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IMPLEMENTATION OF SMALLPOX VACCINATION PLAN

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

SPECIAL HEARING

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IMPLEMENTATION OF SMALLPOX VACCINATION PLAN

WEDNESDAY, JANUARY 29, 2003

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Harkin, Murray, and Landrieu.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, everyone. The hour of 9:30 having arrived, we will begin this hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education. Today we are going to be examining the issue of smallpox, the risk which America and the world faces from a smallpox bioterrorist attack, and what the risks are on inoculation, how well-prepared the United States is to deal with this issue, and it is the fourth in a series of hearings conducted by this subcommittee.

Our first hearing on the subject occurred in 1999, before 9/11, actually on March 16, 1999, to determine the status of the Health, Human Services biopreparedness. Then on October 3, just 3 weeks after 9/11, a hearing was held on the subject of supplemental appropriations, and we were driven out of the Hart Building and out of the Dirksen Building, where we are holding this hearing, by an anthrax attack, and we had to convene the hearing in the bowels of The Capitol, and at that time, we made the request of the Center for Disease Control to provide this subcommittee with a comprehensive list as to all of the potential problems of bioterrorism.

Two additional hearings have been held since October 3, 2001. Actually, this is the fourth, and we are joined by our companion committee, the authorizing committee on Health, Education, Labor, and Pensions, which will be holding a series of roundtable discussions on this subject, which is obviously of great importance.

Last night, in the President's State of the Union speech, he enumerated a number of bioterrorist potentials from Iraq and from Saddam Hussein, and detailed them with some substantial specificity, so we know a real problem does exist. We will be considering two issues of risk, the issue of risk from attack, and the issue of risk from an adverse reaction.

PREPARED STATEMENT

With unanimous consent, a formal opening statement will be included in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

This morning, the Subcommittee on Labor, Health and Human services, and Education will discuss the issue of bioterrorism-preparedness and the implementation of the smallpox vaccination plan. This is the first in a series of hearings in the Congress on this subject. As appropriators, we will focus on the issues of cost, compensation, and safety related to our efforts on smallpox and other biological weapons. Tomorrow, the Health, Education, Labor & Pensions Committee will hold a complementary roundtable discussion of these issues.

This is this subcommittee's fourth hearing related to bioterrorism preparedness. On October 3, 2001, less than a week before the diagnosis of anthrax in a Florida man and the discovery of an anthrax-tainted letter in the Senate, we examined these issues. Two weeks later, Senator Harkin and I were forced to conduct a follow-up hearing in the Capitol as the Senate office buildings were closed due to anthrax contamination.

In fiscal year 2002, over $2.83 billion were appropriated by this subcommittee in the effort to prepare our Nation for potential biological attacks. Among other things, these funds were to be used to: (1) strengthen infrasture at the centers for disease control & prevention and State and local health agencies, (2) fund research into preventions and treatments for likely agents of bioterrorism, and (3) to buy enough smallpox vaccine for every American. Today we will see the status of these efforts.

We have before us this morning, the distinguished directors of two key agencies in the defense of our Nation against biological attacks. The Centers for Disease Control & Prevention is leading the effort to implement the smallpox vaccination plan. The National Institute of Allergy & Infectious Diseases is the lead NIH institute on bioterrorism-related research. Members of our second panel represent groups that will administer the vaccine or be asked to volunteer to be vaccinated.

STATEMENT OF JULIE GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. At this time, we will turn to our first panel, and our lead witness is Dr. Julie L. Gerberding, Director of the Centers for Disease Control and Prevention. She also serves as associate clinical professor of medicine at Emory University, a bachelor and M.D. degree at Case Western in Cleveland, and a master in public health from the University of California in Berkeley.

Dr. Gerberding, thank you for joining us, and we look forward to your testimony.

Dr. GERBERDING. Thank you. I really do appreciate the opportunity to be here to participate.

Senator SPECTER. Dr. Gerberding, when you start, let me remind you what you have already been told. We try to stick to a 5-minute time limit on opening statements. That may seem short. I recently was a speaker at Ambassador Annenberg's memorial service and got 3 minutes, which is the amount of time that former President Ford got and Secretary of State Colin Powell got, so I want you to know that a 5-minute allocation would be considered in some quarters generous.

Dr. GERBERDING. Generous. Thank you.

Senator SPECTER. Let us restart the clock at 5 minutes.

Dr. GERBERDING. Thank you for that. I really appreciate the opportunity to be here and to address you and the committee about the status of the smallpox preparedness program, and we also really thank you and Senator Harkin for the support you have given

us for the terrorism preparedness. We did disseminate $1.1 billion this year to State and local health departments and hospitals to assist us in this effort, so without your support we would not be where we are today.

If I can just have the first graphic here, I want to remind everyone what we are dealing with and why we are here. Smallpox is a deadly and disfiguring disease. It is contagious, and even though we had eradicated natural disease from the face of the earth, we know that it does pose a threat, that there is a possibility of a smallpox attack, and we must take steps to prepare our Nation and to protect our public.

Now, preparedness really consists of four major components. We have got to have policies, we have got to have plans, we have got to have products such as vaccines and antidotes to the side effects, and we have got to have people who are prepared and trained to implement the program. I am going to just make a few comments about each of those four elements.

First of all, as you know, the President stated the smallpox vaccination policy last December, and he advised immunization for the military troops who would be at risk, for civilians who would be part of the initial smallpox response teams that would manage and take care of the initial cases, and for responders and health care workers, who would be at occupational risk for exposure should an attack occur.

The President did not recommend immunization of the civilian population at this time, but he did tell us we needed to be prepared to find a mechanism to give vaccine to the general public for those members of the population who insisted upon having it.

Our planning has progressed rapidly. If I can have the next graphic, it just illustrates in very broad terms the state of our smallpox preparedness before December of 2002, and the way our preparedness looks now. Our States have done a heroic job of rising to the occasion and getting funds both for pre-event immunization of these response teams as well as plans to ensure that we can immunize the entire population in a hurry if we had to, should an actual attack occur. So as of today, we have approved plans for all 50 States for mass vaccination and plans for all 50 States for immunization of the response teams.

Now, what is the timing of this implementation? If I can have the next graphic, I just, in very general terms, want to show you how we are going about implementing the program. Over on the left-hand side of this, two points. First of all, the initial allocation of the appropriation was made in February of 2002. The remaining 80 percent of the funds, of the $1.1 billion, was distributed by June.

In December, the President announced his policy. On January 24, the State of Connecticut was the first State to initiate in a small number of vaccinators the civilian immunization program for responders, and what you can see, then, to the left of this curve is how we propose to expand this program as safely and as efficiently as we possibly can over the next several weeks to months.

Our priority is to immunize the smallpox response teams, but as individual States get up to speed and can do this safely, they will expand to include the broader group of health care workers and first responders who could be at occupational risk, and there is no

time line for completion but, as I said, we are doing this as expeditiously as we safely can.

As of today, in terms of the products necessary for this, the vaccine, we have delivered 98,600 doses of vaccine to 19 States and Los Angeles County. 35 States and Los Angeles County have requested that 187,000 doses of vaccine be delivered in the next several days to weeks, so we are working with States that have heroically risen to this occasion and really are now prepared and approved to receive vaccine and initiate their programs.

PREPARED STATEMENT

Finally, let me just conclude with a statement about the people involved in this. Their safety is our highest concern, and we are engaging in a number of educational programs to educate the vaccine volunteers, the vaccinators in the clinics, the clinicians around the country, and the general public, and we have made many steps to do this, and most notably, I think, in the next few days we will be delivering 3½ million information packets to clinicians around the country to ensure that they can safely take care of the people and advise them about their choice to participate in the program.

So thank you very much again for the opportunity to be here, and I look forward to your questions.

[The statement follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

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 United States.

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.

Senator SPECTER. Thank you very much, Dr. Gerberding. Just a few questions before turning to Dr. Fauci. You commented about, in excess of $1 billion being distributed. This subcommittee had urged a very substantial funding after 9/11, and that was an outgrowth of the October hearing which we had, so that we had close to $3 billion in the supplemental appropriations bill.

The Center for Disease Control has been in urgent need of repairs for many, many years, and it was only when this subcommittee made a site inspection 2½ years ago that we found out

how deplorable the situation was, and in advance of 9/11 this subcommittee took the lead in putting up $170 million to renovate the CDC.

We saw, I personally saw a deplorable situation, with distinguished scientists in quarters and with potentially toxic substance without adequate security, and to have a facility like the Center for Disease Control in that situation was just really astounding. And then the following year, we put up some $255 million. We are on a path to reach in excess of $1 billion to renovate the Center for Disease Control.

This subcommittee has been very, very attentive to medical research and the kinds of issues which you face. Senator Harkin and I have taken the lead on this subcommittee to double the NIH funding, so that it started out at about $12 billion in fiscal year 1996, and with this year's appropriation, we will exceed $27 billion, so it is very important that this subcommittee be informed as to the specifics as to what you need.

Now, you say that you have distributed $1.1 billion at the present time?

Dr. GERBERDING. That is correct.

Senator SPECTER. And what is the basis for that distribution? How do you decide who gets what?

Dr. GERBERDING. This year, the appropriation was divided into the $918 million that went to health care, or to the State and local health departments, and the remainder went for hospital preparedness and the health care facilities.

Senator SPECTER. $918 million went to State and local——

Dr. GERBERDING. State and local health agencies.

Senator SPECTER [continuing]. Health agencies.

Dr. GERBERDING. 50 States, four metropolitan areas, and then several islands that are sovereign and need their independent appropriations. Altogether, there are 62 jurisdictions.

Senator SPECTER. 62 jurisdictions? How far does $918 million go?

Dr. GERBERDING. Well, it has certainly taken us further than we were the year before we got it. What we have asked the health departments to do is to address 16 critical capacities that deal with preparedness for terrorism as well as other public health threats and emergencies.

That includes the kind of planning and program implementation that I discussed. It includes rehabilitation of laboratory facilities, which were in dreadful shape in many jurisdictions. It includes the national pharmaceutical stockpile logistics, so that people can deliver and utilize the measures we have in the stockpile, and it includes provision for communication, alerting, training and overall preparedness of the clinician community.

Senator SPECTER. On Monday, the day before yesterday, Senator Santorum and I visited UPMC, the University of Pittsburgh Medical Center, and we observed a facility which they have set up for decontamination, and the University of Pittsburgh Medical Center has undertaken this on their own, on their own financing. They are seeking what we call an earmark from this subcommittee, but obviously the principal line of funding is going to have to come from the new Department of Homeland Defense, where there is some $38 billion allocated.

Now, admittedly, that has to cover a lot of lines, but I would like to have your evaluation as a follow-up to this hearing, Dr. Gerberding, as to what it is going to take to adequately fund State and local facilities. Wherever I go in my State, and it is just one State, I hear concerns about the adequacy of funding, and people are going to be going to the hospitals, and our public health infrastructure admittedly has been in a sad state.

Let the record show the witness is nodding. Now the witness is smiling.

Dr. GERBERDING. The witness is in complete agreement.

Senator SPECTER. It is a very tough issue, but we have to know the hard facts. You have got to tell us what it is going to take. This subcommittee has demonstrated in the past our capacity to provide what it takes, and I know the President is committed to this, but you professionals are going to have to tell us, and very candidly, for a long time we did not hear from the Centers for Disease Control about what you needed, and it was only when we went to Atlanta that we found out, and you have got to tell us what you need.

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE ON ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Dr. Fauci, we welcome you back to this subcommittee. You are a regular.

Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases, with the National Institutes of Health, came to the NIH in 1860—1968—

Dr. FAUCI. It seems that way.

Senator SPECTER. You have been there almost as long as I have been in elective office, Dr. Fauci—after completing his residency at the New York Hospital/Cornell Medical Center, a native of Brooklyn, M.D. degree from Cornell University Medical College.

Dr. Fauci and I had a lively discussion a few months ago about inoculations and who ought to bear the risk, and I took the position that parents, maybe even grandparents ought to make decisions. I did not want the Government to make a decision for my four grandchildren, and after a while, I think you agreed with me, Dr. Fauci.

Dr. FAUCI. Yes.

Senator SPECTER. We thank you for the very distinguished work you have done. We welcome you here and look forward to your testimony.

Dr. FAUCI. Thank you, Mr. Chairman. It is a pleasure to be here testifying to you and this committee once again on this important subject.

Dr. Gerberding has mentioned the horror of smallpox as a disease, so I will not spend more time on that, except to say in the context of my main theme, namely vaccination, that this devastating disease has shaped civilizations, killing more than 500 million people over the years, a fatal disease in 30 percent of cases, no treatment available. However, a vaccine that has been used now for decades and decades has been responsible for the eradication of smallpox in this country and worldwide.

The vaccine that was used in this country and was put into storage is what we call Dryvax. As you know, I testified before this committee, where we had 15 million in storage. That vaccine is greater than 95 percent effective, and in studies I reported to this committee sometime ago, we showed that, despite decades of storage, it not only maintained its full potency and take rate, but it also could be diluted 1-to-5. We will be using the undiluted Dryvax vaccine on the program that Dr. Gerberding described.

With regard to the adverse effects, these are the numbers that have been gathered from the 1968 cohort. For every million people vaccinated, there will be 14 to 52 serious life-threatening events. There will be 49 to 935 serious but not life-threatening, and one to two deaths per million. These are for primary vaccinees. People who have already been vaccinated have a considerably lower incidence of adverse events associated with this vaccine.

What do we do with adverse events when they are serious enough? We have a standard methodology for approaching. One of them is what we call Vaccinia Immune Globulin, which is derived from the plasma of people who have been vaccinated. It is an antibody that can block the Vaccinia vaccine. We currently have enough now to cover all the possible projected adverse events that we would see in the program that Dr. Gerberding described, and by the summer, we will have enough to cover over 300 million vaccinees.

We also have an experimental product, Sodopavir, which was originally used against sodomegaler virus, which is now in an IND, shown to be effective in animal models against smallpox.

Senator SPECTER. Dr. Fauci, when you now say you have enough to cover all of the adverse effects, quantitatively what do you mean?

Dr. FAUCI. We mean that if you use the projections we showed here of what you might expect per million people vaccinated, the program that Dr. Gerberding described would give you a projected amount that you might see within a bracket of the lower limit and the upper limit. We now have enough Vaccinia Immune Globulin within our stores that we could handle the response and the therapeutic approach to essentially those numbers of adverse events.

So remember, we were discussing months ago, do we have enough VIG, as we call it? The answer right now is yes, we have enough now, and we are making more, so that by the summer we will have enough so that if we have to vaccinate 300 million people we will have enough.

Senator SPECTER. Thank you.

Dr. FAUCI. You are welcome. We are striving for something very important, and that is an attenuated vaccine that would obviate this concern about toxicity. One of the ones we are working on is Modified Vaccinia Ankara, which is a modification of the vaccinia. It is attenuated. Experience in the field shows that they have very, very few toxic side effects and adverse events. We are rapidly pushing this to the point of being able to have enough to use, and that will likely happen within the next couple of years. There is also another attenuated strain that the Japanese use.

I am going to spend the last minute just very quickly reviewing the other types of countermeasures that we have, not only for

smallpox, but for other agents. I presented our strategic plan and our category A research agenda to this committee last year. We now have completed and have published the research agenda for category B and C pathogens.

All of this is anchored on the concept that we will use the basic research agenda that is tried and true and tested at the NIH, but the shift of the paradigm will be a much greater emphasis on the translation of that basic research into new, definable product countermeasures such as diagnostics, therapeutics, and vaccines. Obviously, this will require close collaboration with academia, and particularly with our industrial partners.

Then finally, on this last slide, I talk about what we would say, the preparedness from a research standpoint. To compliment the preparedness that Dr. Gerberding spoke about from a public health standpoint is the vision of the future, to be able to have universal antibiotics and antivirals that could be used against multiple agents, safe and effective new generation vaccines, as well as advances in our capability of modulating the immune system and, finally, molecularly based diagnostics.

PREPARED STATEMENT

At the end of the day, this will have two purposes. One, I believe it will effectively defend us against agents of bioterror, but also what it would do, it would serve as well to be able to defend the population of this country and the world against naturally occurring emerging and reemerging microbes.

Thank you. We would be happy to answer any questions you have.

[The statement follows:]

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

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 United States of America 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 percent 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 United States 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 il-

luminate 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 developed 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.

Senator SPECTER. Thank you, Dr. Fauci.

Before we turn to questions, I would like to turn to our very distinguished Ranking Member, Senator Harkin. We exchange the gavel from time to time and, I like to say, seamlessly. Tom Harkin and Arlen Specter learned a long time ago if you want to get some-

thing done in Washington, you have to be willing to cross party lines. And when you deal with health, that is a public matter.

Tom.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. I apologize for being late. There was an accident in the tunnel out here and I got stuck in the tunnel.

First of all, let me thank you for calling this hearing, Mr. Chairman. This is something that is of vital importance.

I will wait for my turn for questioning.

Senator SPECTER. Okay.

Senator Murray, would you care to make an opening statement?

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Mr. Chairman, I appreciate you having this hearing. I will just submit my statement for the record, but I will just say, this is a huge concern in many communities across my State, as I hear from hospitals and cities who are now feeling the burden of having to implement the vaccines, and a lot of questions about why, how, who is going to pay for it, what the risks are, and so I really appreciate your having this hearing today. I think we need to have these questions answered for our communities.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Mr. Chairman, we all recognize that smallpox poses a threat. The questions we must answer are: How big is that threat? And is the administration's plan appropriate and adequately funded?

From the Anthrax incident here in the Senate, we learned that we need to be prepared.

But today as we consider smallpox, many health care providers and hospital administrators do not have the information they need.

It's hard for them to evaluate the risks and benefits of inoculating their emergency response personnel.

There are simply too many unanswered questions and very few guidelines for helping health care professionals make this important decision.

This uncertainty has led S.E.I.U.—one of the major unions representing nurses—to advise its members to not receive the smallpox vaccine.

Similarly, many hospitals—including several in Washington state—have decided to not participate in Stage One of the Smallpox Response Plan.

We are already asking so much of our emergency room doctors and nurses. We shouldn't ask them to accept these new risks without giving them a better understanding of the actual threat.

Clearly, the administration needs to do a better job of communicating the threat and the potential risks.

I also share the concern of many in my state that unfunded mandates on smallpox will limit their ability to respond to outbreaks of T.B. and other infectious diseases.

In addition to urging the administration to provide more information about the risks and benefits, and to provide adequate funding, I would also urge the Administration to allow access to compensation for those workers who are injured or who suffer adverse health effects from the vaccine.

Relying on Workers Compensation is not the answer because the threshold is set too high, and the outcome is too uncertain.

Recently, I joined with several Senators in sending this message to the White House. I would urge today's witnesses from the administration to carry this message back.

Injured workers and patients should be justly compensated for injury and harm.

As we address the smallpox threat, let's make sure we provide the information, the funding, and the compensation to enable our state and local governments and our health care professionals to respond appropriately.

Senator SPECTER. Thank you, Senator Murray. We will have 5-minute rounds, which is the custom of the subcommittee.

At the outset, my question goes to our preparedness on a long list of potential bioterrorist attack items. We asked the Center for Disease Control about this, and we got this listing last year: anthrax, botulism, plague, smallpox, tularemia, viral hemorrhagic fevers, brucellosis, Epsilon toxin, salmonella, escherichia coli, Glanders, melioidosis, psittacosis, Q fever, ricin toxin, staphylococcal enterotoxin B, typhus fever, viral encephalitis, water threats, and the list goes on and on. I will make these a part of the record so that the recorder will know how to spell them. Maybe somebody even knows how to pronounce them.

[The information follows:]

BIOLOGICAL DISEASES/AGENTS

CATEGORY A

Anthrax (Bacillus anthracis)
Botulism (Clostridium botulinum toxin)
Plague (Yersinia pestis)
Smallpox (variola major)
Tularemia (Francisella tularensis)
Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])

CATEGORY B

Brucellosis (Brucella species)
Epsilon toxin of Clostridium perfringens
Food safety threats (e.g., Salmonella species, Escherichia coli O157:H7, Shigella)
Glanders (Burkholderia mallei)
Melioidosis (Burkholderia pseudomallei)
Psittacosis (Chlamydia psittaci)
Q fever (Coxiella burnetii)
Ricin toxin from Ricinus communis (castor beans) NEW!
Staphylococcal enterotoxin B
Typhus fever (Rickettsia prowazekii)
Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
Water safety threats (e.g., Vibrio cholerae,Cryptosporidium parvum)

CATEGORY C

Emerging infectious disease threats such as Nipah virus and hantavirus

CATEGORY DESCRIPTIONS

Category A Diseases/Agents

The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they

—can be easily disseminated or transmitted from person to person;
—result in high mortality rates and have the potential for major public health impact;
—might cause public panic and social disruption; and
—require special action for public health preparedness.

Category B Diseases/Agents

Second highest priority agents include those that

—are moderately easy to disseminate;
—result in moderate morbidity rates and low mortality rates; and
—require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

Category C Diseases/Agents

Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of

—availability;

—ease of production and dissemination; and

—potential for high morbidity and mortality ratesand major health impact.

Senator SPECTER. Dr. Fauci, let me start with you. We are just talking about one of them today. How well-equipped are we to deal with this long litany of potential risks that somebody may hurl at us?

Dr. FAUCI. It is getting better prepared and better prepared, Mr. Chairman. That is the reason why I showed that slide of the research agenda. At least from the research standpoint, and Dr. Gerberding could comment on the other aspects of it, from the research standpoint, we are specifically targeting essentially the microbes that you mentioned on that list, and I will give you a few very brief examples.

In anthrax, we are working on now what we call the second generation anthrax vaccine. The first one is a more crude vaccine in which you take the supernatant from the cultures of anthrax, and use that to inject it as a vaccine. Using molecular techniques, we now have what is called the recombinant, using recombinant DNA technology, a protective antigen. It is referred to as RPA, and that antigen is highly immunogenic in inducing an immune response, and our hope is not only to have a better, safer vaccine, but also one that does not have to have six vaccination immunizations in the program. Two or three is what we are aiming for.

The other one that we feel is very important that you mentioned is botulism toxin. We have horse antiserum against it. We need to increase that supply, and we have accelerated our research effort to develop a monoclonal antibody against botulism toxin so that it can be used safely and in unlimited quantities.

The final, last example, just as a prototype of what you are referring to, ebola, one of the hemorrhagic fevers that you mentioned, the third, I believe, or fourth or fifth on your list, we have already shown in an animal model that the vaccine that was developed at the NIH against ebola protects a monkey from intraperitoneal challenge from live ebola, and we will be starting phase 1 safety trials in humans in calendar year 2003, so we are making steady, and in some cases rather rapid and impressive progress on the whole array of microbes that you listed in your menu there.

Senator SPECTER. Well, Dr. Fauci, are you saying that we are prepared for this entire laundry list?

Dr. FAUCI. No, we are not prepared. We are not, Mr. Chairman. We are not prepared right at this moment, but we have them—those microbes—in our crosshairs. We have targeted them and some of the ones you have mentioned we actually already have very good antibiotics against them.

Senator SPECTER. Well, what I would like to have you submit to the subcommittee, going over this list, is which items we are prepared for, which items we are not prepared for, what we need to get prepared for all of the items. That is really what we have to make a determination on, and what will the cost be in preparing on all of these items.

Dr. FAUCI. We have actually done that, Mr. Chairman, and we can get an updated version of that to you relatively quickly.

Senator SPECTER. And the other question is, how confident are we that this list is everything? Is it possible that somebody out there may have some other bioterrorist items that are not on this list?

Dr. FAUCI. That is always a possibility, not only an item that might not be on the list—it is unlikely there would be a microbe we have never heard of. That would be extremely unlikely, but what could happen, and there is a feasibility we are concerned about in trying to prepare for, is the genetic mutation of some of those microbes to get them to perhaps elude the antibiotics, where they exist, that we have for them, and/or the body's immune response that you would expect from the vaccine, so that is a concern, and an important part of our priorities is how do we counter the genetic manipulation of microbes?

Senator SPECTER. Before turning to Senator Harkin for his line of questioning, let me say—I have been advised that C-SPAN is starting to carry our hearing live—that we are conducting a hearing, the fourth in a series by this subcommittee, on the potential of bioterrorism, and our focus today is on the issue of smallpox, and we have two experts with us at the moment, Dr. Gerberding from the Center for Disease Control, and Dr. Fauci from the National Institutes of Health, and we are going over the areas of risk of smallpox, the items of risk of other potential bioterrorism items for attack, what progress has been made, and what needs to be done for the future.

At this time, let me yield to my distinguished colleague, Senator Harkin.

Senator HARKIN. Mr. Chairman, thank you again for your leadership on this committee, and for your leadership especially in the whole area of meeting our needs in public health.

As you indicated, we have worked closely together on this. This is truly one of those issues that transcends any kind of party lines, and, again, I would just thank you for continuing this effort to ensure that our public health sector in this country is reinvigorated and rebuilt.

I think we discovered after September 11 that our public health facilities in America had been neglected for far too long, and we as a Congress and the President have committed ourselves to rebuilding and reinvigorating that public health structure throughout the United States. We have provided the funds to do so, and I believe there is a commitment here to continue to provide whatever funds are necessary to upgrade and ensure that our public health facilities around America are first-class, and are ready to meet present needs, but any emerging needs that we might have in the public health sector.

I want to thank you, Dr. Gerberding, for your leadership in this area as the head of the Center for Disease Control and Prevention, and you, Dr. Fauci, for your many years of service to this country at NIH.

There is a lot of concern, I think, amongst us here, and in my State, that the funds that we have provided for upgrading our public health facilities are now going to be needed or siphoned off to

meet this proposal to vaccinate against smallpox on this broad basis that we are talking about. I think the decision has been made to move in that way, but where is the money coming from that will provide the support for the vaccinations?

I find a lot of concern that our State Public Health Directors are saying:

"Wait, you have just given us the money to start upgrading our facilities. We are doing that now. Now we have to slow that down, or stop that, and siphon money off of that for smallpox vaccination."

I guess I would ask you, Dr. Gerberding, to comment on that. How much money are we talking about total that we are going to need for the phase 1 for all the first responders, and if we do decide to go into phase 2—I do not think that has been decided yet, has it? Phase 1 and 2 have been decided. How much are we talking about, in terms of total amounts of money, is that going to cost? Do we have any idea? Can you tell us?

Dr. GERBERDING. This is a very difficult question. I appreciate your asking it. We did put out the $1.1 billion this year for general public health preparedness for terrorism and other threats, and when we put that money out, we were not prepared to implement the vaccination program with those dollars, and so we have to look at what investments have we made that can contribute to this program, and are there gaps in what we have put out, and what is really needed to bring this program forward?

We are providing the vaccine free. We have invested in infrastructure and things like how to deliver the pharmaceutical stockpile, how to train clinicians to be prepared, and so forth, and we have looked at some of the estimates that our colleagues in the States have provided us. At CDC, we did an economic assessment which looks at the indirect and direct costs of the program to get some handle on this, but it is very, very difficult to know, mainly because we have never done this before.

If we look just at what it costs to actually deliver the vaccine to people, to get it into people's arms when they come to a clinic, we think that the cost-per-injection is somewhere between $10 to $15, and for planning purposes, we are using the figure of $13, but that estimate is made on the assumption that the money we just put out, plus the $918 million we expect we will probably be able to put out in August with the next installment of the appropriation from this committee, that we will be able to use that infrastructure to support this program, and we will have to monitor this and look at it as we go forward to identify any gaps.

Senator HARKIN. That figure you just gave me is a little bit better than what I have heard in the past, I must admit. I mentioned in a statement on the floor of the Senate here within the last couple of weeks in talking about this, I was looking at the cost, and it hit me that some of the figures I had been seeing of several hundred dollars a person just seemed to me to be way out of line with what it might cost to vaccinate someone for smallpox.

I hope we get a better handle on this, on just what we are talking about in terms of cost, and what we might have to help reimburse the States, or get money out to the States to help them afford this, but whatever it is, I do not want the—I think this is something we are going to have to deal with separately and apart

from the funding that we have already put out for the upgrading of facilities and to meet the bioterror, other threats we have out there that Senator Specter just talked about, and that you have talked about, Dr. Fauci. It has to be a separate type of thing targeted just for smallpox.

Dr. Fauci, this is a question I have about an article that appeared in The Washington Post about protecting against smallpox, and it says here, "who should not be vaccinated," and obviously, people with weakened immune systems, breast-feeding mothers, younger than 18 years of age.

Dr. FAUCI. Right.

Senator HARKIN. Is that right? I mean, children should not be vaccinated?

Dr. FAUCI. Right now, if you look at the program as it is constituted, health care workers, military, others, children are not included in that. In the case of an emergency, were we to get hit by a smallpox massive attack and we instituted a combination of the ring vaccination with the contacts as well as an extensive, Nationwide vaccination, we certainly would vaccinate children less than 18 years old.

We are talking about the situation right now with the vaccine as it is being used.

Senator HARKIN. Oh, I see. It is not that they are at any special risk, because obviously, when I got vaccinated against smallpox I was in grade school.

Dr. FAUCI. We all were vaccinated as children, but currently the vaccine we are using right now, for the purposes we are using it right now, is not going to be involving children.

Senator HARKIN. It is not a medical situation, then, in other words?

Dr. FAUCI. Well, certainly if you get to infants less than 1 year old, the problem with infants zero to 1 is higher than that in individuals who are older, but the difference between a 17- or 18-year-old and a 21-year-old is essentially nonmeasurable.

Senator HARKIN. I understand. Okay. I did not understand. I think I understand. Thank you very much, Doctor.

Senator SPECTER. Thank you, Senator Harkin.

Senator Murray.

Senator MURRAY. Well, thank you, Mr. Chairman. I think everyone here, particularly in this Capitol Building, is certainly aware of bioterrorist attacks after the anthrax situation that occurred a year ago, and we understand that prevention is important, and we understand the impacts of any kind of bioterrorist attack.

As I go out into my communities across Washington State, many people are expressing real deep concern to me about the risks of vaccinating a population in whole today, and I know that we are just looking at our first responders at this point and health care people who may be exposed early on, but there is a huge question in the minds of many of what kinds of risks we are taking, and what the real risk of a smallpox infection could be.

We all understand it is a horrible disease. We do not want to see any kind of attack occur that would harm our populations, but the question I get all the time is two-fold: What is the risk of this happening? And second: How are we going to pay for its implementa-

tion? There is serious concern in all of my communities—small, rural, suburban, urban—how they are ever going to be able to pay for this without funding from us, so let me start with the risk.

I think we all really want to know what are the real risks of a smallpox attack? Is this something that could potentially end up in the hands of terrorists? Can it be weaponized? Are there more sources than we know? I know there are two known sources, one in Atlanta, and one in Moscow. Are there more than that?

Can either one of you give me a solid answer of what is the real risk of a smallpox attack in this country?

Dr. GERBERDING. I can try to address part of your question. We cannot give you an absolute quantitation of the risk, but I do not think anyone can tell you what is the quantitative probability of a smallpox attack, and I cannot discuss all of the details because some of the information is, of course, classified, but I think our reading of the intelligence that we share with the intelligence community is that there is a real possibility of a smallpox attack from either nations that are likely to be harboring the virus, or from individual entities such as terrorist cells that could have access to the virus.

So we know it is not zero, and I think that is really what we can say with absolute certainty, that there is not a zero risk of a smallpox attack and, as Dr. Fauci pointed out, the disease is so terrible, and anyone in our country under the age of 30 basically has absolutely no immunity to this at all, that should an attack occur, it would be absolutely devastating situation for us, and we have to get our response capacity organized so that should that unthinkable thing happen, we would be able to take the steps we need to very quickly protect our entire country.

We are not recommending immunizing the entire country right now, because there are hazards from the vaccine, and the balance right now in the President's perspective, and he did a very thorough job of assessing all of the risks and benefits and complications of this policy, the conclusion was at this point in time the risk is not sufficient to justify exposing the entire population to the side effects, but we did need to step up to the plate and get our emergency response capacity ready to go should we need it.

Dr. FAUCI. Senator Murray, one other issue, just to answer another part of your question, I agree, we cannot quantify in any accurate way whatever what the risk is, we just cannot, but you asked a question about, can it be weaponized. At the time that the smallpox epidemic, pandemic was declared eradicated, and the WHO asked all of the nations who have supplies of smallpox to either turn it in or destroy it, and there were two, as you mentioned accurately, one in the Soviet Union and one in Atlanta.

The fact is, in the 1970s and 1980s, we know, absolutely documented, that the Soviet Union was mounting a massive biowarfare campaign and making dozens of tons of weaponized smallpox, so the answer to your question of, Can it be weaponized, the answer is, Yes, it can. Yes, it can. Yes, it has been in the past.

Supposedly, those stores have been destroyed, but one of the concerns, again with no definitive evidence, is that if you have dozens and dozens of tons of documented, made smallpox biowarfare at the time of the dissolution of the Soviet Union, when many of those sci-

entists and technicians were in some economic difficulties, the question always arises, could there have been a possibility that some of that material got out of the hands of the guards within the Soviet Union and happened to get into the hands of people who would use it in nefarious way?

I do not have any definitive intelligence that says that happened, but that is not an unreasonable possibility, since it is so easy to grow, and relatively easy to put in a form where you could make large quantities.

Senator MURRAY. Okay. So you can definitively say there are risks in not moving forward in some kind of vaccination?

Dr. FAUCI. Yes.

Senator MURRAY. But you can also definitively say that there are risks in vaccinating our population at the present time, and even on your own web site, you say who should not be vaccinated. I think Senator Harkin said those under 18, pregnant women, nursing women. The risks associated with vaccination are clear as well.

Some of the concerns I am hearing are it is not just the person who is vaccinated, but if they go home, they could infect someone they live with. Is that a real possibility?

Dr. FAUCI. Yes. That is called contact vaccinia, where someone gets vaccinated. That is almost exclusively, though not exclusively, but almost always happens in a situation where someone would go home in household contact of a child who is vaccinated, who passes it on to a sibling in the house, or someone who is vaccinated, and might pass it on to someone with whom they have close contact, like——

Senator MURRAY. A spouse to a pregnant woman.

Dr. FAUCI. Yes. That is an unusual situation, but it is not impossible. We have to realize that there is a risk, though it usually is when you vaccinate children, not exclusively. That is something that we do recognize when we engage in these programs.

Senator MURRAY. Knowing what that risk, then is, what are we doing to educate those who are now responsible in thousands of communities across the country who are being told now to vaccinate? How do we educate them, educate the people who are receiving vaccinations to make sure that we eliminate or as closely as possible reduce the risks associated with vaccination?

Dr. GERBERDING. We are taking many steps to educate a variety of target populations, but let us just start with the vaccine volunteers, the people who are considering whether they are able or willing to participate in this program. We have several different methods. We are using satellite broadcasts, we are using written materials, we are using webcasts, we are also training the clinicians. We are encouraging them to engage in conversations about their own personal risk and their hazard. We are preparing to distribute 3½ million copies of the important elements of this program to clinicians around the United States so that all of the nurses and doctors who might be asked questions or provide consultation will have that information.

We are also working with the public health system and all of the people putting together these clinics so that they can train others. We have put this kind of information in the hands of over 800,000

people so far, and we are working on expanding that even further as we speak.

Today, for example, we are initiating a program to help clinicians working in the vaccine clinics be able to run the clinic and recognize the adverse events of the smallpox vaccine.

Senator MURRAY. Mr. Chairman, I know my time is up. I would just say it is a long ways from Washington, DC to counties out in my State and rural communities, and a lot of steps along the way, and it is incredibly important that we spend the time to make sure people get the information so they can make good decisions about themselves. That has to be a part of that. I was not able to ask about cost, but that is an associated cost as well that we need to understand.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Murray.

Senator Landrieu.

OPENING STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman. I do have a statement to submit for the record. I will just make three very brief points, and I am, of course, interested in hearing from the panel.

First of all, although it is not the actual subject of our subcommittee, I do think that this whole issue should focus the Congress more directly on the nonproliferation issues. We have focused for many years on nonproliferation of nuclear weapons, but there have been calls in this committee. The subject of this committee should remind us and reenergize us into the issue of nonproliferation of biological and chemical weapons. It is one thing to deal with the consequences of an attack. It is another thing to spend some money on the front end in energy preventing the attack by identifying these materials and really investing on the front end, which is not the subject of this subcommittee, but is the subject of the Appropriations Committee generally, and how our resources as a Nation are being used.

Second, I would hope, Mr. Chairman, that our committee would be committed to picking up as close to 100 percent of this cost as possible for the States who are strapped budgetwise. This is part of our sort of defense as a Nation. I hope that we do not go into this looking at a 30–70 match, or a 50–50 match. Just like we pick up about 100 percent of the cost of our military, I think the Federal Government has a real obligation to try to minimize the cost and then pick it up as much as possible.

Third, what comes to mind on this subject is the fairness of our distribution system. It reminds me of the Titanic. When the boat or the ship hit the iceberg, you know, I remember the movie so clearly about all the wealthy people got the lifeboats and the poor people were locked in the lower part of the boat, and ever since I saw that movie, even as a young child, it was quite disturbing, and that view still stays in my mind.

So this distribution system, should an attack occur and we cannot rely on the fairness and equity of the health care system—there are some communities that have lots of nurses, lots of doctors, lots of hospitals, and lots of clinics, and then there are plenty of places, many of them in Louisiana, who have not seen a doctor

in a long time and have to actually recruit nurses to their communities. So this is a huge, huge undertaking for us to try to make sure that everyone is treated not according to the size of their pocketbook in the event of an attack, or their social status in their community, and it is a tremendous obligation we have, so I hope we will really think very carefully about that particular issue as we lay out and appropriate the funds.

PREPARED STATEMENT

The final point I want to make is with the turnover of our personnel, because the pay is usually low, people come in and out of our health care system all the time. I hope we are setting up a national certification, so whether you were trained as a nurse, but then went into another business, if an attack hits, there is a database available of people who have been trained and they can be called from other professions to the front lines, because that is what it is going to take, and that is going to take a whole rethinking of how we do training and certification, and it becomes sort of lifelong certification in the event, because we are in this for the long run.

Mr. Chairman, those are some of my thoughts.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Mr. Chairman, given that just four days have passed since the thirty-seventh Superbowl, an event that has become as much a part of America as apple pie, I thought it would be appropriate to begin my remarks this morning with a tried and true adage from the world of sports, "the best defense is a good offense." This certainly proved true for this weekend for the Tampa Bay Bucks and I think that it applies equally well to the subject at hand. Yesterday, in his State of the Union Speech, President Bush warned, "we must assume that our enemies would use these diseases as weapons and we must act before the dangers are upon us." The evidence suggests that he is right. I, for one, intend to do all that I can to ensure that America stands ready and that our people are protected.

As this committee knows, through the efforts of the Department of Health and Human Services and our state and local officials, America has stockpiled enough vaccine to inoculate our entire population in the event of a smallpox attack. Let that be a message to those who wish to harm us that we are ready to respond quickly and effectively to this emergency. The next step, of course, is to ensure that our plan for delivery of this vaccine is both safe and effective. As a member of the Armed Services Committee, I was briefed extensively about the dangers of mass hysteria in an event of this nature. Through careful planning and federal, state and local cooperation, we can safeguard the health and safety of all Americans.

I would like to personally thank and commend all of those volunteers who have come forward to form the Smallpox Response Teams. Once again, it is the men and women of our law enforcement, our doctors, nurses and other first responders who will help form the first line of defense in this war against terror. Because of you and the men and women of our Armed Forces, Americans can sleep easier tonight knowing that there are people who stand ready to protect them and the freedoms they love.

That being said, I have two concerns that I think need to be discussed further this morning. First, I think it is imperative that the CDC evaluate more fully investigate the rate of serious reactions, the effectiveness of current warnings on the risks of being vaccinated, and consider creating a smallpox vaccination compensation fund, which exists for other vaccines but not for smallpox. Without a reasonable way to reimburse people for their expenses and protect them from undue harm as a result of the vaccination, people may decline to be vaccinated, thus undermining the effectiveness of the program.

Second, I am concerned about whether enough thought has been given to the additional cost these vaccination efforts will place on our already struggling state, local and hospital budgets. Under the President's plan, 10.5 million people are scheduled

to be vaccinated in the next few months. This is yet another example of the President's apparent budget policy, "I say, they pay." Protecting the nation from a small pox attack and effectively managing a small pox crisis should, God forbid, one occur, is the responsibility of the federal government. Therefore, I think that we should be prepared to pick up 100 percent of this cost and not shift this burden to the States.

Finally, I think a lot more thinking has to go into how this plan will be implemented in the event of an attack. Knowing what I do about the vaccination process, it appears to me that it is an enormous task we are undertaking. I think that we must think about the many different communities that could be affected. Most importantly, I hope that we ensure that all Americans, regardless of the socio-economic status, age, or education, will have access to being vaccinated. This calls to mind the example of the Titanic, when they reached a crisis point, it was the wealthy who got the life-boats, the poor were left to die. I hope we will not repeat that mistake in the event of a bio-terrorist attack.

Again, thank you Mr. Chairman for calling this important hearing. I look forward to hearing from the panels.

Senator SPECTER. Thank you very much, Senator Landrieu.

We are going to move ahead to the second panel, but we would like for both Dr. Gerberding——

Senator HARKIN. Can I ask one follow-up question, please?

Senator SPECTER [continuing]. And Dr. Fauci to stay.

Senator Harkin, I am suggesting coming back to the witnesses. We have another panel with five witnesses, and my preference would be to call the next panel and then to ask Dr. Gerberding and Dr. Fauci to stay.

Dr. Gerberding, for example, has a vaccine kit which she wants to demonstrate, and we will come back to you, but I would like, as a matter of sequence, to proceed with the other witnesses.

Dr. GERBERDING. Thank you.

Senator SPECTER. We will call the second panel now: Dr. Brian Strom, Dr. Louis Bell, Mr. Patrick Libbey, Mr. James August, Ms. Jane Colacecchi.

STATEMENT OF BRIAN STROM, M.D., M.P.H. CHAIR, INSTITUTE OF MEDICINE COMMITTEE ON SMALLPOX VACCINATION, DIRECTOR, CENTER FOR CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS, UNIVERSITY OF PENNSYLVANIA

Senator SPECTER. Our first witness here, Dr. Brian Strom, is Chair of the Institute of Medicine Committee on Smallpox Vaccination, which earlier this month released a report advising CDC on its implementation of the vaccination program. Dr. Strom is also professor and Chair of the Department of Biostatistics and Epidemiology at the University of Pennsylvania, received his M.D. from Johns Hopkins and his master's of public health from the University of California at Berkeley.

Dr. Strom, welcome, and we look forward to your testimony.

Dr. STROM. Thank you, Mr. Chairman. Good morning, Mr. Chairman and members of the subcommittee. Thank you for the opportunity to come to speak with you this morning. As mentioned, my name is Brian Strom. I am professor and chair of the Department of Biostatistics and Epidemiology and professor of medicine at the University of Pennsylvania School of Medicine. I am also chair of the Institute of Medicine Committee on Smallpox Vaccine Program Implementation.

The Institute of Medicine and the National Academies is an independent, nongovernmental, nonprofit organization operating under the 1863 congressional charter to the National Academy of

Sciences. The Institute of Medicine has provided advice to the Nation on matters of health and medicine for over 30 years. The Centers for Disease Control and Prevention formally engaged the services of the Institute of Medicine in September 2002, and the Committee on Smallpox Vaccination Program Implementation met for the first time in December 2002.

The committee's areas of expertise include internal medicine, infectious diseases, including smallpox disease and smallpox vaccination, dermatology, pediatrics, nursing, epidemiology, public health law and ethics, public health practice, emergency medicine, and pharmacology. CDC charged the IOM committee with providing advice to CDC and its public health partners on how to best implement the President's policy on pre-event smallpox vaccination, addressing eight areas.

The IOM agreed to provide advice on these areas through a series of timely reports. During its first meeting in late December 2002, the committee heard from CDC, the Department of Defense, Israel's Ministry of Health, and representatives of health professional organizations. The information provided during these presentations and subsequent research were the basis for the committee's deliberations. Based on these deliberations, the committee released its first letter report on January 17, 2003, entitled: "Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation."

The committee would first like to convey its appreciation for the hard work of CDC and its State and local partners in planning the pre-event smallpox vaccination program and helping it to become operational so quickly. CDC has done a tremendous job under very tight time lines. The committee also recognizes that this is a program that is planned nationally but implemented locally. CDC is offering guidance, training, and assistance to its State and local public health partners, but the local programs will be making their own decisions about how and when to operationalize the pre-event smallpox vaccination programs in their communities.

Our report contains 23 recommendations which are summarized in appendix A of the report, and it has been submitted for the record. For the sake of time, I will not discuss all 23 recommendations during my testimony, but would direct you to the full report for a complete description. I will now focus on the committee's four key messages, and draw attention to a few of its recommendations.

The first key message was to highlight the unique nature of the smallpox vaccination program as a public health component of a national bioterrorism preparedness policy focusing on the delivery of clear, consistent, science-based information. The committee believes that it is critically important to stress to potential vaccinees and to the public that the pre-event smallpox vaccination program is not a typical public health program.

Public health vaccination programs are typically undertaken knowing the risks of a disease and knowing they outweigh the risk associated with the vaccination. With the pre-event smallpox vaccination program, the risk of the disease is based on a risk estimate derived by the President and his advisors based on national security issues. In this context, the individuals being asked to take

this vaccine are being asked to volunteer to join smallpox response teams for the benefit of the Nation's bioterrorism preparedness.

The committee believes that the unique aspects of the pre-event smallpox vaccination program need to be communicated clearly and consistently to the American public. Because the smallpox vaccination program is unusual, it is important for the American public to understand that practices in these circumstances might differ from those of traditional vaccination programs. A clear understanding of the risks and unique aspects of the pre-event smallpox vaccination program will be necessary to ensure that all potential vaccinees can make an informed decision about whether or not to participate.

Our second key message was to proceed cautiously, allowing continuous opportunity for adequate and thoughtful deliberation, analysis, and evaluation; embark on phase 2 only after adequate evaluation of phase 1 has occurred. The current program is designed with the best possible efforts in the limited time frame available, but on the basis of data that are decades old. Our scientific approaches have improved since then, and our society has also changed since then. This means that, as modern experience is gained, rapid and real-time mid-course corrections may be necessary.

I would like to stress that, by recommending that CDC proceed cautiously, the 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 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.

I would also like to stress that we have not recommended any specific time interval that is appropriate between the two phases. This is a matter of data analysis, not strictly a matter of time. Recognizing that the CDC has indicated that data analysis will be ongoing throughout phase 1, the time needed to analyze phase 1 data and evaluate the adequacy of different components of the program before embarking on phase 2 may range from hours, to weeks, to months. The committee believes that CDC will be able to determine when enough data analysis has occurred to commence phase 2 safely.

Our third key message was to use a wide range of methods for proactive communication, training, and education, and to customize it to reach diverse audiences, including potential vaccinees, all health——

Senator SPECTER. Dr. Strom, could you sum up at this point? You are over time at this juncture.

Dr. STROM. Sure. I will skip through, sure—all health care providers and the general public. Our last message was to designate one credible, trusted scientist as a key national spokesperson for the campaign and to sharpen and expand communication plans. The spokesperson could be Dr. Gerberding herself, certainly an articulate and credible scientist, or someone else.

Last, I just wanted to make a statement about compensation. Since current discussions about the pre-event campaign are focus-

ing on the issue of compensation for medical expenses or lost income for any health care workers who experience adverse reactions, I wanted to highlight the committee's recommendations there.

First, we felt that the informed consent forms need very explicit notification of the availability, or lack thereof, of compensation for adverse reactions.

Second, we thought that some adverse reactions would be covered by State Worker's Compensation, but others might not. There needs to be clarification about that.

Last, we were concerned that the lack of compensation for adverse reactions might imperil the ability of the pre-event campaign to achieve its goal of preparedness. There are currently no data to determine that, but we recommended that if it is determined that a lack of compensation is jeopardizing overall progress, then the CDC, HHS, and Congress should support all efforts to bring the issue of compensation for adverse reactions to speedy resolution.

PREPARED STATEMENT

Thank you for the opportunity to speak to you today. The committee hopes that its advice is useful to CDC and the broader community. I would be happy to answer any questions you may have.

[The statement follows:]

PREPARED STATEMENT OF DR. BRIAN L. STROM

Good morning, Mr. Chairman and members of the Subcommittee. Thank you for the opportunity to come speak to you this morning. My name is Brian Strom. I am Professor and Chair of the Department of Biostatistics and Epidemiology and Professor of Medicine at the University of Pennsylvania School of Medicine and Chair of the Institute of Medicine (IOM) Committee on Smallpox Vaccination Program Implementation. The Institute of Medicine of the National Academies is an independent, non-governmental, non-profit organization operating under the 1863 congressional charter to the National Academy of Sciences. The Institute of Medicine has provided advice to the nation on matters of health and medicine for over 30 years.

The Centers for Disease Control and Prevention (CDC) formally engaged the services of the Institute of Medicine in September 2002, and the Committee on Smallpox Vaccination Program Implementation met for the first time in December 2002. The committee's areas of expertise include internal medicine, infectious diseases (including smallpox disease and smallpox vaccination), dermatology, pediatrics, nursing, epidemiology, public health law and ethics, public health practice, emergency medicine, and pharmacology.

CDC charged the IOM committee with providing advice to CDC and its public health partners on how to best implement the President's policy on pre-event smallpox vaccination, addressing the following eight areas:

1. the informed consent process;
2. contraindications screening;
3. the system in place to assess the safety profile of the smallpox vaccine;
4. guidance for the treatment of vaccine complications;
5. professional training programs CDC is developing;
6. the communications efforts;
7. guidance CDC offers to states in developing their implementation plans; and
8. overall progress at achieving the goals of the program.

The Institute of Medicine agreed to provide advice on these areas through a series of timely reports.

During its first meeting December 18–20, 2002, the committee heard from CDC, the Department of Defense, Israel's Ministry of Health, and representatives of health professional organizations. The information provided during these presentations and subsequent research were the basis for the committee's deliberations. Based on these deliberations, the committee released its first letter report on Janu-

ary 17, 2003, titled "Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation."

The committee would first like to convey its appreciation for the hard work of CDC and its state and local partners in planning the pre-event smallpox vaccination program and helping it to become operational so quickly. CDC has done a tremendous job under very tight timelines.

Before getting into some of the committee's recommendations and key messages, I would like to point out that the committee realizes that while it had been working on the report, CDC had been moving ahead with plans for the vaccination program. Thus, the committee recognizes that CDC may have already accomplished some of the recommendations laid out in our report.

The committee also recognizes that this is a program that is planned nationally, but implemented locally. CDC is offering guidance, training, and assistance to its state and local public health partners, but the local programs will be making their own decisions about how and when to operationalize the pre-event smallpox vaccination program in their communities.

The report contains 23 recommendations, which are summarized in Appendix A of the report. For the sake of time, I will not discuss all 23 recommendations during my testimony, but would direct you to the full report for a complete description of the recommendations, which I am submitting for the record. I will now focus on the committee's four key messages and draw attention to a few of the recommendations.

Our first key message was: *Highlight the unique nature of the smallpox vaccination program as a public health component of a national bioterrorism preparedness policy, focusing on the delivery of clear, consistent, science-based information.*

The committee believes that it is critically important to stress to potential vaccinees and the public that the pre-event smallpox vaccination program is not a typical public health program. Public health vaccination programs are typically undertaken knowing the risks of the disease, and knowing they outweigh the risks associated with the vaccination. With the pre-event smallpox vaccination program, the risk of the disease is based on a risk estimate derived by the President and his advisors, based on national security issues. In this context, the individuals being asked to take this vaccine are being asked to volunteer to join smallpox response teams, for the benefit of the nation's bioterrorism preparedness. The committee believes that the unique aspects of the pre-event smallpox vaccination program need to be communicated clearly and consistently to the American public. Because the smallpox vaccination program is unusual, it is important for the American public to understand that practices in these circumstances might differ from those in traditional vaccination programs. A clear understanding of the risks and unique aspects of the pre-event smallpox vaccination program will be necessary to ensure that all potential vaccinees can make an informed decision about whether to participate.

Our second key message was: *Proceed cautiously, allowing continuous opportunity for adequate and thoughtful deliberation, analysis, and evaluation. Embark on phase II only after adequate evaluation of phase I has occurred.*

The current program is designed with the best possible efforts in the limited time frame available, but on the basis of data that are decades old. Our scientific approaches have improved since then, and our society has also changed during this time. This means that, as modern experience is gained, rapid and real-time mid-course corrections might be necessary.

I would like to stress that by recommending that CDC "proceed cautiously," the 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.

I would also like to stress that we have not recommended any specific time interval that is appropriate between the two phases. This is a matter of data analysis, not strictly a matter of time. Recognizing that the CDC has indicated that data analysis will be ongoing throughout phase I, the time needed to analyze phase I data and evaluate the adequacy of different components of the program before embarking on phase II (such as screening guidelines and surveillance for adverse reactions), may range from hours to weeks to months. The committee believes that CDC will be able to determine when enough data analysis has occurred to commence phase II safely.

One way to evaluate the adequacy of different components of the program would be to take advantage of differences in the way that public health departments and hospitals administer their local smallpox vaccination programs. Because local vac-

cination programs will be making their own decisions about the types of bandages to use, specific site care instructions, adverse reaction investigation, degree of patient contact allowed, and whether to grant administrative leave to vaccinated health care workers, the committee urged CDC to utilize and analyze these data before embarking on phase II.

Our third key message was: *Use a wide range of methods for proactive communication, training, and education, and customize it to reach diverse audiences, including potential vaccinees, all health care providers, and the general public.*

The committee heard evidence that there is much confusion about smallpox disease, the vaccine, and the details of the vaccination program. The committee strongly believes that clear, consistent communications to many different types of audiences is intrinsic to the success of the pre-event smallpox vaccination program. Given the potential for misinformation and confusion, and the complexity of vaccine information, it is necessary to begin a campaign of informing and educating the general public as soon as possible. Waiting until reports of serious adverse reactions surface is too little too late. Communicating in a time of crisis can only be effective if adequate communication and education have occurred during preparedness planning.

Our last key message was: *Designate one credible, trusted scientist as key national spokesperson for the campaign and sharpen and expand communication plans and strategies to ensure rapid, transparent, and sustained contact with the media throughout implementation.*

For the public to maintain confidence in the pre-event smallpox vaccination program and CDC, the committee believes that it is important for CDC to speak from its strength—the science of public health. Discussion of national security matters is best left to national security experts. The public's confidence in the vaccination program will be strengthened by the availability of a key scientific spokesperson who can provide credible and consistent information in a manner that is easily understandable to many different audiences. The spokesperson could be Dr. Gerberding herself, certainly an articulate and credible scientist, or someone else.

Since current discussions of the pre-event smallpox vaccination program are focusing on the issue of compensation for medical expenses or lost income for any health workers who experience adverse reactions from the smallpox vaccine, I will highlight the committee's recommendations that relate to this issue.

Although not specifically identified as an item for our deliberation, the committee did believe strongly that we needed to address the issue of compensation since it could have implications to the issues of informed consent and progress at achieving the overall goal of the program (that being increasing the nation's bioterrorism preparedness), both of which are clearly within our mandate.

The committee recommended that informed consent forms include explicit notification of the availability—or lack thereof—of compensation for adverse reactions. The committee was concerned that many potential vaccinees may falsely assume that the provisions of the Homeland Security Act of 2002 or the federal Vaccine Injury Compensation Program would provide compensation for medical expenses or income loss experienced as a result of receiving or being exposed to the smallpox vaccine (when there are no instances of negligence). This information may be an important factor that could weigh on a potential vaccinee's decision about whether to receive the vaccine.

The committee also recognized that some adverse reactions experienced by vaccinees may be covered by state worker's compensation programs. However, there is much uncertainty and confusion surrounding the types of vaccine adverse reactions and circumstances leading to those adverse reactions that would be coverable under each state's worker's compensation law. Because of this, the committee recommended that CDC and its state and local public health partners work to clarify the scope of worker's compensation for adverse reactions to the smallpox vaccine.

The committee was also concerned that the lack of compensation for adverse reactions might—I stress, "might"—imperil the ability of the pre-event vaccination program to achieve its goal of preparedness to respond to a smallpox attack. There currently are no data to determine whether or not the lack of compensation for adverse reactions is indeed a deterrent to receiving the vaccine. However, the committee recommends that IF it is determined that lack of compensation is jeopardizing overall progress at achieving the goals of the program (which is an item in our charge), then CDC and the Department of Health and Human Services should support all efforts to bring the issue of compensation for adverse reactions—including those reactions that occur despite non-negligent manufacture and administration of the vaccine—to speedy resolution.

The committee offered many additional recommendations related to the implementation of the pre-event smallpox vaccination program. I would be happy to answer questions about any additional recommendations of interest to you.

Thank you for the opportunity to speak to you today. The IOM Committee on Smallpox Vaccination Program Implementation hopes that its advice is useful to CDC and the broader community concerned about the success of the pre-event smallpox vaccination program. I would be happy to answer any questions you may have.

STATEMENT OF LOUIS M. BELL, M.D., CHAIR, DIVISION OF INFECTIOUS DISEASE, CHILDREN'S HOSPITAL OF PHILADELPHIA

Senator SPECTER. Thank you, Dr. Strom. We now turn to Dr. Louis M. Bell, chief of the Division of General Pediatrics at Children's Hospital of Philadelphia, also serves as Medical Director for the Hospital Infection Control Department at Children's Hospital, received his M.D. from the University of Maryland, and did his residency at Hahnemann in Philadelphia. Thank you for joining us, Dr. Bell, and the floor is yours.

Dr. BELL. Thank you. It is a pleasure to have this opportunity to speak to the committee on this complex topic of smallpox vaccination and its particular impact on the pediatric hospital population. I am here today representing the physicians, nurses, and other health care providers and administrators at the Children's Hospital of Philadelphia, and I will attempt to summarize a number of issues that we, as a hospital, have been considering in response to President Bush's December 13 call to develop a voluntary pre-event smallpox vaccination program.

The Children's Hospital of Philadelphia is regarded as a world leader in pediatrics. We operate the largest pediatric health care system in the United States, handling more than 770,000 outpatient visits each year. On our main campus in Philadelphia, we admit more than 20,000 children annually and have approximately 65,000 emergency department visits each year.

Now, I recite these statistics not to impress the committee, but rather, to help you understand two points, first that we are fortunate to have some of the brightest people in pediatric medicine deliberating on this issue and, second, we must carefully consider the risks and benefits of introducing smallpox vaccination into a pediatric health care environment. This is critically important, since a high percentage of the patients we treat at the Children's Hospital of Philadelphia are very ill or have weakened immune systems.

Let me share with you four questions we have posed, and some of our thinking to date. The first question: What is the risk of exposure to smallpox through bioterrorism? Fortunately, there have been no cases of smallpox seen in the world for approximately 25 years. Based on our current information, it is difficult to ascertain this risk at this time.

The second question is: What are the risks of smallpox vaccination in this hospital environment? To consider this side of the equation, what do we know about the vaccine? Well, we know that the vaccinia virus, which is the virus used in the vaccine, is effective in preventing smallpox. We know that this vaccine protects against smallpox if a person is inoculated within days after exposure. We know that a person who is vaccinated may spread the virus to other people or other parts of their own body, and the vaccine certainly has its side effects, which have been outlined previously.

Persons with immune systems that are weakened have a greater risk for these adverse events.

Now, the next question that we think is important, again, viewing this from the vulnerable population in a hospital, is: What is the risk that vaccinia virus might spread from the arm of a health care worker to a hospitalized child? An article by Kent Sepkowitz, which will appear shortly in the New England Journal of Medicine, reviews the spread of smallpox vaccine virus in hospitals from 1907 until 1975. The spread of this vaccine virus has been reported 12 times in that interval. Eight of the 12 reports of spread within a hospital were in children, and in pediatric wards in children's hospitals. Most of the time, it is spread by a health care provider who transmits the virus on their hands to the patient.

According to this review, the chance of being infected in the hospital could be as high as 10 percent. Nine of the 85 people who were thus infected by contact died as a result of this infection from the vaccine virus, thus, our past experience with the vaccine shows that there are, indeed, potential risks to this in this vulnerable population within a hospital.

The next and final question is: Are the risks for using the smallpox vaccine in 2003 greater than they were in the 1940s and 1950s and 1960s? Which is what we are drawing this information from, and we think the answer to this question is yes. Due to advances in medical treatment, both the risk and the risk pool have increased dramatically over the last 20 years. For example, children and infants are on steroids, they are undergoing cancer chemotherapy, they are receiving kidney, heart, liver, bone marrow transplantation. All of these children are immunosuppressed.

Second, in general, we are asked to vaccinate into a pool of young health care workers who are 30 years old or less, and who have not been vaccinated previously.

Third, in addition to the thousands of sick children that we care for, we may have a health care worker who is immunocompromised actually in that environment, so therefore, weighing these risks and benefits, the Children's Hospital of Philadelphia does not currently recommend voluntary smallpox vaccinations for its frontline health care workers in our institution.

Senator SPECTER. Dr. Bell, that is a very important conclusion. Would you elaborate why?

Dr. BELL. Well, again, I think the issue is the vulnerable population that we serve, the concerns that, although perhaps not high, there is a risk. There is a risk that this virus vaccine could infect a severely ill or an immunocompromised child within this environment and potentially die.

Senator SPECTER. We will come back for more questions in the Q and A, but just one follow-up at this point. You say because of the clientele you serve. If you were not serving children, but were serving adults, would you have a different conclusion?

Dr. BELL. Well, I think that—I am not sure that the risks are tremendously different between the very sick adults and sick infants. However, with some of the data we have from prior, from the 1940s and 1950s and 1960s, it does seem that hospitalized children may be at increased risk, given the reports and the review of the data.

Senator SPECTER. I pursue the question with you because it is rather startling an institution of your prestige would decline to inoculate.

Dr. BELL. Well, I think this is a point in time. We are, at this moment, declining to do this. This is a very complicated issue. I think new data, new changes in what we know about the risk from the other side in terms of the risk of being exposed to smallpox will be a day-to-day affair in how we process this.

PREPARED STATEMENT

I just want to make a point, though, that this decision in no way diminishes our willingness to enlist our hospital staff and resources should this unthinkable thing happen. We will be there and care for children if this does happen, but at this point in time, weighing these risks and benefits, and the risks to our patient population, we have made this decision.

[The statement follows:]

PREPARED STATEMENT OF DR. LOUIS M. BELL

Good morning. It's a pleasure to have the opportunity to speak to this committee on the complex topic of smallpox vaccination and its particular impact on the pediatric hospital population. I am Dr. Louis M. Bell, and I have been a practicing pediatrician for almost 20 years. I am Division Chief of General Pediatrics at The Children's Hospital of Philadelphia and Chair of the Infection Control and Prevention Committee at the Hospital. I also hold an endowed chair in pediatric medicine at Children's Hospital and am co-author of a book entitled "Vaccines: What Every Parent Should Know."

I am board certified in both pediatric infectious diseases and pediatric emergency medicine. For more than a decade, I have been involved in research that has focused on vaccine education and improving vaccine delivery to urban children.

I am here today representing the physicians, nurses, health care providers and administrators at The Children's Hospital of Philadelphia. I will attempt to summarize a number of issues that we, as a Hospital, have been considering in response to President Bush's December 13, 2002 call to develop a voluntary pre-event smallpox vaccination program.

The Children's Hospital of Philadelphia is regarded as a world leader in pediatrics. We operate the largest pediatric healthcare system in the United States, handling more than 770,000 outpatient visits each year. On our main campus in Philadelphia, Children's Hospital handles more than 20,000 inpatient admissions annually, with approximately 65,000 emergency department visits each year. We provide primary, specialty and home care services to children and their families in more than 40 locations throughout Pennsylvania, New Jersey and Delaware.

In addition, The Children's Hospital of Philadelphia is recognized as one of the world's leading pediatric research facilities. We rank second among children's hospitals in National Institutes of Health funding, making us one of the largest and most prestigious pediatric research programs in the nation.

We are also a national resource, accepting referrals from hospitals across the United States, providing specialized cardiac care, fetal therapy, cancer treatment, organ transplantation and other specialty services to children of all ages, from before birth through young adulthood.

I recite these statistics not to impress the Committee, but rather, to help you understand two points. First, that we have some of the best minds in pediatric medicine deliberating on this issue. Second, we must carefully consider the risks and benefits of introducing smallpox vaccination into a pediatric healthcare environment. This is critically important since a high percentage of the patients we treat at The Children's Hospital of Philadelphia are very ill or have weakened immune systems

Let me share with you some of the questions we've posed and some of our thinking to date.

MEDICAL CONSIDERATIONS

1. What is the risk of exposure to smallpox through bioterrorism?

No case of smallpox has been seen in the world for approximately 25 years. The only known way to introduce smallpox is through bioterrorism. Based on current information, it is difficult to ascertain the risks at this time.

2. What are the risks of the smallpox vaccine?

To consider this from a risk/benefit equation, we can look back to previous experiences. What do we know about the vaccine? We know that the vaccinia virus, which is the virus used in the vaccine, is effective in preventing smallpox. This vaccine protects against smallpox if a person is inoculated within days after exposure. We also know that this is a live vaccine that is inoculated on the skin. After inoculation, the vaccine virus grows and forms a scab that falls off in 2 to 3 weeks. As long as the scab is present, the person who is vaccinated may spread the virus to other people or to other parts of their body. The vaccine has its side effects, which are most severe in those who have never been vaccinated previously. In addition, persons whose immune systems are weakened or have eczema are at even a greater risk of adverse outcomes.

Perhaps the most important question remains . . .

3. What is the risk that the vaccinia virus might spread from the arm of the health care worker to a hospitalized child?

An article by Dr. Kent Sepkowitz, which will appear shortly in the *New England Journal of Medicine*, reviews the spread of the smallpox vaccine in hospitals 12 times between 1907 and 1975. Eight of the 12 reports involved hospitalized children. A total of 85 children and adults were infected by health care providers who transmitted the virus on their hands. According to this data, the chance of being infected in the hospital could be as high as 10 percent. In fact, nine of the 85 people (11 percent) died as a result of the smallpox vaccine. Thus, our past experience with the vaccine shows that there are potential risks to its use.

4. Are the risks for using the smallpox vaccine in 2003 greater than in the 1940s, 1950s and 1960s?

We think the answer to this question is yes. Due to advances in medical treatment, both the risks and the risk pool have increased dramatically over the last 20 years. For example, children and infants on steroids, undergoing cancer chemotherapy, or receiving kidney, heart, liver or bone marrow transplantations are immune suppressed. Second, in general, we are vaccinating health care workers who are less than 30 years old and have never been vaccinated previously. Third, in addition to the thousand of sick children treated by our Hospital, we have healthcare workers who are also immunocompromised.

Therefore, after carefully weighing these risks against the benefits, The Children's Hospital of Philadelphia does not currently recommend voluntary smallpox vaccinations for its frontline healthcare workers. This decision is based on thorough analysis of all available data, taking into account concerns about the safety and side effect profile of the vaccine for our staff as well as the potential impact on our patient population.

As a tertiary care pediatric medical center, a high percentage of our young patient population is immunocompromised. We are concerned that the introduction of newly vaccinated healthcare workers could expose our patients and employees to unnecessary risks.

We recognize that this is a complicated issue. Our policy will continue to be evaluated and assessed against new data, scientific advances such as the development of a new generation of smallpox vaccine and changes in world events.

Lastly, we wish to emphasize that this decision in no way diminishes our willingness to enlist our hospital staff and resources should the unthinkable happen and there is a smallpox outbreak in the Philadelphia area.

OPERATIONAL CONSIDERATIONS

In addition to the medical issues raised above, healthcare institutions must also consider a number of operational impacts.

1. Who will bear the medical cost of treating adverse reactions to the smallpox vaccine in health care providers who volunteer to be vaccinated?

2. Taking into account that introducing the vaccine virus into a population of hospitalized children carries increased risk, should different consideration be given to pediatric institutions?

3. Should administrative leave be granted for health care workers in children's hospitals who volunteer to be vaccinated?

4. In addition to these considerations, we recommend that a centralized database collect information about adverse reactions which occur nationwide as a result of smallpox vaccination. This data should be made public.

CONCLUSION

Mr. Chairman, we share the administration's concern that the possibility of smallpox as a weapon of bioterrorism is real. We expect to participate fully in keeping this country safe. In our daily work as physicians and scientists, we carefully weigh the risks and benefits of keeping our patients safe.

The issue of smallpox vaccination presents a complicated picture of risks that needs further clarification. We hope that our testimony will provide government policymakers and other healthcare institutions additional insight into the specific medical risks and operational impacts of smallpox vaccinations at pediatric hospitals.

Mr. Chairman, I am ready to respond to any questions the Committee might have.

Senator SPECTER. Thank you, Dr. Bell. Stand by. There will be some more questions for you.

STATEMENT OF PATRICK LIBBEY, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

Senator SPECTER. We turn now to Mr. Patrick Libbey, executive director of the National Association of County and City Health Officials. He had been director of the Thurston County Public Health and Social Service Department in Olympia, Washington. B.A. from Evergreen College in Washington State.

Thank you for joining us, Mr. Libbey, and we look forward to your testimony.

Mr. LIBBEY. Thank you. Good morning, Mr. Chairman, members of the committee. As noted, I, up until 5 months ago, had served as the director of a local health department in Washington State for the past 17 years. I thank you for the opportunity to address the committee from the perspective of the actual point of implementation of the smallpox vaccination program.

Ultimately, all vaccinations will be given at a community level, most often by your local public health system. We are committed to successfully preparing the Nation for a smallpox outbreak, but success needs to be defined particularly in the first stage—this first phase—as being ready to appropriately respond to an initial smallpox case and being ready to rapidly begin vaccinating in greater numbers other first responders or the whole population if the assessment of threat is significantly increased, or should a case occur.

We believe it is prudent to assure that there is a ready capacity of voluntarily pre-immunized people to perform disease investigation and containment, and able to treat an initial case, and ready to begin vaccination of a larger circle of people, up to and including the entire population.

Success also means that clinician expertise and community awareness about smallpox disease and vaccination is improved, and that disease surveillance is in place that can rapidly detect and respond in the event of an outbreak.

We also believe it is unfortunate that numerical goals, the use of 500,000, the use of 10 million as figures, which were simply earlier planning projections, appear to have replaced these true measures of what successful implementation of this first stage ought to be. It really should be a simple question: Are we ready, in the

event a case is discovered, or if there is significant increase in the announcement relative to the threat?

I also am here to say, smallpox vaccination is fundamentally different from any of our other current vaccination efforts. It is not like lining people up in a mall for a flu shot. There are three significant components to smallpox vaccination, to actually having the ability to deliver and carry this out on a voluntary pre-event basis.

First is the necessary planning and community preparation. This includes the identification and recruitment of vaccinees, the community and clinician education, further targeted education to specific groups, including emergency medical technicians, other first responders, the issues of logistics, of receiving, storing, and securing the vaccine, the physical logistics, and the list goes on in terms of what is necessary to have that community preparation.

Then there is the actual, clinical delivery of the vaccination itself. This is the part that most people see. In this vaccination effort for smallpox, it is much more complex in the required steps than other vaccinations. Following the CDC clinical guidelines for a post-event, there are a number of additional steps. Intake is more complex, the informed consent process is significantly more involved, a significant amount of screening, the administration of the vaccine is fundamentally different, and within that clinical setting, having to make sure that post-vaccination instructions are given and understood.

Last, there is follow-up. Unlike other vaccinations, smallpox will require an extensive follow-up capacity. The vaccination site is recommended to be looked at daily, the take must be read, there must be an information and triage capacity in place to respond to concerns about reactions, and that includes both what are within probably normal reactions to smallpox, but outside the normal experience of people with immunizations, as well as those that would be considered adverse, and there must be a clear linkage and established referral pattern to treatment services in the event of an adverse. We know, by comparison, that these differences from other vaccinations are of significance, and we have begun costing those.

Let me just—by comparison, your flu clinic, for example, requires virtually no significant amount of community preparation, other than generally making it known and available, promoting its availability, and there is no significant follow-up system. A well-run, planned flu clinic, you will have a patient enter and exit in a matter of very few minutes. Well-run can be as few as 5. The same for an emergency mass immunoglobulin clinic in the event of an outbreak of hepatitis A in a community.

The smallpox clinic, on the other hand, requires the extensive community preparation, the follow-up capacity, and the much more complex vaccination phase. Three weeks ago, the Arlington County Health Department, at the request of the Secretary's office, conducted a mock clinic, vaccinating 1,000 persons, using the CDC clinical guidelines, and this was reviewed by an HHS-selected time-motion consultant.

It took about an hour for a potential vaccinee from the point of entry to the point of exit to go through those necessary steps. Compare that, again, to the notion of being in and out of a flu in a matter of 5 minutes or fewer. That also includes the 30 percent of peo-

ple, by virtue of the system, that were screened out that were not appropriate to be vaccinated.

With all respect to Dr. Gerberding, I must respectfully but strongly disagree with her assessment of the cost of doing this business. At CDC's request, we have been costing these stages. This is our business. This is what your local health departments do. We have the expertise in organizing and conducting vaccination efforts. We have now cost projections from four large metropolitan areas throughout the country. Taking these particular stages apart, and comparable activities, cost range currently for all three stages runs from a low of $142 to a high of $222.

In Arlington County, the mock clinic that I had mentioned, for the vaccination stage only, not even setting it up, not the pre-community or post-follow-up, the costs that they came out of that with, reviewed by their HHS consultant, was about $100 per person through that.

What you see when you get a vaccination, and what it takes to do a vaccination, are not the same, and it is very easy for us to think from our own vaccination experience.

I must also tell you that local health departments are diverting staff and funding from other bioterrorism preparedness efforts to work almost exclusively on smallpox vaccination. We know from a recent survey that local public health departments have made significant progress over the last year in improving their overall readiness, and most of this, frankly, can be attributed to the Federal resources that you collectively have made available to improve that readiness in the 16 critical areas Dr. Gerberding mentioned.

Senator SPECTER. Mr. Libbey, you are 2 minutes over. Could you summarize, please?

PREPARED STATEMENT

Mr. LIBBEY. I can. Two things I would say in conclusion. We are, in fact, diverting our bioterrorism resources, leaving us less prepared, and probably regressing in the progress we have made, and we are also starting to clearly see a number of communities that other public health plans, including chronic disease screenings, cancer screenings and the like, we are starting to draw resources from that to be able to speak specifically to smallpox. We need to progress. We need to do it, stay small, go slow, and assure that we have the resources to do it appropriately.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF PATRICK M. LIBBEY

Good morning, Mr. Chairman and members of the subcommittee. I am Patrick M. Libbey. I am Executive Director of the National Association of County and City Health Officials (NACCHO). NACCHO is the organization representing the almost 3,000 local public health departments in the country. Before beginning work here in Washington, DC last year, I served as NACCHO's President and was Director of the Thurston County, Washington, Department of Health and Social Services for 17 years. I have been deeply engaged in bioterrorism preparedness at both the local and federal levels. I am here today to explain the challenges faced by local public health agencies in implementing the President's smallpox vaccination program and what resources we believe are needed to meet those challenges.

NACCHO and its members are committed to doing everything within our power to achieve success in preparing the nation for an outbreak of smallpox, should that

terrible event ever occur. Our definition of success is that the nation will have the ability to identify a smallpox outbreak as soon as possible, to ramp up and vaccinate as many persons as necessary to contain an outbreak, and to vaccinate voluntarily every medically eligible United States resident in a safe and timely manner should that become essential to save lives. The Department of Health and Human Services (HHS) has recognized that the plans and systems needed to achieve this success will vary greatly among states and localities. We fully concur with this approach. Therefore, we believe that success will not be measured in terms of numbers of persons vaccinated in the coming months. Rather, success will be measured by the ability of states and localities to demonstrate that there is a workable, tested plan in place to contain any smallpox outbreak, and sufficient numbers of public health and medical care personnel vaccinated to provide care for the initial cases, to do the epidemiologic footwork that will be necessary to identify persons who have been in contact with infected individuals, and to be the first vaccinators in a mass vaccination campaign.

SMALLPOX VACCINATION IS DIFFERENT

We in public health have long experience in successfully mounting immunization campaigns to prevent such diseases as polio, measles, influenza, or Hepatitis A, in both routine and emergency circumstances. Smallpox vaccination, particularly in the absence of any known cases or known threat, is different. The live virus vaccine carries risks of side effects that are greater and more serious than the risks of any other vaccine we use. The only purchaser of the vaccine is the federal government. Planning, implementing, and evaluating a national smallpox vaccination program in a way that maximizes effectiveness and minimizes risk to individuals therefore involves many more components than routine immunization programs. There is much more to it than lining people up in a mall to get their flu shots.

A smallpox vaccination program has three basic components. The first is community preparation, which involves planning, training, and community education. Many local public health agencies are assisting their states in identifying who should be vaccinated. This has involved intensive work both with public health staff and with hospitals and other health care providers, as well as the general public. The needs for education and information have been great. Planning a vaccination clinic includes components that would be expected for any such enterprise—identifying and arranging for a site, for security, for managing the flow of people, for staffing, for transportation and storage of vaccine and supplies, and for record-keeping. However, the novel and riskier nature of smallpox vaccination requires additional steps that take time and resources. There must be a communication plan to inform the community and the media about what is taking place. Existing information technology systems may require modification to handle special requirements for follow-up of persons vaccinated and reporting, tracking and management of adverse events.

The second component is actual administration of the vaccine. The Centers for Disease Control and Prevention (CDC) has promulgated guidelines for post-event smallpox vaccination clinics and this model is being adapted for pre-event smallpox vaccination now. According to these guidelines, the personnel required at a clinic site include: a registration staff; a patient education staff to provide the information and obtain the documentation necessary to assure informed consent; medical screeners to review each prospective vaccinee's medical history forms and interview each person; medical assistants to prepare the vaccine and keep supplies at hand; persons trained to administer the vaccine and observe for any immediate reactions; administrative staff to assure proper record-keeping; staff to direct people and control clinic flow; security staff; and emergency medical personnel to address any serious medical events that might take place. All of these people must be trained in advance to conduct their jobs safely and effectively. The Arlington County (Virginia) Public Health Department recently conducted a mock clinic according to these guidelines and HHS is working on an evaluation so that the guidelines can be improved. That clinic required 80 staff on-site to serve 90–100 prospective vaccinees per hour for eight hours.

The third stage is post-vaccination follow-up and evaluation. The job is not over when a person has been pricked by a bifurcated needle 15 times. The Advisory Committee on Immunization Practices recommends daily checks of the vaccination sites of health care workers to assure the site is properly dressed, to check for a proper take, and to spot any swelling, rash, or other adverse reaction. We also fully expect that a certain number of "worried well" who are vaccinated will request follow-up assessments. It is therefore necessary to plan for and designate staff to assess vaccination takes and assess or refer suspected adverse events. In addition, there must

be a plan for obtaining and distributing vaccinia immune globulin (VIG), which is used to treat adverse reactions, and a cadre of medical professionals trained to diagnose and treat adverse reactions.

IMPACT OF SMALLPOX VACCINATION PROGRAM ON LOCAL PUBLIC HEALTH AGENCIES

Implementing a smallpox vaccination program with all these components and complexities is a tall order indeed. We believe it can be done, given sufficient time and resources. State and local public health agencies, working with hospitals and physicians, are doing it now and we will continue. However, the crush of the current smallpox vaccination activity is taking a large toll on public health agencies. We do not believe it can be sustained without serious harm to a public health system that has already redoubled its efforts in order to improve the national's overall public health preparedness.

NACCHO is monitoring the local experience with smallpox vaccination and conducted a brief Web-based survey last week to determine how the program has affected local public health agencies thus far. We received responses from 718 agencies, representing a broad range in terms of the size of population served, from under 20,000 to large metropolitan areas. A positive finding was that 37 percent of the respondents indicated that smallpox or other bioterrorism preparedness work is enhancing their other public health activities. We believe that this is because public health preparedness requires building new relationships and devising new ways of working within the community. Such new relationships—with hospitals, physicians, emergency responders—improve the effectiveness of other public health activities, too.

However, more than half (58 percent) reported that smallpox work is hurting their other bioterrorism preparedness efforts. Some agencies never received bioterrorism preparedness funding and therefore are spending other funds for smallpox vaccination. Others are rapidly spending down their bioterrorism funding on smallpox vaccination, rather than using it to fulfill many other requirements for bioterrorism preparedness described in CDC's cooperative agreements with the states. Our survey respondents were especially concerned about preparing to fulfill the public health role in responding to acts of terrorism using other agents, such as anthrax, ricin, or nuclear materials. This information confirms our concern that the emphasis on smallpox vaccination is indeed beginning to compromise our ability to prepare for other acts of terrorism. We are losing the most important potential of bioterrorism preparedness funding, which was to help states and localities build the capacities needed to address multiple public health threats.

It is equally alarming to us that more than one-third (35 percent) of the survey respondents reported that smallpox already is negatively affecting other public health programs. Public health clinics that provide such services as childhood and influenza immunizations have been deferred, delayed, or canceled in 182 jurisdictions due to the demands of smallpox vaccination. Staff members who worked in communicable disease control are now focusing exclusively on smallpox, causing work such as control of tuberculosis and sexually transmitted diseases to lag. It is important to note that these negative impacts occurred even before a single person was vaccinated. We are gravely concerned that, if diversion of general public health resources to smallpox vaccination continues and grows, our communities will become more vulnerable to ongoing public health threats. We will compromise our ability to prevent and respond to influenza, childhood diseases, West Nile virus, contaminated drinking water, food-borne illness, and chronic diseases.

COSTS OF SMALLPOX VACCINATION

Early estimates of the cost of smallpox vaccination to state and local governments were about $85 per person. We are now beginning to assess actual cost data, obtained from a small sample of jurisdictions using a template that ensures that the costs are comparable. We have available current estimates from four large urban public health agencies. The costs per vaccine are $142, $155, $177 and $220. They include all planning, training, communication, data management, clinic implementation and follow-up costs. We believe that this cost range is more realistic than smaller numbers that address clinic costs only. The Arlington County Health Department's cost per person for implementing a mock smallpox vaccination clinic using CDC's guidelines was about $100, a figure that does not include any of the planning and community preparation component or post-vaccination follow-up.

If it became necessary to vaccinate a much larger group of persons than the initial public health and medical care response teams, certain fixed costs, such as planning and epidemiologic surveillance, would not change much and would be spread over a larger number of individuals. Other costs, such as staff time at clinics, might in-

crease because more intensive education and screening would likely be required for vaccinees who are not already trained public health or medical personnel.

We expect to obtain more extensive cost data as the smallpox vaccination program moves forward and will be pleased to share our information with the Committee. There clearly will be differences in cost among states and localities. However, we believe we have sufficient information now to demonstrate that smallpox vaccination costs are high, certainly far higher than $10 or $20 per person, and that state and local governments do not have the resources to bear these costs for much longer.

Many local public health agencies are reporting that the amount of federal bioterrorism funds made available to them, if any, no longer covers the costs of what is expected now to vaccinate public health and medical teams, let alone any expanded number of vaccinees. Redirecting all our bioterrorism funds to smallpox halts our progress in bioterrorism preparedness and leaves us increasingly vulnerable to other agents. It is also detracting from ongoing local public health work to protect and provide service to local communities. We strongly urge the Committee to heed these reports from actual local public health practice and provide state and local health departments and other parties who must also bear these costs with the funds to fulfill the President's mandate.

There are many other current obstacles to successful implementation of smallpox vaccination. I have attached a statement presented on NACCHO's behalf to the Institute of Medicine Committee on Smallpox Vaccination Implementation on December 19, 2002 that addresses other issues of great importance.

Chairman Specter and Senator Harkin, you have been leaders in providing funding for public health preparedness and in recognizing that local public health departments serve on the front lines in battling public health crises of all types. We are grateful for your continuing support. I will be happy to answer any questions you have and to provide whatever other available information you may wish for the record. Thank you.

Attachment.

STATEMENT OF PATRICK LIBBEY, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS, PRESENTED TO THE INSTITUTE OF MEDICINE COMMITTEE ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, DECEMBER 19, 2002

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 com-

municating 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 10 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 10 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.

Senator SPECTER. Thank you very much, Mr. Libbey.

STATEMENT OF JAMES AUGUST, DIRECTOR, HEALTH AND SAFETY, AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES

Senator SPECTER. We now turn to Mr. James August, director of Health and Safety for the American Federation of State, County, and Municipal Employees. In that position, he oversees the development of training on the identification and control of chemical, biological, ergonomic safety and security hazards in the workplace. Master of public health from the University of California at Los Angeles.

Thank you for joining us, Mr. August, and we look forward to your testimony.

Mr. AUGUST. Mr. Chairman and members of the committee, I am James August, and I direct the occupational health and safety program for the American Federation of State, County, and Municipal Employees, a labor union of 1.3 million members, including over 350,000 health care workers and first responders. We appreciate the opportunity to address a matter of great importance to our members, their families, coworkers, and patients.

Earlier this month, AFSCME president Gerald McEntee and other union leaders called on President Bush to delay implementation of the smallpox vaccination plan until a number of very serious safety concerns and workplace issues are resolved. I will quickly summarize our concerns, and I have submitted more extensive written testimony for the record.

It is our position that the vaccination program should be delayed until a comprehensive plan is implemented with the following safeguards, many of which mirror what is being done in the military smallpox plan. Prior to receiving the vaccine, workers must be educated about the risks of vaccination to themselves and the potential for transmitting the vaccinia virus to patients, family members and other contacts. Workers must not be pressured in any way into volunteering by their employers, and there must be no reprisals against workers who decline to be vaccinated for any reason.

Given the potential serious side effects of smallpox vaccine which others have described, workers must be carefully screened. Prevention is extremely important here. Those who might have a contraindication for the vaccine must be offered free and confidential medical testing. There must be vigilant medical surveillance following vaccinations to rapidly respond to adverse reactions. Workers must have access to necessary medical treatment, including the availability of VIG.

The Food and Drug Administration needs to quickly approve the use of bifurcated needles with a built-in safety feature to administer the vaccine, consistent with the Needle Stick Safety and Protection Act which Congress passed in 2002. It is absolutely crucial that public health systems be provided resources to safely implement a vaccination program, and should not be forced to divert funds from core public health programs, as the previous witness described.

As you know, the States are facing their worst fiscal crisis since World War II. The challenges and risks of the smallpox program are far too great to impose on State and local health departments and hospitals without additional funding.

Last, I will address the compensation issue, which I was specifically asked to comment on. In short, State and Federal Worker's Compensation programs do not provide an adequate safety net. Some Worker's Compensation programs may not cover claims of workers who have an adverse reaction because they have volunteered to be vaccinated.

Some State Worker's Compensation programs do not require coverage for all workers. Other States exclude, or permit exclusion of self-employed workers, which is a particular concern in hospitals that rely on self-employed agency and contract workers, and since Worker's Compensation only applies to injuries that are work-related, a household member or a patient who becomes sick or disabled from the vaccinia due to contact with a vaccinated worker will not be eligible for any benefits at all.

Now, even where Worker's Compensation is applicable, workers will not be fully compensated. Most programs replace only two-thirds of workers' earnings. There are also limits on the maximum weekly benefits, which means the more highly compensated health care workers cannot receive anything approaching adequate replacement of their lost income. Also, due to waiting periods, Worker's Compensation will not apply to the estimated one-third of workers who will have a reaction that will make them too ill to work from one to a few days. In addition, there are caps on medical care, posing a particular problem for workers who suffer a severe side effect.

In short, Worker's Compensation programs will not provide the compensation and medical care that injured workers or individuals made ill by contact with vaccinated workers would need and deserve.

The Federal Government has initiated the vaccination program to protect the country against an intentional release of smallpox. It is unacceptable to ask health care and emergency workers to volunteer to be on the front lines in the defense of the Nation and at the same time tell them that if they or their family members are harmed by the vaccine, they are on their own regarding medical care and compensation. Therefore, it is necessary and appropriate for the Federal Government to establish uniform protections.

The National Vaccine Injury Compensation Program for children is an adaptable model for a Federal no-fault smallpox compensation program. It must be easy to access, provide prompt payment, and fully reimburse affected individuals with respect to income and medical costs.

In conclusion, the current smallpox vaccination program raises a number of serious safety and workplace problems. The prudent course of action at this time is to pause, look at the problems more closely, and then let us correct the problems that exist. We are eager to assist in designing a program that protects the Nation and addresses the concerns of frontline health care and public safety workers.

PREPARED STATEMENT

Thank you for allowing me to present our views on this important matter and, at the appropriate time, I would be pleased to answer any questions you may have.

[The statement follows:]

PREPARED STATEMENT OF JAMES AUGUST

I am James August and I direct the Occupational Health and Safety program for the American Federation of State, County and Municipal Employees (AFSCME), a labor union of 1.3 million members. AFSCME represents over 350,000 health care workers and first responders, many of whom will be asked to receive the smallpox vaccine in the coming months under the vaccination program launched last week. I appreciate the opportunity to address a matter of great importance and urgency to our members, their families, coworkers and patients.

AFSCME has closely monitored the development of the Centers for Disease Control and Prevention's (CDC) Smallpox Response Plan, particularly the evolution of the smallpox vaccination component. In the fall of 2001, the plan called for inoculating 150 CDC staff, who would investigate and respond to a confirmed or suspected case(s), and initiate a vaccination program anywhere in the country within twelve hours. There was widespread opinion that such a small number of vaccinated medical personnel employing the ring vaccination strategy used during the worldwide smallpox eradication effort would not be sufficient in this modern and mobile society, particularly if smallpox was intentionally released simultaneously in multiple locations. At the June 2002 Institute of Medicine (IOM) meeting to examine the risks and appropriate responses to a smallpox attack, CDC and other government agencies involved in bioterrorism response planning were discussing the need to vaccinate between 10,000 and 20,000 health care workers. In October 2002, the Advisory Committee on Immunization Practices (ACIP) recommended that approximately 500,000 health care workers be vaccinated. Near the end of last year, President Bush called for 10 million additional health care and emergency workers to be vaccinated in a second wave.

THE NEED TO DELAY THE SMALLPOX VACCINATION PROGRAM

AFSCME agrees with the Institute of Medicine Committee's statement that: "Given this profile of high vaccination risk and likely very low to zero benefit, the administration's policy to offer vaccination to public health, medical, and emergency workers must be implemented in a most prudent and cautious manner." Earlier this month, AFSCME President Gerald W. McEntee and other union leaders called on President Bush to delay implementation of the smallpox vaccination plan until a number of serious safety concerns and workplace issues were satisfactorily resolved. Local unions and nurse associations in a number of states, including AFSCME's Local 1199 in Philadelphia, are recommending that their members not volunteer to participate until these issues are addressed. AFSCME recognizes the need to prepare the nation for a range of possible biological attacks. However, we have grave concerns that the smallpox vaccination program is being implemented without a comprehensive and federally funded plan that will ensure that the vaccinations are administered safely and that those who suffer adverse effects from the vaccination and exposure to the vaccinia virus will receive compensation and medical care. The absence of a federally funded, comprehensive approach to the civilian vaccination program is in stark contrast to the Department of Defense's more thorough program for the military.

PROTECTING SMALLPOX RESPONDERS AND THE PUBLIC DURING IMPLEMENTATION OF THE PROGRAM

The vaccination program should be delayed until a comprehensive plan is designed and implemented with the following safeguards.

—Vaccinations should be administered only with full and informed consent.

—Prior to receiving the vaccine, workers must be trained about the risks and benefits of vaccination to themselves, as well as the potential for and consequences of transmitting the vaccinia virus to patients, family members and other contacts. Educational information must also be made available to family members of potential vaccination volunteers.

—Workers must be informed about the availability of compensation, or lack thereof, in the event of side effects that require time from work. Workers must also be informed about the availability of medical care in the event of an adverse reaction.

—Potential responders should be fully informed of their job responsibilities in the event there are smallpox cases.

—Workers should not be pressured into volunteering by their employers, and there should be no discrimination or reprisals against workers who decline to be vaccinated for any reason. In addition, there must be no discrimination against workers who experience an adverse reaction to the vaccinia.

—Given the well-known and serious side effects of the smallpox vaccine, workers must be carefully screened, including an interview with an appropriate health care professional. Those persons who might have a contraindication for the vaccine must be offered free and confidential medical testing.

—There must be vigilant active medical surveillance following vaccinations to rapidly identify and respond to adverse reactions. Workers must have access to necessary medical treatment, including the availability of Vaccinia Immune Globulin (VIG). There must also be surveillance and medical treatment available to those who suffer accidental transmission of the vaccinia virus from a vaccinated worker.

—The Food and Drug Administration (FDA) must expeditiously approve the use of bifurcated needles with a built-in safety feature consistent with the requirements of the Needlestick Safety and Protection Act of 2000. The needles included in the smallpox kits being shipped to the states do not include an integrated safety feature to prevent needlestick injuries that can transmit bloodborne diseases from patients to health care workers. Safety-designed devices for vaccinations have been approved for marketing by the FDA. However, the safer devices cannot be used by health departments and hospitals until the FDA approves the substitution of safer devices for the unsafe needles included in the smallpox kit.

THE NEED FOR NEW FEDERAL RESOURCES FOR IMPLEMENTATION IN THE STATES

Public health systems, including state and local health departments, hospitals, laboratories, and other entities included in the smallpox response plan, must be provided with new and adequate federal resources to safely and effectively implement the smallpox vaccination program. Adequate funding and requirements for educating, screening, monitoring and treating workers must be provided to avoid serious vaccine induced adverse effects. Public health departments and hospitals should not be forced to divert resources from core public health programs or other bioterrorism preparedness activities in order to carry out the smallpox vaccination program. When authorizers designed requirements for states to receive bioterrorism preparedness grants early last year, they did not include requirements for implementing a vaccination program. Furthermore, the CDC's *Notice of Cooperative Agreement Award* announcing the requirements for biopreparedness grants, issued in February 2002, did not include the implementation of a smallpox vaccination program as one of the seven activities to be funded under awarded grants. Collectively, states are facing a $67 billion budget shortfall for fiscal year 2003 and another $60 to $85 billion for fiscal year 2004, the worst fiscal crisis the states have experienced since World War II. The costs, challenges, and risks of the smallpox program are too great to impose on state and local governments without new federal funding.

INADEQUACY OF COMPENSATION AND CARE UNDER WORKERS' COMPENSATION

Congress must address the need for compensation and medical care for persons who are injured as the result of receiving the vaccine, or individuals who are harmed as a result of contact with a person who has been vaccinated. State and federal workers' compensation programs do not provide an adequate safety net. In

a survey of the states, the Association of State and Territorial Health Officials revealed that there is great uncertainty about whether workers' compensation will be applicable. Indeed, American Insurance Association's chief counsel on workers' compensation has declared, "I do not see where comp would pay for either the [smallpox] vaccine or for the adverse effects of an inoculation."——(*Business Insurance*, January 13, 2003.)

The gaps in coverage and applicability are significant. Some workers' compensation programs may not cover the claims of workers who have adverse reactions because they have voluntarily agreed to be vaccinated. In a classic Catch-22 situation, one AFSCME local has reported that due to the voluntary nature of the vaccination, medical expenses resulting from a serious injury will not be covered by the workers' compensation program. These same workers have also been informed that their health insurance coverage will not apply because the injury would be considered work-related. Other states exclude or permit exclusion of self-employed workers, a particular concern in hospitals that rely upon self-employed, agency and contract workers including nurses and emergency room physicians. In Texas, workers' compensation is not compulsory for private employers. Finally, since workers' compensation only applies to injuries that are work-related, a family member or patient who becomes sick or disabled from the vaccinia due to contact with a vaccinated health care worker, will not be eligible to file claims under state workers' compensation programs.

Even where workers' compensation plans recognize adverse effects from smallpox vaccine as work-related and compensable, workers will not be fully compensated. Most state workers' compensation programs replace only two-thirds of workers' earnings. The same is true for the program covering federal workers who are vaccinated. There are also limits on the maximum weekly benefits, which means that more highly compensated health care workers cannot receive adequate replacement of their lost income. For example, the 2002 maximum weekly payment for Total Temporary Disability in California is $490, and only $400 in New York. (See www.aflcio.org/yourjobeconomy/safety/wc/upload/unemploy.pdf for more information on benefits levels available under state workers' compensation programs.) All states have a waiting period before any compensation is provided, usually in the range of three to seven days. Wages lost during this time will not be compensated unless the worker is off work for an extended period, which is typically 14 to 28 days. Therefore, workers' compensation will not apply to the estimated one-in-three workers who will have a reaction that will make them too ill to work from one to a few days. In addition, there are caps on medical care, posing a particular problem for workers who suffer severe illness or injury as a result of the vaccinia. Death benefits also vary widely. In Florida, the death benefit is only $103,000, regardless of the size of a worker's family or income at the time of death.

The federal government has initiated the vaccination program to protect the country against an intentional release of smallpox. Since the smallpox vaccination program is a national effort, there should be uniform protections that adequately compensate injured workers. It is unacceptable to ask health care and emergency workers to volunteer to be on the front lines in the defense of the nation and at the same time tell them that if they or their family members are harmed by the vaccine, they are on their own regarding medical care and compensation. The National Vaccine Injury Compensation Program, for children injured by vaccines, provides a model, with adaptation for workers, for a federal no-fault compensation system. A smallpox compensation system must be easy to access, provide prompt payments, and fully reimburse affected individuals with respect to income and medical costs.

CONCLUSION

The President's smallpox vaccination program raises a number of serious and unresolved safety and workplace issues. The prudent course of action at this time is to pause, carefully examine the problems, and correct the deficiencies. We are prepared to assist in designing and implementing a program that protects this nation from an intentional release of biological agents and that adequately addresses the health, safety and livelihood of front line health care workers and first responders, their families and their patients.

Senator SPECTER. Thank you very much, Mr. August.

STATEMENT OF JANE COLACECCHI, DIRECTOR, IOWA DEPARTMENT OF PUBLIC HEALTH

ACCOMPANIED BY MARY JONES, DIVISION DIRECTOR, EPIDEMIOLOGY, EMS AND DISASTER OPERATIONS, IOWA DEPARTMENT OF PUBLIC HEALTH

Senator SPECTER. Our final witness on this panel is Ms. Jane Colacecchi, interim director of the Iowa Department of Public Health, previously served in the Governor's Office as policy advisor to Governor Vilsack, a graduate of the University of Southern California, and she is accompanied by Ms. Mary Jones, who is the program director of the Office of Medical and Public Health Disaster Preparedness in the Iowa Department of Public Health.

Welcome, and the floor is yours.

Ms. COLACECCHI. Thank you. We are here today representing Iowa on the need to implement the State's vaccination program. Mary Jones is with me, and serves in a leadership capacity for the organizational oversight and responsibility for disaster terrorism activities within the context of the State's overall public health system. She is here today to assist with any specific questions you may have on operations.

We are honored to appear before the subcommittee today, and particularly Senator Harkin of Iowa, an important long-time advocate for public health. We would like to thank Chairman Specter and Senator Harkin for their dedication and commitment to securing funding for this important initiative. The Iowa Department of Public Health greatly appreciates your leadership.

We are also honored to provide testimony on one of the most critical issues facing our Nation, bioterrorism preparedness, specifically the smallpox vaccination program. The comments that we provide are from the perspective of a State health department as it interacts with Federal agencies and with our local public health, hospital, and first responder partners.

In April 2002, Iowa was awarded $11.5 million from the CDC to upgrade State and local public health jurisdictions in preparedness for and response to bioterrorism and other outbreaks of infectious disease and other public health threats and emergencies. Additionally, Iowa was awarded $1.3 million from HRSA to upgrade hospital, EMS, and other health care entities in preparedness for and response to bioterrorism.

From the CDC and HRSA funds we have allocated at the local, regional, and State levels. Through the use of these funds, we have established six planning regions for public health and health care, with membership from local public health, hospitals, EMS, and emergency management. Each region meets monthly and is actively engaged in development of regional bioterrorism preparedness and response plans.

We have conducted a series of educational sessions on bioterrorism and have held multiple conference calls with local public health and hospitals regarding smallpox planning. We have implemented a Statewide plan to request and receive pharmaceuticals and medical supplies from the Federal Government to distribute on a regional basis to local communities for public use. We have implemented a 24–7 emergency notification system for each county health department through a Statewide paging system, and we

have disseminated public information materials on bioterrorism and smallpox through a supplement in every newspaper in the State.

Since December 13, 2003, when President Bush announced his policy on vaccination for smallpox and receipt of subsequent guidance from the CDC, Iowa has been diligently developing a voluntary smallpox vaccination plan and operation procedures for public health and health care smallpox teams. No funding has been allocated for the smallpox vaccination program. Rather, it has been recommended that States redirect funds from the CDC bioterrorism cooperative agreement to the smallpox vaccination program. As a result, our priority has been changed from building a system of multithreat bioterrorism preparedness to preparedness for a single biological agent.

Redirecting of funds from the CDC bioterrorism cooperative agreement to develop and implement State smallpox plans will affect our ability to build a system of bioterrorism preparedness and response by not funding certain critical capacities benchmarks and recipient activities. Smallpox vaccination planning and implementation is damaging other aspects of bioterrorism preparedness, not to mention other public health programs, such as prevention and treatment of sexually transmitted disease, childhood immunizations, or flu immunizations. Without additional resources, some of these programs may have to be delayed or canceled to meet the needs of the smallpox vaccination program.

Cost estimates were assembled in an attempt to reflect the State's cost to develop and implement the phase 1 pre-event smallpox program. It is estimated that the cost per vaccine for Iowa is approximately $400. This cost includes all associated costs, and is not limited to just the administration of the vaccine.

This includes program development, coordination, management, including education, training, adverse event surveillance, data management reporting, statistical service, public information and education, pre-vaccination screening, volunteer interviewing to exclude from vaccination those with contraindications, education, collecting demographic data and medical data and screening interviews, vaccine and vaccination clinics, which includes vaccine receipt distribution, stockpile management, storage, vaccination administration, providing bandages, supplies to volunteers, clinic setup and operations, staffing, record-keeping, and security, with vaccinators, with initial vaccinator training and education materials, salary, travel, lodging to staff clinics, volunteer vaccines, or reimbursement volunteer salaries for vaccination time and vaccine take check time, and then adverse events, both direct and indirect costs of complications of smallpox vaccine for adults.

Iowa is developing 15 health care smallpox teams, six regional and public health smallpox response teams, with an estimated total vaccine plan of approximately 1,000 public health and health care workers for the phase 1 program, for a total cost of $400,000.

Vaccination is expected to arrive in Iowa by the end of this week. Vaccinator training is scheduled for February 3 through 4 of 2003, with clinics to commence at the end of February. It should be noted that cost estimates for the program will be reduced in subsequent

phases, as some activities will become maintenance or not be necessary.

We must not lose sight of our mission to build a comprehensive system of public health and health care preparedness for and response to bioterrorism, outbreaks of infectious disease and other public health threats and emergencies. It is critical that we sustain the mission of building public health and health care infrastructure, personnel systems, response capacity, and training for bioterrorism. By sustaining the development and implementation of Iowa's multidisciplinary and multiuse system of bioterror preparedness and response, we will be prepared and able to respond in any biological crisis effectively and efficiently. Therefore, additional funding for the smallpox vaccination is needed.

PREPARED STATEMENT

Thank you again for the opportunity to provide testimony on this matter of critical national importance. We would be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF JANE COLACECCHI

Mr. Chairman, Members of the Subcommittee, I am Jane Colacecchi, Interim Director of the Iowa Department of Public Health and with me is Mary Jones, Director for the Division of Epidemiology, EMS, and Disaster Operations at the Iowa Department of Public Health. She has served in a leadership capacity for organizational oversight and operational responsibility for disaster/terrorism activities within the context of the state's overall public health system. We are here today representing Iowa on the immediate need for funding to develop and implement the state's smallpox vaccination program.

We are honored to appear before the subcommittee today, and particularly Senator Harkin, as one of Iowa's Senators and an important, longtime advocate for public health. We would like to thank Chairman Specter and Senator Byrd for their dedication and commitment to securing funding for this important initiative. The Iowa Department of Public Health greatly appreciates your leadership.

We are also honored to provide testimony on one of the most critical issues facing our nation: bioterrorism preparedness, specifically the Smallpox Vaccination Program. The comments that we will provide are from the perspective of a state health department as it interacts with federal agencies and with our local public health, hospital, and first responder partners.

In April of 2002 Iowa was awarded $11.5 million from CDC to upgrade state and local public health jurisdictions in preparedness for and response to bioterrorism, other outbreaks of infectious diseases, and other public health threats and emergencies. Additionally, Iowa was awarded $1.3 million from HRSA to upgrade hospital, EMS, and other health care entities in preparedness for and response to bioterrorism. This funding has been critical as we begin building the nation's public health and healthcare bioterrorism preparedness program. This funding must be maintained to support ongoing bioterrorism system development as well as preparedness for other public health emergencies. We would like to acknowledge and thank you for the work you have done in securing this funding for public health and healthcare.

Funds from CDC and HRSA have been allocated at the local, regional and state levels. Through the use of these funds we have:

—Established six planning regions for public health and health care with membership from local public health, hospitals, EMS and emergency management. Each region meets monthly and they are actively engaged in development of regional bioterrorism preparedness and response plans.

—Conducted a series of educational sessions on bioterrorism and have held multiple conference calls with local public health and hospitals regarding smallpox planning.

—Implemented a statewide plan to request and receive pharmaceuticals and medical supplies from the federal government to distribute on a regional basis to local communities for public use.

—Implemented a 24/7 emergency notification system for each county health department through a statewide paging system.
—Disseminated public information materials on bioterrorism and smallpox through a supplement in every newspaper in the state.

Each of the cooperative agreements outline mandated critical capacities, benchmarks, and recipient activities that must be funded and completed during the cooperative agreement period. These activities all significantly contribute to building a statewide system of public health and healthcare infrastructure in preparedness for and response to bioterrorism. Thousands of hours have been invested by state and local public health, healthcare, and emergency management agencies and personnel in development of these activities in order to build an efficient, and effective statewide system of public health and healthcare bioterrorism services that is fully integrated into Iowa's Homeland Security and Emergency Response Plan.

BACKGROUND AND PROBLEM

Since December 13, 2003 when President Bush announced his policy on vaccination for smallpox and receipt of subsequent guidance from CDC, Iowa has been diligently developing a voluntary state smallpox vaccination plan and operational procedures for public health and healthcare smallpox teams. No funding has been allocated for the smallpox vaccination program; rather it has been recommended that states redirect funds from the CDC Bioterrorism Cooperative Agreement to the Smallpox Vaccination Program. As a result, our priority has been changed from building a system of multi-threat bioterrorism preparedness to preparedness for a single biological agent. Redirecting of funds from the CDC Bioterrorism Cooperative Agreement to develop and implement state smallpox plans will affect our ability to build a system of bioterrorism preparedness and response by not funding certain critical capacities, benchmarks and recipient activities.

Smallpox vaccination planning and implementation is damaging other aspects of bioterrorism preparedness, not to mention other public health programs such as: prevention and treatment of sexually transmitted diseases, childhood immunizations, or flu immunizations. Some of these programs may have to be delayed or canceled to meet the needs of the smallpox vaccination program.

The risk of a widespread domestic smallpox attack may be low, and the benefits of a vaccination program may be limited if our citizens are never exposed to the smallpox virus. However in the event of exposure to the virus, the benefits of a vaccination program for our citizens may be very high. Therefore Iowa is fully committed to participation in the public health component of the national bioterrorism preparedness strategy.

Funding is one of the greatest obstacles facing state success in program development and implementation. The pre-event smallpox vaccination program is a statewide effort to coordinate and manage public health and healthcare smallpox teams, create medical specialty referral mechanisms, plan and assure the availability of the vaccine and vaccination clinics, and monitor and manage adverse events. Appropriations for the smallpox program should build capacity to move states into the Phase 2 vaccination program and at the same time build local infrastructure for mass vaccination or treatment if the need should ever arise. Planning for and responding to terrorism or to any other public health threat or emergency requires full resources of all local, state, and federal entities.

SMALLPOX VACCINATION PROGRAM IMPLEMENTATION COST ESTIMATIONS

Cost estimations for Iowa's Pre-Event Phase 1 Smallpox Vaccination Program are based on information obtained from "Cost Estimations of Vaccinating Adults with Smallpox (Vaccinia) in the U.S.: Stage 1 Vaccination Program": prepared by Ismael Ortega-Sanchez and Benjamin Schwartz, CDC, National Immunization Program, Epidemiology Surveillance Division. Draft Version dated November 6, 2002 and from estimations made by the Iowa Department of Public Health.

Cost estimations were assembled in an attempt to reflect state costs to develop and implement the Phase 1 Pre-Event Smallpox Program. It is estimated that the cost per vaccinee is $400.00. This includes costs associated with:

—*Program*.—development, coordination, and management (education, training, adverse event surveillance, data management, reporting, statistical services, public information and education),
—*Pre-Vaccination Screening*.—volunteer interviewing (exclude from vaccination those with contraindications, education, collecting demographic data, medical data and screening interviews),
—*Vaccine and Vaccination Clinics*.—includes vaccine receipt, distribution, stockpile management, storage, vaccination administration, providing bandage sup-

plies to the volunteers, clinic set-up and operations, staffing, record keeping and security,

—*Vaccinators*.—initial vaccinator training and education materials, salary, travel and lodging to staff clinics,

—*Volunteer Vaccinees*.—reimburse volunteer salaries for vaccination time and vaccine take-check time,

—*Adverse Events*.—both direct and indirect costs of complications of smallpox vaccination for adults.

Iowa is developing 15 healthcare smallpox teams, 6 regional public health smallpox response teams with an estimated total vaccination plan of approximately 1,000 public health and health care workers for the Phase 1 program for a total cost of $400,000. Vaccination is expected to arrive in Iowa by the end of this week. Vaccinator training is scheduled for February 3—4, 2003 with clinics to commence at the end of February. It should be noted that cost estimates for the program will be reduced in subsequent phases since some activities will become maintenance only, or not be necessary. Caution must be used when considering costs for adverse events, medical care, and liability given the ongoing debate of what will and will not be covered by health insurance, workers compensation, and protections provided by the enactment of the Homeland Security Act.

SUMMARY

Public health is a new and vital partner in homeland security and national defense for bioterrorism and as such, must build a system of preparedness and response that may be integrated into existing state and federal emergency response and homeland security plans.

We must not lose sight of our mission to build a comprehensive system of public health and healthcare preparedness for and response to bioterrorism, outbreaks of infectious diseases and other public health threats and emergencies. It is critical that we sustain the mission of building public health and health care infrastructure: personnel, systems, response capacity and training for bioterrorism. By sustaining the development and implementation of Iowa's multidisciplinary and multi-use system of bioterrorism preparedness and response, we will be prepared and able to respond in any biological crisis effectively and efficiently. Therefore, additional funding for the smallpox vaccination program is needed.

Thank you again for the opportunity to provide testimony on this matter of critical national importance. We would be happy to answer questions.

Senator SPECTER. Thank you very much for your testimony, Ms. Colacecchi.

We will now begin another round of questions, and I would like for our earlier two witnesses, Dr. Gerberding and Dr. Fauci, to join us. I begin on a focus on the issue of risk, and that is obviously very difficult to assess. What is the likelihood that someone will attack the United States with smallpox?

Dr. Fauci testified that you cannot quantify—he said that it could be weaponized. We know from the experience in the Soviet Union. Dr. Bell says that it is difficult to ascertain, and this subcommittee will pursue this question beyond the confines of the medical experts. We will inquire of the intelligence agencies as well to see if we can find out more as to what the risk factor is.

It is instructive that there are a number of hospitals around the country who are declining to vaccinate. USA Today published on January 20 a survey for which they purport to have contacted by telephone the public health officials in all 50 States, and they came to the conclusion that the dissenters are a tiny fraction of the 3,000 hospitals recruited by State health officials to vaccinate doctors, but there are some more than 80 hospitals from every region in the United States, including leading teaching hospitals and large urban public hospitals, which are forgoing the vaccinations.

There is an interesting commentary by doctors at the Medical College of Virginia Hospitals, where they say that instead of having a vaccination program, they would like to have 4,000 vaccines

locked up in a refrigerator so that they could then vaccinate the staff where a problem arose, because the vaccine can be taken up to 4 days after exposure and still be effective.

Dr. Fauci, let me start with you. Do you agree that the vaccine can be taken up to 4 days after exposure and still be effective?

Dr. FAUCI. There are data from a number of studies, including one from Bangladesh many years ago, that if you vaccinate someone following exposure, there is a window of about 3 to 4 days in which, if you can get them vaccinated, there is a high probability that you could prevent them from getting infected. You could extend that out a little bit more if you think in terms of muting the extent of the infection, or the complications subsequent to the infection, and so there are data from a number of studies suggesting that, in fact, you do have a window of approximately 3 or so days.

Senator SPECTER. Dr. Gerberding, when there are going to be vaccinations, you have a fairly substantial group which will be vaccinated, and then you can have some better idea as to what the risk factors are when you talk about one to two people out of a million dying and 14 to 52 with life-threatening reactions, and 1,000 per million with serious reactions such as rash, will the people who are accepting voluntary inoculations provide a significant base to make an evaluation as to whether those risk estimates are accurate?

Dr. GERBERDING. I think we have a long history of using this exact same vaccine product and the same protocol, and we have the old data. Our concern is, the old data does not necessarily apply to the conditions of our current population, so we do need to monitor as we go forward, and we will have more accurate information as the program evolves.

Senator SPECTER. How many people are going to be vaccinated under the current plans?

Dr. GERBERDING. The States have requested vaccination for about 450,000 people during this first phase. The number in the second phase, where we expand to include the people at occupational risk in the police, fire department and other health care workers, could be up to 10 million, although we do not think that immunizing all 10 million is likely.

Senator SPECTER. Well, certainly it is not a desirable situation to be one of those who is vaccinated with these risks, and to use them as a basis for making a further determination, but if you vaccinate people into the millions, you will have a better evidentiary base to assess risk, will you not?

Dr. GERBERDING. We will have more data as we go forward, and that is why it is so important that we collect this information as we go, and we are also learning from the military, because there is a military immunization program.

Senator SPECTER. And how many are likely to be vaccinated in the military?

Dr. GERBERDING. I do not have the figures. Part of the information is not publicly disclosed at this time because it has to do with force readiness, but they are anticipating immunizing many thousands of people.

Senator SPECTER. Well, the uncomplimentary phrase comes to my mind of being guinea pigs here, really, which we do not want

to subject anybody to, but if it is accepted on a voluntary basis—of course, the military is not voluntary, but we may have a better evidentiary base to shed some light on what Dr. Bell is concerned about.

This is obviously going to be an ongoing matter, but we lack any real, quantifiable assessment of risk of attack here, and there are comments about North Korea and Iraq likely having the smallpox virus, and then we have to quantify it and evaluate it in terms of all this other long list, so it is going to require a lot of analysis, thought and further study.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I think, Mr. Chairman, you have raised the basic issue that I think we really have to get at here. You said the issue of risk, and I think we need to have some clearheaded thinking on this, and we need the best information we can have from the experts, Dr. Fauci, Dr. Gerberding, about the experience.

It is not as though we have never experienced smallpox before, but we have a wealth of experience about smallpox, how it is transmitted, what the effects are. We also know from past experiences how it can be contained, so I think we have to begin to think about this in terms of what the real threat is.

Ms. Colacecchi, I think, in her testimony, and I underline this, because I think, again, she is talking about this in terms of: "Are we going in the direction that is going to siphon off a lot of money for one threat, as opposed to building a system that will protect our people against multithreats in this country." As a result, to quote Ms. Colacecchi: "our priority has been changed from building a system, a multithreat bioterrorism preparedness, to preparedness for a single biological agent."

So again, what is this threat? For example, I read in one of the magazines, Newsweek, Time, I do not know what it was, about how Saddam Hussein, if he has this smallpox, what he would do is, he would find a willing martyr, inoculate that person with the smallpox virus, put that person on an airline, the airline flies to the United States, it has got 200 or 300 people on board, they all disembark in New York, and they go to this place and that place and this place, all carrying the smallpox virus. A very scary scenario.

How real is that, Dr. Fauci? How is the smallpox virus transmitted? If you have it, can you transmit it from you to me right here?

Dr. FAUCI. I would not be able to transmit it from me to you where we are staying. It usually occurs, with some exceptions—in all of biology, there is a bell-shaped curve, there is what usually happens and then there are exceptions. There are exceptions if you have very close contact and you do not get infected, and there are exceptions if you do not have extremely close contact and you do, but for the most part, it is accepted through close personal contact, usually within family members, or people who spend a lot of time in close quarters together.

That could be in a hospital setting from a health worker who is taking care of a patient who comes in either with recognized smallpox or unrecognized smallpox, or if someone is infected and they

go home and there is the close household setting. That is the usual way that smallpox is transmitted.

Senator HARKIN. I think we need to get to this, because not too long ago, not too many years ago, 15 years ago, where we got in all kinds of scary scenarios on how HIV was transmitted, until finally the medical experts said "No, there are certain ways, and then, beyond that, you cannot transmit it and contact HIV virus."

Dr. FAUCI. Just to make one other point, that is the way that naturally occurring smallpox is transmitted. What that does not take into account is an unknown—and getting back to the statement that I made before, I cannot or we cannot quantitate that risk, but in a situation in which, for example, a material might be spread in an aerosolized way, that breaks the paradigms of someone just getting it and going into the home and having the very close personal contact within a family.

Again, I do not know the likelihood of that, but the information that we have on how we disseminate smallpox is based on the natural evolution of a naturally occurring epidemic, and you just need to take that into consideration. I do not know what weight you want to give to it, but you at least need to consider it.

Senator HARKIN. I agree we need to consider it, but we need to consider it, again, in the framework of what data and what facts we know about viruses or about smallpox virus in particular here. I have heard about the aerosolization of smallpox virus, but how long would the smallpox virus live in the atmosphere?

Dr. FAUCI. Quantitatively, significantly less than, for example, anthrax spores, but certainly not just seconds. When the Soviets were making their weaponized form of smallpox, it was for the purpose of putting it in bomblets to be used through missiles. Again, this is something that we know happened. Whether it is applicable today, given our current situation, we cannot quantitate that, but even if you have the virus that does not last long in the sunlight, which would certainly weaken if not kill it within a reasonable period of time, the aerosolized component is something that we do not have experience with.

You very appropriately, Senator, made the point that we know a lot about smallpox. We know a lot about naturally occurring smallpox. We do not know anything about weaponized, deliberate bioterrorist smallpox.

Senator HARKIN. Do we know anything at all, from your data, about the virus itself and whether it—can it be, has it been modified? Has it been changed? We do not know that, do we?

Dr. FAUCI. That is a possibility, but we do not have any definitive evidence that there has been genetically mutated smallpox. We have no data on that.

Senator HARKIN. And no information that I am aware of that we have on that. So again, I come back to making sure that we have adequate data, or at least information available on smallpox, on the virus, how it is transmitted, and the threat assessment.

Now, correct me if I am wrong, but it just seems to me that if there is any kind of an outbreak of smallpox, that CDC has developed over time procedures to be followed for building these rings of protection around any kind of an outbreak, so again, if we are prepared, and we have that in place, that would answer not just

smallpox, but other possible viral outbreaks, or anthrax, or whatever it might be, that might be used as a weapon, but if we are just zeroing in only on smallpox, are we taking a threat that might be very small, spending a lot of money getting everybody very upset and excited about this, and perhaps causing some unknown, unanticipated illnesses and deaths, rather than building the system that will truly protect the American people not just against smallpox, but against all other kinds of threats that might come along?

Dr. GERBERDING. Senator, we appreciate so much your perspective on this. This is basically the whole premise of the CDC's terrorism preparedness program, that we need to build a foundation of capacity to deal with all threats, but having said that, the investments we are making in this capacity to immunize responders for smallpox, and then getting them into a shape where we could immunize the entire population, is a capacity that will serve us well for whatever countermeasure we have to deliver, so if we can do this for smallpox, we can deliver antibiotics efficiently for anthrax, we could deliver botulism toxin efficiently if we have a botulism exposure, so it is not totally unrelated to the principle that you are articulating.

If I could just make a quick statement here to give you some idea about how this works, when we get a call that says there is a highly suspect case of smallpox, or something that could be smallpox, two things happen immediately. One is, we get the clinicians in that place to get the sample to the nearest laboratory that our appropriation from this committee helped support, and get that example to CDC so we can very quickly know for sure if it is or it is not, and we can do that in about 12 hours.

Simultaneously with that, we send our smallpox advance teams on a plane that we can charter if necessary, even if the air space is closed, carrying one of these kits, which carries enough vaccine to immunize 1,500 people, and our response teams would take this right to that ring of the contacts, and do everything possible to prevent the spread from that circle of the initial case and the contacts therein, so that helps us.

Once we have an exposure, we know what to do to contain spread, but we also believe that once we have a single case of smallpox, the expectation in all communities will be, now the threat is no longer questionable, it has happened, and so everyone will need immunization, and we need to be able to be prepared to respond to that as well.

Senator HARKIN. Thank you very much, Dr. Gerberding.

Mr. LIBBEY. Senator, if I might, from the point of the actual implementation I would agree with Dr. Gerberding to the extent that preparing for smallpox in some areas, particularly the phase that we described as community preparation, ties us into the issue managing the stockpile for other issues and the like, but the level of resources specific to the vaccination itself, and to the necessary follow-up care, have limited application to other forms of preparedness.

Senator SPECTER. Thank you very much, Senator Harkin.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman, and thank you, really, to all of our witnesses today. I think that all of us are hearing a lot of concerns from our communities about what their responsibility is going to be and how they are going to pay for this, weighed against the risks that clearly have been outlined, but how real they are, and Mr. Libbey, I am glad you responded, because I did want to ask you, Dr. Gerberding is speaking from a national perspective and putting a model together, and certainly in the case of where smallpox actually occurred, I think we all know that is different from what we are looking at right now, which is prevention, and you responded shortly to that, but I would like to ask you specifically, do you see that model being in place?

You talked in your testimony about diverting from other resources and other public health care crises. Does this model help you, or does it take it away from other things that public health officials are trying to do?

Mr. LIBBEY. It has helped in some regards in terms of the public health community making better and stronger connections with the medical care community, other parts of the emergency management systems of their community. In that regard, it has been helpful, but that would be the case of overall bioterrorism preparedness.

What we have heard in a survey of about 715 respondents, two-thirds said it has detracted from their ability to provide other public health services, as well as from other bioterrorism more broadly, that general preparedness.

Senator MURRAY. Because of a singular focus on one issue?

Mr. LIBBEY. Because of the singular focus to the issue. There will likely be, I would not disagree, some residual level of value to preparedness, but to suggest that it is an equivalent transfer suitable for other agents or other issues, we would question.

Senator MURRAY. You in your testimony said that in metropolitan areas it would cost between $142 and $222 a person to inoculate. I was actually out in Mason County, which is not far from where used to be—a very small rural community who were very concerned about the costs. Rural communities, would the price be higher, because you do not have as many people?

Mr. LIBBEY. I think the difference expressed by Iowa is a very good example of that, the time travel, the distance, and the fewer numbers.

Ms. COLACECCHI. We have larger per capita numbers because we have taken a rather conservative approach in the number of people that we are inoculating, but we do have increased costs due to the rural nature of our State in terms of travel, and the ability to train people on a Statewide basis.

Senator MURRAY. I think that is what we are hearing from a lot of our communities, is how, with all the other burdens they are in right now, they are going to pay for this risk, and whether the risk is worth it. Certainly, these are difficult questions for all of us.

Dr. Gerberding, I wanted to go back to you again, because I listened carefully to Dr. Bell and his testimony in thinking through the process at his hospital and deciding not to inoculate their health care officials. I know I am hearing from several hospitals in my State that have gone through the same process and come to the

same conclusion, not children's hospitals, other hospitals, because patients in hospitals today are much sicker than they were 30 or 40 years ago, and could possibly be at much higher risk, and weighing those risks is a very difficult decision for any hospital administrator.

How do you respond to Dr. Bell or to the hospitals in my State and argue to them a case that is a different conclusion than they have come to?

Dr. GERBERDING. I am very respectful of the perspective of the panel, in fact of all the panelists. I think we are all struggling to find the right balance here between risk and preparedness and expediency and, as I said in my testimony, the safety of the individuals and the patients involved, and this really has to be the highest imperative for us.

When we put together this implementation plan, we were very cognizant of what our goal was. Our goal was to ensure that we had sufficient preparedness capacity so that, should we have a smallpox attack, we would have the initial infrastructure and personnel to be able to mount a much broader population campaign. That does not require every hospital to participate. It requires that, in a jurisdiction, there are sufficient resources in the health care delivery system to take care of the initial cases of smallpox.

So we knew that not every hospital would choose to participate. We anticipated that in our calculations, and I am very respectful of the decision of individual hospitals, but having said that, I must also say that we are concerned about spread to patients when we are immunizing health care personnel, and we have gotten expert input from two advisory committees, our Advisory Committee on Immunization Practices, as well as our Specialist in Hospital Infection Control, to help us identify what are the hazards to patients and what we need to do to protect them.

So we have a number of steps that would be required in a facility to ensure that patients are safe, and that includes the hygiene, the covering of the wound, and a daily check of each immunized health care worker to make sure that their inoculation site is not spreading and that it is properly covered, and that the hazard to patients is minimized.

Senator MURRAY. And are you concerned that in many communities, they do not have the resources, so given this concern now, they are diverting resources from other public health issues they may have?

Dr. GERBERDING. I really look forward to working with NACCHO and other organizations that are assessing that. We received progress reports from the jurisdictions in November to assess where they were in terms of their implementation of the expectations from the appropriation that went out in June. Our feedback from that progress report was that people had taken excellent steps toward achieving the expected capacities, but if there has been a change in that, we will need to get it again as we go out for the next round of evaluation, and so we will take that concern very seriously.

Senator MURRAY. I know my time is running out, but Dr. Fauci, I wanted to ask you one other question. We know there are risks to children and pregnant women. What research is taking place at

the institutes that will help us better evaluate the long-term impacts on early childhood development, or pregnant women, or fetal development? Is there any research going on, and what do we know today?

Dr. FAUCI. To my knowledge, no. I would have to get back to you on that. That would be through the National Institute of Child Health and Development, so that would not be in our institute, but I can get that back to you, Senator Murray.

Senator MURRAY. Okay. I would really like to know that. Thank you.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Murray.

On the issue of containment, as opposed to prevention, Senator Santorum and I were at Carnegie Mellon recently, and the University of Pittsburgh Medical Center, where they are collaborating on software to identify people who have signs which might be some bioterrorist attack, and they collate material from hospitals and from doctors and other medical centers in a context of putting all the pieces together to try to determine if we are in the incipient beginning stage of a bioterrorist attack.

Now, if we have 4 days—Dr. Fauci, you were not definitive on that. You told me about the Bangladesh data, but you did not tell me what Dr. Fauci thought about it, but if we really have 4 days—do we have 4 days, Dr. Fauci, in your judgment?

Dr. FAUCI. I would only have to look at the data, because we do not have experience. The last case of smallpox that occurred in the United States, I was 9 years old, so I do not have experience in that regard, but with regard to the information in the literature, I would say that that is a strong suggestion that, indeed, you do have a 3- to 4-day window.

Senator SPECTER. Well, how far along are we on detection? The New York Times had a front page story a few days ago about eight centers being designated in the United States to collate the material to try to predict at a very early stage whether we are being subjected to an anthrax attack, or to a smallpox attack.

How good are we at that, and how good could we become, and if we could really catch it at the outset, and had 4 days, and had the suggestion made by the Richmond medical facility to have vaccines in the refrigerator, then we do not have to vaccinate all these people and take all these risks if we could really contain it with that time interval.

What do you think Dr. Gerberding?

Dr. GERBERDING. We want to be able to detect this virus at its release, if it is an aerosol release. We are not there yet. Even with the detection systems that have been deployed, we cannot guarantee that we would be able to detect it.

Senator SPECTER. We are not there yet. When you say yet, are there prospects for getting there?

Dr. GERBERDING. I think the technology is rapidly evolving. Some of the research NIH and others are doing will get us there.

Senator SPECTER. Is the NIH doing the research?

Dr. GERBERDING. The NIH is doing some research.

Senator SPECTER. Well, they have lots of money. Dr. Fauci has lots of money.

We have loaded them up with money, $12 billion to $27 billion. On what date will we have the answer? On what date next month will we have the answer to that, Dr. Fauci?

Dr. FAUCI. You know, Mr. Chairman——

Senator SPECTER. Do you want a good appropriation this year again?

Dr. FAUCI. I am going to give you the right answer for that appropriation, Mr. Chairman. We have fundamentally not environmental sensor-type research, but we have research to detect in the very, very early stage if someone is exposed.

For example, you can do molecular diagnostics where, prior to the virus being in a form where it could be culturable, when someone comes in with a suspected case, you would send a specimen down to the CDC for identification.

What we are striving for in the research that is going on at the NIH is to develop molecular techniques that can actually detect either the genetic material of the smallpox prior to the point where it is obvious that it has turned into a disease, in other words, post-exposure, but prior to the symptomatology stage.

Senator SPECTER. How practical is it to follow the recommendation of the Richmond medical unit to have 4,000 vaccines in a refrigerator to be able to spring into action? Can that be disseminated and dispersed around the country, so that we are in a position to respond within 4 days?

Dr. GERBERDING. The most important part of detection for this problem is the astute clinician who recognizes the first patient. If they miss the first patient, we will miss the 4-day window.

Senator SPECTER. Well, how good is our dissemination of information? We really ought to be able to educate the clinicians on this, should we not?

Dr. GERBERDING. We are doing everything we can. That is part of the 3½ million kits that we are sending out to all clinics this month.

Senator SPECTER. These are clinicians who went to medical school. Did the medical school teach them?

Dr. GERBERDING. That is right, but, you know, they did not see a case. I do not think there was much emphasis on any of these agents when we were in school, because they are such rare diseases.

Senator SPECTER. Are the medical schools responding now?

Dr. GERBERDING. Yes, they are.

Senator SPECTER. They are now teaching it?

Dr. GERBERDING. Yes, they are.

Senator SPECTER. And the medical publications are carrying information to educate those who might not know it?

Dr. GERBERDING. The major medical journals have all carried articles. For example, the Journal of the American Medical Association, which is probably the most widely read journal, has had information for clinicians on every one of the select agents.

Senator SPECTER. Well, in the event that any clinician is now watching C-SPAN, Dr. Gerberding, tell them what to look for. This is a great educational tool.

Dr. GERBERDING. You are absolutely right. Any patient who presents with fever and a rash, particularly a rash that has evolved

over several days in the context of someone who is quite ill and has the characteristic appearance of the——

Senator SPECTER. Symptoms?

Dr. GERBERDING. Symptoms of smallpox include high fevers, muscle aches, head aches, and, in general, one of the reasons why we can contain it after a case has developed is because the people who have it are so sick that they are not out in the community spreading it, they are home in bed, sometimes infecting their contacts.

Senator SPECTER. What should the clinician do after observing such symptoms?

Dr. GERBERDING. If there is a suspicion, the immediate step is to isolate the patient from others in the health environment so there is no spread in the emergency room or the clinic. The second thing is to call the——

Senator SPECTER. And what kind of facility should hospitals have for isolating? I said that 2 days ago Senator Santorum and I were at UPMC, University of Pittsburgh Medical Center, and they had a decontamination room, if the next step is isolation, give a little description to the hospitals as to what they ought to be doing to prepare for that.

Dr. GERBERDING. Well, as Dr. Fauci said, this virus is primarily spread by close contact. We call that droplet transmission, occasionally through the air, but most of the transmission is through close contact, so simply taking the person and putting them in a separate room, and preferably a room that has the same kind of air circulation that we use for tuberculosis patients, and which most facilities have now, because they had to do it as TB came back in, so that you isolate them from spreading the virus through their skin to other patients, and also through the air.

Senator SPECTER. Is there any real risk from moving the patient from the time the clinician spots the symptoms to some room on the sixth floor, or some distant part of the hospital?

Dr. GERBERDING. Well, we would like to be able to get patients to that kind of area with the minimum amount of direct contact with other health care workers and other patients.

Senator SPECTER. So you would recommend that this room be close to the emergency entry?

Dr. GERBERDING. That would be ideal.

Senator SPECTER. What other tips do you have for the hospital?

Dr. GERBERDING. I think the hospitals really need to think about how they will get all of the people in the front line of the delivery system alert to this, because the infectious disease doctors and the skin doctors are aware of it, but not all of the primary care doctors, not all of the residents and interns, so there has to be a comprehensive commitment and education of all the clinicians who are doing triage.

Senator SPECTER. So the hospitals ought to disseminate this information.

Dr. GERBERDING. The hospitals need to do it, and CDC and HHS are working very hard to make sure they do have the tools.

Senator SPECTER. Does CDC have a nice booklet that could be distributed to the hospitals to give to all the clinicians?

Dr. GERBERDING. We do. So far, we have distributed 70,000 copies of something called the fever rash poster, which outlines how to diagnose and identify this disease and, as I said, this 3½ million mailing is going out as soon as we get all of the addresses of the nurses and the clinicians at the local level.

Senator SPECTER. 3½ million?

Dr. GERBERDING. Correct.

Senator SPECTER. Is that adequate?

Dr. GERBERDING. Well, it is the biggest step we have ever taken to provide direct information in the hands of clinicians, but it comes on top of the Internet, the satellite broadcast, CD–ROM's, the medical publications, our speaking at medical conventions and so on.

Senator SPECTER. Is this information on symptoms available on the Internet?

Dr. GERBERDING. Absolutely. This is a picture of the poster that we have distributed to so many clinicians. This is a miniature version of it. This is easily available on our web site.

Senator SPECTER. So tell anybody who is listening or watching C–SPAN what to look for on the Internet.

Dr. GERBERDING. Go to www.cdc.gov, and one of the first headings there will link you directly to our smallpox page, and we have a special service there that is just for clinicians, so they can go into a segment of our web that gives them the specialized information that a nurse or a physician or other medical provider would need.

Senator SPECTER. Dr. Gerberding, we are sort of winging it here as to how you inform clinicians, but would you give some thought and get back to the committee in a week as to what ought to be done in a systematic way?

Dr. GERBERDING. Absolutely.

Senator SPECTER. And what you might require by way of funding to get it done promptly, and maybe some allocation of current resources, with a commitment by the Congress to reimburse you so you can go ahead and get this information available?

Dr. GERBERDING. Thank you, sir.

Senator SPECTER. Mr. Libbey, when smallpox vaccinations were administered routinely in the 1950s and 1960s, did the public health system carry out the follow-up actions, the extensive follow-up that you say is now necessary, and what has changed since then that would require the extensive and costly follow-up that you have testified about?

Mr. LIBBEY. Several conditions, to my knowledge, and I may have been even younger then 9 at that point. There was not that same level of extensive follow-up, a couple of reasons different. The issue of risk and threat was different, because the disease was present. I suspect if the disease were present now, we would have less involved processes both in the vaccination and potentially in the follow-up. We do know and anticipate that there will be adverse reactions.

We also know, absent 30 years of providing this vaccination, people are going to see the reaction and not understand that it is within, may well be within what is normally to be expected, there will be inquiry that will demand time and attention, and that there will be adverse reactions that need to be screened.

I would also suggest that one of the changes in the last 30 years in some ways is a change, as was mentioned earlier, the potential vulnerability of the population, but I would also suggest the nature, the litigious nature of our society has changed somewhat, that makes having these pieces in place.

I would also point to, these are requirements of the program guidelines provided to us for clinical operation of the program from our Federal partners.

Senator SPECTER. Dr. Gerberding, you wanted to show your vaccination.

Dr. GERBERDING. Yes. I just wanted to make sure that the committee was aware of what the needles look like and what the vaccine would come like. I mentioned the Vaccipack that would be taken out. If we had to vaccinate the population, we have already kitted and ready to go the smallpox vaccine for 150,000 doses per kit that our national pharmaceutical stockpile would deliver, and what a kit looks like is basically this.

There is a small vial of vaccine that we would add a diluent to using this needle, and then the vaccine needles that we are using right now, we are distributing to you and the other members of the committee, which is a little needle that looks like a miniature salad fork or cocktail fork that would be poked into the arm 3 to 15 times to administer the inoculation, and I think one of the achievements of the appropriation that we have received this year is that our national pharmaceutical stockpile can do this efficiently and effectively, and we can simultaneously deliver this vaccine to every major jurisdiction in the country within 24 hours, just like Federal Express.

We can get this out from the stockpile repositories to the front end very, very quickly. That is an enormous step forward in our capacity, and we absolutely would not have been able to do that without the support from this committee, both because we now have enough vaccine to immunize everybody, so we have the supply, but we also have this logistical system to get it to people if we need it, so our preparedness has improved, and we really thank you so much for that investment.

Senator SPECTER. Well, we are pleased to hear that the funding the subcommittee has initiated has been so fruitful.

Well, we thank all of you for coming today. I think this has been a very, very productive hearing in terms of identifying very, very key factors, and perhaps in educating people as to what we need to do, but a great deal more needs to be done, and this subcommittee intends to pursue the question of risk.

Dr. Fauci, just one more question to you. Do you have any indication as to which countries have smallpox potential for bioterrorism attacks?

Dr. FAUCI. No, I do not, Mr. Chairman. The only thing I have is what I believe you have also, is what we have read in the newspapers about various intelligence reports, but I do not have information of intelligence that you do not have yourself.

Senator SPECTER. Well, what we need to do is to try to make the intelligence available to the public, if there is any, and we may not be dealing with much to work on. We can pursue the line that the

Soviet Union had weaponized smallpox. That is an important factor.

This sort of comes under the same category as our effort to buy down their nuclear weapons, the so-called Nunn-Lugar buy-down, where have put in hundreds of millions of dollars, but we need to get a better assessment on risk, and we need to have a better assessment as to the 4-day interval and move ahead with the identification of these symptoms, and to try to educate clinicians as to what ought to be done, and then to try to get the hospitals to have the isolation rooms like the one I saw on Monday to move ahead.

And I think time is of the essence. We cannot take anything for granted. We have had a year-and-a-half, but who knows what is going to come next.

Well, we will all pursue the matter together.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 11:40 a.m., Wednesday, January 29, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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