Vaccine Liability in the Era of Bioterrorism

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INTRODUCTION

This paper analyzes Section 304 of the Homeland Security Act of 2002, as amended in April 2003, which sets forth liability protection for participants in the current national smallpox vaccination program. It explains to nonlawyers the state of liability protection as it stands in mid-2003.

Section 304 (or “the Homeland Security Act” or “the Act”) has been controversial since its enactment—in part because liability protection could have been structured in a variety of ways. Some controversy was inevitable, though, as the issue of vaccine liability in the era of bioterrorism is new territory. Until now, national defense has never been a factor in a decision to vaccinate civilians. Theoretically, vaccination could reduce the anticipated rewards of a biological attack, possibly deterring the proliferation and use of a particular agent. But as will be discussed, the smallpox vaccination program has not progressed as initially anticipated, partially because of concerns about liability. The recent experience with the smallpox vaccine is therefore instructive for future vaccination programs.

A brief description of the main approaches to vaccine liability is presented first, followed by an analysis of the liability protection provided under Section 304. The paper then concludes with a discussion of several key principles related to liability that policymakers should consider when vaccines are used to defend against bioterrorism.

APPROACHES TO VACCINE LIABILITY

There are four important historical precedents to handling vaccine liability, which are not always mutually exclusive: (1) the government can substitute itself as defendant and accept liability on behalf of the participants in the vaccination program; (2) the government can decide that no one needs to be held liable and establish a no-fault compensation program; (3) the government can indemnify (i.e., reimburse) vaccine manufacturers and distributors, providers, and other participants after they have been sued and a judgment issued against them; or (4) the government can alter the normal rules of litigation and/or compensation. Each of these methods has its proponents and critics, each will affect various stakeholders differently, and each alleviates different concerns.

The government as defendant: the Federal Tort Claims Act

Under the historic legal doctrine that “the king can do no wrong,” the federal government is immune from all liability and cannot be sued without its consent. Recognizing the inherent inequities that resulted from such sweeping protection, the federal government has waived its sovereign immunity in some circumstances. With the enactment of the Federal Tort Claims Act (FTCA) in 1946, the federal government agreed to substitute itself as defendant when federal employees, who were acting within the scope of their office or employment, are sued.

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in tort. Tort has been defined as a “private or civil wrong or injury, including action for bad faith breach of contract, for which the court will provide a remedy in the form of an action for damages.” When the government substitutes itself as defendant under the FTCA, federal employees cannot be sued in tort and special rules govern the lawsuit—for example, the lawsuit must be brought in federal court, there is no right to a jury, and punitive damages (i.e., damages that “punish” intentional or egregious misconduct) are not allowed. The Swine Flu Act—the law that established the National Swine Flu Immunization Program in 1976–77 and provided liability protection to vaccine manufacturers and other participants in the program—was initially based solely on this approach, as was Section 304.

Laws that waive government immunity are construed narrowly by the courts. The rationale is that because the government is otherwise immune from liability unless it explicitly waives that immunity, the government, not the courts, should decide the extent of that waiver. Therefore, federal courts interpreting Section 304 and other laws that invoke the FTCA will tend to limit the circumstances under which the government accepts liability. But as no court has yet interpreted Section 304, the extent of liability protection is not yet known.

In addition, different federal courts do not always interpret the same law the same way. Starting from the highest court, the federal court system consists of the U.S. Supreme Court, 13 Courts of Appeals, including the Federal Circuit, and more than 90 district courts. District courts fall under the supervision of the Courts of Appeals. For example, Maryland, Virginia, West Virginia, and North and South Carolina are in the Fourth Circuit Court of Appeals. Texas, Mississippi, and Louisiana are in the Fifth Circuit. If a case is brought in a district court in Virginia, an appeal is filed with the Fourth Circuit Court of Appeals; if it is brought in a Texas district court, the Fifth Circuit Court of Appeals will review the decision.

Although Circuit Court of Appeals decisions can be appealed to the U.S. Supreme Court, the Supreme Court hears only the cases it agrees to hear. When disagreement exists on the interpretation of a particular federal law among the Circuits and the disagreement is important, the Supreme Court often reviews the issue, presumably settling the matter once and for all. Therefore, the ultimate extent of liability protection under the Homeland Security Act may not be known for years.

No-fault compensation

The term “no-fault compensation” means that compensation is provided without a showing that someone did something wrong. Compensation is a concept closely related to but different from liability. In this context, compensation refers to the amount of money a vaccine recipient who experiences an adverse reaction will receive, whereas liability refers to who will be held legally responsible for the adverse reactions of the smallpox vaccine and the extent of that responsibility.

The National Vaccine Injury Compensation Program (VICP) is an example of a no-fault compensation scheme. In the early 1980s, increased numbers of lawsuits were filed related to DTP vaccines (diphtheria, tetanus, pertussis) and other childhood vaccines. Vaccination rates among children fell, and vaccine manufacturers left the market, causing vaccine shortages that threatened the nation’s health. In response, Congress passed the National Childhood Vaccine Injury Act of 1986 establishing the VICP. The VICP covers vaccines that the Centers for Disease Control and Prevention (CDC) recommends for routine administration to children, including DTP, measles, mumps, rubella, and polio.

To receive compensation, an individual or individual’s family claiming an injury or death resulting from a qualifying childhood vaccine must first file a petition with the U.S. Court of Federal Claims. The petitioner must show that: (1) the injury that occurred is listed on the Vaccine Injury Table and was not due to an alternative cause; or (2) the vaccine caused the condition; or (3) the vaccine significantly aggravated a preexisting condition. A physician at the U.S. Department of Health and Human Services (DHHS) reviews the petition to determine if the petitioner is eligible for compensation and issues a report. A Department of Justice attorney files the report with the

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928 USCS § 1346(b) (2003).
1028 USCS § 2402 (2003).
1342 USCS § 247b(j)-(l) (repealed 1978).
1642 USCS §§ 300aa-10 through 34 (2003).
1842 USCS §§ 300aa-1 through 34 (2003).
19Centers for Disease Control and Prevention, National Vaccine Injury Compensation Program, note 17.
Federal Claims Court and represents DHHS’s position in hearings before a “special master,” who decides whether compensation should be awarded. That decision can be appealed. If the petitioner is found ineligible for compensation or is dissatisfied with the award, the petitioner can then sue the vaccine manufacturers and/or administrators of the vaccine directly in state or federal court subject to modifications of state tort law. 20

The VICP has been criticized, 20,21,22 and there have been repeated efforts to amend it. 23,24 For example, it has been argued that the VICP has become highly adversarial, that proving causation is extremely difficult, and that the limitations on attorneys’ fees and expenses make experienced attorneys unwilling to represent claimants. 25

In the same legislation that amended Section 304, the Smallpox Emergency Personnel Protection Act of 2003, Congress passed a new law providing no-fault compensation to eligible smallpox vaccine recipients. 26 A detailed discussion of these compensation provisions and of compensation issues in general is beyond the scope of this article, but the interaction of Section 304 with the compensation provisions of the Smallpox Emergency Personnel Protection Act is discussed below.

Indemnification

Indemnification is a third option potentially available to Congress. With indemnification, a vaccine manufacturer, for example, would remain the defendant in a lawsuit and could be found liable, but the government contractually agrees to reimburse the manufacturer for damages awarded against it. Indemnification can take many forms. The government could agree to pay all or part of an award and may or may not pay the cost of litigation.

With respect to smallpox vaccine liability, it had been proposed that indemnification could be provided through Executive Order 10789, 27 as amended in October 2001, 28 which allows DHHS to enter into certain contracts in connection with national defense. Some have argued that Executive Order 10789 in particular, and indemnification in general, does not give enough protection to the vaccine industry. 29,30 For example, it was stated in written testimony submitted to Congress in 2001 that Executive Order 10789 is a “very crude plan” and “severely limited” because it is discretionary, restricted to liability costs later judged to be reasonable, and applies only where the plaintiff obtained the vaccine directly from the government. 31

As of late 2002, pursuant to Executive Order 10789, as amended, DHHS purportedly had entered into indemnification agreements with two smallpox manufacturers, Wyeth and Aventis Pasteur, and was negotiating with a third, Acambis Baxter. 32 However, a February 2003 amendment to Executive Order 10789 33 may limit this option. Executive Order 10789 now states that after March 1, 2003, with limited exceptions, no executive department or agency (including DHHS) shall enter into

such indemnification agreements with respect to any matter—such as vaccines—that has been or could be designated “qualified anti-terrorism technology” under the Support Anti-terrorism by Fostering Effective Technologies Act of 2002, or “SAFETY Act,”\textsuperscript{34} which is discussed below.

Changing the rules of litigation

Congress could adjust the rules of litigation through legislation. The SAFETY Act, enacted by different sections of the Homeland Security Act,\textsuperscript{35} allows the Secretary of Homeland Security to designate any product, equipment, service, device, or technology as “qualified anti-terrorism technology” after several criteria are considered.\textsuperscript{36}

Manufacturers of vaccines against potential bioweapon agents theoretically could meet the criteria if the vaccines are considered products that, for example, “would be effective in facilitating the defense against acts of terrorism”\textsuperscript{37} or there existed an “extraordinarily large or extraordinarily unquantifiable potential third party liability risk exposure.”\textsuperscript{38} Once a product qualifies as anti-terrorism technology, a series of restrictions and special rules apply to lawsuits filed against the seller of the product with respect to acts of terrorism. For example, the lawsuit must be brought in federal court,\textsuperscript{39} punitive damages or other damages not intended to compensate for actual loss, as well as interest prior to judgment, are not allowed,\textsuperscript{40} liability can be no greater than the limits of liability insurance “reasonably available,”\textsuperscript{41} and the so-called government contractor defense (which shields a contractor from tort liability if its product is manufactured in accordance with government specifications) is strengthened in some cases.\textsuperscript{42} In addition, once a product is deemed qualified anti-terrorism technology, liability for all claims “arising out of, relating to, or resulting from an act of terrorism”\textsuperscript{43} with respect to the anti-terrorism use of such technology is capped at the limits of liability insurance coverage required under the SAFETY Act. Because no court has ever interpreted the SAFETY Act, the liability exposure is uncertain.\textsuperscript{44} Nevertheless, the seller of the qualified anti-terrorism technology is still sued under more favorable rules and will not pay a judgment against it above what insurance would pay.

Congress also could have drafted legislation similar to the Price-Anderson Act,\textsuperscript{45} which deals with injury and death related to nuclear incidents and, among other things, places a cap on liability. In addition, the government could have simply prohibited all or most lawsuits against vaccine manufacturers and other participants in the smallpox vaccination program. For example, legislation is now before Congress that would prohibit most lawsuits against gun manufacturers and others in the gun industry, including some alleging willful misconduct.\textsuperscript{46}

The lawsuits that still would be permitted appear to be relatively few and subject to strict limitations. This is a drastic measure, as access to the courts is severely restricted and there are no alternative defendants to pursue (e.g., a suit against the government in place of the protected industry).

LIABILITY PROTECTION UNDER SECTION 304 OF THE HOMELAND SECURITY ACT FOR PARTICIPANTS IN THE NATIONAL SMALLPOX VACCINATION PROGRAM

Section 304 provides liability protection to a range of participants involved in the administration of the smallpox vaccine, including manufacturers, distributors, hospitals, physicians, nurses, and others. The Act refers to these participants as “covered persons” and deems them federal employees of the U.S. Public Health Service (PHS) for liability purposes,\textsuperscript{47} subject to a few modifications.\textsuperscript{48} Lawsuits alleging personal injury and death


\textsuperscript{35}See note 34.


\textsuperscript{37}6 USCS § 441(b)(7) (2003).

\textsuperscript{38}6 USCS § 441(b)(3) (2003).

\textsuperscript{39}6 USCS § 442(a) (2003).

\textsuperscript{40}6 USCS § 442(b)(1) (2003).

\textsuperscript{41}6 USCS §§ 443(a)(2) & (c) (2003).

\textsuperscript{42}6 USCS § 442(d) (2003).


\textsuperscript{45}42 USCS § 2210 (2003).


\textsuperscript{47}42 USCS § 233(p)(1) (2003) (The Public Health Service, a federal agency in the U.S. Department of Health and Human Services, is administered by the Assistant Secretary for Health under the supervision of the Secretary of Health and Human Services. 42 USCS § 202 (2003)).

against PHS employees who were acting within the scope of their office or employment are not allowed under the Public Health Service Act (PHS Act). Instead, as discussed above, the federal government substitutes itself as defendant, accepting liability on behalf of the participants through the FTCA, also subject to a few modifications. Thus, Section 304 amends and modifies the liability section of the PHS Act, which, in turn, modifies the FTCA.

For liability protection to occur under Section 304, six requirements must be met. If one of the requirements is missing, there is no protection. Liability protection is afforded to (1) a “covered person” while acting within the scope of such person’s office or employment with respect to (2) claims alleging personal injury or death arising out of administration of a “covered countermeasure against smallpox” that is (3) used to prevent or treat smallpox, or used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure, and if administered by (4) a qualified person to (5) specified categories of people during (6) a time period specified in a declaration issued by the Secretary of Health and Human Services.

The Secretary’s declaration, which triggers liability protection, must conclude that “an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals.” Thus, a bioterrorism attack does not have to take place to trigger the Act, nor is bioterrorism even required, although the agent must be smallpox. On January 24, 2003, Secretary Tommy Thompson issued the first such declaration (“the Declaration”) and published it in the Federal Register as required (see Appendix A).

Which vaccines and treatments does Section 304 of the Homeland Security Act cover?

By its express wording, the Act protects only against vaccines and treatments considered “covered countermeasures against smallpox.” If the same vaccines and treatments are used for a pathogen other than smallpox—for example, to prevent the spread of monkeypox—Section 304 does not apply. Moreover, if vaccines or treatments are developed or used for other possible bioterrorism agents (e.g., bacteria such as plague, toxins such as botulinum, viruses such as ebola, etc.), the Act must be amended or a new law enacted.

A covered countermeasure can be any substance (1) used to prevent or treat smallpox, including vaccinia or another vaccine; or (2) “used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure.” With respect to the first category, while vaccination given within the first few days after exposure to smallpox can prevent or ameliorate the subsequent illness, currently there are no treatments for smallpox approved by the Food and Drug Administration. The second category is potentially much broader since the April 2003 amendments and could include such treatments as vaccinia immune globulin (VIG), Cidofovir, antibiotics, vidarabine, trifluridine, and those

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49 See, e.g., 42 USCS §§ 233(a), (c), & (e) (2003).
50 42 USCS § 233(p) (2003).
57 The meaning of the term “adverse effects” in the Act is undefined. The Centers for Disease Control and Prevention define “adverse events” as “untoward effects observed or reported after vaccinations, but a causal relationship between the two have yet to be established.” By contrast, an “adverse reaction” is a complication that has been demonstrated to be caused by the vaccine. Centers for Disease Control and Prevention. Smallpox vaccination and adverse reactions: guidance for clinicians. MMWR 2003;52(No. RR-4):1-28 (note p. 8).
61 Prior to the April 2003 amendments, 42 USCS § 233(p)(7)(A)(i) (2002) defined the term covered countermeasure to include substances (1) used to prevent or treat smallpox (including the vaccinia or another vaccine); or (2) vaccinia immune globulin (VIG) used to control or treat the adverse effects of vaccinia inoculation. As only VIG was mentioned to treat the adverse effects of the vaccine, other potential treatments for adverse effects such as Cidofovir, could not strictly qualify as a covered countermeasure. However, the Declaration states that “Cidofovir [sic] may be useful in treating smallpox in humans.” 68 Fed. Reg. 4212 § 1(i)(2) (January 28, 2003). Prior to the April amendments, the government might have argued that because Cidofovir may be used to treat smallpox and therefore may qualify as a covered countermeasure under category 1, it may also be used to treat the vaccine’s adverse effects (under category 2), even though it did not qualify for that reason. Whether a court would have agreed with this position is unclear. See United States v. Mead, 533 U.S. 218, 121 S.Ct. 2164 (2001).
used in supportive care. If VIG and Cidofovir, for example, qualify as covered countermeasures, the “substances” used to treat their adverse effects could also be included.

To qualify as a covered countermeasure, the “substance” must also be explicitly identified in the Secretary’s declaration. The current declaration identifies only three countermeasures: (1) vaccinia (smallpox) vaccines, including Dryvax; (2) Cidofovir and derivatives thereof; and (3) VIG. As it is silent with respect to all other substances that would otherwise qualify under the Act, their administration is not covered at this time.

In addition, liability protection only applies to claims “arising out of the administration of a covered countermeasure.” This phrase was not initially defined in the Homeland Security Act, and this ambiguity caused tremendous concern among healthcare providers. The April 2003 amendments define this phrase broadly to include four types of activities: (1) determining whether or under what conditions an individual should receive a covered countermeasure; (2) obtaining the individual’s informed consent to administer a covered countermeasure; (3) monitoring, management, or care of the immediate site of administration on the body of a covered countermeasure or evaluation of whether the countermeasure’s administration has been effective; or (4) transmission of the vaccinia virus by an individual vaccinated according to the Act.

Which individuals and institutions have liability protection under Section 304 of the Homeland Security Act?

Only those considered “covered persons” are protected from liability under the Act. The term initially only included four categories of individuals or entities, but the April 2003 amendments added four more categories, as well as making modifications to some of the original four. A “covered person” now includes: (1) manufacturers and distributors of a covered countermeasure; (2) healthcare entities involved in the administration of a covered countermeasure broadly defined; (3) a “qualified person” who administers the countermeasure; (4) a state, its political subdivisions, and agencies and officials of both providing guidance, advice, or assistance to a program administering covered countermeasures or otherwise supervising or administering that program; (5) individuals vaccinated according to the Act, who unintentionally transmit vaccinia to someone else, or the entities that employ those individuals or where those individuals are otherwise authorized to provide healthcare; (6) officials, agents, and employees of a person described in categories (1), (2), (3), or (4); (7) contractors and volunteers working for and performing the function of a covered person in categories (1), (2) or (4); and (8) individuals authorized to provide healthcare for the healthcare entities in category (2) or the entities described under category (5). (See Appendix B for exact statutory language.) Public safety personnel who are not healthcare providers (such as police officers and firefighters) but who are eligible to get vaccinated under the Declaration (see below) would likely have to qualify as covered persons under category (6) or (7).

Before the April 2003 amendments, the Declaration also clarified the definition of “covered person” to address concerns that the term would be interpreted too narrowly. The Declaration’s definitions should be considered superseded by the April 2003 amendments, which were specifically enacted by Congress.

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63 Bartlett J, note 60.
66 42 USCS § 233(p)(2)(B) (emphasis supplied).
69 The definition does not specifically include obtaining informed consent as does the definition of “arising out of administration of a covered countermeasure.” See 42 USCS § 233(p)(7)(D)(ii).
70 A “qualified person” means a licensed health professional or other individual authorized to administer the countermeasure under the law of the state where the countermeasure was administered or otherwise authorized by the Secretary to administer the countermeasure. 42 USCS § 233(p)(7)(C) (2003).
71 If the Declaration is eventually amended or a new declaration issued to permit vaccination of the general public, it seems unlikely that the federal government has agreed in this category to deem all members of the general public as employees of the Public Health Service and accept liability on their behalf. Rather, this category appears to suggest by the wording “otherwise authorized to provide health care” (42 USCS § 233(p)(7)(B)(v)(II) (2003) (emphasis supplied), that this category protects healthcare workers, as well as the hospitals or clinics where they work, from lawsuits based on the healthcare worker’s unintentional transmission of vaccinia. However, because this language is unclear, an argument could be made that all individuals eligible to get vaccinated under a declaration would be covered persons.
75 It is not clear what type of deference courts would give to the definitions provided in the Secretary’s declaration. See United States v. Mead, note 62. According to Section 304, the Secretary may issue a declaration to trigger its liability provisions and specify what substances qualify as covered countermeasures, who is eligible to get vaccinated, and the effective period of a declaration. 42 USCS § 233(p)(2)(A) (2003). Section 304 does not give the Secretary explicit authority to use the declaration procedure to clarify the Act’s meaning. Also, Section 304 has a specific provision for definitions, 42 USCS § 233(p)(7)(2003), suggesting that Congress wanted to set the parameters for liability and not delegate that function to the Secretary.
Must a provider or other covered person administer a vaccine or other treatment during a specific timeframe?

The government waives its immunity and agrees to substitute itself as defendant only during the effective period of a declaration—currently specified from January 24, 2003, until and including January 23, 2004. A provider will not be protected from liability if the provider administers a vaccine or other countermeasure before or after that period. The Act provides no time constraints on how short or long that effective period can be, and, therefore, the Secretary has complete discretion to decide on the timeframe unless other laws limit that discretion. All that is required from the Secretary on this point is that the declaration explicitly state the beginning and ending dates of its effective period. The Secretary also has authority to shorten or extend that period.

Exactly when to administer a covered countermeasure during the effective period of the Declaration will be an important consideration for providers and hospitals. Adverse events following vaccination might not present themselves until weeks after vaccination and complications could last for months. Depending on what particular “substances” qualify as covered countermeasures, the effective period needs to be at least long enough to vaccinate all those eligible for vaccination and long enough to control or treat the adverse events. Clearly, hospitals should not vaccinate anyone in the last few weeks of the effective period to allow for any adverse events to become apparent.

What groups of individuals can be vaccinated under the Secretary’s Declaration?

The Declaration lists four categories of individuals eligible to receive covered countermeasures: (1) healthcare workers who monitor or treat individuals eligible to receive a countermeasure under the Declaration, or individuals who contracted vaccinia unintentionally and are deemed to have been vaccinated according to the Act; (2) members of smallpox response teams or teams identified as such by state or local government entities or DHHS; (3) public safety personnel, including law enforcement officers, firefighters, security personnel, and emergency medical personnel, who assist these teams; and (4) personnel associated with certain federal government facilities abroad. The government has agreed to assume liability on behalf of covered persons only if the vaccine or other countermeasure is administered by a “qualified person” to an individual within one of these categories (or if the qualified person has reasonable grounds to believe that the individual is within one of the categories). Therefore, if a provider mistakenly believes that a patient is eligible to receive a smallpox vaccine and that belief is reasonable (which a federal court would ultimately determine), the provider will have liability protection, assuming that the other requirements of the Act have been met. A provider will not have liability protection if the provider vaccinates a friend, family member, or other medical professional who is not within a category of individuals specified in the Declaration.

Even though a person is eligible to get vaccinated under the Declaration, it does not mean that the individual should get vaccinated. For example, at this time individuals with eczema, a compromised immune status, or other identified contraindications should not be vaccinated, because there is no “confirmed, imminent, or likely exposure to the smallpox virus” and the potential for serious adverse reactions exists. A potential vaccine recipient must understand these and other risks, as well as the benefits and alternatives to vaccination, in order to make an informed decision about whether or not to get vaccinated. Thus, before administering any medical treatment or procedure in a clinical setting, including vaccines, a healthcare provider has a legal duty to obtain “informed consent” from the patient. Informed consent is a complicated area of law and state laws vary considerably, although there are two broad standards: the physician standard and the patient standard. In general, the physician standard looks to what a reasonable physician would disclose to a patient under the same circumstances, whereas the patient standard looks to what a reasonable patient would consider material in order to make an informed decision. Indiana law, for example, appears to combine the two: “a physician must disclose the facts and risks of a treatment which a reasonably prudent physician would be expected to disclose under like circumstances, and which a reasonable person would want to know.”

Under the FTCA, federal courts apply “the law of the place where the act or omission occurred.” This language means that the federal court hearing a case under Section 304 will apply the tort law of the state in which the suit was brought, which includes whether informed

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79 See note 78.
80 Bartlett J, note 60.
82 42 USCS § 233(p)(B) (2003).
83 See note 70 for definition of “qualified person.”
84 Bartlett J, note 60.
87 28 USCS § 1346(b) (2003).
consent was given (at least with respect to licensed vaccines). Common sense might suggest that if a person files suit in a federal court, federal law would apply and, if brought in a state court, state law would apply, but in fact federal courts often apply state law.

The CDC requires states to provide more than 30 pages of information and a video to help potential vaccine recipients decide whether or not to get vaccinated. This voluminous material likely meets the informed consent standard of most states. Obviously, this package would be impractical for mass vaccination of the general public, so the CDC is currently developing shorter, more appropriate material. To limit its liability exposure, the federal government should determine if this shorter version will comply with the various states’ informed consent laws with respect to mass vaccination programs.

Does the fact that state tort law applies under the Federal Tort Claims Act raise other potential concerns?

The fact that federal courts apply state tort law under the FTCA means that liability and compensation may often depend on where an individual alleging a vaccine-related injury files a lawsuit. In practical terms, this means that the same set of facts in one state could require a provider to reimburse the government for a damage award, whereas if the suit was brought in another state, the provider might be held liable but owe nothing (see discussion below on gross and simple negligence). Likewise, an injured party may receive a huge award in one state and comparatively little in another. Inconsistent court decisions were made under the Swine Flu Act, and it is likely that that would happen again under the Homeland Security Act.

Different courts interpreting the same law differently encourages “forum shopping.” For example, if a person knows that one state has a cap on damages, that person might choose to get vaccinated in another state where damages are unlimited. The Washington, DC, metropolitan area (covering DC, Northern Virginia, and Maryland) as well as the two Kansas Cities (Kansas City, Kansas, and Kansas City, Missouri) are just two examples of places where forum shopping could easily occur.

Perhaps there is no better illustration of this point than the doctrine of contributory negligence. Although defined differently among the states, the concept of contributory negligence basically means that the plaintiff’s (i.e., the person bringing the suit) own negligence contributed to his or her injuries, and that that contribution has legal consequences. In some states, if the plaintiff and defendant are found negligent, damages against the negligent defendant are reduced (referred to as comparative negligence). In other states, the plaintiff may be barred from all recovery (i.e., the defendant is held not liable, and the plaintiff receives no compensation). For example, with respect to medical negligence claims in Virginia and Maryland, if the plaintiff’s contributory negligence is concurrent with the physician’s negligence, the physician may be absolved of any liability. Concurrent contributory negligence barring recovery has been found when a patient fails to disclose an accurate medical history to a physician and suffers an adverse reaction to medication the physician prescribes. It is not difficult to imagine that, in the context of a national smallpox vaccination program, an individual might fail to disclose past eczema or other skin conditions that pose a risk of serious adverse reactions. In the litigation under the Swine Flu Act, the government raised the defense of contributory negligence, and it should be anticipated that it would do so again under Section 304.

Does Section 304 of the Homeland Security Act provide liability protection to healthcare providers if the vaccinia virus is unintentionally transmitted to others?

Three immediate questions flow from this broader one. First, if a physician is vaccinated and unintentionally transmits the vaccinia virus to a patient or someone else, does that physician and the facility where he or she provides healthcare have liability protection? Second, if a

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89 The federal court would apply federal law in other circumstances such as to determine if a claim is excluded or procedurally barred from the Federal Tort Claims Act.
94 Susan O’Neal, Contributory Negligence in Medical Malpractice: Recent Application in the Context of the Suicidal Patient, 69 Miss. L.J. 925 (1999).
physician vaccinates a patient and that patient unintentionally transmits the virus to someone else, are the physician and the facility protected? Third, if the patient who was vaccinated infects someone else, who infects someone else, who infects someone else, is protection afforded? Although the language in the Act is cumbersome, even as amended, the answer to all three questions appears to be “yes,” in most cases, provided the requirements of the Act were met.

Several provisions in the Act—three of which were added by the April 2003 amendments—address “accidental vaccinia inoculation” or contact vaccinia, defined as “an inadvertent vaccinia virus infection in a person other than the vaccine recipient.” The main provision works by making a presumption (under two sets of circumstances) that an individual with contact vaccinia contracted it from someone who was properly vaccinated under the Act. If that presumption is not rebutted (i.e., proven to be false), the individual with the contact vaccinia will then be deemed for purposes of liability to have been eligible to get vaccinated and to have been properly vaccinated under the Act. In practical terms, this means that the individual with contact vaccinia alleging complications must sue the federal government under Section 304, and not the provider or other covered person. If, however, the presumption is shown to be false—for example, a provider vaccinated a family member who was not in a category of eligible vaccine recipients identified in the Declaration—the government will not accept liability on behalf of that provider and the provider could be sued directly.

The two sets of circumstances under which the presumption applies are broad and would likely cover most cases of contact vaccinia: (1) the individual contracts vaccinia during the effective period of the Declaration or by 30 days after the period ends; or (2) the individual has resided with, or has had contact with, a person properly vaccinated under the Act and contracts vaccinia after the date that person was vaccinated.

How does the government substitute itself as defendant?

Before the government substitutes itself as defendant, the U.S. Attorney General must certify that the action or proceeding is (1) against a covered person and (2) is based on a claim alleging personal injury or death arising out of the administration of a covered countermeasure. The Attorney General’s certification conclusively establishes that the action or proceeding is (1) against a covered person and (2) is based on a claim alleging personal injury or death arising out of the administration of a covered countermeasure “for purposes of jurisdiction.” The Attorney General’s decision to certify or not has several likely implications. Suppose the Attorney General certifies that a provider is a covered person and that the claim arises out of the administration of a covered countermeasure, resulting in the government’s substituting itself as defendant. If the plaintiff does not think that the provider should be considered a covered person or that the claim does not arise out of the administration of a covered countermeasure, that plaintiff could ask a federal court to review the Attorney General’s certification, and a federal court will review it. If the court agrees with the plaintiff that the provider is not a covered person or that the claim does not arise out of the administration of a covered countermeasure, the government will not be allowed to substitute itself as defendant, but the case still will proceed against the provider in federal court. The case remains in federal court, even though under other circumstances a state court would preside over the case against the provider. This provision is significant, in part, because federal and state courts have different rules of procedure that govern the conduct of trials. Depending on the state, some state rules may be more favorable to plaintiffs than the federal rules or vice versa. In addition, if the Attorney General refuses to certify that the claim arises out of the administration of a covered countermeasure or that the

97 See 42 USCS § 233(p)(2)(C) (2003) (providing the circumstances under which the federal government will accept liability for the unintentional transmission of vaccinia); 42 USCS §§ 233(p)(2)(C)(i)(II) (2003) (amendments inserted “has resided with, or has had contact with” broadening the circumstances under which the presumption applies); 233(p)(2)(D) (2003) (entirely new provision likely making more clear that covered persons who unintentionally transmit vaccinia are protected from liability); 233(p)(7)(B)(v) (2003) (entirely new provision likely protecting healthcare workers who unintentionally transmit vaccinia and the entities where they provide healthcare) (see note 71); and 233(p)(7)(D) (2003) (entirely new provision making the unintentional transmission of vaccinia considered “arising out of administration of a covered countermeasure” when section 304 applies).

98 Bartlett J, note 60.


100 See 42 USCS § 233(p)(4)(A) (2003).

101 In the Homeland Security Act, the Attorney General’s certification conclusively establishes that the action or proceeding is (1) against a covered person and (2) is based on a claim alleging personal injury or death arising out of the administration of a covered countermeasure “for purposes of jurisdiction.” 42 USCS § 233(p)(4)(B) (2003) (emphasis supplied). In this context, jurisdiction refers to whether the case will be heard in a federal or state court. The Federal Tort Claims Act (FTCA) has similar language: “This certification of the Attorney General shall conclusively establish scope of office or employment for purposes of removal.” 28 USCS § 2679(d)(2) (2003) (emphasis supplied). The Supreme Court has referred to the words “for purposes of removal” as “statutory fog,” Gutierrez de Martinez v. Lamagno, 515 U.S. 417, 425, 115 S.Ct. 2227, 2232 (1995), and it is likely that Congress changed “removal” to “jurisdiction” in the Homeland Security Act to clear up the confusion. Thus, while the language in the Homeland Security Act is slightly different from the language in the FTCA in this respect, cases interpreting the FTCA are instructive.

102 See Ross v. Bryan, 309 F.3d 830 (4th Cir. 2002); Singleton v. United States, 277 F.3d 864 (6th Cir. 2002).
provider is a covered person, the provider can contest that decision, but the vaccine recipient cannot.\textsuperscript{103}

\textit{Once the government is substituted as defendant, are there any circumstances under which the provider or other covered person can still be liable?}

Yes. If the provider or other covered person does not cooperate with the government, the government does not have to accept liability on behalf of that person. It is unreasonable to assume that the government will agree to substitute itself as defendant if it cannot defend the case properly. Section 304 explicitly requires covered persons to cooperate with the government in the processing and defense of a claim or action.\textsuperscript{104} Under the FTCA, the person alleging a vaccine-related injury must exhaust administrative remedies before filing suit in federal court.\textsuperscript{105} Therefore, the covered person must cooperate with the government at both the agency and court levels. Cooperation may include such things as answering lengthy interrogatory questions, furnishing internal documents, sitting for depositions, or appearing as a witness at trial or a hearing. If a federal court finds that a provider or other covered person has failed to cooperate, it will substitute that person as the defendant in the lawsuit in place of the government. The government then will no longer be obliged to defend the claim or incur any liability on behalf of the covered person.\textsuperscript{106}

The Act also has a specific provision granting the government financial recourse against a covered person in a few instances, even if the government remains as defendant in the lawsuit. The government can recover from the covered person that portion of the payment (whether by administrative determination, settlement, or court judgment), including interest and costs of litigation, resulting from the covered person’s gross negligence, reckless or illegal conduct, or willful misconduct.\textsuperscript{107} This means that if a court finds a provider’s actions only negligent in the administration of a vaccine and awards damages to the plaintiff, the provider does not have to reimburse the government any money related to that award. Covered persons are therefore financially protected from their own negligence. If, however, the provider is deemed grossly negligent, the provider must reimburse the government for that conduct. Negligence is a complicated area of law, and the difference between gross and simple negligence is not always clear, even in a single state.\textsuperscript{108}

Consider additionally that what is deemed negligent conduct in the administration of a vaccine pre-attack might not be considered negligence post-attack. That there are 50 states and the District of Columbia with their own negligence laws is nothing short of daunting.

The government also can recover from a covered person that portion of the payment, including interest and costs of litigation, resulting from the covered person’s failure to carry out any contractual obligations assumed with the government.\textsuperscript{109}

If Section 304 of the Homeland Security Act does not provide compensation, how does an eligible smallpox vaccine recipient who experiences an adverse reaction get compensated?

Section 304 provides liability protection for vaccine manufacturers, providers, and other participants in the smallpox vaccination program, but it does not directly set forth compensation for vaccine recipients. Even though the Act does not address compensation directly, it does explain the procedures that a vaccine recipient must follow in order to pursue compensation. A vaccine recipient must first apply for compensation available under Part C of the Smallpox Emergency Personnel Protection Act before pursuing a claim under Section 304.\textsuperscript{110} If the adverse event is recognized as a “covered injury” and the vaccine recipient is a “covered individual” (i.e., a member of a smallpox emergency response plan),\textsuperscript{111} compensation will be provided without the vaccine recipient’s having to prove that the provider or other covered person did something wrong (i.e., no-fault compensation). If the Secretary fails to make a final determination as to compensation within 240 days or if the individual is dissatisfied with the award after a determination has been made, the individual can then pursue a claim under the FTCA through Section 304.\textsuperscript{112} Because

\begin{thebibliography}{99}
\bibitem{105}42 USCS § 233(p)(5)(A) (2003).
\bibitem{107}42 USCS § 233(p)(5)(B) (2003). If a covered person fails to cooperate and the government is released from the lawsuit, it appears that the suit could be transferred to a state court if the federal court no longer has jurisdiction.42 USCS § 233(p)(5)(B)(i)(2003).
\bibitem{110}42 USCS § 233(p)(6)(A) (2003).
\bibitem{111}42 USCS § 233(p)(3)(A)(i) (2003). Prior to enactment of the compensation provisions of the Smallpox Emergency Personnel Protection Act (see note 26), after presenting an administrative claim to the U.S. Department of Health and Human Services, a vaccine recipient experiencing an adverse event could then bring a suit in federal court.
\bibitem{112}42 USCS §§ 239, 239a (2003).
\end{thebibliography}
the amount of compensation is limited (e.g., presently capped at $262,100 for death benefits and for loss of employment income for those temporarily disabled),\textsuperscript{113} it may not adequately compensate serious adverse reactions of the smallpox vaccine.

If a particular case eventually does end up in federal court, the FTCA changes some of the rules of litigation, making it more difficult for a plaintiff to prove the case. For example, the FTCA does not allow claims based on strict liability.\textsuperscript{114} In general, strict liability means that the plaintiff does not have to prove fault by the defendant because the law imposes liability just by virtue of the activity that the defendant engages in (e.g., the use of explosives in a residential area). Thus, under Section 304, the plaintiff must prove culpability equal to or rising above the level of negligence to receive compensation above what may be offered by Part C. This means that even when all of the requirements of Section 304 are met, no matter how severe the personal injury, including death, there is no further compensation beyond what may be available under Part C unless there is a finding of fault.\textsuperscript{115}

Also, under the FTCA, attorneys’ fees are paid out of the award and are limited,\textsuperscript{116} and the government will not pay interest accumulated prior to judgment or, with a minor exception, punitive damages (i.e., those that punish intentional or egregious conduct).\textsuperscript{117} Because only punitive damages are prohibited, courts can award damages that exceed actual monetary loss.\textsuperscript{118} What those damages are depends on state law. For example, Pennsylvania law holds (although it will likely change) that “damages are to be compensatory to the full extent of the injury sustained.”\textsuperscript{119} In a 1983 decision under the Swine Flu Act applying Pennsylvania law, damages included past and future medical expenses; past lost earnings; lost future earning capacity; and past, present, and future pain and suffering (physical pain and suffering, mental anguish, inconvenience, disfigurement, humiliation, and the loss of enjoyment of life) resulting in an award of nearly $4 million.\textsuperscript{120} By contrast, in a late 1990 evaluation, at least 35 states had placed a cap on compensatory damages, which varied substantially as to the types of actions and damages capped as well as the total dollar amount.\textsuperscript{121}

If a vaccine recipient is dissatisfied with the compensation awarded under Part C of the Smallpox Emergency Personnel Protection Act or dissatisfied with what can be awarded in a claim against the government under Section 304 of the Homeland Security Act, can that individual pursue a claim against the provider or covered person anywhere else?

No. Section 304 states: “The remedy provided by subsection (a) [i.e., FTCA] shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses, except for a proceeding under part C of this title.”\textsuperscript{122} This so-called “exclusivity” provision likely prohibits any other lawsuit if Section 304 applies. However, the phrase “this subsection encompasses,” which refers to Section 304, should allow lawsuits based on the administration of the smallpox vaccine or other covered countermeasure when Section 304 is not implicated (e.g., the use of smallpox vaccines to prevent the spread of monkeypox)\textsuperscript{123} or if the vaccine is provided on the black market or otherwise in violation of Section 304. In such cases, the normal rules of litigation would apply. Unfortunately, there is no Congressional record on this provision, and the language differs slightly from the exclusivity language that applies to regular PHS employees,\textsuperscript{124} so its reach is not entirely clear.


\textsuperscript{115}By contrast, lawsuits brought under the Swine Flu Act could be based on “any theory of liability” according to state law, including strict liability. 42 USCS § 247b(k)(2)(A)(i) (repealed 1978).

\textsuperscript{116}28 USCS § 2678 (2003).


\textsuperscript{120}McDonald v. United States, 555 F. Supp. 935 (M.D. Pa. 1983), aff’d, 738 F.2d 423 (3d Cir. 1984).


\textsuperscript{122}42 USCS § 233(p)(3)(B) (2003).

\textsuperscript{123}See Centers for Disease Control and Prevention, note 56.

\textsuperscript{124}The exclusivity language applying to regular Public Health Service (PHS) employees states that “[t]he remedy . . . shall be exclusive of any other civil action or proceeding by reason of the same subject-matter. . . . “ 42 USCS § 233(a) (2003). The exclusivity language in the Federal Tort Claims Act (FTCA) (28 USCS § 2679(b)(1)(2003)), which applies to federal employees in general, is similar to that applying to PHS employees; however, federal employees can still be sued in their individual capacity for violations of the U.S. Constitution or if another federal statute authorizes suit (28 USCS § 2679(b)(2) (2003)). See Willens JA, \textit{Title 28, Chapter 171—The Federal Tort Claims Act: 28 USCS § 2679—Exclusiveness of remedy}, National Institute for Trial Advocacy, available at http://www.briefworks.com/FTCA%20Commentary4.htm (accessed 01/13/2003).
For those cases that do fall within the purview of Section 304, the issue of exclusivity has tremendous implications for potential plaintiffs. If the federal government has been substituted as defendant under the Homeland Security Act, the claim is brought pursuant to the FTCA. The FTCA has 13 enumerated exceptions in which the government will not accept liability for the acts or omissions of its employees. The result is that when the government substitutes itself as defendant for one of its employees, but one of the exceptions applies, the claim against the government is dismissed and the plaintiff is prevented from suing the employee as well. Two of the exceptions—the so-called discretionary function exception and the intentional torts/misrepresentation exception—may be particularly problematic to individuals hoping to recover against the government under the Homeland Security Act. Although a discussion of these exceptions is beyond the scope of this article, many claims alleging negligence in the administration of the smallpox vaccine that would have been allowed if a vaccine manufacturer or provider had remained defendant may never see a day in court because the government becomes the defendant under the FTCA.

**BIODEFENSE AND VACCINE LIABILITY: PRINCIPLES TO CONSIDER**

Laws cannot be written to avoid all confusion and satisfy everyone affected by them. Inevitably, issues will arise that were not understood at the time of drafting. Moreover, laws set forth obligations and assign responsibility so individual interests will necessarily conflict. There is no easy balance among the competing goals of encouraging certain categories of individuals to get vaccinated while discouraging others, or providing adequate compensation to injured parties while limiting liability so manufacturers will produce desired vaccines and others in the private sector will administer them. However, the recent experience with the smallpox vaccine suggests several key principles related to liability that policymakers should consider when vaccines are used to defend against bioterrorism. As the smallpox vaccination program evolves and the liability and compensation schemes are tested, more lessons will be learned for future vaccination programs that involve potential agents of bioterrorism.

**Liability cannot be separated from compensation**

The government initially hoped to vaccinate approximately 439,000 civilian smallpox response team members in Phase I of the smallpox vaccination program, but as of April 18, 2003 (before compensation was offered), only 33,444 civilians had been vaccinated. This low participation was attributed, in part, to the widespread concern among healthcare providers that the Homeland Security Act did not provide them adequate liability protection or compensation. In fact, soon after the Homeland Security Act was enacted (November 25, 2002), government officials, associations, and individuals called for new law addressing the compensation issues. Fair, adequate, and prompt no-fault compensation and adequate liability protection must be provided to those expected to implement a pre-attack national vaccination program established in the name of national security, especially when the risk of attack with a particular biological agent is indeterminate or not imminent.

**Ongoing communication with the various stakeholders is critical**

What is endorsed as fair and adequate liability protection and compensation will be achieved only with the input and partnership of those expected to implement the program. Responding to concerns raised about Section 304’s liability protection and the lack of compensation, on April 24, 2003, Congress passed the Smallpox Emergency Personnel Protection Act, which President Bush signed on April 30, 2003.

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125. 28 USCS § 2680 (2003).
127. 28 USCS § 2680(a) (2003).
128. 28 USCS § 2680(h) (2003).
132. Manning A. Second round of smallpox vaccinations begins despite weak response. USA Today 2003 Apr 23, Pg. 6D.
April 30, 2003. The amendments to Section 304 are clear improvements and address many of the criticisms that have been raised, demonstrating that the federal government can actively engage the stakeholders and quickly act to address their concerns. However, as of July 18, 2003 (nearly three months after the compensation provisions had been enacted), still only 37,971 civilians had been vaccinated.

For practical purposes, the civilian smallpox vaccination program is almost at a standstill. The federal government should conduct or fund a study to determine the reasons behind the continued reluctance to participate in this vaccination program. Whether it is because the compensation now available is inadequate or for a reason unrelated to compensation and liability—for example, has the failure to find biological weapons in Iraq engendered belief that the threat of a smallpox attack is too low to justify the risks of the vaccine?—the answers should provide insight for this and future vaccination programs where national security issues are involved.

The extent of liability protection and compensation should be clear prior to the desired implementation date

The Homeland Security Act was enacted on November 25, 2002, and became effective 60 days later on January 24, 2003, enabling vaccination to go forward on that date. The current Declaration, which lists the vaccines and treatments covered under the Act, specifies who can get vaccinated, and clarifies the Act itself, was also issued on January 24, 2003. Although the government had hoped for wide-scale vaccinations to begin on January 24, on that date only four healthcare workers were vaccinated in one state. More than half of the 62 jurisdictions with vaccination plans approved by the CDC had not even requested the vaccine, and most of those remaining had requested delivery of the vaccine after that date.

Much confusion existed over the extent of liability protection under the Act at the time vaccination began, and compensation issues were still very much unresolved. A declaration should be issued sufficiently before the desired implementation date for the attorneys of providers, hospitals, and other participants to analyze the law and advise their clients accordingly.

Liability laws that protect participants in vaccination programs should have flexibility to address new circumstances that may arise

The Homeland Security Act gives the Secretary explicit permission to shorten and extend the effective period of a declaration, and more than one declaration can be issued. This flexibility is essential because healthcare providers have liability protection for administering the smallpox vaccine and covered treatments only during this period. When the current deadline approaches (January 23, 2004), the Secretary will need to determine—after consultation with hospital representatives and healthcare providers—if the period should be extended to make sure that all treatments continued to be covered. In addition, the current Declaration lists only vaccinia vaccines, Cidofovir, and VIG as covered countermeasures. In the future, the Secretary may decide to add to the list additional treatments that can be used to treat the adverse reactions of these countermeasures. Because the course of an illness and the effects of treatments can have many unknowns, vaccine liability laws should have flexibility of this sort, but they must not be so flexible that liability protection is unclear or might be applied arbitrarily.

Post-attack liability and compensation should be established before an attack

Now is the time to think about and provide for liability protection and compensation after a smallpox attack has occurred, because other factors come into play that the current laws do not adequately address. For example, in a post-attack scenario, getting proper informed consent from mass numbers of people prior to vaccination will present an entirely new set of management and organizational issues. In fact, some ethicists suggest that it might be “morally obligatory to dispense with the ordinary requirements of informed consent” post-attack, provided adequate no-fault compensation is provided. But except in limited circumstances, the current compensation scheme applies to a pre-attack scenario. Additionally, individuals with certain medical conditions who should not be vaccinated pre-attack might be recommended for vaccination post-attack, requiring extensive educational efforts. Post-attack vaccination also might require the use of investigational vaccines that do not have FDA approval, raising other liability concerns. Once an attack has occurred, the risk-benefit paradigm changes, and individuals and hospitals may be more willing to accept the risks associated with smallpox vaccination. The federal government, in partnership with the other stakeholders—including state and local governments, public health professionals, industry representatives, experts in the field of vaccine delivery, and potential vaccine recipients—needs to

work through these and other such issues before an attack occurs, and where necessary, enact new legislation to address a post-attack scenario.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Declaration Regarding Administration of Smallpox Countermeasures

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services is issuing this notice pursuant to section 224(p)(2)(A) of the Public Health Service Act to make a declaration regarding administration of smallpox countermeasures. The Secretary provides policy determinations regarding administration of countermeasures, and declares that a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified in the declaration for prevention or treatment of smallpox or control or treatment of adverse events related to smallpox vaccination to categories of individuals named in the declaration who may be involved in a wide range of activities associated with the administration of countermeasures against smallpox. Effective dates of the declaration, and relevant definitions are also provided.

DATES: This Notice and the attached declaration are effective as of January 24, 2003.


SUPPLEMENTARY INFORMATION:
The Secretary issues the following declaration pursuant to section 224(p)(2)(A) of the Public Health Service Act, 42 U.S.C. 233(p)(2)(A):

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 (Pub. 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 inculcating 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 who whose services 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 Cidofovir’s effectiveness in treating lethal pox virus infections that are similar to smallpox, Cidofovir 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) Cidofovir 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) 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 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.


Tommy G. Thompson, Secretary.

[FR Doc. 03-2012 Filed 1-24-03; 12:00 am]
BILLING CODE 4150-24-P
Appendix B: Definition of “Covered Person,”
42 USCS § 233(p)(7)(B)

(7) Definitions. As used in this subsection, terms have the following meanings...
(B) Covered person. The term “covered person”, when used with respect to the administration of a covered countermeasure, means a person who is—
(i) a manufacturer or distributor of such countermeasure;
(ii) a health care entity under whose auspices—
(I) such countermeasure was administered;
(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;
(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or
(IV) an evaluation was made of whether the administration of a countermeasure was effective;
(iii) a qualified person who administered such countermeasure;
(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to administration of such countermeasures;
(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—
(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or
(II) an entity that employs an individual described by clause (I) or where such individual has privileges or is otherwise authorized to provide health care;
(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);
(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or
(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).