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H. R. 1770

IN THE SENATE OF THE UNITED STATES

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Received

AN ACT

To provide benefits and other compensation for certain individuals with injuries resulting from administration of smallpox countermeasures, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Smallpox Emergency
3 Personnel Protection Act of 2003”.

4 **SEC. 2. SMALLPOX EMERGENCY PERSONNEL PROTECTION.**

5 Title II of the Public Health Service Act (42 U.S.C.
6 202 et seq.) is amended by adding at the end the following
7 part:

8 “PART C—SMALLPOX EMERGENCY PERSONNEL
9 PROTECTION

10 **“SEC. 261. GENERAL PROVISIONS.**

11 “(a) DEFINITIONS.—For purposes of this part:

12 “(1) COVERED COUNTERMEASURE.—The term
13 ‘covered countermeasure’ means a covered counter-
14 measure as specified in a Declaration made pursu-
15 ant to section 224(p).

16 “(2) COVERED INDIVIDUAL.—The term ‘cov-
17 ered individual’ means an individual—

18 “(A) who is a health care worker, law en-
19 forcement officer, firefighter, security per-
20 sonnel, emergency medical personnel, other
21 public safety personnel, or support personnel
22 for such occupational specialities;

23 “(B) who is or will be functioning in a role
24 identified in a State, local, or Department of
25 Health and Human Services smallpox emer-

1 agency response plan (as defined in paragraph
2 (7)) approved by the Secretary;

3 “(C) who has volunteered and been se-
4 lected to be a member of a smallpox emergency
5 response plan described in subparagraph (B)
6 prior to the time at which the Secretary pub-
7 licly announces that an active case of smallpox
8 has been identified either within or outside of
9 the United States; and

10 “(D) to whom a smallpox vaccine is admin-
11 istered pursuant to such approved plan during
12 the effective period of the Declaration (includ-
13 ing the portion of such period before the enact-
14 ment of this part).

15 “(3) COVERED INJURY.—The term ‘covered in-
16 jury’ means an injury, disability, illness, condition,
17 or death (other than a minor injury such as minor
18 scarring or minor local reaction) determined, pursu-
19 ant to the procedures established under section 262,
20 to have been sustained by an individual as the direct
21 result of—

22 “(A) administration to the individual of a
23 covered countermeasure during the effective pe-
24 riod of the Declaration; or

1 “(B) accidental vaccinia inoculation of the
2 individual in circumstances in which—

3 “(i) the vaccinia is contracted during
4 the effective period of the Declaration or
5 within 30 days after the end of such pe-
6 riod;

7 “(ii) smallpox vaccine has not been
8 administered to the individual; and

9 “(iii) the individual has been in con-
10 tact with an individual who is (or who was
11 accidentally inoculated by) a covered indi-
12 vidual.

13 “(4) DECLARATION.—The term ‘Declaration’
14 means the Declaration Regarding Administration of
15 Smallpox Countermeasures issued by the Secretary
16 on January 24, 2003, and published in the Federal
17 Register on January 28, 2003.

18 “(5) EFFECTIVE PERIOD OF THE DECLARA-
19 TION.—The term ‘effective period of the Declara-
20 tion’ means the effective period specified in the Dec-
21 laration, unless extended by the Secretary.

22 “(6) ELIGIBLE INDIVIDUAL.—The term ‘eligible
23 individual’ means an individual who is (as deter-
24 mined in accordance with section 262)—

1 “(A) a covered individual who sustains a
2 covered injury in the manner described in para-
3 graph (3)(A); or

4 “(B) an individual who sustains a covered
5 injury in the manner described in paragraph
6 (3)(B).

7 “(7) SMALLPOX EMERGENCY RESPONSE
8 PLAN.—The term ‘smallpox emergency response
9 plan’ or ‘plan’ means a response plan detailing ac-
10 tions to be taken in preparation for a possible small-
11 pox-related emergency during the period prior to the
12 identification of an active case of smallpox either
13 within or outside the United States.

14 “(b) VOLUNTARY PROGRAM.—The Secretary shall
15 ensure that a State, local, or Department of Health and
16 Human Services plan to vaccinate individuals that is ap-
17 proved by the Secretary establishes procedures to ensure,
18 consistent with the Declaration and any applicable guide-
19 lines of the Centers for Disease Control and Prevention,
20 that—

21 “(1) potential participants are educated with
22 respect to contraindications, the voluntary nature of
23 the program, and the availability of potential bene-
24 fits and compensation under this part;

1 “(2) there is voluntary screening provided to
2 potential participants that can identify health condi-
3 tions relevant to contraindications; and

4 “(3) there is appropriate post-inoculation med-
5 ical surveillance that includes an evaluation of ad-
6 verse health effects that may reasonably appear to
7 be due to such vaccine and prompt referral of, or the
8 provision of appropriate information to, any indi-
9 vidual requiring health care as a result of such ad-
10 verse health event.

11 **“SEC. 262. DETERMINATION OF ELIGIBILITY AND BENE-**
12 **FITS.**

13 “(a) IN GENERAL.—The Secretary shall establish
14 procedures for determining, as applicable with respect to
15 an individual—

16 “(1) whether the individual is an eligible indi-
17 vidual;

18 “(2) whether an eligible individual has sus-
19 tained a covered injury or injuries for which medical
20 benefits or compensation may be available under sec-
21 tions 264 and 265, and the amount of such benefits
22 or compensation; and

23 “(3) whether the covered injury or injuries of
24 an eligible individual caused the individual’s death
25 for purposes of benefits under section 266.

1 “(b) COVERED INDIVIDUALS.—The Secretary may
2 accept a certification, by a Federal, State, or local govern-
3 ment entity or private health care entity participating in
4 the administration of covered countermeasures under the
5 Declaration, that an individual is a covered individual.

6 “(c) CRITERIA FOR REIMBURSEMENT.—

7 “(1) INJURIES SPECIFIED IN INJURY TABLE.—
8 In any case where an injury or other adverse effect
9 specified in the injury table established under section
10 263 as a known effect of a vaccine manifests in an
11 individual within the time period specified in such
12 table, such injury or other effect shall be presumed
13 to have resulted from administration of such vaccine.

14 “(2) OTHER DETERMINATIONS.—In making de-
15 terminations other than those described in para-
16 graph (1) as to the causation or severity of an in-
17 jury, the Secretary shall employ a preponderance of
18 the evidence standard and take into consideration all
19 relevant medical and scientific evidence presented for
20 consideration, and may obtain and consider the
21 views of qualified medical experts.

22 “(d) DEADLINE FOR FILING REQUEST.—The Sec-
23 retary shall not consider any request for a benefit under
24 this part with respect to an individual, unless—

1 “(1) in the case of a request based on the ad-
2 ministration of the vaccine to the individual, the in-
3 dividual files with the Secretary an initial request
4 for benefits or compensation under this part not
5 later than one year after the date of administration
6 of the vaccine; or

7 “(2) in the case of a request based on acci-
8 dental vaccinia inoculation, the individual files with
9 the Secretary an initial request for benefits or com-
10 pensation under this part not later than two years
11 after the date of the first symptom or manifestation
12 of onset of the adverse effect.

13 “(e) **STRUCTURED SETTLEMENTS AT SECRETARY’S**
14 **OPTION.**—In any case in which there is a reasonable likeli-
15 hood that compensation or payment under section 264,
16 265, or 266(b) will be required for a period in excess of
17 one year from the date an individual is determined eligible
18 for such compensation or payment, the Secretary shall
19 have the discretion to make a lump-sum payment, pur-
20 chase an annuity or medical insurance policy, or execute
21 an appropriate structured settlement agreement, provided
22 that such payment, annuity, policy, or agreement is actu-
23 arially determined to have a value equal to the present
24 value of the projected total amount of benefits or com-

1 pensation that the individual is eligible to receive under
2 such section or sections.

3 “(f) REVIEW OF DETERMINATION.—

4 “(1) SECRETARY’S REVIEW AUTHORITY.—The
5 Secretary may review a determination under this
6 section at any time on the Secretary’s own motion
7 or on application, and may affirm, vacate, or modify
8 such determination in any manner the Secretary
9 deems appropriate. The Secretary shall develop a
10 process by which an individual may file a request for
11 reconsideration of any determination made by the
12 Secretary under this section.

13 “(2) JUDICIAL AND ADMINISTRATIVE RE-
14 VIEW.—No court of the United States, or of any
15 State, District, territory or possession thereof, shall
16 have subject matter jurisdiction to review, whether
17 by mandamus or otherwise, any action by the Sec-
18 retary under this section. No officer or employee of
19 the United States shall review any action by the Sec-
20 retary under this section (unless the President spe-
21 cifically directs otherwise).

22 **“SEC. 263. SMALLPOX VACCINE INJURY TABLE.**

23 “(a) SMALLPOX VACCINE INJURY TABLE.—

24 “(1) ESTABLISHMENT REQUIRED.—The Sec-
25 retary shall establish by interim final regulation a

1 table identifying adverse effects (including injuries,
2 disabilities, illnesses, conditions, and deaths) that
3 shall be presumed to result from the administration
4 of (or exposure to) a smallpox vaccine, and the time
5 period in which the first symptom or manifestation
6 of onset of each such adverse effect must manifest
7 in order for such presumption to apply.

8 “(2) AMENDMENTS.—The Secretary may by
9 regulation amend the table established under para-
10 graph (1). An amendment to the table takes effect
11 on the date of the promulgation of the final rule
12 that makes the amendment, and applies to all re-
13 quests for benefits or compensation under this part
14 that are filed on or after such date or are pending
15 as of such date. In addition, the amendment applies
16 retroactively to an individual who was not with re-
17 spect to the injury involved an eligible individual
18 under the table as in effect before the amendment
19 but who with respect to such injury is an eligible in-
20 dividual under the table as amended. With respect to
21 a request for benefits or compensation under this
22 part by an individual who becomes an eligible indi-
23 vidual as described in the preceding sentence, the
24 Secretary may not provide such benefits or com-
25 pensation unless the request (or amendment to a re-

1 quest, as applicable) is filed before the expiration of
2 one year after the effective date of the amendment
3 to the table in the case of an individual to whom the
4 vaccine was administered and before the expiration
5 of two years after such effective date in the case of
6 a request based on accidental vaccinia inoculation.

7 **“SEC. 264. MEDICAL BENEFITS.**

8 “(a) IN GENERAL.—Subject to the succeeding provi-
9 sions of this section, the Secretary shall make payment
10 or reimbursement for medical items and services as rea-
11 sonable and necessary to treat a covered injury of an eligi-
12 ble individual, including the services, appliances, and sup-
13 plies prescribed or recommended by a qualified physician,
14 which the Secretary considers likely to cure, give relief,
15 reduce the degree or the period of disability, or aid in less-
16 ening the amount of monthly compensation.

17 “(b) BENEFITS SECONDARY TO OTHER COV-
18 ERAGE.—Payment or reimbursement for services or bene-
19 fits under subsection (a) shall be secondary to any obliga-
20 tion of the United States or any third party (including
21 any State or local governmental entity, private insurance
22 carrier, or employer) under any other provision of law or
23 contractual agreement, to pay for or provide such services
24 or benefits.

1 **“SEC. 265. COMPENSATION FOR LOST EMPLOYMENT IN-**
2 **COME.**

3 “(a) IN GENERAL.—Subject to the succeeding provi-
4 sions of this section, the Secretary shall provide compensa-
5 tion to an eligible individual for loss of employment income
6 (based on such income at the time of injury) incurred as
7 a result of a covered injury, at the rate specified in sub-
8 section (b).

9 “(b) AMOUNT OF COMPENSATION.—

10 “(1) IN GENERAL.—Compensation under sub-
11 section (a) shall be at the rate of $66\frac{2}{3}$ percent of
12 the relevant pay period (weekly, monthly, or other-
13 wise), except as provided in paragraph (2).

14 “(2) AUGMENTED COMPENSATION FOR DE-
15 PENDENTS.—If an eligible individual has one or
16 more dependents, the basic compensation for loss of
17 employment income as described in paragraph (1)
18 shall be augmented at the rate of $8\frac{1}{3}$ percent.

19 “(3) CONSIDERATION OF OTHER PROGRAMS.—

20 “(A) IN GENERAL.—The Secretary may
21 consider the provisions of sections 8114, 8115,
22 and 8146a of title 5, United States Code, and
23 any implementing regulations, in determining
24 the amount of payment under subsection (a)
25 and the circumstances under which such pay-
26 ments are reasonable and necessary.

1 “(B) MINORS.—With respect to an eligible
2 individual who is a minor, the Secretary may
3 consider the provisions of section 8113 of title
4 5, United States Code, and any implementing
5 regulations, in determining the amount of pay-
6 ment under subsection (a) and the cir-
7 cumstances under which such payments are
8 reasonable and necessary.

9 “(4) TREATMENT OF SELF-EMPLOYMENT IN-
10 COME.—For purposes of this section, the term ‘em-
11 ployment income’ includes income from self-employ-
12 ment.

13 “(c) LIMITATIONS.—

14 “(1) BENEFITS SECONDARY TO OTHER COV-
15 ERAGE.—

16 “(A) IN GENERAL.—Any compensation
17 under subsection (a) shall be secondary to the
18 obligation of the United States or any third
19 party (including any State or local govern-
20 mental entity, private insurance carrier, or em-
21 ployer), under any other law or contractual
22 agreement, to pay compensation for loss of em-
23 ployment income or to provide disability or re-
24 tirement benefits.

1 “(B) RELATION TO OTHER OBLIGA-
2 TIONS.—Compensation under subsection (a)
3 shall not be made to an eligible individual to
4 the extent that the total of amounts paid to the
5 individual under such subsection and under the
6 other obligations referred to in subparagraph
7 (A) is an amount that exceeds the rate specified
8 in subsection (b)(1). If under any such other
9 obligation a lump-sum payment is made, such
10 payment shall, for purposes of this paragraph,
11 be deemed to be received over multiple years
12 rather than received in a single year. The Sec-
13 retary may, in the discretion of the Secretary,
14 determine how to apportion such payment over
15 multiple years.

16 “(2) NO BENEFITS IN CASE OF DEATH.—No
17 payment shall be made under subsection (a) in com-
18 pensation for loss of employment income subsequent
19 to the receipt, by the survivor or survivors of an eli-
20 gible individual, of benefits under section 266 for
21 death.

22 “(3) LIMIT ON TOTAL BENEFITS.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B)—

1 “(i) total compensation paid to an in-
2 dividual under subsection (a) shall not ex-
3 ceed \$50,000 for any year; and

4 “(ii) the lifetime total of such com-
5 pensation for the individual may not ex-
6 ceed an amount equal to the amount au-
7 thorized to be paid under section 266.

8 “(B) PERMANENT AND TOTAL DIS-
9 ABILITY.—The limitation under subparagraph
10 (A)(ii) does not apply in the case of an eligible
11 individual who is determined to have a covered
12 injury or injuries meeting the definition of dis-
13 ability in section 216(i) of the Social Security
14 Act (42 U.S.C. 416(i)).

15 “(4) WAITING PERIOD.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (B), an eligible individual shall
18 not be provided compensation under this section
19 for the first 5 work days of loss of employment
20 income.

21 “(B) EXCEPTION.—Subparagraph (A)
22 does not apply if the period of loss of employ-
23 ment income of an eligible individual is 10 or
24 more work days.

1 “(5) TERMINATION OF BENEFITS.—No pay-
2 ment shall be made under subsection (a) in com-
3 pensation for loss of employment income once the el-
4 igible individual involves reaches the age of 65.

5 “(d) BENEFIT IN ADDITION TO MEDICAL BENE-
6 FITS.—A benefit under subsection (a) shall be in addition
7 to any amounts received by an eligible individual under
8 section 264.

9 **“SEC. 266. PAYMENT FOR DEATH.**

10 “(a) DEATH BENEFIT.—

11 “(1) IN GENERAL.—The Secretary shall pay, in
12 the case of an eligible individual whose death is de-
13 termined to have resulted from a covered injury or
14 injuries, a death benefit in the amount determined
15 under paragraph (2) to the survivor or survivors in
16 the same manner as death benefits are paid pursu-
17 ant to the Public Safety Officers’ Benefits Program
18 under subpart 1 of part L of title I of the Omnibus
19 Crime Control and Safe Streets Act of 1968 (42
20 U.S.C. 3796 et seq.) with respect to an eligible de-
21 ceased (except that in the case of an eligible indi-
22 vidual who is a minor with no living parent, the legal
23 guardian shall be considered the survivor in the
24 place of the parent).

25 “(2) BENEFIT AMOUNT.—

1 “(A) IN GENERAL.—The amount of the
2 death benefit under paragraph (1) in a fiscal
3 year shall equal the amount of the comparable
4 benefit calculated under the Public Safety Offi-
5 cers’ Benefits Program under subpart 1 of part
6 L of title I of the Omnibus Crime Control and
7 Safe Streets Act of 1968 (42 U.S.C. 3796 et
8 seq.) in such fiscal year, without regard to any
9 reduction attributable to a limitation on appro-
10 priations, but subject to subparagraph (B).

11 “(B) REDUCTION FOR PAYMENTS FOR
12 LOST EMPLOYMENT INCOME.—The amount of
13 the benefit as determined under subparagraph
14 (A) shall be reduced by the total amount of any
15 benefits paid under section 265 with respect to
16 lost employment income.

17 “(3) LIMITATIONS.—

18 “(A) IN GENERAL.—No benefit is payable
19 under paragraph (1) with respect to the death
20 of an eligible individual if—

21 “(i) a disability benefit is paid with
22 respect to such individual under the Public
23 Safety Officers’ Benefits Program under
24 subpart 1 of part L of title I of the Omni-

1 bus Crime Control and Safe Streets Act of
2 1968 (42 U.S.C. 3796 et seq.); or

3 “(ii) a death benefit is paid or payable
4 with respect to such individual under the
5 Public Safety Officers’ Benefits Program
6 under subpart 1 of part L of title I of the
7 Omnibus Crime Control and Safe Streets
8 Act of 1968 (42 U.S.C. 3796 et seq.).

9 “(B) EXCEPTION IN THE CASE OF A LIM-
10 TATION ON APPROPRIATIONS FOR DISABILITY
11 BENEFITS UNDER PSOB.—In the event that dis-
12 ability benefits available to an eligible individual
13 under the Public Safety Officers’ Benefits Pro-
14 gram under subpart 1 of part L of title I of the
15 Omnibus Crime Control and Safe Streets Act of
16 1968 (42 U.S.C. 3796 et seq.) are reduced be-
17 cause of a limitation on appropriations, and
18 such reduction would affect the amount that
19 would be payable under subparagraph (A) with-
20 out regard to this subparagraph, benefits shall
21 be available under paragraph (1) to the extent
22 necessary to ensure that the survivor or sur-
23 vivors of such individual receives a total amount
24 equal to the amount described in paragraph (2).

25 “(b) ELECTION IN CASE OF DEPENDENTS.—

1 “(1) IN GENERAL.—In the case of an eligible
2 individual whose death is determined to have re-
3 sulted from a covered injury or injuries, if the indi-
4 vidual had one or more dependents under the age of
5 18, the legal guardian of the dependents may, in lieu
6 of the death benefit under subsection (a), elect to re-
7 ceive on behalf of the aggregate of such dependents
8 payments in accordance with this subsection. An
9 election under the preceding sentence is effective in
10 lieu of a request under subsection (a) by an indi-
11 vidual who is not the legal guardian of such depend-
12 ents.

13 “(2) AMOUNT OF PAYMENTS.—Payments under
14 paragraph (1) with respect to an eligible individual
15 described in such paragraph shall be made as if such
16 individual were an eligible individual to whom com-
17 pensation would be paid under subsection (a) of sec-
18 tion 265, with the rate augmented in accordance
19 with subsection (b)(2) of such section and with such
20 individual considered to be an eligible individual de-
21 scribed in subsection (c)(3)(B) of such section.

22 “(3) LIMITATIONS.—

23 “(A) AGE OF DEPENDENTS.—No pay-
24 ments may be made under paragraph (1) once

1 the youngest of the dependents involved reaches
2 the age of 18.

3 “(B) BENEFITS SECONDARY TO OTHER
4 COVERAGE.—

5 “(i) IN GENERAL.—Any payment
6 under paragraph (1) shall be secondary to
7 the obligation of the United States or any
8 third party (including any State or local
9 governmental entity, private insurance car-
10 rier, or employer), under any other law or
11 contractual agreement, to pay compensa-
12 tion for loss of employment income or to
13 provide disability benefits, retirement bene-
14 fits, life insurance benefits on behalf of de-
15 pendents under the age of 18, or death
16 benefits.

17 “(ii) RELATION TO OTHER OBLIGA-
18 TIONS.—Payments under paragraph (1)
19 shall not be made to with respect to an eli-
20 gible individual to the extent that the total
21 of amounts paid with respect to the indi-
22 vidual under such paragraph and under
23 the other obligations referred to in clause
24 (i) is an amount that exceeds the rate of
25 payment that applies under paragraph (2).

1 If under any such other obligation a lump-
2 sum payment is made, such payment shall,
3 for purposes of this subparagraph, be
4 deemed to be received over multiple years
5 rather than received in a single year. The
6 Secretary may, in the discretion of the Sec-
7 retary, determine how to apportion such
8 payment over multiple years.

9 “(c) BENEFIT IN ADDITION TO MEDICAL BENE-
10 FITS.—A benefit under subsection (a) or (b) shall be in
11 addition to any amounts received by an eligible individual
12 under section 264.

13 **“SEC. 267. ADMINISTRATION.**

14 “(a) ADMINISTRATION BY AGREEMENT WITH OTHER
15 AGENCY OR AGENCIES.—The Secretary may administer
16 any or all of the provisions of this part through Memo-
17 randum of Agreement with the head of any appropriate
18 Federal agency.

19 “(b) REGULATIONS.—The head of the agency admin-
20 istering this part or provisions thereof (including any
21 agency head administering such Act or provisions through
22 a Memorandum of Agreement under subsection (a)) may
23 promulgate such implementing regulations as may be
24 found necessary and appropriate. Initial implementing
25 regulations may be interim final regulations.

1 **“SEC. 268. AUTHORIZATION OF APPROPRIATIONS.**

2 “For the purpose of carrying out this part, there are
3 authorized to be appropriated such sums as may be nec-
4 essary for each of the fiscal years 2003 through 2007, to
5 remain available until expended, including administrative
6 costs and costs of provision and payment of benefits. The
7 Secretary’s payment of any benefit under section 264,
8 265, or 266 shall be subject to the availability of appro-
9 priations under this section.

10 **“SEC. 269. RELATIONSHIP TO OTHER LAWS.**

11 “Except as explicitly provided herein, nothing in this
12 part shall be construed to override or limit any rights an
13 individual may have to seek compensation, benefits, or re-
14 dress under any other provision of Federal or State law.”.

15 **SEC. 3. AMENDMENTS TO PROVISION REGARDING TORT LI-**
16 **ABILITY FOR ADMINISTRATION OF SMALL-**
17 **POX COUNTERMEASURES.**

18 (a) AMENDMENT TO ACCIDENTAL VACCINIA INOCU-
19 LATION PROVISION.—Section 224(p)(2)(C)(ii)(II) of such
20 Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is amended by strik-
21 ing “resides or has resided with” and inserting “has re-
22 sided with, or has had contact with,”.

23 (b) DEEMING ACTS AND OMISSIONS TO BE WITHIN
24 SCOPE OF EMPLOYMENT.—Section 224(p)(2) of such Act
25 (42 U.S.C. 233(p)(2)) is amended by adding at the end
26 the following new subparagraph:

1 “(D) ACTS AND OMISSIONS DEEMED TO BE
2 WITHIN SCOPE OF EMPLOYMENT.—

3 “(i) IN GENERAL.—In the case of a
4 claim arising out of alleged transmission of
5 vaccinia from an individual described in
6 clause (ii), acts or omissions by such indi-
7 vidual shall be deemed to have been taken
8 within the scope of such individual’s office
9 or employment for purposes of—

10 “(I) subsection (a); and

11 “(II) section 1346(b) and chap-
12 ter 171 of title 28, United States
13 Code.

14 “(ii) INDIVIDUALS TO WHOM DEEMING
15 APPLIES.—An individual is described by
16 this clause if—

17 “(I) vaccinia vaccine was admin-
18 istered to such individual as provided
19 by subparagraph (B); and

20 “(II) such individual was within
21 a category of individuals covered by a
22 declaration under subparagraph
23 (A)(i).”.

1 (c) EXHAUSTION; EXCLUSIVITY; OFFSET.—Section
2 224(p)(3) of such Act (42 U.S.C. 233(p)(3)) is amended
3 to read as follows:

4 “(3) EXHAUSTION; EXCLUSIVITY; OFFSET.—

5 “(A) EXHAUSTION.—

6 “(i) IN GENERAL.—A person may not
7 bring a claim under this subsection unless
8 such person has exhausted such remedies
9 as are available under part C of this title,
10 except that if the Secretary fails to make
11 a final determination on a request for ben-
12 efits or compensation filed in accordance
13 with the requirements of such part within
14 240 days after such request was filed, the
15 individual may seek any remedy that may
16 be available under this section.

17 “(ii) TOLLING OF STATUTE OF LIM-
18 TATIONS.—The time limit for filing a claim
19 under this subsection, or for filing an ac-
20 tion based on such claim, shall be tolled
21 during the pendency of a request for bene-
22 fits or compensation under part C of this
23 title.

24 “(iii) CONSTRUCTION.—This sub-
25 section shall not be construed as super-

1 seding or otherwise affecting the applica-
2 tion of a requirement, under chapter 171
3 of title 28, United States Code, to exhaust
4 administrative remedies.

5 “(B) EXCLUSIVITY.—The remedy provided
6 by subsection (a) shall be exclusive of any other
7 civil action or proceeding for any claim or suit
8 this subsection encompasses, except for a pro-
9 ceeding under part C of this title.

10 “(C) OFFSET.—The value of all compensa-
11 tion and benefits provided under part C of this
12 title for an incident or series of incidents shall
13 be offset against the amount of an award, com-
14 promise, or settlement of money damages in a
15 claim or suit under this subsection based on the
16 same incident or series of incidents.”.

17 (d) REQUIREMENT TO COOPERATE WITH UNITED
18 STATES.—Section 224(p)(5) of such Act (42 U.S.C.
19 233(p)(5)) is amended in the caption by striking “DE-
20 FENDANT” and inserting “COVERED PERSON”.

21 (e) AMENDMENT TO DEFINITION OF COVERED
22 COUNTERMEASURE.—Section 224(p)(7)(A)(i)(II) of such
23 Act (42 U.S.C. 233(p)(7)(A)(i)(II)) is amended to read
24 as follows:

1 “(II) used to control or treat the
2 adverse effects of vaccinia inoculation
3 or of administration of another cov-
4 ered countermeasure; and”.

5 (f) AMENDMENT TO DEFINITION OF COVERED PER-
6 SON.—Section 224(p)(7)(B) of such Act (42 U.S.C.
7 233(p)(7)(B)) is amended—

8 (1) by striking “includes any person” and in-
9 serting “means a person”;

10 (2) in clause (ii)—

11 (A) by striking “auspices” and inserting
12 “auspices—”;

13 (B) by redesignating “such counter-
14 measure” and all that follows as clause (I) and
15 indenting accordingly; and

16 (C) by adding at the end the following:

17 “(II) a determination was made
18 as to whether, or under what cir-
19 cumstances, an individual should re-
20 ceive a covered countermeasure;

21 “(III) the immediate site of ad-
22 ministration on the body of a covered
23 countermeasure was monitored, man-
24 aged, or cared for; or

1 “(IV) an evaluation was made of
2 whether the administration of a coun-
3 termeasure was effective;”;

4 (3) in clause (iii) by striking “or”;

5 (4) by striking clause (iv) and inserting the fol-
6 lowing:

7 “(iv) a State, a political subdivision of
8 a State, or an agency or official of a State
9 or of such a political subdivision, if such
10 State, subdivision, agency, or official has
11 established requirements, provided policy
12 guidance, supplied technical or scientific
13 advice or assistance, or otherwise super-
14 vised or administered a program with re-
15 spect to administration of such counter-
16 measures;

17 “(v) in the case of a claim arising out
18 of alleged transmission of vaccinia from an
19 individual—

20 “(I) the individual who allegedly
21 transmitted the vaccinia, if vaccinia
22 vaccine was administered to such indi-
23 vidual as provided by paragraph
24 (2)(B) and such individual was within
25 a category of individuals covered by a

1 declaration under paragraph (2)(A)(i);

2 or

3 “(II) an entity that employs an
4 individual described by clause (I) or
5 where such individual has privileges or
6 is otherwise authorized to provide
7 health care;

8 “(vi) an official, agent, or employee of
9 a person described in clause (i), (ii), (iii),
10 or (iv);

11 “(vii) a contractor of, or a volunteer
12 working for, a person described in clause
13 (i), (ii), or (iv), if the contractor or volun-
14 teer performs a function for which a per-
15 son described in clause (i), (ii), or (iv) is
16 a covered person; or

17 “(viii) an individual who has privileges
18 or is otherwise authorized to provide health
19 care under the auspices of an entity de-
20 scribed in clause (ii) or (v)(II).”.

21 (g) AMENDMENT TO DEFINITION OF QUALIFIED
22 PERSON.—Section 224(p)(7)(C) of such Act (42 U.S.C.
23 233(p)(7)(C)) is amended—

24 (1) by designating “is authorized to” and all
25 that follows as clause (i) and indenting accordingly;

1 (2) by striking “individual who” and inserting
2 “individual who—”; and

3 (3) by striking the period and inserting “; or
4 “(ii) is otherwise authorized by the
5 Secretary to administer such counter-
6 measure.”.

7 (h) DEFINITION OF “ARISING OUT OF ADMINISTRA-
8 TION OF A COVERED COUNTERMEASURE”.—Section
9 224(p)(7) of such Act (42 U.S.C. 233(p)(7)) is amended
10 by adding at the end the following new subparagraph:

11 “(D) ARISING OUT OF ADMINISTRATION
12 OF A COVERED COUNTERMEASURE.—The term
13 ‘arising out of administration of a covered
14 countermeasure’, when used with respect to a
15 claim or liability, includes a claim or liability
16 arising out of—

17 “(i) determining whether, or under
18 what conditions, an individual should re-
19 ceive a covered countermeasure;

20 “(ii) obtaining informed consent of an
21 individual to the administration of a cov-
22 ered countermeasure;

23 “(iii) monitoring, management, or
24 care of an immediate site of administration
25 on the body of a covered countermeasure,

1 or evaluation of whether the administration
2 of the countermeasure has been effective;
3 or

4 “(iv) transmission of vaccinia virus by
5 an individual to whom vaccinia vaccine was
6 administered as provided by paragraph
7 (2)(B).”.

8 (i) TECHNICAL CORRECTION.—Section
9 224(p)(2)(A)(ii) of such Act (42 U.S.C. 233(p)(2)(A)(ii))
10 is amended by striking “paragraph (8)(A)” and inserting
11 “paragraph (7)(A)”.

12 (j) EFFECTIVE DATE.—This section shall take effect
13 as of November 25, 2002.

Passed the House of Representatives April 11, 2003.

Attest:

JEFF TRANDAHL,

Clerk.