox vaccine policy statement. If the risk of smallpox increases to the degree that widespread vaccination of children is felt to be warranted, the risk of serious adverse event from the vaccine would have to be compared to the risk of infection. In at least some circumstances, it is likely that the risk of disease would be greater than the potential risk of vaccination.

Question 4. Until we know the new Baxter-Acambis smallpox vaccine works and that there are sufficient doses, we will have to rely on the Dryvax vaccine to protect our children in the event of an outbreak. Since the Dryvax vaccine will have to be diluted, don't we need to know if such a vaccine is still safe and effective in children—regardless of the positive results obtained through adult testing? If clinical trials are developed to re-study the Dryvax vaccine in children, what are your thoughts on how such a trial should be structured?

Answer. The clinical trials as initially proposed by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) and regulated by the Food and Drug Administration was appropriately structured. The protocol for this research study entitled "A Multicenter Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax Administered to Children 2 to 5 Years of Age" is articulated in the October 31, 2002, Federal Register Notice. However, in a letter dated, January 24, 2003, to the Harbor-UCLA Medical Center one of the sites of the clinical trial, the FDA and the Office for Human Research Protections determined that——

> bioterrorism preparedness plans have evolved such that, under current plans, the potential to use diluted Dryvax in children will no longer exist. In the absence of plans to use diluted Dryvax in children, the Secretary, HHS and the Commission. FDA have determined that there is no justification for this particular clinical investigation to proceed.

We believe that the decision is not correct for the reasons noted in the last paragraph of our answer to question 1 and 2 and as noted in our response to the Federal Register notice that further details our view on the clinical trials.

The American Academy of Pediatrics appreciates the opportunity to continue to work with you to assure that the appropriate research, therapeutic provisions and policies are in place to protect children against the threat of a biologic, chemical or nuclear attack. We look forward to continuing to work with you and your staff.

RESPONSE TO QUESTIONS OF SENATOR GREGG FROM MARTHA BAKER

Question 1. In a January 26, the International Association of Industrial Accident Boards and Commissions, a not-for-profit trade association representing most of the government agencies charged with the administration of workers' compensation systems throughout the U.S. and other countries, issued a press release stating that:

"The IAIABC conducted an informal survey of experts in workers' compensation agencies. None of the experts expressed any doubt about the workers' compensation coverage for a worker who suffers an adverse health reaction to a smallpox vaccination done in connection with their work States like Kentucky, Connecticut and Wisconsin have issued opinions on the issue, which confirm coverage for injuries caused through this work related vaccination program.

"Administrative law judges contacted by the IAIABC expressed no reservations over coverage in current law.

"Thus, it appears that workers should have a basis for a claim against workers' compensation in most states, just as for any other disease in that state."

If state workers' compensation programs will most likely provide medical care and benefits for lost wages for vaccinated workers, why would it be necessary to create a new federal compensation system for them?

While it is correct that the International Association of Industrial Accident Boards and Commissions (IAIABC) is the leading non-profit organization of state workers' compensation commissions, its executive director. Gregory Krohm, who issued the January 26, 2003 press release, stated that he did so on his own initiative, after mistakenly deciding that the leading medical studies on smallpox vaccinia, cited by MAID Director Anthony Fauci and CDC Director Julie Gerberding were out of date and inapplicable to a US population with higher percentages of immune-compromised individuals.[1]

Moreover, Mr. Krohm conducted his "survey" himself, by calling "at least a dozen [workers' compensation] administrators" whom he knew. Mr. Krohm stated that he told one of the people lie "surveyed," Robert Snashall, Chairman of the New York State Workers' Compensation Board. "I do not see any basis for alarm. I don't like to scare people if there's no basis for being afraid."

Neither Chairman Snashall, nor the New York State Workers' Compensation Board has issued any statement on workers' compensation coverage of smallpox. Indeed, major workers' compensation insurers in New York State have repeated the statements of American Insurance Association assistant general counsel, Bruce Wood:

> "I do not see where comp would pay for either the vaccine or for the adverse effects of an inoculation. My question is: Where's the injury? For comp to be implicated there needs first to be an injury. Simply inoculating workers as a purely prophylactic exercise, where there has not been an injury, is not covered. Would comp pay for the effects of any other inoculation? No."[2]

Mr. Krohm also admitted that statutory waiting period requirements ranging from 7-42 days in state workers' compensation programs would make it impossible to compensate anyone who became too ill to work after being vaccinated.

While Mr. Krohm maintains that any worker requiring medical care after vaccination will receive it under workers' compensation, he concedes that such cases may well have to be decided by workers' compensation administrative law judges. Indeed, the one example cited in his press release of January 26, quotes the Kentucky workers' compensation board, which states. "Ultimately, if a healthcare worker suffers a vaccination related reaction and files a contested claim, compensability under Kentucky's workers' compensation law would have to be decided by an administrative law judge."

The Association for State and Territorial Health Officers (ASTHO) did a survey of state workers' compensation programs in January, 2003, with the intent of determining the extent of coverage by state workers' compensation programs for injuries resulting from the smallpox vaccination. Of the 30 state workers' compensation programs contacted by state health departments, only 6 responded that they would provide coverage to all workers.

However, it is clear from this data that there is wide disparity in what states are saving, with an overwhelming number raising many issues about the ability or willingness to cover injuries resulting from the smallpox vaccine. Some are saying that

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[1] Interview with with Gregory Krohm, Executive Director, International Association of Industrial Accident Boards and Commissions, February 10, 2003.

[2] "Smallpox Vaccine Program Creates Dilemma for WC Insurers." Risk and Insurance.com, February 10, 3003; "Vaccine Raises Claim Issues," Business Insurance, January 13, 2001.

if the vaccination is voluntary and not "required" than it would not be covered. Others are saying while state compensation programs may say yes. "hospitals and counties are paving their own costs of workers' comp, and some of them have said no to any coverage." Still others raise the fact that because of waiting periods, workers will not be covered unless, for example, they are out for more than 10 days. For your information, we have attached is a copy of the ASTHO study.

Similarly, an AFL-CIO survey of 41 State Workers Compensation programs as of 2/25/03 reports the following:

12 states have stated they will provide coverage for smallpox injuries

states expect to provide coverage based on case law, but have no official statement guaranteeing coverage

9 states will not cover smallpox injuries

4 will not cover for private sector workers, but will cover state workers

11 are still reviewing to decide whether they will provide coverage

We might add that your question notes that Wisconsin said they will cover work-related vaccine injuries, but an AFSCME local in LaCrosse was told that their workers' compensation coverage will not apple in the event of an injury.

Aside from all the questions about workers' compensation made abundantly clear from the ASTHO survey, state workers' compensation laws do not cover all workers, including many nurses and doctors who work as private contractors.

Volunteering for vaccination should not be a game of maybe you will, maybe you won't. Workers need to know what relief they, or their families. Will receive if someone should become ill. Just as the Department of Defense provides full medical care and lost wage compensation to military and civilian personnel in its smallpox vaccination program, a federal smallpox compensation fund is required to provide for the necessary medical care and lost wages for civilians persons suffering reactions to the vaccine.

Question 2. Isn't it true that the federal smallpox workers' compensation program proposed by SEIU, AFSCME, AFL-CIO, and others would provide more generous compensation than would be available under any of the existing state compensation programs?

As described above, there are significant gaps in state workers' compensation coverage that will deny necessary medical care and lost wages to civilians who agree to serve the Nation by receiving the smallpox vaccine. The American Insurance Association, whose member companies provide workers' compensation insurance, has stated that adverse reactions arising from the federal smallpox vaccination program do not even qualify as compensable injuries.

Since the federal smallpox program has been ordered by the President, acting in his capacity as Commander-in-Chief to protect the Nation, and since the special circumstances and reactions to the vaccine all result from the federal program, a federal compensation program is required to close all of the gaps in state workers' compensation programs that will very necessary medical care and compensation to affected workers and patients. We also believe that rather than compare our proposed federal compensation program to workers' compensation, it is important to look at what DoD is providing in terms of compensation to military personnel who are injured by the vaccine.

Patients or household members who become ill as a result of contact with a first responder who has received the smallpox vaccine will, under no circumstances, be eligible for any coverage under state workers' compensation laws. Their only recourse is under the Federal Tort Claims Act, as specified by Section 304 of the Homeland Security Act. As the Committee is no doubt aware, such claims are virtually impossible to win since they require proof of negligence in the manufacture or administration of the vaccine. What we have here are adverse consequences that are a known result of the vaccine. In these circumstances, no one is likely to recover under the FTCA. Moreover, few, if any courts will find negligence under the circumstance described by the President in his declaration of December 13, 2002 and the Secretary of Health and Human Services Declaration of January 24, 2003.

Question 3. Why should we create a workers' compensation program that gives preferential treatment to smallpox vaccine injuries over other kinds of injuries?

The federal smallpox vaccination is not, as CDC Director Julie Gerberding has stated, a public health program. It is a national security program conducted in time of war. Just as the Armed Forces of the United States are fully protected with all necessary medical care and compensation for themselves and their household members to defend the Nation against a terrorist smallpox attack, so each civilian who volunteers to serve the Nation at the request of the President of the United States must be fully protected with all necessary medical care and compensation. More-

over, full medical care and compensation must be provided to household members and patients who become ill as a result of exposure to a person vaccinated under this federal program. To do anything less is to jeopardize the safety and security of the American people.

Question 4. Having reviewed the proposal put forth by SEIU, et al., I noticed that there is no prohibition on workers from seeking recovery under both this new federal and a state workers' compensation program.

Is that intentional, or would this new federal compensation program be the exclusive remedy?

If a state's workers' compensation program does coyer such injuries, shouldn't a worker be required to go through that state's compensation program?

We agree that if a state workers' compensation program does cover such injuries that it would be the first source of benefits. An injured worker would only seek recovery from a federal compensation program for health costs and lost wages and benefits if the state workers' compensation program does not cover any or all of the health costs or lost wages and benefits. It is not our intention that an injured worker should receive double payment. However, we strongly believe a federal compensation program must be in place to ensure that any injured worker, and in case of death, receives appropriate payment, if not covered from any other source, for health care costs, lost wages and benefits, and pain and suffering.

Question 5. The proposal put forth by SEIL", et al., would require employers to give employees up to four days of paid leave for workers who don't feel well after being vaccinated.

Why can't regular sick leave take care of this? Why should we give more rights to this group of people to get a special type of sick leave?

Should an employee who develops a sinus infection while serving with the Army Reserve over the weekend get a special type of sick leave?

As stated in the response to Question 3 above, the federal smallpox vaccination program has been ordered by the President of the United States to protect the Nation in time of war. Just as all military and civilian personnel vaccinated under the DoD's smallpox program receive all necessary medical care and compensation, so, too, should all civilians who are first responders.

Many first responders do not have sufficient sick leave. It is also important to note that the reactions caused by the smallpox vaccine are not naturally occurring diseases like a sinus infection. All available medical and epidemiological research makes it clear that certain illnesses are predictable and direct consequences of receiving or coming in contact with one who has received the federally administered smallpox vaccine.[3]

With specific reference to the Army Reserve, it is our understanding that an Army Reserve individual DOES get a "special type of sick leave" if injured during his or her service. If a Reserve soldier suffers an injury or illness related to his or her service, then he or she is placed on active duty but unable to perform status until the injury is healed to the degree that he or she could return to active duty. At that point, he or she is returned to Reserve status and to their civilian job. If the injury does not heal, the person can be discharged from the military with a disability—thus allowing access to VA for long-term treatment.

With the example of the sinus infection, the person would probably not get this special status because a sinus infection would not prevent the person from fulfilling, their active duty requirements—nor would it be possible unambiguously to determine that the infection was caused in the line of duty over the weekend.

However, if a Reserve soldier contracted a significant illness, including having an adverse reaction to the smallpox vaccine, during their 2 week service (where it would be clear that they sot sick during their service) they would be retained on active duty. (There is a big differences between a sinus infection and adverse reactions to the vaccine, which are known.) They would be treated at a military hospital until they are able to perform their duties again—at which point they would return to civilian service. Anyone who is genuinely injured due to their service in the Reserves is in fact given a "special type of sick leave". Furthermore, DoD has decided that if a spouse or child of a reservist gets sick, the reservist will be put on active duty so that DoD insurance care-taking can be extended to the family member. We should be doing no less for civilian responders who are injured as a result of the smallpox vaccine and have right to paid "sick leave" after volunteering to help their country during a period of crisis.

Question 6. The proposal put forth by SEIU, et al., prohibits discrimination or retaliation in the workplace based upon an individual's refusal to be vaccinated. As

[3] Kent A. Sepkowitz, M.D., How Contagious Is Vaccinia? N Engl J Med 348;5, January 30, 2003.

part of this, it imposes an appeal process and protections similar to those provided to whistleblowers under the Energy Reorganization Act. However, the proposed anti-discrimination provisions do not deal with whistleblowers.

How is a proposal designed to protect whistleblowers applicable or even appropriate in this case?

Why should we create legislation—one which creates a new private cause of action against employers—to address a practice that we have no evidence has even occurred?

Congress has routinely enacted legislation to prevent employers from retaliating against employees who assert their rights under the Constitution, federal statutes, regulatory and executive orders. [4]

When he announced the federal smallpox program on December 13, 2002, the President was very clear that the program must be a voluntary program. No individual may be compelled to receive a smallpox vaccination unless he or she freely decides to do so. The Institute of Medicine, in its January 17, 2003 Letter Report to CDC Director Gerberding stated:

> "It is easy to imagine situations whereby a potential vaccinee will not feel free to decline vaccination. A potential vaccinee might not wish to disclose fears about the risk of the vaccine, particularly in regard to one's own or a personal contact's HIV or pregnancy status, or even the fear of treating a smallpox victim. While in large hospitals or public health departments, other vaccinees might be available to volunteer for sevice, in small hospitals, a potential vaccinee might be the only worker with a specific, essential expertise and to decline could put the hospital or clinic at risk of incomplete coverage in the case of a smallpox outbreak. To decline vaccination could lead to rumors about the health status of decliners or their family members. Thus, a vaccinee who would otherwise decline to Volunteer for vaccination might feel coerced into participation." [5]
>
> "Vaccinees should not feel any pressure to receive the vaccine, for fear that a medical condition that they do not want to disclose may be discovered by the vaccination clinic or potentially, by their employer."

Pressures to vaccinate sufficient numbers of first responders at hospitals throughout the country have been great, however, and there have already been news reports citing retaliatory action taken against maritime workers who refused to be vaccinated. [6] Consequently, it is necessary to protect employees against potential discrimination that could well arise if they refuse to participate in the vaccine program. State workers' compensation laws routinely protect employees filing claims from employer retaliation. Similarly, Congress saw fit to protect energy workers and mass transportation workers from the actual and perceived threats of employer retaliation. The federal smallpox vaccination program is too important to the security of the Nation not to be administered in a manner which fully protects individual rights and the public's health. Indeed, the Institute of Medicine has also cited the need to protect individual rights in the smallpox program by requiring a comprehensive process of informed consent. The antidiscrimination provisions proposed are vital component of that effort because the dangers of vaccinating people who should not receive the vaccinia far outweigh the burden to an employer who discriminates against workers for exercising their rights.

There are numerous safety and health, environmental and other statutes that include antiretaliation provisions and procedures for work-related activities. These include the Energy Reorganization Act, the Surface Transportation Act, the Mine Safety and Health Act and many others. These statutes coyer a range of different kinds of protected activities (e.g. whistleblowing, exercising rights, refusing hazardous work). The Department of Labor has been given responsibility for enforcing these various provisions. We suggested the Energy Reorganization Act as an example since it includes an administrative mechanism for considering and deciding complaints, rather than requiring court litigation, a process that we believe is too cumbersome. For smallpox vaccination legislation, we would propose that anti-retaliation protection be provided for workers who decline to participate in the program and for workers who suffer adverse effects.

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[4] See e.g. Civil Rights Act of 1964, as amended, 42 USC §1983; Black Lung Benefits Act, 30 USC §938; FLSA, 29 USC §215(a)(3); Workforce Investment Act, 29 USC §2938(4); OSHA, 29 USC §660(c); Equal Employment Opportunity Act; 32 USC §12203; and Family & Medical Leave Act, 29 USC §2615.

[5] IOM Letter Report, January 17, 2003, p. 12.

[6] NY Times, TX news reports.

Question 7. The proposal put forth by SEIU, et al., requires that "only the safest and most efficacious needles meeting the requirements of OSHA's BBP standard may be used." The proposal also requires the FDA to issue a license for the use of a sheathed-bifurcated needle before the commencement of the vaccine program.

Doesn't this proposal go beyond the requirements of the BBP standard by requiring the use of a specific-FDA approved needle?

The proposal would also extend OSHA's BBP standard to state and local public employees, including those states that are not OSHA state-plan states. This is a significant extension of OSHA's jurisdiction. Are there any existing OSHA requirements that extend to state and local public employees in non-OSHA plan states?

In April 2002, the FDA approved the licensing of bifurcated needles with integrated safety features by a company called Univec. The needle is identical to the Precision conventional bifurcated needle, except that it is attached to a needle hub (like a conventional syringe) and has a sliding sheath safety feature.

Univec is currently selling these needles to health departments and others to use to practice giving smallpox injections. In an unscientific survey of SEIU nurses, these nurses prefer the safer Univec needle over the conventional Precision product. First, the needle is much easier to hold (remember, 30 years ago nurses did not wear latex gloves, which makes it that much more difficult to hold the small conventional bifurcated needle). Secondly, the needle has a sliding sheath mechanism, similar in design to other safer needles on the market that meet OSHA's definition of a needle with integrated safety features.

Even though the FDA licensed this safer bifurcated needle, this needle was not licensed as part of the complete kit submitted by Wyeth to the FDA. Therefore, this safer bifurcated needle cannot be used to administer the smallpox vaccine according to the FDA. For the safer needle to be legally used, we are told by FDA staff that Wyeth would need to submit a supplement to their smallpox vaccine application and seek such approval from FDA.

What we are seeking in legislation is the requirement that the safer bifurcated needles be used in the administration of the vaccine if it is approved by the FDA for this purpose and if it is available to the states. As part of this national security program, CDC has purchased and distributed 50 million conventional needles as part of a vaccine kit without giving health departments, hospitals and health care workers the opportunity to use a safer device. It would also appear to make little sense to distribute a safer device as part of a vaccine kit only for the private sector and state and local health care facilities in OSHA state-plan states. Consequently, we recommend that the safer bifurcated needle be made available to all health facilities, both public and private, administering the vaccine. We are not asking for a change in the OSHA standards to accomplish the goal of using safer needles as part of this unique national program. If licensed by FDA as part of the vaccine kit, CDC can simple use the sheathed needles as part of the kit rather than the unsheathed.

[Whereupon, at 12:20 p.m., the committee was adjourned.]

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