

Homeland Security Act of 2002

SEC. 304. CONDUCT OF CERTAIN PUBLIC HEALTH-RELATED ACTIVITIES.

(a) **IN GENERAL-** With respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats carried out by the Department of Health and Human Services (including the Public Health Service), the Secretary of Health and Human Services shall set priorities, goals, objectives, and policies and develop a coordinated strategy for such activities in collaboration with the Secretary of Homeland Security to ensure consistency with the national policy and strategic plan developed pursuant to section 302(2).

(b) **EVALUATION OF PROGRESS-** In carrying out subsection (a), the Secretary of Health and Human Services shall collaborate with the Secretary in developing specific benchmarks and outcome measurements for evaluating progress toward achieving the priorities and goals described in such subsection.

(c) **ADMINISTRATION OF COUNTERMEASURES AGAINST SMALLPOX-** Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding the following:

“(p) **ADMINISTRATION OF SMALLPOX COUNTERMEASURES BY HEALTH PROFESSIONALS-**

“(1) **IN GENERAL-** For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

“(2) **DECLARATION BY SECRETARY CONCERNING COUNTERMEASURE AGAINST SMALLPOX-**

“(A) **AUTHORITY TO ISSUE DECLARATION-**

“(i) **IN GENERAL-** The Secretary may issue a declaration, pursuant to this paragraph, concluding 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.

“(ii) **COVERED COUNTERMEASURE-** The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (8)(A)) for purposes of administration to individuals during the effective period of the declaration.

“(iii) **EFFECTIVE PERIOD-** The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently

amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

`(iv) PUBLICATION- The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

`(B) LIABILITY OF UNITED STATES ONLY FOR ADMINISTRATIONS WITHIN SCOPE OF DECLARATION- Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual only if--

`(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

`(ii)(I) the individual was within a category of individuals covered by the declaration; or

`(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

`(C) PRESUMPTION OF ADMINISTRATION WITHIN SCOPE OF DECLARATION IN CASE OF ACCIDENTAL VACCINIA INOCULATION-

`(i) IN GENERAL- If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual--

`(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

`(II) shall (unless such presumption is rebutted) be deemed for purposes of this subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

`(ii) CIRCUMSTANCES IN WHICH PRESUMPTION APPLIES- The presumption and deeming stated in clause (i) shall apply if--

`(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph

(A) or by the date 30 days after the close of such period; or

(II) the individual resides or has resided with an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccination after such date.

(3) EXCLUSIVITY OF REMEDY- The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses.

(4) CERTIFICATION OF ACTION BY ATTORNEY GENERAL- Subsection (c) applies to actions under this subsection, subject to the following provisions:

(A) NATURE OF CERTIFICATION- The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

(B) CERTIFICATION OF ATTORNEY GENERAL CONCLUSIVE- The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

(5) DEFENDANT TO COOPERATE WITH UNITED STATES-

(A) IN GENERAL- A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

(B) CONSEQUENCES OF FAILURE TO COOPERATE- Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate--

(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

(ii) the United States shall not be liable based on the acts or omissions of such person; and

(iii) the Attorney General shall not be obligated to defend such action.

(6) RECOURSE AGAINST COVERED PERSON IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION-

(A) IN GENERAL- Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any

provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

`(B) VENUE- The United States may maintain an action under this paragraph against such person in the district court of the United States in which such person resides or has its principal place of business.

`(7) DEFINITIONS- As used in this subsection, terms have the following meanings:

`(A) COVERED COUNTERMEASURE- The term `covered countermeasure' or `covered countermeasure against smallpox', means a substance that is--

`(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

`(II) vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and

`(ii) specified in a declaration under paragraph (2).

`(B) COVERED PERSON- The term `covered person', when used with respect to the administration of a covered countermeasure, includes any person who is--

`(i) a manufacturer or distributor of such countermeasure;

`(ii) a health care entity under whose auspices such countermeasure was administered;

`(iii) a qualified person who administered such countermeasure; or

`(iv) an official, agent, or employee of a person described in clause (i), (ii), or (iii).

`(C) QUALIFIED PERSON- The term `qualified person', when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered.'

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