



SMALLPOX QUESTIONS AND ANSWERS

Section 304 of the Homeland Security Act

GENERAL

Q.1. What is the purpose of Section 304 of the Homeland Security Act?

A.1. Manufacturers of smallpox vaccine and those healthcare entities that would administer the vaccine 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 alleviate these liability concerns and therefore ensure that vaccine is available and can be administered, particularly in the event of a smallpox-related actual or potential public health emergency such as a bioterrorist incident. (added Dec 13, 2002)

Q.2. In general, what does Section 304 provide?

A.2. Section 304 provides an exclusive remedy against the United States for injury or death attributable to smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin ("smallpox countermeasures"). This means that no claim for liability for injury or death attributable to a smallpox countermeasure could be brought against entities or individuals who are covered by Section 304's protections. (added Dec 13, 2002)

Q.3. When do the provisions of Section 304 become effective?

A.3. The effective date, as established in Section 4 of the Homeland Security Act, is January 24, 2003. If vaccination is to begin sooner, Section 304 would apply at that earlier time only if Congress enacts legislation moving up the effective date. (added Dec 13, 2002)

FILING A CLAIM

Q.4. If I am injured as a result of receiving a smallpox countermeasure, how do I know if I can file a Section 304 claim?

A.4. Section 304 is triggered if and when a smallpox countermeasure is administered pursuant to a declaration by the Secretary of Health and Human Services. The declaration will specify the administration of particular countermeasures to one or more categories of individuals, and it will state how long it is in effect. An individual described in the declaration who receives one of those countermeasures from a qualified person while the declaration is in effect, and who is injured as a result, may file a claim under Section 304. (added Dec 13, 2002)

Q.5. Who is a "qualified person?"

A.5. Qualified persons 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 the countermeasure is administered by a qualified person. (added Dec 13, 2002)

Q.6. If I contract vaccinia without having received smallpox vaccine, can I file a Section 304 claim?

A.6. Individuals who were not inoculated, 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 was inoculated pursuant to the declaration, may submit claims. (added Dec 13, 2002)

Q.7. What is the process for filing a Section 304 claim?

A.7. Anyone who believes he or she has a claim for money damages attributable to injury or death due to smallpox countermeasures must submit an administrative claim with an appropriate agency of the United States within two years. If the agency denies the claim, or if no action is taken on the claim within six months, the injured individual may file suit in federal court. (added Dec 13, 2002)

Q.8. May the Secretary make the declaration prior to the occurrence of a bioterrorist incident or public health emergency?

A.8. A declaration can be made if the Secretary concludes that an actual or potential bioterrorist incident or other actual or potential public health emergency makes the administration advisable. The Secretary can, therefore, make the declaration prior to the occurrence of a bioterrorist incident or public health emergency. (added Dec 13, 2002)

COVERED ENTITIES

Q.9. What entities are covered by Section 304's protections?

A.9. With respect to administration of a covered countermeasure, manufacturers and distributors of countermeasures, healthcare entities under whose auspices the countermeasure is administered, and licensed health care professionals or other individuals authorized to administer the countermeasure under state law are covered by Section 304. In addition, any official, agent, or employee of any of these entities is also covered. (added Dec 13, 2002)

Q.10. Are state and local health departments and their employees covered by Section 304?

A.10. State and local health departments that act as distributors of countermeasures or that are healthcare entities under whose auspices countermeasures are administered are covered by Section 304. Their officials, agents, or employees are also covered for actions arising out of the administration of a countermeasure. (added Dec 13, 2002)

Q.11. Does Section 304 contain any limitations for covering these entities?

A.11. 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 item A.9 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 A.9, 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. (added Dec 13, 2002)

OTHER

Q.12. What effect does Section 304 have upon federal or state workers' compensation schemes?

A.12. Workers covered by state workers' compensation statutes who suffer work-related injuries from the countermeasure may be barred from submitting a Section 304 claim if those state laws constitute an exclusive remedy. Federal employees who suffer such work-related injuries may only file claims pursuant to the Federal Employees' Compensation Act. (added Dec 13, 2002)

Q.13. What legal standards apply to Section 304 claims?

A.13. In general, suits would be governed by state law as to liability and damages, except when provisions of the federal law provided otherwise. For example, a claimant must demonstrate that the injury or death attributable to the countermeasure was the result of a negligent or wrongful act or omission, regardless of the standard in the state where the act or omission occurred. (added Dec 13, 2002)

Q.14. Does the statute authorize payment for lost time from work or health care costs necessary for treating the injury?

A.14. If a claimant prevails on a Section 304 claim, damages would be determined according to state law, within any limits imposed by federal law. While loss of income and health care costs generally are recoverable, Section 304 does not establish a "no-fault" compensation program. See items A.2 and A.13. Individuals may wish to review their health insurance policies to determine whether they cover health-care costs for injuries attributable to administration of a smallpox countermeasure. For information on Section 304's interaction with workers' compensation claims, see item A.12. (added Dec 13, 2002)

Q.15. Are all persons working in a vaccination clinic covered by Section 304?

A.15. A vaccination clinic, as a healthcare entity under whose auspices a countermeasure is administered, is covered by Section 304 protections. Any official, employee, or agent of such a vaccination clinic would therefore also be covered by Section 304 protections for actions arising out of the administration of a countermeasure. See item A.9. (added Dec 13, 2002)

Q.16. Will hospitals or other institutions who employ vaccinees but who do not operate as a clinic administering countermeasures be covered by Section 304 protections?

A.16. Hospitals and institutions under whose auspices countermeasures are administered are covered by Section 304 protections. 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. See "Guidance for the Healthcare Community Concerning Section 304 of the Homeland Security Act" at <http://www.bt.cdc.gov/agent/smallpox/vaccination/healthcare-304-guidance.asp>. (updated Jan 17, 2003)

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)
January 17, 2003