

tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

#### (7) Qualified pandemic or epidemic product

The term “qualified pandemic or epidemic product” means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),<sup>2</sup> biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))<sup>2</sup> that is—

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb-3, 360bbb-3a, 360bbb-3b].

#### (8) Qualified person

The term “qualified person”, when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

#### (9) Security countermeasure

The term “security countermeasure” has the meaning given such term in section 247d-6b(c)(1)(B) of this title.

#### (10) Serious physical injury

The term “serious physical injury” means an injury that—

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(July 1, 1944, ch. 373, title III, §319F-3, as added Pub. L. 109-148, div. C, §2, Dec. 30, 2005, 119 Stat. 2818; amended Pub. L. 113-5, title IV, §402(g)(2), (3), Mar. 13, 2013, 127 Stat. 196.)

#### REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(8)(B), (c)(5)(A), (B)(i), (ii)(I), (C)(i), and (i)(7)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Chapter V of the Act is classified generally to subchapter V (§351 et seq.) of chapter 9 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Rules of Civil Procedure, referred to in subsec. (e)(6)(B), (9), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

The Public Readiness and Emergency Preparedness Act, referred to in subsec. (h), is div. C of Pub. L. 109-148, Dec. 30, 2005, 119 Stat. 2818, which enacted this section, section 247d-6e of this title, and provisions set out as a note under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 2005 Amendment note set out under section 201 of this title and Tables.

#### AMENDMENTS

2013—Subsec. (i)(1)(C). Pub. L. 113-5, §402(g)(3)(A), inserted “, 564A, or 564B” after “564”.

Subsec. (i)(7)(A)(iii). Pub. L. 113-5, §402(g)(2), added cl. (iii).

Subsec. (i)(7)(B)(iii). Pub. L. 113-5, §402(g)(3)(B), inserted “, 564A, or 564B” after “564”.

#### § 247d-6e. Covered countermeasure process

##### (a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d-6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the “Covered Countermeasure Process Fund” for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

##### (b) Payment of compensation

###### (1) In general

If the Secretary issues a declaration under 247d-6d(b) of this title, the Secretary shall, after amounts have by law been provided for

<sup>2</sup>So in original. A third closing parenthesis probably should appear.

the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

**(2) Elements of compensation**

The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title shall not apply.

**(3) Rule of construction**

Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 239e of this title.

**(4) Determination of eligibility and compensation**

Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 239a of this title (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

**(5) Covered countermeasure injury table**

**(A) In general**

The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

**(B) Amendments**

The provisions of section 239b of this title (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

**(C) Judicial review**

No court of the United States, or of any State, shall have subject matter jurisdiction

to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

**(6) Meanings of terms**

In applying sections 239a, 239b, 239c, 239d, and 239e of this title for purposes of this section—

(A) the terms “vaccine” and “smallpox vaccine” shall be deemed to mean a covered countermeasure;

(B) the terms “smallpox vaccine injury table” and “table established under section 239b of this title” shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

**(c) Voluntary program**

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d-6d of this title and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

**(d) Exhaustion; exclusivity; election**

**(1) Exhaustion**

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d-6d(d) of this title against a covered person (as such term is defined in section 247d-6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d-6d(d) of this title.

**(2) Tolling of statute of limitations**

The time limit for filing a civil action under section 247d-6d(d) of this title for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

**(3) Rule of construction**

This section shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, to exhaust administrative remedies.

**(4) Exclusivity**

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d-6d of this title.

**(5) Election**

If under subsection (a) the Secretary determines that a covered individual qualifies for

compensation, the individual has an election to accept the compensation or to bring an action under section 247d-6d(d) of this title. If such individual elects to accept the compensation, the individual may not bring such an action.

**(e) Definitions**

For purposes of this section, the following terms shall have the following meanings:

**(1) Covered countermeasure**

The term “covered countermeasure” has the meaning given such term in section 247d-6d of this title.

**(2) Covered individual**

The term “covered individual”, with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

**(3) Covered injury**

The term “covered injury” means serious physical injury or death.

**(4) Declaration**

The term “declaration” means a declaration under section 247d-6d(b) of this title.

**(5) Eligible individual**

The term “eligible individual” means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.

(July 1, 1944, ch. 373, title III, §319F-4, as added Pub. L. 109-148, div. C, §3, Dec. 30, 2005, 119 Stat. 2829.)

REFERENCES IN TEXT

H. Con. Res. 95 of the 109th Congress, referred to in subsec. (a), is H. Con. Res. 95, Apr. 28, 2005, 119 Stat. 3633, which is not classified to the Code.

**§ 247d-7. Demonstration program to enhance bioterrorism training, coordination, and readiness**

**(a) In general**

The Secretary shall make grants to not more than three eligible entities to carry out demonstration programs to improve the detection of pathogens likely to be used in a bioterrorist attack, the development of plans and measures to respond to bioterrorist attacks, and the training of personnel involved with the various responsibilities and capabilities needed to respond to acts of bioterrorism upon the civilian population. Such awards shall be made on a competitive basis and pursuant to scientific and technical review.

**(b) Eligible entities**

Eligible entities for grants under subsection (a) are States, political subdivisions of States, and public or private non-profit organizations.

**(c) Specific criteria**

In making grants under subsection (a), the Secretary shall take into account the following factors:

(1) Whether the eligible entity involved is proximate to, and collaborates with, a major research university with expertise in scientific training, identification of biological agents, medicine, and life sciences.

(2) Whether the entity is proximate to, and collaborates with, a laboratory that has expertise in the identification of biological agents.

(3) Whether the entity demonstrates, in the application for the program, support and participation of State and local governments and research institutions in the conduct of the program.

(4) Whether the entity is proximate to, and collaborates with, or is, an academic medical center that has the capacity to serve an uninsured or underserved population, and is equipped to educate medical personnel.

(5) Such other factors as the Secretary determines to be appropriate.

**(d) Duration of award**

The period during which payments are made under a grant under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

**(e) Supplement not supplant**

Grants under subsection (a) shall be used to supplement, and not supplant, other Federal, State, or local public funds provided for the activities described in such subsection.

**(f) Government Accountability Office report**

Not later than 180 days after the conclusion of the demonstration programs carried out under subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Commerce and the Committee on Appropriations of the House of Representatives, a report that describes the ability of grantees under such subsection to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel involved with the various responsibilities and capabilities needed to deal with bioterrorist threats.

**(g) Authorization of appropriations**

There is authorized to be appropriated to carry out this section \$6,000,000 for fiscal year 2001, and such sums as may be necessary through fiscal year 2006.

(July 1, 1944, ch. 373, title III, §319G, as added Pub. L. 106-505, title I, §102, Nov. 13, 2000, 114 Stat. 2323; amended Pub. L. 108-271, §8(b), July 7, 2004, 118 Stat. 814.)

AMENDMENTS

2004—Subsec. (f). Pub. L. 108-271 substituted “Government Accountability Office” for “General Accounting Office” in heading.