

## *Disaster Readiness Advisory #10*

# Update National Smallpox Vaccination Program for Hospital Workers

January 31, 2003

### **A Message to America's hospitals:**

On January 24, 2003, U.S. Department of Health and Human Services (HHS) Secretary Tommy Thompson issued a declaration (Attachment 1), required under Section 304 of the Homeland Security Act, and officially launched the federal government's smallpox vaccination program. In addition to kicking off this national vaccination program, the declaration further clarified key pieces of Section 304, which is intended to provide liability protection for hospitals, health care workers, practitioners and others who participate in the vaccination program. An earlier, narrow interpretation of the section, issued in December by the Centers for Disease Control and Prevention (CDC), raised serious concerns about liability protection for those who would participate (i.e., hospitals and their employees) in the program.

Since that earlier interpretation, however, the AHA has worked closely with the White House, Congress, HHS, CDC and the Department of Justice to further clarify issues surrounding this interpretation of hospital and health care worker liability protection. The resulting guidance document (Attachment 2), issued January 16, included an HHS interpretation that moves closer to the intent of Section 304. The guidance clarified that a participating hospital in the vaccination program is a covered entity, regardless of where its smallpox response team is vaccinated – whether vaccination occurs at the participating hospital or elsewhere, such as at a public health department clinic. Secretary Thompson's declaration goes a step further by addressing another of our concerns, making clear that all members of a participating hospital's team are covered, whether employees or not, such as non-employed medical staff.

We still have concerns, however, regarding the program. Both the guidance and the declaration continue to reference that coverage is provided only while “acting within the scope of employment;” that is, potentially limiting protection for vaccinated persons who inadvertently spread the infection caused by the smallpox vaccine's virus (vaccinia) outside the participating hospital. It also does not address our concern for non-participating hospitals, which should be protected when they utilize health care workers who have been vaccinated as part of a state or federal plan. On January 27, the AHA sent a letter to Secretary Thompson that responds to his declaration and addresses these two outstanding issues on liability protection. The letter can be found on the Disaster Readiness page under What's New at [www.aha.org](http://www.aha.org). We'll continue to work with the administration to achieve the full protection intended under Section 304.

Also at issue, noted by the AHA and others, is that Section 304 does not establish a compensation program to pay for injuries or illnesses caused by administration of the smallpox vaccine. In order to recover any payment under this provision, an injured person must show that his injury is due to the negligence or wrongful act of an entity covered under Section 304's protections. In the absence of negligence, persons injured by the vaccine can seek redress only through their private health care and Worker's Compensation insurance. It's still questionable as to whether even these sources will cover medical conditions and lost wages due to vaccination adverse reactions. Hospitals and their health care workers have expressed serious concerns about the lack of such a national "no-fault" injury compensation program. The AHA has been actively supporting the creation of a national injury compensation program for smallpox vaccination that is similar to the fund created for childhood vaccine injuries.

These most recent activities follow President Bush's December 13, 2002 announcement to offer voluntary pre-outbreak smallpox vaccinations to health care workers, public health staff and community first responders. The voluntary vaccination program is being rolled out in several stages, by vaccinating:

- Up to 500,000 health care workers on hospital smallpox response teams and public health teams for easier mobilization to provide critical services in the event of a bioterrorist attack involving smallpox.
- Up to 10 million traditional first responders, such as emergency medical services, law enforcement and fire services personnel.
- Those who insist on being vaccinated. While the federal government is not recommending vaccination for the general public at this time, President Bush said it would be made available to those who insist on being vaccinated. This last stage is not expected to begin until 2004, when the Food and Drug Administration is expected to license a newer form of the smallpox vaccine.

The associated risks of a smallpox vaccination cause serious concerns for hospitals and health care workers. Because the vaccine uses a live vaccinia virus (related to but not the same as the variola virus that causes smallpox), there is a risk that individuals who are vaccinated and those who have close contact with the recently vaccinated – such as family members, patients, and visitors – can become ill or even die from vaccine reactions. Those most at risk for serious side effects, and for whom vaccination would be contraindicated, include persons with weakened immune systems, such as those with HIV infection and persons on drugs that suppress the immune system; persons with certain skin disorders, such as atopic dermatitis and eczema; and pregnant women. The CDC estimates that 15 to 49 of every one million people receiving the smallpox vaccine will have serious or life-threatening adverse reactions, and that one or two will die. As a result, hospitals and their workers must make a personal and difficult decision about participating in the program.

After reviewing this advisory, I hope you'll share it with your legal counsel, members of your disaster readiness team, and medical staff leadership.

The AHA continues to seek answers to remaining questions and concerns about liability protections, compensation, and other issues of the proposed vaccination program. **As**

**information develops, the AHA will continue to provide you with updates in additional disaster readiness advisories on these and related topics.**

Sincerely,



Dick Davidson  
President

January 31, 2003

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Attachment 1

**DECLARATION REGARDING ADMINISTRATION OF SMALLPOX  
COUNTERMEASURES**

**I. POLICY DETERMINATIONS:**

- 1) The attacks of September and October 2001 have heightened concern that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad.
- 2) In light of these concerns, and in order to advance the public health and national security, the President announced the smallpox vaccination program on December 13, 2002.
- 3) Given the potential for a bioterrorist incident, administration of smallpox countermeasures is advisable within the terms of this declaration.
- 4) Smallpox vaccine is currently recommended domestically only for smallpox response teams, health care workers, and emergency response workers.
- 5) The U.S. Government is making smallpox countermeasures available to personnel associated with certain U.S. facilities abroad and administration of these countermeasures to such personnel is advisable within the terms of this declaration.
- 6) Liability protections for manufacturers and distributors of smallpox countermeasures and the hospitals, health care facilities, and health care workers who will receive them and treat potentially infected smallpox cases are integral to ensuring maximum participation in the vaccination program.
- 7) Section 304 of the Homeland Security Act (P.L. 107-296) is intended to alleviate liability concerns and therefore ensure that vaccine is available if necessary to protect the public health.

- 8) Administration of a countermeasure such as smallpox vaccine is necessarily more involved than the act of placing a drop of vaccine on a two-pronged needle and inoculating a person's arm. Determining who is contraindicated; monitoring, management, and care of the countermeasure site; evaluation of countermeasure "takes;" and contact transmission of vaccinia, among other things, all arise out of and are directly related to and part of the administration of the countermeasure. All such acts also potentially give rise to legal liability that, without sufficient protections, may significantly discourage participation in the smallpox vaccination program.
- 9) Under current domestic planning, many health care entities will designate individuals to receive countermeasures at a hospital or vaccination clinic determined by the state. To achieve a successful vaccination program and because it is impractical to have countermeasures administered at every health care entity involved in the program, it is critical that health care entities participate in this manner and that their personnel be protected while acting within their scope of employment.
- 10) It is important to the successful implementation of the vaccination program that those workers employed by health care entities under whose auspices a countermeasure is administered be protected by Section 304 while acting within the scope of their employment.
- 11) Health care entities use numerous staffing arrangements to carry out daily functions. Individuals designated to receive covered countermeasures and subsequently treat potential smallpox cases may fall into any of these arrangements. Liability protection for these individuals, to the extent described below, is necessary to encourage participation in the smallpox vaccination program.
- 12) Based upon scientific data from animal model studies examining Cidofivir's effectiveness in treating lethal pox virus infections that are similar to smallpox, Cidofivir may be useful in treating smallpox in humans.

## II. DECLARATION

I, Tommy G. Thompson, Secretary of the Department of Health and Human Services, have concluded, in accordance with authority vested in me under section 224(p)(2)(A) of the Public Health Service Act, that a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified in this declaration for prevention or treatment of smallpox or control or treatment of adverse events related to smallpox vaccination, to categories of individuals named in this declaration. The countermeasures set forth below shall be considered to be administered pursuant to this declaration when used for prevention or treatment of smallpox, or to control or treat the adverse effects of smallpox vaccination.

This declaration may be amended as circumstances require.

III. COVERED COUNTERMEASURES: Countermeasures to be administered pursuant to this declaration are:

- 1) Vaccinia (Smallpox) Vaccines, including the Dryvax vaccine;
- 2) Cidofivir and derivatives thereof;
- 3) Vaccinia Immune Globulin (VIG).

IV. INDIVIDUALS COVERED BY THIS DECLARATION: Individuals to whom it is advisable to administer the covered countermeasures specified above are:

- 1) Health care workers who may be called upon to monitor or treat any persons who are either (a) covered by this declaration or (b) are deemed to be individuals to whom a covered countermeasure was administered by a qualified person, whether domestically or abroad, pursuant to section 224(p)(2)(C) of the Public Health Service Act;
- 2) Any person who is a member of a smallpox response team or teams identified by state[s] or local government entities or the United States Department of Health and Human Services;
- 3) Public safety personnel, including, but not limited to, law enforcement officers, firefighters, security, and emergency medical personnel who may be called upon to assist smallpox response teams specified in paragraph IV(2) above; and
- 4) Personnel associated with certain U.S. Government facilities abroad.

V. EFFECTIVE DATES: The declaration is effective January 24, 2003 until and including January 23, 2004. The effective period may be extended or shortened by subsequent amendment to this declaration.

VI. DEFINITIONS: For the purposes of this declaration, including any claim brought against the United States pursuant to Section 224 of the Public Health Service Act ("PHS"), as amended by Section 304 of the Homeland Security Act, the following definitions will be used:

- 1) "Administration of a covered countermeasure" as used in Section 224(p)(1) of the PHS Act includes, but is not limited to, the physical administration of a covered countermeasure; education and screening of covered countermeasure recipients; monitoring, management, and care of the covered countermeasure site; evaluation of covered countermeasure "takes;" and contact transmission of vaccinia.

- 2) “Health care entity under whose auspices such countermeasure was administered” as used in Section 224(p)(7)(B)(ii) of the PHS Act, includes but is not limited to, hospitals, clinics, state and local health departments, health care entities, and contractors of any of those entities that (a) administer covered countermeasures; (b) designate officials, agents, or employees to receive or administer covered countermeasures; or (c) are identified by state or local government entities or the United States Department of Health and Human Services to participate in the vaccination program, whether that participation is in the United States or abroad.
- 3) “Official, agent, or employee” as used in Section 224(p)(7)(B)(iv) of the PHS Act and with respect to health care entities under whose auspices covered countermeasures are administered, includes health care workers who share any employment or other staffing relationship with the health care entity.

Dated:

/s/Tommy G. Thompson

Tommy G. Thompson

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*Note from the AHA: This declaration was published in the Federal Register on January 28, 2003. It can be accessed at:*

<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-2012.pdf>

*Attachment 1*

*Source: Office of the Secretary, U.S. Department of Health and Human Services*

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Attachment 2

### **Guidance for the Healthcare Community Concerning Section 304 of the Homeland Security Act**

Manufacturers of smallpox vaccine and those healthcare entities under whose auspices the vaccine would be administered have raised concerns about their potential liability for involvement in a federal smallpox vaccination campaign. Section 304 of the Homeland Security Act is intended to relieve these liability concerns and therefore ensure that vaccine is available and can be administered in the event of an actual or potential public health emergency.

The following represents the Department of Health and Human Services’ interpretation of Section 304, but is not an exhaustive review of Section 304’s provisions in all contexts.

#### **Overview**

Under Section 304, no claim for liability for injury or death arising out of the administration of smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin ("countermeasures") can be brought against entities or individuals who are covered by Section 304's protections. Instead these claims must be made against the United States.

Section 304 is triggered when the Secretary of Health and Human Services declares that administration of a countermeasure is advisable. The Secretary can make the declaration upon concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes the administration advisable, meaning that it can be made prior to the occurrence of a bioterrorist incident or public health emergency.

Among other things, the declaration will specify the category or categories of individuals it covers, and it will state how long it is in effect. It also will specify the countermeasures it covers, including vaccinia (smallpox) vaccine, cidofovir, and vaccinia immune globulin. To fully implement Section 304, the declaration also will provide further clarification of the statute's coverage.

Section 304 does not establish a compensation program that pays for any injury caused by administration of a smallpox countermeasure. In order to recover any payment pursuant to Section 304, an injured person must show that his/her injury is due to the negligence or wrongful act of an entity covered by Section 304's protections.

### **Who Can File a Claim**

Section 304 claims may be filed by:

- (1) injured individuals described in the declaration who, while the declaration is in effect, receive a declared countermeasure from a licensed health professional or other individual authorized to administer countermeasures under state law, or
- (2) injured individuals who did not receive a countermeasure, but who nonetheless contract vaccinia during the period of the Secretary's declaration or 30 days thereafter, or who reside or resided with an individual who did receive a countermeasure pursuant to the declaration.

Anyone in these categories who believes he or she has a claim attributable to injury or death due to a smallpox countermeasure must submit an administrative claim with an appropriate agency of the United States within two years of the accrual of that claim. If an administrative claim is denied, or if no action is taken on the claim within six months, the injured individual may file suit in federal court.

### **Who is Protected**

The entities and individuals covered by Section 304's protections are:

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- (1) manufacturers and distributors of countermeasures,
- (2) hospitals, clinics, and other healthcare entities under whose auspices the countermeasures are administered, and
- (3) licensed health care professionals or other individuals authorized to administer the countermeasures under state law (“qualified persons”).

Officials, agents, and employees of any of these entities are also covered for claims arising out of the administration of a countermeasure that occur within the scope of employment.

#### Scope of Protection for State and Local Health Departments

State and local health departments that act as distributors of countermeasures or that are healthcare entities under whose auspices countermeasures are administered, as well as their officials, agents, and employees, are covered by Section 304.

#### Scope of Protection for Hospitals and Vaccine Clinics

Hospitals and other institutions that operate as vaccination clinics are covered by Section 304’s protections for claims arising out of the administration of a countermeasure.

In addition, the Secretary’s declaration may determine that hospitals that designate employees to receive smallpox countermeasures under a state’s smallpox plan are considered to be participants in the program and thus are healthcare entities under whose auspices the countermeasure is administered. In these circumstances, we believe that hospitals or other institutions that employ these vaccinees but that do not operate as a clinic administering countermeasures would be covered by Section 304 protections for claims arising out of the administration of a countermeasure.

#### Scope of Protection for Healthcare Workers

“Qualified persons,” as noted above, are licensed health professionals or other individuals authorized to administer smallpox countermeasures under state law. Section 304 claims may be filed for injuries due to administration of countermeasures only if a qualified person administers the countermeasure.

Qualified persons are generally covered by Section 304’s protections for claims arising out of the administration of a countermeasure that occur within the scope of the qualified person’s employment. In addition, Section 304’s protections cover individuals who are officials, agents, and employees of entities listed in the Who is Protected section, above.

#### **Limitations**

If a claim under Section 304 is based on an action or omission by a particular manufacturer, health care professional, or other person listed under Who Is Protected, above, and that person



fails to cooperate with the Government in the defense of the claim, the United States will not be liable for any damages resulting from that person's act or omission.

Also, if the United States makes a payment on a claim, and the payment is based (partly or wholly) on gross negligence, recklessness, illegal conduct, or willful misconduct by the manufacturer, health care professional, or other person listed under item Who Is Protected, or based on the person's violation of a contract with the United States, the United States may recover that portion of the payment (with interest and litigation costs) from that person.

### **Workers' Compensation**

Workers' compensation laws differ from state to state. If a work-related injury is covered by a particular state's workers' compensation law, that state's law will determine whether the worker can sue any other person aside from the employer.

Workers may be barred from submitting a Section 304 claim if those state laws constitute an exclusive remedy (See attached diagram). If, on the other hand, the state law does allow a lawsuit against a party other than the worker's employer, and the lawsuit is against an entity or individual listed in the Who is Protected section, the worker would have to bring the lawsuit pursuant to Section 304 and prove that a negligent or wrongful act occurred.

Federal employees who suffer work-related injuries may only file claims pursuant to the Federal Employees' Compensation Act.

Section 304 does not bar workers' compensation claims in the way it bars other suits. Other statutes, e.g., the Federal Tort Claims Act, that create similar remedies and that exclude other claims have been interpreted as not excluding workers' compensation claims.

Finally, workers' compensation claims themselves are not transformed by this legislation into separate claims covered by Section 304.