



**Statement
of the
American Hospital Association
before the
Institute of Medicine
Committee on Smallpox Vaccination Program Implementation
on
Hospitals' Views on the Federal Smallpox Vaccine Program**

December 19, 2002

Good afternoon, I am Roslyne Schulman, Senior Associate Director for Policy Development at the American Hospital Association (AHA). The AHA represents nearly 5,000 hospitals, health systems, networks, and other providers of care. We appreciate this opportunity to present our position on the federal government's smallpox vaccination plan.

Let me start by making one thing very clear: America's hospitals and health systems support this voluntary vaccination program, because our job – our mission – is to protect and improve the health of the communities we serve. The nation's hospitals are committed to taking all necessary steps to prepare for the previously unthinkable possibility of a terrorist attack using a biological weapon such as smallpox. Our members tell us that they want to be a part of this program for that very reason – because their job is to protect their communities.

They are also dedicated to protecting the people who work in hospitals, and the patients who come to them in times of need. Ensuring the health and safety of hospital workers and patients is critical to hospital disaster readiness planning. Several aspects of the federal smallpox vaccination plan remain unclear in this regard, leaving many unanswered questions that must be addressed. We have been engaged in ongoing discussions with the White House and the Department of Health and Human Services (HHS) about these issues and we hope to see them resolved in an appropriate and timely manner. Key among them are issues of liability and compensation, implementation and timing.

LIABILITY AND COMPENSATION

We need to ensure that hospitals and health care workers who volunteer to participate in the federal smallpox vaccination program are protected from potential liability arising out of this initiative. Under Section 304 of the Homeland Security Act, the following receive protection from liability:

- Manufacturers of smallpox vaccine
- Those health care entities under whose auspices the vaccine is administered, as well as their employees, officials and agents
- Physicians, nurses and others who administer the vaccine and
- Those who are vaccinated and certain third parties – for example, a health care worker who receives the vaccine and a family member or contact of a vaccinee who may be accidentally inoculated with the virus.

Congress intended this provision to provide liability protection to hospitals in exchange for their participation in the government's efforts to lessen communities' vulnerability to bioterrorism. The AHA believes that any hospitals that participate in the program, including those with employees who are vaccinated, those who have vaccinated non-employed physicians or other health professionals on staff, and those with a reasonable connection to anyone who may be inadvertently infected, should be covered by Section 304.

We are seriously concerned that a recent question and answer document posted on the Centers for Disease Control and Prevention (CDC's) Web site seems to suggest that the government may view this provision too narrowly. The CDC's document indicates that hospitals that are not actually administering smallpox vaccinations on-site would not be protected from liability. This would mean that only hospitals operating as a "vaccination clinic" would be legally protected from liability. Based on information we have from our state, regional and metropolitan hospital associations, several states will not be using hospitals as vaccination clinics. In these states, vaccinations will be conducted elsewhere – at public health clinics, for example. However, the fact that these hospitals are not actually administering vaccine does not relieve them from other responsibilities of participation in the program – responsibilities that could expose them to significant liability. In a November 22 supplementary guidance to states, CDC outlined these responsibilities to include:

- identifying individual health care workers to be offered vaccine
- pre-program education
- screening
- adverse event evaluation and treatment
- daily vaccination site management
- evaluation of vaccination takes

While the statute is carefully drafted to protect individuals and entities from liability for inadvertently infecting others, the CDC's interpretation would appear to eliminate this protection for certain hospitals. The CDC's interpretation would also lead to potential exposure to claims by hospital employees and medical staff or other non-employed health care providers. Many hospitals agreed to participate in the vaccination program with the understanding that Section 304 would cover their activities. If the scope of Section 304 is not made clear, a hospital, acting in its role as an employer, may incur liability for its employees' participation in the vaccination program.

We disagree with CDC's interpretation of the law and are concerned that this interpretation will reduce the number of hospitals (and their employees and physicians) that would otherwise have a significant interest in participating in this important program.

Given hospitals' relationship with the public health system, and their strong interest in protecting their communities, employees and their nation, many hospital administrators have been prepared to volunteer their personnel and organizations for the program. However, we have received numerous reports that unless this matter is resolved, hospital attorneys have advised against participating. We believe this outcome is avoidable and that Section 304 need not be interpreted so narrowly.

We continue to work with the Administration to obtain written clarification stating that hospitals that do not act as vaccination clinics – but otherwise participate in the program, employ those vaccinated, have vaccinated non-employed physicians or other health care professionals on staff – should be covered under Section 304.

Beyond the issue of medical liability protection, the AHA is concerned that the Homeland Security Act does not contemplate a no-fault type compensation fund for those who experience complications from the smallpox vaccine, nor does it compensate for employee time lost due to infection or illness as a result of vaccination. Thus, if hospital employees experience serious adverse reactions, their only recourse would be worker compensation. However, because the vaccination program is voluntary for health care workers and is not a “condition of employment,” it is not clear whether state worker compensation funds would cover those hospital employees who become ill.

The AHA believes that, because health care workers volunteering to be vaccinated against smallpox are acting in the best interests of their communities and their nation, they should be supported in the event they experience serious complications from the vaccine. This could be accomplished through the creation of a federal compensation fund similar to the federal Vaccine Injury Compensation Fund – the program that compensates those injured by certain childhood vaccines.

IMPLEMENTATION

Clarification is also needed in several areas regarding implementation of the vaccination plan.

Chief among them:

- **Furloughs** – We need a clear statement from the Administration about whether hospital personnel should be placed on administrative leave after being vaccinated in order to prevent secondary transmission of infections within health care facilities. Although the CDC’s Advisory Committee on Immunization Practices (ACIP) has made recommendations against the need for routine administrative leave for health care workers who have received a

smallpox vaccination, HHS has not, to our knowledge, formally adopted these recommendations.

In its October recommendations, the ACIP stated that routine furlough is unnecessary unless health care workers are physically unable to work due to side effects of the vaccine, have extensive skin lesions which cannot be adequately covered, or do not adhere to the recommended infection control precautions. Further, the ACIP notes that, as long as the worker's vaccination site is appropriately covered with gauze and semi-permeable dressing, and further covered with clothing, and thorough infection control precautions (especially thorough hand hygiene) are followed, the likelihood of transmission by direct person-to-person contact can be minimized. However, the absence of formal adoption of the ACIP's recommendations by HHS has led to a great deal of confusion and mixed messages in the field.

- **Employee testing** – Clarification also is needed about whether pre-vaccination tests are necessary to screen out health care workers who should not receive the vaccine – such as those who are pregnant or who may be infected with the HIV virus. The ACIP has recommended against the need for mandatory screening tests prior to vaccination as long as a thorough medical history and interview are completed and people are informed of the risks. However, HHS has not officially adopted these recommendations. Further, the Administration has indicated, in documents released upon the President's announcement last week, that those persons who might have a contraindication for the vaccine should be referred to the local public health department or another health care provider for testing. However, there remain questions about who will pay for such testing. Again, clarity is needed.

TIMING

There are two key concerns regarding the timing of the program.

- First, the provisions of the Homeland Security Act, including its liability provisions, are not effective until January 24, 2003. This will very likely cause a delay in implementation of the plan until that date, so that those providing the vaccine are protected from liability arising out of the program. The AHA urges the federal government, in short order, to clearly state that vaccinations of health care workers will not begin until this effective date.
- Second, there is a question regarding the period of time that states will have to conduct vaccinations of hospital health care workers. In its November 22 guidance, CDC stated that “[i]mmunization operations should be completed within 30 days of the program’s announced start date.” This is clearly not enough time to vaccinate 500,000 health care workers, especially in light of the many issues that need to be clarified. There are other reasons that a longer period of time should be provided to complete this first stage of smallpox vaccinations. For instance, the ACIP has wisely recommended staggering by three weeks vaccinations of health care workers within an individual patient care unit in a hospital, to minimize the number of people who could be on sick leave concurrently as a result of the normal reactions to the vaccine (e.g. soreness, fever, headache, body ache and fatigue), which usually occur eight to 10 days after inoculation. The CDC predicts that 30 percent of those receiving the smallpox vaccine will be unable to work for a period of time due to reactions. In addition, hospitals continue to struggle with serious workforce shortages, which are more acute in the early part of the year due to staff colds,

flus and other illnesses. To exacerbate staffing shortages via an overly ambitious timeline for this vaccination program would not be advisable – and would undermine hospital readiness to respond to emergencies or larger scale disasters. The AHA strongly recommends that the Administration provide for more flexibility in the schedule for vaccinations.

Again, America's hospitals and health systems wholeheartedly support the federal government's plans for voluntary vaccination to protect our communities from the potential of a terrorist attack that may use smallpox as a weapon. However, we need clarification on the important issues I've addressed so that this initiative can work effectively and efficiently, and truly achieve its goal of protecting our citizens.