

108TH CONGRESS
1ST SESSION

S. 719

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2003

Mr. GREGG introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures.

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

3 **SECTION 1. SHORT TITLE.**

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

1 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

3 Part A of title II of the Public Health Service Act
4 (42 U.S.C. 202 et seq.) is amended by inserting after sec-
5 tion 224 the following:

6 **“SEC. 224A. PROTECTION FOR SMALLPOX EMERGENCY**
7 **PERSONNEL.**

8 “(a) DEFINITIONS.—In this section:

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

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

15 “(A) who is—

16 “(i) a health care worker, law enforce-
17 ment officer, firefighter, security personnel,
18 emergency medical personnel, other public
19 safety personnel, or support personnel for
20 such occupational specialties who is identi-
21 fied in a State or local, or Department of
22 Health and Human Services smallpox
23 emergency response plan that is approved
24 by the Secretary; or

25 “(ii) an individual with respect to
26 whom the Secretary determines and de-

1 clares that it is advisable to administer the
2 vaccine (not including any individual to
3 whom the Secretary determines only that
4 such vaccine should be made available);
5 and

6 “(B) to whom a smallpox vaccine is admin-
7 istered during the period in which the Declara-
8 tion is effective (including the portion of such
9 period before the date of enactment of this sec-
10 tion) and—

11 “(i) with respect to an individual de-
12 scribed in subparagraph (A)(i), ending on
13 the later of—

14 “(I) the expiration of the 180-
15 day period that begins on the effective
16 date of the initial interim final regula-
17 tions to implement this section; or

18 “(II) the expiration of the 180-
19 day period that begins on the date on
20 which an individual becomes identified
21 in the plan specified under subpara-
22 graph (A)(i); and

23 “(ii) with respect to an individual de-
24 scribed by subparagraph (A)(ii), ending on
25 the earlier of—

1 “(I) the date on which the Sec-
2 retary publicly announces that an ac-
3 tive case of smallpox has been identi-
4 fied either within or outside the
5 United States; or

6 “(II) the termination of the Dec-
7 laration.

8 “(3) COVERED INJURY.—The term ‘covered in-
9 jury’ includes—

10 “(A) an injury, disability, illness, condition,
11 or death determined, pursuant to the proce-
12 dures established under subsection (c), to have
13 been sustained as the direct result of adminis-
14 tration to an individual of a covered counter-
15 measure during the effective period of the Dec-
16 laration (other than a minor injury such as
17 minor scarring or minor local reaction); and

18 “(B) an injury, disability, illness, condi-
19 tion, or death determined, pursuant to the pro-
20 cedures established under subsection (c), to
21 have been sustained as the direct result of acci-
22 dental vaccinia inoculation through contact with
23 and individual who is (or who was accidentally
24 inoculated by) an individual in a category speci-
25 fied in article IV of the Declaration to whom

1 vaccinia vaccine has been administered during
2 the effective period of the Declaration (other
3 than a minor injury such as minor scarring or
4 minor local reaction).

5 “(4) DECLARATION.—The term ‘Declaration’
6 means the Declaration Regarding Administration of
7 Smallpox Countermeasures issued by the Secretary
8 of Health and Human Services on January 24,
9 2003, and published in the Federal Register on Jan-
10 uary 28, 2003, including any subsequent amend-
11 ment.

12 “(5) ELIGIBLE INDIVIDUAL.—The term ‘eligible
13 individual’ means an individual who is (as deter-
14 mined in accordance with section 3)—

15 “(A) a covered individual who sustains a
16 covered injury as the direct result of adminis-
17 tration of a covered countermeasure; or

18 “(B) any individual who contracts vaccinia
19 during the effective period of the Declaration or
20 within 30 days after the end of such period—

21 “(i) to whom vaccinia vaccine was not
22 administered; and

23 “(ii) who sustains a covered injury as
24 the direct result of contracting vaccinia.

1 “(6) SECRETARY.—Except as provided other-
2 wise, the term ‘Secretary’ means the Secretary of
3 Health and Human Services.

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

11 “(b) VOLUNTARY PROGRAM.—The Secretary shall—

12 “(1) ensure that a State, local, or Department
13 of Health and Human Services plan to vaccinate in-
14 dividuals that is approved by the Secretary estab-
15 lishes administrative procedures to ensure the edu-
16 cation and screening of potential participants, and
17 that the decision by a covered individual to partici-
18 pate is voluntary, consistent with the Declaration
19 and guidelines of the Centers for Disease Control
20 and Prevention; and

21 “(2) ensure that any State, local, or Depart-
22 ment of Health and Human Services plan to vac-
23 cinate individuals that is approved by the Secretary
24 is consistent with the Declaration.

25 “(c) DETERMINATION OF ELIGIBILITY.—

1 “(1) IN GENERAL.—The Secretary, in consulta-
2 tion with the Attorney General and the Secretary of
3 Labor, shall establish administrative procedures for
4 determining, as applicable with respect to an indi-
5 vidual—

6 “(A) whether the individual is an eligible
7 individual;

8 “(B) whether the individual has sustained
9 a covered injury or injuries for which medical
10 benefits and employment income-loss compensa-
11 tion may be available under subsections (e) and
12 (f), and the amount of such benefits or com-
13 pensation; and

14 “(C) whether the covered injury or injuries
15 of the individual constitute a compensable dis-
16 ability, or caused the individual’s death, for
17 purposes of benefits under subsection (g).

18 “(2) COVERED INDIVIDUALS.—The Secretary
19 may accept a certification, by a Federal, State, or
20 local government entity or private health care entity
21 participating in the administration of covered coun-
22 termeasures under the Declaration, that an indi-
23 vidual is an individual in a category specified in arti-
24 cle IV of the Declaration to whom such a counter-
25 measure has been administered by the applicable

1 deadline specified in subsection (a)(2)(B), as estab-
2 lishing that the individual is a covered individual.

3 “(3) DETERMINATION OF CAUSATION.—

4 “(A) INJURIES SPECIFIED IN INJURY
5 TABLE.—In any case where an injury or other
6 adverse effect specified in the injury table es-
7 tablished under subsection (d) as a known ef-
8 fect of a covered countermeasure manifests in
9 an individual within the time period specified in
10 such table, such injury or other effect shall be
11 rebuttably presumed to have resulted from ad-
12 ministration of such covered countermeasure.

13 “(B) OTHER DETERMINATIONS.—In mak-
14 ing determinations other than those described
15 in subparagraph (A) as to the causation or se-
16 verity of an injury, the Secretary shall take into
17 consideration all relevant medical and scientific
18 evidence presented for consideration, and may
19 obtain and consider the views of qualified med-
20 ical experts.

21 “(4) DEADLINE FOR FILING CLAIM.—The Sec-
22 retary shall not consider any claim for a benefit
23 under this subsection with respect to an individual
24 unless an initial claim is filed under this section, al-

1 leging a covered injury to such individual, not later
2 than—

3 “(A) the date a covered countermeasure
4 was administered to the individual; or

5 “(B) in the case of a claim based on con-
6 tact vaccination (as described in subsection
7 (a)(5)(B)), the date of the first symptom or
8 manifestation of onset of an adverse effect of
9 such vaccination.

10 “(5) REVIEW OF DETERMINATION.—

11 “(A) SECRETARY’S REVIEW AUTHORITY.—

12 The Secretary may review a determination
13 under this subsection at any time on the Sec-
14 retary’s own motion or on application, and may
15 affirm, vacate, or modify such determination.
16 The Secretary shall develop a process by which
17 a claimant may file a request for reconsider-
18 ation of any determination made by the Sec-
19 retary under this subsection.

20 “(B) JUDICIAL AND ADMINISTRATIVE RE-
21 VIEW.—No court of the United States, or of
22 any State, District, territory or possession
23 thereof, shall have subject matter jurisdiction to
24 review, whether by mandamus or otherwise, any
25 decision, determination, action, or regulation by

1 the Secretary under this subsection. No officer
2 or employee of the United States shall review
3 any action by the Secretary under this sub-
4 section (unless the President specifically directs
5 otherwise).

6 “(d) COUNTERMEASURE INJURY TABLE.—

7 “(1) SMALLPOX COUNTERMEASURE INJURY
8 TABLE.—The Secretary, taking into consideration all
9 relevant medical and scientific evidence, shall estab-
10 lish by interim final regulation a table identifying—

11 “(A) adverse effects (including injuries,
12 disabilities, illnesses, conditions, and deaths)
13 that shall be presumed to result from the ad-
14 ministration of (or exposure to) a covered coun-
15 termeasure; and

16 “(B) the time periods in which the first
17 symptom, or manifestation of onset of each
18 such adverse effect, must manifest in order for
19 such presumption to apply.

20 “(2) AMENDMENTS.—The Secretary may
21 amend by regulation the table established under
22 paragraph (1). Such amendments shall apply retro-
23 actively to claims filed or pending at the time of the
24 promulgation of final amending regulations and to
25 claims filed after such promulgation.

1 “(3) EFFECT OF REVISED TABLE.—If at any
2 time the Smallpox Countermeasure Injury Table es-
3 tablished under paragraph (1) is revised and the ef-
4 fect of such revision is to permit an individual who
5 was not, before such revision, eligible to seek pay-
6 ment or compensation under this section, such per-
7 son may file a claim not later than 2 years after the
8 effective date of the revision, except that no payment
9 or compensation may be provided under this section
10 with respect to a smallpox countermeasure-related
11 injury or death covered under the revision of the
12 table if such injury or death occurred more than 2
13 years before the date of the revision of the table.

14 “(4) PROHIBITION.—The Secretary may not
15 provide any compensation under the program under
16 this section for any minor scarring or minor local re-
17 action or for an eligible individual who is not a cov-
18 ered individual if the eligible individual does not sus-
19 tain a physical injury.

20 “(e) MEDICAL BENEFITS.—

21 “(1) IN GENERAL.—Subject to paragraph (2),
22 an eligible individual shall be entitled to payment by
23 the Secretary for medical items and services as rea-
24 sonable and necessary to treat a covered injury. The
25 Secretary may consider the provisions of chapter 81

1 of title 5, United States Code, (and the imple-
2 menting regulations with respect to such chapter)
3 and section 2115 of this Act in determining the
4 amount of such payment and the circumstances
5 under which such payments are reasonable and nec-
6 essary.

7 “(2) LIMITATIONS.—

8 “(A) BENEFITS SECONDARY TO OTHER
9 COVERAGE.—The obligation of the Secretary to
10 pay for any services or benefits under para-
11 graph (1) shall be secondary to the obligation
12 of the United States or any third party (includ-
13 ing any State or local governmental entity, pri-
14 vate insurance carrier, or employer) under any
15 other provision of law or contractual agreement,
16 to pay for or provide such services or benefits.

17 “(B) NO BENEFITS FOR MEDICARE-ELIGI-
18 BLE INDIVIDUAL.—No benefits shall be avail-
19 able to an individual under this subsection with
20 respect to any period in which the individual is
21 eligible for benefits under title XVIII of the So-
22 cial Security Act (42 U.S.C. 1395 et seq.).

23 “(f) COMPENSATION FOR LOST EMPLOYMENT IN-
24 COME.—

1 “(1) IN GENERAL.—Subject to paragraphs (2)
2 and (3), an eligible individual shall be entitled to
3 payment of compensation by the Secretary for loss
4 of employment income incurred as a result of a cov-
5 ered injury, at the rate specified in paragraph (2).

6 “(2) AMOUNT OF COMPENSATION.—

7 “(A) IN GENERAL.—Compensation under
8 this subsection shall be at the rate of $66\frac{2}{3}$ per-
9 cent of the relevant pay-period (e.g., weekly,
10 monthly) pay, except as provided in paragraph
11 (B).

12 “(B) AUGMENTED COMPENSATION FOR
13 DEPENDENTS.—An eligible individual with one
14 or more dependents is entitled to have the basic
15 compensation for loss of employment income as
16 described in paragraph (A) augmented at the
17 rate of $8\frac{1}{3}$ percent.

18 “(C) CONSIDERATION OF OTHER PRO-
19 GRAMS.—The Secretary may consider the provi-
20 sions of sections 8114 and 8115 of title 5,
21 United States Code (and any implementing reg-
22 ulations), in determining the amount of pay-
23 ment under this paragraph and the cir-
24 cumstances under which such payments are
25 reasonable and necessary.

1 “(D) TREATMENT OF SELF-EMPLOYMENT
2 INCOME.—For purposes of this subsection—

3 “(i) the term ‘employment income’ in-
4 cludes income from self-employment; and

5 “(ii) for purposes of computation of
6 pay and determination of wage-earning ca-
7 pacity under subparagraph (A), self-em-
8 ployment income shall be treated as wages.

9 “(3) LIMITATIONS.—

10 “(A) BENEFITS SECONDARY TO OTHER
11 COVERAGE.—The obligation of the Secretary to
12 pay compensation under paragraph (1) shall be
13 secondary to the obligation of the United States
14 or any third party (including any State or local
15 governmental entity, private insurance carrier,
16 or employer), under any other law or contrac-
17 tual agreement, to pay compensation for loss of
18 employment income.

19 “(B) NO BENEFITS FOR DEATH OR PER-
20 MANENT AND TOTAL DISABILITY.—No payment
21 shall be made under this subsection in com-
22 pensation for loss of employment income due to
23 the death or permanent and total disability of
24 an eligible individual.

1 “(C) LIMIT ON TOTAL BENEFITS.—Total
2 benefits paid to an individual under this sub-
3 section shall not exceed \$50,000.

4 “(D) WAITING PERIOD.—An eligible indi-
5 vidual is not entitled to compensation under
6 this subsection for the first 5 work days of dis-
7 ability.

8 “(g) PAYMENT FOR DEATH AND PERMANENT,
9 TOTAL DISABILITY.—

10 “(1) BENEFIT FOR PERMANENT AND TOTAL
11 DISABILITY.—Subject to the succeeding provisions of
12 this subsection, an eligible individual who is deter-
13 mined, in accordance with the procedures established
14 under subsection (c), to have a covered injury or in-
15 juries meeting the definition of disability in section
16 216(i) of the Social Security Act (42 U.S.C. 416(i))
17 shall be entitled to have payment made by the Sec-
18 retary of an amount determined under paragraph
19 (3), in the same manner as disability benefits are
20 paid pursuant to the Public Safety Officers’ Benefits
21 Program under subpart 1 of part L of title I of the
22 Omnibus Crime Control and Safe Streets Act of
23 1968 (42 U.S.C. 3796 et seq.) with respect to an eli-
24 gible public safety officer (except that payment shall
25 be made to the parent or legal guardian, in the case

1 of an eligible individual who is a minor or is subject
2 to legal guardianship).

3 “(2) DEATH BENEFIT.—Subject to the suc-
4 ceeding provisions of this subsection, in the case of
5 an eligible individual whose death is determined, in
6 accordance with the procedures established under
7 subsection (c), to have directly resulted from a cov-
8 ered injury or injuries a death benefit in the amount
9 determined under paragraph (3) shall be payable by
10 the Secretary to the survivor or survivors in the
11 same manner as death benefits are paid pursuant to
12 the Public Safety Officers’ Benefits Program under
13 subpart 1 of part L of title I of the Omnibus Crime
14 Control and Safe Streets Act of 1968 (42 U.S.C.
15 3796 et seq.) with respect to an eligible deceased
16 public safety officer (except that payment shall be
17 made to the parent or legal guardian, in the case of
18 an eligible individual who is a minor or is subject to
19 legal guardianship).

20 “(3) BENEFIT AMOUNT.—The amount of the
21 disability or death benefit under paragraph (1) or
22 (2) in a fiscal year shall, subject to paragraph
23 (5)(B), equal the amount of the comparable benefit
24 calculated under the Public Safety Officers’ Benefits
25 Program under subpart 1 of part L of title I of the

1 Omnibus Crime Control and Safe Streets Act of
2 1968 (42 U.S.C. 3796 et seq.) in such fiscal year,
3 without regard to any reduction attributable to a
4 limitation on appropriations.

5 “(4) REDUCTION FOR PAYMENTS FOR LOST EM-
6 PLOYMENT INCOME.—The amount of the benefit as
7 determined under paragraph (3) shall be reduced by
8 the total amount of any benefits paid under sub-
9 section (f) with respect to lost employment income.

10 “(5) LIMITATIONS.—

11 “(A) DISABILITY BENEFITS.—Except as
12 provided in subparagraph (C), no benefit is
13 payable under paragraph (1) with respect to the
14 disability of an eligible individual if—

15 “(i) a disability benefit is paid or pay-
16 able with respect to such individual under
17 Public Safety Officers’ Benefits Program
18 under subpart 1 of part L of title I of the
19 Omnibus Crime Control and Safe Streets
20 Act of 1968 (42 U.S.C. 3796 et seq.); or

21 “(ii) a death benefit is paid or payable
22 with respect to such individual under para-
23 graph (2) or the Public Safety Officers’
24 Benefits Program under subpart 1 of part
25 L of title I of the Omnibus Crime Control

1 and Safe Streets Act of 1968 (42 U.S.C.
2 3796 et seq.).

3 “(B) DEATH BENEFITS.—Except as pro-
4 vided in subparagraph (C), no benefit is payable
5 under paragraph (2) with respect to the death
6 of an eligible individual if—

7 “(i) a disability benefit is paid with
8 respect to such individual under paragraph
9 (1) or the Public Safety Officers’ Benefits
10 Program under subpart 1 of part L of title
11 I of the Omnibus Crime Control and Safe
12 Streets Act of 1968 (42 U.S.C. 3796 et
13 seq.); or

14 “(ii) a death benefit is paid or payable
15 with respect to such individual under the
16 Public Safety Officers’ Benefits Program
17 under subpart 1 of part L of title I of the
18 Omnibus Crime Control and Safe Streets
19 Act of 1968 (42 U.S.C. 3796 et seq.).

20 “(C) EXCEPTION IN THE CASE OF A LIM-
21 TATION ON APPROPRIATIONS FOR DISABILITY
22 BENEFITS UNDER PSOB.—In the event that dis-
23 ability benefits available to an eligible individual
24 under the Public Safety Officers’ Benefits Pro-
25 gram under subpart 1 of part L of title I of the

1 Omnibus Crime Control and Safe Streets Act of
2 1968 (42 U.S.C. 3796 et seq.) are reduced be-
3 cause of a limitation on appropriations, and
4 such reduction would affect the amount that
5 would be payable under subparagraph (A) or
6 (B) without regard to this subparagraph, bene-
7 fits shall be available under paragraph (1) or
8 (2) to the extent necessary to ensure that such
9 individual (or the survivor or survivors of such
10 individual) receives a total amount equal to the
11 amount described in paragraph (3).

12 “(h) ADMINISTRATION.—

13 “(1) ADMINISTRATION BY AGREEMENT WITH
14 OTHER AGENCY OR AGENCIES.—The Secretary may
15 administer any or all of the provisions of this section
16 through Memorandum of Agreement with the Attor-
17 ney General or the Secretary of Labor.

18 “(2) REGULATIONS.—The head of the agency
19 administering this section or any provisions thereof
20 (including any agency head administering such sec-
21 tion or provisions through a Memorandum of Agree-
22 ment under paragraph (1)) may promulgate such
23 implementing regulations as may be determined nec-
24 essary and appropriate. Initial implementing regula-
25 tions may be interim final regulations.

1 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated such sums as may be
3 necessary for fiscal year 2003 and each succeeding fiscal
4 year to carry out this section, to remain available until
5 expended, including administrative costs and costs of pro-
6 vision and payment of benefits.

7 “(j) RELATIONSHIP TO OTHER LAWS.—

8 “(1) NO PREEMPTION OF INDIVIDUAL
9 RIGHTS.—Except as otherwise provided in this sec-
10 tion, nothing in this section shall be construed to
11 override or limit any rights an individual may have
12 to seek compensation, benefits, or redress under any
13 other provision of Federal or State law.

14 “(2) RELATIONSHIP TO THE FEDERAL TORT
15 CLAIMS ACT.—

16 “(A) EXHAUSTION REQUIREMENT.—An in-
17 dividual may not seek any remedy that may be
18 available under section 224(p) (providing a
19 cause of action under the Federal Tort Claims
20 Act for injuries resulting from administration of
21 smallpox countermeasures under such section
22 224(p)) unless such individual has first filed a
23 claim for payment or compensation under this
24 section and has received a final determination
25 with respect to such claim, except that if the

1 Secretary fails to make a final determination on
2 a claim for payment or compensation filed in
3 accordance with the requirements of this section
4 within 240 days after such claim was filed, the
5 individual may seek any remedy that may be
6 available under section 224(p).

7 “(B) OFFSET OF COMPENSATION AGAINST
8 FEDERAL TORT CLAIMS ACT RECOVERY.—The
9 value of any compensation or benefits paid to
10 an individual, or the survivor, survivors, or the
11 estate of such an individual with respect to an
12 injury, pursuant to a claim under this section,
13 shall be offset against any award to such indi-
14 vidual or to the individual’s survivor, survivors,
15 or estate under section 224(p) with respect to
16 the same injury.”.

17 **SEC. 3. EXHAUSTION; EXCLUSIVITY; OFFSET.**

18 Paragraph (3) of section 224(p) of the Public Health
19 Service Act (42 U.S.C. 233(p)(3)) is amended to read as
20 follows:

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

22 “(A) EXHAUSTION.—

23 “(i) IN GENERAL.—A person may not
24 bring a claim under this subsection unless
25 such person has exhausted such remedies

1 as are available under the Smallpox Emer-
2 gency Personnel Protection Act of 2003.

3 “(ii) TOLLING OF STATUTE OF LIM-
4 TATIONS.—The time limit for filing a claim
5 under this subsection, or for filing an ac-
6 tion based on such claim, shall be tolled
7 during the pendency of a claim under the
8 Smallpox Emergency Personnel Protection
9 Act of 2003.

10 “(iii) CONSTRUCTION.—This sub-
11 section shall not be construed as super-
12 seding or otherwise affecting the applica-
13 tion of a requirement, under chapter 171
14 of title 28, United States Code, to exhaust
15 administrative remedies.

16 “(B) EXCLUSIVITY.—The remedy provided
17 by subsection (a) shall be exclusive of any other
18 civil action or proceeding for any claim or suit
19 this subsection encompasses, except for a civil
20 action or proceeding under such Act.

21 “(C) OFFSET.—The value of all compensa-
22 tion or benefits paid to an individual, or to the
23 survivor, survivors, or the estate of the indi-
24 vidual with respect to an injury, pursuant to a
25 claim under this section, shall be offset against

1 any award to such individual or to the individ-
2 ual's survivor, survivors, or estate under this
3 subsection with respect to the same injury.”.

○