

The Smallpox Vaccination Plan: Challenges and Next Steps

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Witness:

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Testimony:

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

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

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

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

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

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

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

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

Jackson Memorial is one of the largest public hospital in the country. On any given day,

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

Nurses, doctors, and management at our hospital decided that any volunteer who could accidentally expose vulnerable patients to the virus in the vaccine should be put on administrative leave until they were no longer shedding the live virus in the vaccine. In our hospital – as in just about every hospital across the country – understaffing is a constant issue. Too few nurses are already under pressure to provide quality care to patients who are sicker than ever before. Recent studies suggest that the smallpox vaccine will make up to 1 in 3 nurses too sick to work for a few days – and those are just the people with normal reactions.

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

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

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

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

Our hospital is providing free and confidential testing for any volunteers who want to be sure they aren't pregnant or infected with HIV before they volunteer for this vaccine. Our service men and women in the military who are candidates for the vaccine are being offered such protection, but as of yet, the federal government has not agreed to pay for such tests for civilian health worker volunteers. Spending a relatively small amount on preventative testing can reduce the cost of any compensation fund, as adverse effects are

less likely if people at high risk are identified and screened out. Not everyone will need testing, but there must be mandatory screening with free voluntary testing where such follow-up is indicated. Not only must testing be confidential, but smallpox responders must be protected against any discrimination or retaliation on the job if they refuse to be vaccinated.

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

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

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

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

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

The Homeland Security Act protects the drug companies who produced the vaccine and the hospitals who administer it from liability. If workers, their patients, or their family members get sick as a result of the vaccine, they'll be lucky if they receive a "get well" card from our elected leaders. I think we can do better than that – and I hope you do, too. Nurses at my hospital had a voice in how our smallpox vaccination plan will be implemented because we have a union. But most health care workers aren't so lucky. Without action by Congress, the safety of this plan for workers and our patients will depend a lot on where you live and which hospital you work in.

Even our hospital hasn't been able to answer the question of what will happen if one of us, or one of our patients, or someone we live with gets really sick from this vaccine. At Jackson Memorial we are fortunate since our employer has agreed to pay for up to seven days of administrative leave for those of us who have less severe reactions.

But what happens after that is an unknown. Where can health care workers or others

suffering injury or illness from the vaccine or exposure to the vaccine turn to for coverage of medical care and lost wages.

State and federal workers' compensation programs do not provide an adequate safety net. We have already heard that some state workers' compensation programs won't cover us and others won't do enough. Some workers' compensation programs may not cover the claims of workers who have adverse reactions because they have voluntarily agreed to be vaccinated. Some state workers' compensation laws do not require coverage for all workers. Since workers' compensation only applies to injuries that are work-related, it won't provide any protection for patients or family members who could be at risk. Even where applicable, workers will not be fully compensated. Most workers' compensation programs replace only two-thirds of workers' earnings. There are also limits on the maximum weekly benefits, which means that more highly paid health care workers cannot receive anything approaching adequate replacement of their lost income. In addition, there are caps on medical care, posing a particular problem for workers who suffer a severe side effect. Clearly, for most civilian responders and others who become ill from exposure to the vaccine, the workers' compensation program will not be there for us.

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

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

The Need for Federal Legislation

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

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

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

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

3. Medical Surveillance and Treatment of volunteers, patients, co-workers, and household members for any adverse effects of the vaccine. Treatment must be available at no cost to those suffering adverse reactions to the vaccine as well as protections to ensure no lost wages or benefits if they are required to take time off from work. A federal compensation program must be available for those suffering from more serious adverse reactions. For those responders or others who have no health insurance, there must be some provision, such as temporary Medicaid coverage, to ensure that treatment costs are covered. In addition, the Institute of Medicine has recommended a much stronger system of reporting adverse reactions to the vaccine.

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

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

Conclusion

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

Thank you.

OUTLINE FOR SMALLPOX LEGISLATION

The following are the critical elements that must be included in any federal legislation related to the implementation of a National Smallpox Vaccination Program for all potential smallpox responders (includes the anticipated 10 million civilian health care workers and first responders) and their household contacts, co-workers, patients, and the general public who by reason of contact could contract the vaccinia virus or other illnesses resulting from the smallpox vaccine. Since this is a program for national defense, there must be a comparable range of protections and services provided to the civilian smallpox volunteers as are being provided to military personnel and defense contractors through the Department of Defense smallpox program.

I. Urgency for legislation to protect potential Smallpox Responders. With the civilian smallpox responder program expected to begin January 24, it is imperative that emergency legislation be passed and signed into law prior to the start date that would provide for a Smallpox Responder Protection Program in accordance with the elements listed below and that sufficient appropriations are also approved to carry out a comprehensive program. Any legislation must include new funding to states to provide for education, screening, medical surveillance, and treatment; protection against discrimination in the workplace; requirement to use safer needles; and compensation due to adverse reactions and inability to work.

II. Education, Screening, and Medical Surveillance Program

The legislation shall include new funding to the states to establish state programs with the requirements listed below. States are responsible for ensuring that all these requirements are carried out.

• Mandatory Education

Prior to the initiation of a vaccination program, a mandatory education program on the smallpox vaccine for all potential smallpox responders, their household contacts, and co-workers who may be exposed to the vaccinia virus.

1. The mandatory education program for smallpox responders shall be similar in format to the requirements for education under the OSHA Bloodborne Pathogens Standard (OSHA 1910.1030(g)(2)).
2. The mandatory education must explain verbally and in writing the screening and medical surveillance program; the risks for those smallpox responders vaccinated, their household contacts, patients, and co-workers; coverage for lost wages and benefits and on-going medical care for those injured by the vaccine directly or as a result of contact with someone who received the vaccine; the injury compensation program, and the right to refuse the vaccine without being discriminated against at work.
3. All written information must be available in easy to read form and distributed to all smallpox responders, as well as household contacts, co-workers, and patients potentially exposed to the vaccinia virus through those who were vaccinated. Where appropriate, multilingual materials should be developed. This information should also be available on a website established by the state or through the CDC that is the central source for all information available to the public on the National Smallpox Vaccine Program.
4. Employers shall be responsible for ensuring that all potential smallpox responders and their co-workers receive the mandatory education program.
5. This program shall be available free of cost and shall be available on work time.

• Medical Screening

Provide free and confidential medical screening

1. Confidential medical screening must be available to everyone volunteering for the vaccine to determine if there are any health risks for the smallpox responder or their household contacts that would eliminate or delay the smallpox responder as a candidate for vaccination. Any test results and information collected during medical screening must be considered protected health information and not available to employers.
2. Medical screening shall include appropriate medical examination and testing.
3. Any willing smallpox responder must agree to confidential medical screening prior to vaccination.
4. Medical screening shall be free and done on work time.

- Medical Surveillance and Treatment

Provide on-going medical surveillance and treatment.

1. For the first four weeks following the vaccination, there must be on-going monitoring for all those who were vaccinated to determine if there are any adverse reactions that require immediate medical treatment. Medical surveillance will be done by the agency or facility that vaccinated the first responders. However, it is the responsibility of the state public health agency to ensure that adequate medical surveillance is carried out in accordance with the CDC guidelines for active surveillance and follow-up.

2. Immediate evaluation and required medical treatment shall be provided to anyone who appears to have an adverse reaction to the vaccine, including co-workers and household contacts of the vaccinated smallpox responder. The agencies or facilities designated by the state to carry out the smallpox vaccination program are responsible for ensuring that anyone who has an adverse reaction shall receive immediate evaluation and treatment, if needed.

3. Those vaccinated, affected co-workers and household contacts shall receive all medical surveillance and treatment free of cost and without any loss of wages or benefits. All costs related to surveillance and treatment and lost wages and benefits shall be borne by the federal government as provided under Sections III and IV.

4. Adequate protection for those vaccinated will be provided to minimize accidental transmission of the vaccinia virus to co-workers, patients, household contacts, and the public.

5. Those responsible for medical surveillance shall make a determination when a worker should be removed from regular work in order to protect patients and co-workers as a result of an adverse reaction to the vaccine. Workers relieved of work for this reason shall not suffer any loss in wages or benefits.

6. The federal government must ensure that there are adequate supplies of the vaccinia immune globulin (VIG) available through the state public health agencies to assist in treatment of adverse reactions. Anyone injured by the lack of available VIG must be able to sue the federal government under the Smallpox Vaccine Injury Compensation law.

7. Similar to DoD's Vaccine Adverse Reporting System, the federal agency responsible for administering the National Smallpox Vaccine program shall establish a uniform reporting system for adverse responses to the smallpox vaccine so the public can fully evaluate the risks of the vaccine. (CDC has issued in its smallpox guidelines a requirement for states for filing Vaccine Adverse Event Reporting System (VAERS) Reports.)

- Protection Against Discrimination

Protect all smallpox responders from job discrimination or retaliation for refusal to be vaccinated.

1. There must be no discrimination in the workplace based on an individual's decision whether or not to participate in the smallpox vaccination program.

2. An appeal process must be available if a worker is discriminated against for refusal to be vaccinated. Antidiscrimination protections afforded workers shall be similar to those provided employees under Section 211, 42USC 5851(b)(1)(Energy Reorganization Act) and administered by DOL subject to 29CFR Part 24 – Procedures for the Handling of Discrimination Complaints under Federal Protection Statutes. Employees will also be afforded the right to sue employers who violate the prohibition against discrimination.

- Each workplace where smallpox responders are present must ensure that systems are in place to protect vulnerable patients from being exposed to smallpox responders who have had the vaccine, and to inform patients of the safeguards that have been put into place.
- Administer the vaccine with safer needles. Only the safest and most efficacious bifurcated needles meeting OSHA's Bloodborne Pathogens Standard may be used to administer the smallpox vaccine. Sheathed needles are now available for the smallpox vaccine. Before the commencement of the vaccine program, the FDA must issue the license for use of the sheathed bifurcated needles for the smallpox vaccine. The 50 million needles the government shipped to health care facilities with the vaccine do not comply with the Needlestick Safety and Prevention Act of 2000 designed to protect health care workers and patients from accidental needlesticks. To the extent available in the marketplace, the use of safer needles shall be implemented either by direct purchase by CDC or reimbursement through CDC. States must ensure that the vaccine is administered with safer devices in all public and private workplaces.
- Full funding to state public health agencies to enable every state to develop and carry out the required education, screening, medical surveillance, and treatment programs. Such funds should be new monies available as an emergency appropriation to the states. States should not have to siphon funds now being used to strengthen state and local public health infrastructure to fund the smallpox program.

III. Provision of free medical treatment for smallpox responders, for household contacts, co-workers, patients, and others who are injured as a result of contact with someone who received the vaccine.

For those without insurance or whose insurance would not cover treatment of adverse reactions to smallpox as an exclusion or because of high deductible.

Options:

- Require the state departments of health through the designated smallpox agencies, facilities, or providers to provide medical treatment. The state grant program must include sufficient monies to enable the public health departments to provide the direct medical care, reimburse providers for care, or contract for such care.
- At state option, extend Medicaid coverage temporarily to smallpox responders who become ill as a result of their own participation in the National Smallpox Vaccination Program or develop symptoms after coming in contact with an individual who has participated in the program. (Modeled after the coverage provided to people who have been diagnosed with breast and cervical cancer through the CDC early detection program.)

IV. Leave Rights for Smallpox Responders

Experts say approximately 1 in 3 people who are vaccinated will feel too sick to work or to provide proper patient care for one or more days.

- All vaccinated smallpox responders, affected co-workers and household contacts who are not well enough to work must have up to 4 days of leave without loss of wages or benefits. Employers may seek reimbursement for wages and benefits paid to these workers.
- In the interest of public safety, employers shall make a determination if a smallpox responder who has an adverse response to the vaccine shall be placed on leave or transferred to another position. The responder shall not suffer any loss of wages, leave or benefits.

- Any health care facility or other employer that decides that vaccinated smallpox responders should be transferred or placed on leave to protect vulnerable patients must ensure that the individual does not lose wages, accumulated leave or other benefits.

V. National Smallpox Vaccine Injury Compensation Program

- Notwithstanding Section 304 of the Homeland Security Act, a national vaccine injury compensation program must be established providing compensation to any smallpox responders injured as a result of receiving the vaccine. It must also provide compensation to persons who are injured as a result of coming into contact with a person who has been vaccinated. For adverse reactions that are recognized consequences of the vaccine, the right to recover shall be on a no fault basis, similar to the Injury Table used for the Childhood Vaccine Injury Compensation system. This means that if one of these conditions occurs there is no requirement to prove that the vaccine or the manner of administration caused the injury. (Presumption of statutory dependency.)
- Coverage under the compensation system is designed for the less routine consequences or adverse reactions to the vaccine including but not limited to: autoinoculation to other sites, generalized vaccinia, eczema vaccinatum, progressive vaccinia, post-vaccination encephalitis, blindness, vaccinia necrosum or death.
- System must have a mechanism for proving causation for other consequences. Like the CVIC system, this allows for any adverse consequences that may not be listed on the injury table to be proved as having been caused by the vaccine or administration.
- System must be simple to access: filing forms with one agency and receiving quick response.
- Compensation must include provision for medical costs, pain and suffering, lost wages and a fair system for determining damages. Caps acceptable but must be fair. There should be provision for recovery of wages and benefits by anyone injured even if the condition is reversible and the individual can be expected to return to work. In order to ensure that the individual volunteer does not bear the brunt of direct hardships, there needs to be a requirement for employers to continue wages and benefits while the individual is off work with a right for the employer to subrogate and receive reimbursement from the compensation fund. In the case of catastrophic permanent injury or death, there has to be a system for determining payment of lost wages and pain and suffering. In either case the compensation fund must pay or reimburse for all medical costs.
- Administrative system for determining damages must be relatively speedy and simple. CVIC system is a good model.
- Trust Fund must be established that is funded directly by Appropriations. Since the vaccine has been purchased and is being distributed at expense of the federal government a vaccine surcharge system cannot be used.

VI. Liability Protection

Section 304(c)(7)(B) of the Homeland Security Act of 2002 must be amended to clarify that a vaccinated person who transmits vaccinia accidentally is a “covered person” and immune from liability for injury caused by transmission of vaccinia.

Prepared by the AFL-CIO, American Federation of State and County Municipal Employees (AFSCME), the American Federation of Teachers (AFT) and the Service Employees International Union (SEIU).

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