

108TH CONGRESS
1ST SESSION

H. R. 1413

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 2003

Mr. BURR (for himself, Mr. TAUZIN, Mr. BILIRAKIS, Mr. UPTON, Mr. NORWOOD, Mr. WHITFIELD, and Mr. PICKERING) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

- 1 *Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*
- 2 **SECTION 1. SHORT TITLE.**
- 3 This Act may be cited as the “Smallpox Emergency
- 4 Personnel Protection Act of 2003”.

1 SEC. 2. SMALLPOX EMERGENCY PERSONNEL PROTECTION.

2 Title II of the Public Health Service Act (42 U.S.C.
3 202 et seq.) is amended by adding at the end the following
4 part:

5 "PART C—SMALLPOX EMERGENCY PERSONNEL

6 PROTECTION

7 "SEC. 261. DEFINITIONS.

8 “For purposes of this part:

9 “(1) VACCINE.—The term ‘vaccine’ or ‘smallpox
10 vaccine’ means vaccinia (smallpox) vaccines, includ-
11 ing the Dryvax vaccine.

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

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

19 “(B) who is or will be functioning in a role
20 identified in a State, local, or Department of
21 Health and Human Services smallpox emer-
22 gency response plan approved by the Secretary;
23 and

1 “(i) during the effective period of the
2 Declaration (including the portion of such
3 period before the enactment of this part);

4 and

5 “(ii) not later than the latest of—

6 “(I) 180 days after the effective
7 date of the initial interim final regula-
8 tions implementing this part;

9 “(II) 120 days after becoming an
10 individual in an occupation described
11 in subparagraph (A); or

12 “(III) 120 days after becoming
13 an individual identified as a member
14 of a smallpox emergency response
15 plan described in subparagraph (B).

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

23 “(A) administration to the individual of a
24 vaccine during the effective period of the Dec-
25 laration; 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 resided with,
10 or has been in contact with, an individual
11 who is (or who was accidentally inoculated
12 by) a covered individual.

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

16 “(a) IN GENERAL.—The Secretary shall establish
17 procedures for determining, as applicable with respect to
18 an individual—

19 “(1) whether the individual is an eligible indi-
20 vidual;

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

1 “(3) whether the covered injury or injuries of
2 an eligible individual constitute a compensable dis-
3 ability, or caused the individual’s death, for purposes
4 of benefits under section 266.

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

10 “(c) CRITERIA FOR REIMBURSEMENT.—

11 “(1) INJURIES SPECIFIED IN INJURY TABLE.—
12 In any case where an injury or other adverse effect
13 specified in the injury table established under section
14 263 as a known effect of a vaccine manifests in an
15 individual within the time period specified in such
16 table, such injury or other effect shall be presumed
17 to have resulted from administration of such vaccine.

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

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

4 “(1) in the case of a request based on the ad-
5 ministration of the vaccine to the individual, the in-
6 dividual provides notice to the Secretary of an ad-
7 verse effect of the vaccination not later than one
8 year after the date of administration of the vaccine;
9 or

10 “(2) in the case of a request based on acci-
11 dental vaccinia inoculation, the individual provides
12 notice to the Secretary of an adverse effect of such
13 vaccination not later than two years after the date
14 of the first symptom or manifestation of onset of the
15 adverse effect.

16 “(e) REVIEW OF DETERMINATION.—

17 “(1) SECRETARY’S REVIEW AUTHORITY.—The
18 Secretary may review a determination under this
19 section at any time on the Secretary’s own motion
20 or on application, and may affirm, vacate, or modify
21 such determination in any manner the Secretary
22 deems appropriate.

23 “(2) JUDICIAL AND ADMINISTRATIVE RE-
24 VIEW.—No court of the United States, or of any
25 State, District, territory or possession thereof, shall

1 have subject matter jurisdiction to review, whether
2 by mandamus or otherwise, any action by the Sec-
3 retary under this section. No officer or employee of
4 the United States shall review any action by the Sec-
5 retary under this section (unless the President spe-
6 cifically directs otherwise).

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

8 “(a) SMALLPOX VACCINE INJURY TABLE.—

9 “(1) ESTABLISHMENT REQUIRED.—The Sec-
10 retary shall establish by interim final regulation a
11 table identifying adverse effects (including injuries,
12 disabilities, illnesses, conditions, and deaths) that
13 shall be presumed to result from the administration
14 of (or exposure to) a smallpox vaccine, and the time
15 period in which the first symptom or manifestation
16 of onset of each such adverse effect must manifest
17 in order for such presumption to apply.

18 “(2) AMENDMENTS.—The Secretary may
19 amend by regulation the table established under
20 paragraph (1). Amendments shall apply retroactively
21 to claims pending at the time of promulgation of
22 final amending regulations and to claims filed subse-
23 quently. If the effect of such amendment is to per-
24 mit an individual who was not, before such amend-
25 ment, eligible for compensation under this part, such

1 individual may file a request for compensation or file
2 an amended request for such compensation not later
3 than one year after the effective date of such amend-
4 ment in the case of an individual to whom the vac-
5 cine was administered and two years in the case of
6 a request for compensation based on accidental
7 vaccinia inoculation.

8 **“SEC. 264. MEDICAL BENEFITS.**

9 “(a) IN GENERAL.—Subject to the succeeding provi-
10 sions of this section, the Secretary shall make payment
11 or reimbursement for medical items and services as rea-
12 sonable and necessary to treat a covered injury of an eligi-
13 ble individual. The Secretary may consider the Federal
14 Employees Compensation Act (5 U.S.C. 8103) and its im-
15 plementing regulations in determining the amount of such
16 payment and the circumstances under which such pay-
17 ments are reasonable and appropriate.

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

1 establish mechanisms and procedures for providing the sec-
2 ondary benefits under this section.

3 **“SEC. 265. COMPENSATION FOR LOST EMPLOYMENT IN-**
4 **COME.**

5 “(a) IN GENERAL.—Subject to the succeeding provi-
6 sions of this section, the Secretary shall provide compensa-
7 tion to an eligible individual for loss of employment income
8 incurred as a result of a covered injury, at the rate speci-
9 fied in subsection (b).

10 “(b) AMOUNT OF COMPENSATION.—

11 “(1) IN GENERAL.—Compensation under this
12 section shall be at the rate of 66 2/3 percent of
13 monthly employment income. The Secretary may
14 consider the Federal Employees Compensation Act
15 (5 U.S.C. 8114 and 8115) and its implementing reg-
16 ulations in determining the amount of such payment
17 and the circumstances under which such payments
18 are reasonable and appropriate.

19 “(2) TREATMENT OF SELF-EMPLOYMENT IN-
20 COME.—For purposes of this section, the term ‘em-
21 ployment income’ includes income from self-employ-
22 ment.

23 “(c) LIMITATIONS.—

24 “(1) BENEFITS SECONDARY TO OTHER COV-
25 ERAGE.—Any compensation under subsection (a)

1 shall be secondary to the obligation of the United
2 States or any third party (including any State or
3 local governmental entity, private insurance carrier,
4 or employer), under any other law or contractual
5 agreement, to pay compensation for loss of employ-
6 ment income and shall not be made to the extent
7 that compensation for loss of employment income
8 has been made under such other obligations in an
9 amount that equals or exceeds the rate specified in
10 subsection (b)(1).

11 “(2) NO BENEFITS FOR DEATH OR PERMANENT
12 AND TOTAL DISABILITY.—No payment shall be made
13 under this section in compensation for loss of em-
14 ployment income subsequent to the receipt by an eli-
15 gible individual (or his survivor or survivors) of ben-
16 efits under section 266 for death or permanent and
17 total disability.

18 “(3) LIMIT ON TOTAL BENEFITS.—Total bene-
19 fits paid to an individual under this section shall not
20 exceed \$50,000.

21 “(4) WAITING PERIOD.—An eligible individual
22 shall not be provided compensation under this sec-
23 tion for the first 5 work days of disability.

1 **“SEC. 266. PAYMENT FOR DEATH AND PERMANENT, TOTAL**2 **DISABILITY.**

3 “(a) BENEFIT FOR PERMANENT AND TOTAL DIS-
4 ABILITY.—The Secretary shall pay to an eligible individual
5 who is determined to have a covered injury or injuries
6 meeting the definition of disability in section 216(i) of the
7 Social Security Act (42 U.S.C. 416(i)) an amount deter-
8 mined under subsection (c), in the same manner as dis-
9 ability benefits are paid pursuant to the PSOB program
10 in section 1201(b) of the OCCSSA with respect to an eligi-
11 ble public safety officer (except that payment shall be
12 made to the parent or legal guardian, in the case of an
13 eligible individual who is a minor or is subject to legal
14 guardianship).

15 “(b) DEATH BENEFIT.—The Secretary shall pay, in
16 the case of an eligible individual whose death is deter-
17 mined to have resulted from a covered injury or injuries,
18 a death benefit in the amount determined under sub-
19 section (c) to the survivor or survivors in the same manner
20 as death benefits are paid pursuant to PSOB program in
21 section 1201 of the OCCSSA with respect to an eligible
22 deceased (except that in the case of an eligible individual
23 who is a minor with no living parent, the legal guardian
24 shall be considered the survivor in the place of the parent).

25 “(c) BENEFIT AMOUNT.—

1 “(1) IN GENERAL.—The amount of the dis-
2 ability or death benefit under subsection (a) or (b)
3 in a fiscal year shall equal the amount of the com-
4 parable benefit calculated under the PSOB in such
5 fiscal year, without regard to any reduction attrib-
6 utable to a limitation on appropriations, but subject
7 to paragraph (2).

8 “(2) REDUCTION FOR PAYMENTS FOR LOST EM-
9 PLOYMENT INCOME.—The amount of the benefit as
10 determined under paragraph (1) shall be reduced by
11 the total amount of any benefits paid under section
12 265 with respect to lost employment income.

13 “(d) BENEFIT IN ADDITION TO MEDICAL BENE-
14 FITS.—A benefit under this section shall be in addition
15 to any amounts received by an eligible individual under
16 section 264.

17 “(e) LIMITATIONS.—

18 “(1) DISABILITY BENEFITS.—Except as pro-
19 vided in paragraph (3), no benefit is payable under
20 subsection (a) with respect to the disability of an eli-
21 gible individual if—

22 “(A) a disability benefit is paid or payable
23 with respect to such individual under the
24 PSOB; or

1 “(B) a death benefit is paid or payable
2 with respect to such individual under subsection
3 (b) or the PSOB.

4 “(2) DEATH BENEFITS.—No benefit is payable
5 under subsection (b) with respect to the death of an
6 eligible individual if—

7 “(A) a disability benefit is paid with re-
8 spect to such individual under subsection (a) or
9 the PSOB; or

10 “(B) a death benefit is paid or payable
11 with respect to such individual under the
12 PSOB.

13 “(3) EXCEPTION IN THE CASE OF A LIMITA-
14 TION ON APPROPRIATIONS FOR DISABILITY BENE-
15 FITS UNDER PSOB.—In the event that disability ben-
16 efits available to an eligible individual under the
17 PSOB program are reduced because of a limitation
18 on appropriations, and such reduction would affect
19 the amount that would be payable under paragraph
20 (1) or (2) without regard to this paragraph, benefits
21 shall be available under subsection (a) or (b) to the
22 extent necessary to ensure that such individual (or
23 his survivor or survivors) receives a total amount
24 equal to the amount described in subsection (c).

25 “(f) REFERENCES.—References in this section—

1 “(1) to the Public Safety Officers’ Benefits
2 Program or PSOB are references to the program
3 under part L, subpart 1 of title I of the OCCSSA;
4 and

5 “(2) to the OCCSSA are to the Omnibus Crime
6 Control and Safe Streets Act of 1968 (42 U.S.C.
7 3796 et seq.).

8 "SEC. 267. ADMINISTRATION.

9 "(a) ADMINISTRATION BY AGREEMENT WITH OTHER
10 AGENCY OR AGENCIES.—The Secretary may administer
11 any or all of the provisions of this part through Memo-
12 randum of Agreement with the head of any appropriate
13 Federal agency.

14 "(b) REGULATIONS.—The head of the agency admin-
15 istering this part or provisions thereof (including any
16 agency head administering such Act or provisions through
17 a Memorandum of Agreement under subsection (a)) may
18 promulgate such implementing regulations as may be
19 found necessary and appropriate. Initial implementing
20 regulations may be interim final regulations.

21 "SEC. 268. PARTICIPANT EDUCATION REGARDING SMALL-
22 POX EMERGENCY RESPONSE PLANS.

23 In reviewing State, local, or Department of Health
24 and Human Services smallpox emergency response plans
25 described in section 261, the Secretary shall ensure that

1 such plans are consistent with guidelines of the Centers
2 for Disease Control and Prevention with respect to the
3 education of individual participants (including information
4 as to the voluntary nature of the program and the avail-
5 ability of potential benefits under this part), and the ade-
6 quate screening of individuals for vaccine contraindica-
7 tions.

8 **“SEC. 269. AUTHORIZATION OF APPROPRIATIONS.**

9 “For the purpose of carrying out this part, there are
10 authorized to be appropriated such sums as may be nec-
11 essary for each of the fiscal years 2003 through 2007, to
12 remain available until expended, including administrative
13 costs and costs of provision and payment of benefits.

14 **“SEC. 270. RELATIONSHIP TO OTHER LAWS.**

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

19 **SEC. 3. AMENDMENTS TO PROVISION REGARDING TORT LI-**
20 **ABILITY FOR ADMINISTRATION OF SMALL-**
21 **POX COUNTERMEASURES.**

22 (a) AMENDMENT TO ACCIDENTAL VACCINIA INOCU-
23 LATION PROVISION.—Section 224(p)(2)(C)(ii)(II) of such
24 Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is amended by strik-

1 ing “resides or has resided with” and inserting “has re-
2 sided with, or has had contact with.”.

3 (b) DEEMING ACTS AND OMISSIONS TO BE WITHIN
4 SCOPE OF EMPLOYMENT.—Section 224(p)(2) of such Act
5 (42 U.S.C. 233(p)(2)) is amended by adding at the end
6 the following new subparagraph:

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

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

16 “(I) subsection (a); and
17 “(II) section 1346(b) and chap-
18 ter 171 of title 28, United States
19 Code.

20 “(ii) INDIVIDUALS TO WHOM DEEMING
21 APPLIES.—An individual is described by
22 this clause if—

23 “(I) vaccinia vaccine was admin-
24 istered to such individual as provided
25 by subparagraph (B); and

1 “(II) such individual was within
2 a category of individuals covered by a
3 declaration under subparagraph
4 (A)(i).”.

5 (c) EXHAUSTION; EXCLUSIVITY; OFFSET.—Section
6 224(p)(3) of such Act (42 U.S.C. 233(p)(3)) is amended
7 to read as follows:

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

9 “(A) EXHAUSTION.—

10 “(i) IN GENERAL.—A person may not
11 bring a claim under this subsection unless
12 such person has received a determination
13 about remedies available under section
14 262.

15 “(ii) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a claim
16 under this subsection, or for filing an action based on such claim, shall be tolled
17 during the pendency of a determination by
18 the Secretary under section 262.

21 “(iii) CONSTRUCTION.—This subsection shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171

1 of title 28, United States Code, to exhaust
2 administrative remedies.

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

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

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

23 “(II) used to control or treat the
24 adverse effects of vaccinia inoculation

1 or of administration of another cov-
2 ered countermeasure; and”.

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

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

8 (2) in clause (ii)—

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

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

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

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

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

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

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

22 (1) by designating “is authorized to” and all
23 that follows as clause (i) and indenting accordingly;
24 (2) by striking “individual who” and inserting
25 “individual who—”; and

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

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

1 of the countermeasure has been effective;

2 or

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

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

○