

108TH CONGRESS
1ST SESSION

H. R. 865

To protect the health and safety of individuals receiving smallpox vaccinations and to provide compensation and assured access to care for individuals injured by the vaccine, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2003

Mr. WAXMAN (for himself, Mr. BROWN of Ohio, Mrs. CAPPS, and Mr. MARKEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and the Workforce, 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 protect the health and safety of individuals receiving smallpox vaccinations and to provide compensation and assured access to care for individuals injured by the vaccine, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Smallpox Vaccine
5 Compensation and Safety Act of 2003”.

1 **SEC. 2. SMALLPOX VACCINATIONS.**

2 The Public Health Service Act (42 U.S.C. 201 et
3 seq.) is amended by adding at the end the following:

4 **“TITLE XXIX—ADDITIONAL**
5 **VACCINE PROVISIONS**

6 **“SEC. 2901. COVERED COUNTERMEASURE.**

7 “For purposes of this title, the terms “covered coun-
8 termeasure” and “covered countermeasure against small-
9 pox” have the meanings given to those terms in section
10 224(p)(7)(A).

11 **“SEC. 2902. GRANTS TO ASSIST STATE AND LOCAL GOVERN-**
12 **MENTS IN MEETING THE COSTS OF SMALL-**
13 **POX INOCULATION PROGRAMS.**

14 “(a) IN GENERAL.—

15 “(1) GRANTS.—For the purposes described in
16 paragraph (2), the Secretary shall make an allot-
17 ment each fiscal year for each State in an amount
18 determined in accordance with subsection (e). The
19 Secretary shall make a grant to the State of the al-
20 lotment made for the State for the fiscal year if the
21 State submits to the Secretary an application at
22 such time, in such manner, and containing such in-
23 formation as the Secretary may require.

24 “(2) PURPOSES.—A funding agreement for a
25 grant under this section is that the State involved

1 will expend the grant only for the following pur-
2 poses:

3 “(A) Providing for the administration of
4 covered countermeasures against smallpox.

5 “(B) Monitoring the health of individuals
6 receiving covered countermeasures against
7 smallpox or individuals in close contact with in-
8 dividuals receiving such countermeasures.

9 “(C) Providing for the conduct of epide-
10 miological studies related to the administration
11 of covered countermeasures against smallpox.

12 “(b) SUPPLEMENT NOT SUPPLANT.—A funding
13 agreement for a grant under this section is that the State
14 involved will use the grant to supplement and not supplant
15 funds received from other sources for the purposes de-
16 scribed in subsection (a).

17 “(c) LOCAL INVOLVEMENT.—A funding agreement
18 for a grant under this section is that the State involved
19 will ensure that a suitable portion of the amount received
20 under the grant is expended at the local level.

21 “(d) REQUIREMENTS.—

22 “(1) IN GENERAL.—A funding agreement for a
23 grant under this section is that the State involved
24 will comply with the requirements of this subsection.

25 “(2) EDUCATION PROGRAM.—

1 “(A) ESTABLISHMENT.—Each State that
2 receives a grant under this section shall estab-
3 lish an education program to provide to each in-
4 dividual to whom a covered countermeasure
5 against smallpox is proposed to be administered
6 an explanation of—

7 “(i) the screening and medical surveil-
8 lance and evaluation programs available
9 under paragraphs (3) and (4);

10 “(ii) the risks and benefits from ad-
11 ministration of such countermeasure for
12 such individuals and those individuals with
13 whom they have close contact;

14 “(iii) the availability of the compensa-
15 tion program under section 224(q);

16 “(iv) the eligibility of the individual to
17 receive health care as described in this Act;

18 “(v) the right of the individual to
19 refuse the administration of any covered
20 countermeasure against smallpox;

21 “(vi) the right of an individual who
22 exercises the option described in clause (v)
23 to be protected from disciplinary action
24 under section 2903; and

1 “(vii) the general functions and duties
2 that such individual may be expected to
3 carry out if there is a smallpox outbreak.

4 “(B) EXPLANATIONS.—Explanations pro-
5 vided under subparagraph (A)—

6 “(i) shall be made available in a form
7 that is easily read and understood;

8 “(ii) shall be provided, as appropriate,
9 in languages other than English;

10 “(iii) shall be made available to those
11 individuals who reside with individuals to
12 whom such covered countermeasure is pro-
13 posed to be administered and, as appro-
14 priate, to patients treated by individuals
15 who have received a covered counter-
16 measure; and

17 “(iv) shall be made available without
18 charge or loss of wages or benefits to an
19 individual to whom a covered counter-
20 measure against smallpox is proposed to be
21 administered and to the individuals de-
22 scribed in clause (iii).

23 “(3) SCREENING PROGRAM.—

24 “(A) IN GENERAL.—Each State that re-
25 ceives a grant under this section shall, for each

1 individual to whom a covered countermeasure
2 against smallpox is proposed to be adminis-
3 tered—

4 “(i) provide without charge counseling
5 services that describe conditions which may
6 exacerbate the risks of receiving such coun-
7 termeasure; and

8 “(ii) offer on a voluntary basis,
9 screening and testing that can identify
10 health conditions that can reasonably be
11 expected to significantly increase risks to
12 the health of such individual, including
13 screening and testing for human immuno-
14 deficiency virus, eczema or other signifi-
15 cant chronic skin irritation, pregnancy,
16 and such other conditions as determined
17 appropriate by the Secretary.

18 “(B) RESULTS.—The results or other in-
19 formation (including information concerning an
20 individual’s refusal to be screened or tested)
21 generated or obtained from the screening and
22 testing described in subparagraph (A)—

23 “(i) shall be deemed protected health
24 information under the meaning of the term
25 in the regulations promulgated pursuant to

1 the authority of section 264(c) of the
2 Health Insurance Portability and Account-
3 ability Act of 1996;

4 “(ii) shall not be made available to an
5 employer; and

6 “(iii) shall be provided without charge
7 to the individual receiving such screening
8 and testing.

9 “(4) MEDICAL SURVEILLANCE AND EVALUA-
10 TION PROGRAM.—If the Secretary declares vaccinia
11 vaccine or any other measure to be a covered coun-
12 termeasure under section 224(p), each State that re-
13 ceives a grant under this section shall ensure that an
14 ongoing active medical surveillance and evaluation
15 program is provided to all individuals to whom such
16 countermeasure is administered and to the close con-
17 tacts of such individuals. Such program shall—

18 “(A) be provided from the date that
19 vaccinia vaccine or another covered counter-
20 measure is administered to a date that is not
21 less than 60 days from the date of administra-
22 tion;

23 “(B) include evaluation of any adverse
24 health effect that may reasonably appear to be
25 due to vaccinia vaccine or another covered

1 countermeasure and shall provide prompt med-
2 ical treatment or referral of any individual re-
3 quiring health care as a result of such adverse
4 health effect; and

5 “(C) be provided without charge to any in-
6 dividual to whom vaccinia vaccine or another
7 covered countermeasure is administered and to
8 the close contacts of such individuals.

9 “(5) NEEDLES.—If the Secretary declares
10 vaccinia vaccine to be a covered countermeasure
11 under section 224(p), each State that receives a
12 grant under this section shall ensure that for any
13 administration of such vaccine, the individual admin-
14 istering such vaccine shall use a sheathed bifurcated
15 needle—

16 “(A) to the extent that such needle is ap-
17 proved under the Federal Food, Drug, and Cos-
18 metic Act; and

19 “(B) to the extent that such sheathed bi-
20 furcated needle is available in such State.

21 “(e) FUNDING.—

22 “(1) AUTHORIZATION OF APPROPRIATIONS.—
23 For carrying out this section, there are authorized
24 to be appropriated \$850,000,000 for fiscal year

1 2003 and such sums as may be necessary for each
2 subsequent fiscal year.

3 “(2) ALLOCATION.—From the amounts appro-
4 priated and available for allotment under this sub-
5 section for any fiscal year, the Secretary shall allot
6 to each State that submits an application in accord-
7 ance with subsection (a)(1) an amount that is the
8 greater of—

9 “(A) the base amount as determined under
10 paragraph (3); or

11 “(B) the minimum amount as determined
12 under paragraph (4).

13 “(3) BASE AMOUNT.—For each State receiving
14 an award under this section, the Secretary shall de-
15 termine the base amount, which shall be equal to the
16 product of—

17 “(A) the amount appropriated under this
18 subsection for the fiscal year, less an amount
19 equal to the sum of all minimum amounts de-
20 termined for the States under paragraph (4);
21 and

22 “(B) the percentage constituted by the
23 ratio of an amount equal to the population of
24 the State over an amount equal to the total
25 population of the States (as indicated by the

1 most recent data collected by the Bureau of the
2 Census).

3 “(4) MINIMUM AMOUNT.—For each State re-
4 ceiving an award under this subsection, the min-
5 imum amount is—

6 “(A) in the case of each of the several
7 States, the District of Columbia, and the Com-
8 monwealth of Puerto Rico, an amount equal to
9 the lesser of—

10 “(i) \$5,000,000; or

11 “(ii) if the amount appropriated under
12 this subsection is less than \$667,000,000,
13 an amount equal to 0.75 percent of the
14 amount appropriated under this sub-
15 section; or

16 “(B) in the case of each of American
17 Samoa, Guam, the Commonwealth of the
18 Northern Mariana Islands, and the United
19 States Virgin Islands, an amount determined by
20 the Secretary to be appropriate, except that
21 such amount may not exceed the amount deter-
22 mined under subparagraph (A).

23 **“SEC. 2903. PROTECTION FROM DISCIPLINARY ACTION.**

24 “(a) FINDING.—The Congress finds that unlawful
25 employment practices described in subsection (b) are det-

1 rimental to the general public health and an interference
2 with the interstate control of infectious disease.

3 “(b) IN GENERAL.—It shall be an unlawful employ-
4 ment practice for an employer—

5 “(1) to fail or refuse to hire or to discharge any
6 individual, or otherwise to discriminate against any
7 individual with respect to the compensation, terms,
8 conditions, or privileges of employment of the indi-
9 vidual, because of a refusal or inability to receive the
10 administration of a covered countermeasure against
11 smallpox or because of an adverse reaction or reac-
12 tions to such countermeasure; or

13 “(2) subject to subsection (c), to limit, seg-
14 regate, or classify the employees of the employer in
15 any way that would deprive or tend to deprive any
16 individual of employment opportunities or otherwise
17 adversely affect the status of the individual as an
18 employee, because of a refusal or inability to receive
19 a covered countermeasure against smallpox or be-
20 cause of an adverse reaction or reactions to such
21 countermeasure.

22 “(c) EXCEPTION.—

23 “(1) IN GENERAL.—This section does not pro-
24 hibit an employer from limiting, segregating, or
25 classifying for a period of 30 days or less an em-

1 ployee to whom a covered countermeasure against
2 smallpox has been administered for the purpose of
3 protecting the close contacts (including patients) of
4 such employee.

5 “(2) REGULAR WAGES AND BENEFITS RE-
6 QUIRED.—Nothing in paragraph (1) shall be con-
7 strued to permit an employer to reduce the wages or
8 benefits of an employee because a covered counter-
9 measure against smallpox has been administered to
10 such employee.

11 “(d) DEFINITIONS OF EMPLOYEE AND EMPLOYER.—
12 The terms ‘employee’ and ‘employer’ have the meanings
13 given such terms in section 701 of the Civil Rights Act
14 of 1964 (42 U.S.C. 2000e), except that the terms ‘em-
15 ployee’ and ‘employer’ shall also include the meanings
16 given such terms in section 717 of the Civil Rights Act
17 of 1964 (42 U.S.C. 2000e–16).

18 “(e) FILING COMPLAINTS AND PROCEDURES.—

19 “(1) COMPLAINT.—

20 “(A) IN GENERAL.—Not later than 180
21 days after an alleged violation of subsection (b)
22 has occurred, the employee alleging such viola-
23 tion or another individual at the employee’s re-
24 quest, may file a complaint with the Secretary.

1 “(B) NOTICE.—Not later than 15 days
2 after receipt of a complaint described in sub-
3 paragraph (A), the Secretary shall notify the
4 employer alleged in the complaint to have com-
5 mitted a violation of subsection (b) of the filing
6 of such complaint.

7 “(2) FINDINGS AND PRELIMINARY ORDER.—

8 “(A) IN GENERAL.—Not later than 60
9 days after receiving a complaint described in
10 paragraph (1), the Secretary shall—

11 “(i) conduct an investigation of the
12 matters alleged in the complaint;

13 “(ii) determine whether it is reason-
14 able to believe that the complaint has
15 merit; and

16 “(iii) notify the complainant and the
17 employer alleged to have committed the
18 violation of subsection (b) of the deter-
19 mination.

20 “(B) REASONABLE BELIEF THAT A VIOLA-
21 TION HAS OCCURRED.—If the Secretary deter-
22 mines pursuant to subparagraph (A) that it is
23 reasonable to believe that a violation of sub-
24 section (b) has occurred, the Secretary shall in-
25 clude with the notice under such subparagraph

1 findings and a preliminary order for the relief
2 provided under paragraph (3).

3 “(C) OBJECTIONS.—

4 “(i) IN GENERAL.—Not later than 30
5 days after receipt of the notice under sub-
6 paragraph (A), the complainant and the
7 employer alleged to have committed the
8 violation of subsection (b) may file objec-
9 tions to the findings or the preliminary
10 order and request a hearing on the record.

11 “(ii) REINSTATEMENT.—The filing of
12 objections under clause (i) does not stay a
13 reinstatement ordered in the preliminary
14 order.

15 “(iii) FAILURE TO OBJECT.—If a
16 hearing is not requested pursuant to the
17 requirements of clause (i), the preliminary
18 order is final and not subject to judicial re-
19 view.

20 “(D) HEARINGS AND FINAL ORDER.—

21 “(i) HEARINGS.—A hearing under
22 this subsection shall be conducted expedi-
23 tiously.

24 “(ii) FINAL ORDER.—Not later than
25 120 days after the end of a hearing under

1 this subsection, the Secretary shall issue a
2 final order.

3 “(iii) SETTLEMENT.—At any time
4 prior to the issuance of a final order, any
5 further action under this subsection may
6 be ended by a settlement agreement made
7 by the complainant and the employer al-
8 leged to have committed the violation of
9 subsection (b), and approved by the Sec-
10 retary.

11 “(3) RELIEF.—

12 “(A) IN GENERAL.—If the Secretary deter-
13 mines on the basis of a complaint, that an em-
14 ployer violated subsection (b) of this section,
15 the Secretary shall order such employer to pro-
16 vide relief including—

17 “(i) taking affirmative action to abate
18 the violation;

19 “(ii) reinstating the complainant to
20 the former position with the same pay and
21 terms and privileges of employment; and

22 “(iii) paying compensatory damages,
23 including back pay.

24 “(B) COSTS INCURRED IN BRINGING A
25 COMPLAINT.—If the Secretary issues an order

1 under subparagraph (A), and the complainant
2 so requests, the Secretary may order that the
3 employer who violated subsection (b) pay the
4 costs (including attorney's fees) reasonably in-
5 curred by the complainant in bringing the com-
6 plaint, as determined by the Secretary.

7 “(f) JUDICIAL REVIEW AND VENUE.—

8 “(1) IN GENERAL.—Not later than 60 days
9 after an order has been issued under subsection (e),
10 a party adversely affected by such order may file a
11 petition for review in the United States circuit court
12 for the circuit in which the violation occurred or in
13 which the party resided on the date of the violation.

14 “(2) REVIEW.—A review conducted pursuant to
15 this subsection shall be heard and decided expedi-
16 tiously.

17 “(3) REVIEW IN OTHER PROCEEDINGS.—An
18 order of the Secretary subject to review under this
19 subsection is not subject to judicial review in a
20 criminal or other civil proceeding.

21 “(g) CIVIL ACTIONS TO ENFORCE.—If an employer
22 fails to comply with an order issued under subsection (e),
23 the Secretary shall bring a civil action to enforce such
24 order in the United States district court for the district
25 in which the violation occurred.

1 **“SEC. 2904. MEDICAL LEAVE FOR CERTAIN VACCINE RE-**
2 **CIPIENTS.**

3 “(a) IN GENERAL.—In accordance with regulations
4 promulgated by the Secretary, an employee (as defined in
5 section 3 of the Fair Labor Standards Act of 1938) shall
6 be entitled to a total of not more than 4 workdays of paid
7 leave because of a health condition that makes the em-
8 ployee unable to perform the functions of the position of
9 such employee that arose as a result of the employee hav-
10 ing received or come into close contact with an individual
11 who received a covered countermeasure against smallpox.

12 “(b) APPLICATION OF CERTAIN PROVISIONS.—Leave
13 shall be provided under subsection (a) in accordance with
14 the provisions of the Family and Medical Leave Act of
15 1993 except that—

16 “(1) such leave shall be provided for a condition
17 described in subsection (a) regardless of whether
18 such condition requires inpatient care or continuing
19 treatment;

20 “(2) such leave shall be fully paid; and

21 “(3) this section shall apply to all employers re-
22 gardless of size.

23 “(c) REIMBURSEMENT FROM THE PROGRAM.—

24 “(1) NON-FEDERAL EMPLOYEES.—Any em-
25 ployer, other than a Federal agency, that provides
26 paid leave to an employee for the reasons described

1 in subsection (a) may seek reimbursement for such
2 leave from the compensation program under section
3 224(q).

4 “(2) FEDERAL EMPLOYEES.—A Federal agency
5 that provides leave under this section shall treat
6 such leave as paid administrative leave.

7 **“SEC. 2905. RESPONSIBILITIES OF THE SECRETARY.**

8 “(a) SUPPLIES OF VACCINIA IMMUNE GLOBULIN.—
9 If the Secretary declares vaccinia vaccine to be a covered
10 countermeasure under section 224(p), the Secretary shall
11 ensure that adequate supplies of vaccinia immune globulin
12 are made available to any individual to whom vaccinia vac-
13 cine is administered during the period of such declaration.

14 “(b) UNIFORM SYSTEM OF REPORTING.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish a uniform system for reporting adverse re-
17 sponses to any covered countermeasure against
18 smallpox to the Secretary.

19 “(2) REPORT TO CONGRESS.—Not later than 1
20 year after the date of enactment of this Act and
21 every year in which covered countermeasures against
22 smallpox are administered, the Secretary shall sub-
23 mit to the Committee on Health, Education, Labor,
24 and Pensions of the Senate and the Committee on
25 Energy and Commerce of the House of Representa-

1 tives, a report that describes for the preceding
2 year—

3 “(A) the number of individuals to whom a
4 covered countermeasure against smallpox was
5 administered; and

6 “(B) the number and kind of adverse reac-
7 tions caused by the administration of a covered
8 countermeasure against smallpox.

9 **“SEC. 2906. PROVISION OF NEEDLES.**

10 “The Director of the Centers for Disease Control and
11 Prevention shall provide needles to States that receive a
12 grant under section 2902 for the purpose of administering
13 vaccinia vaccine in accordance with section 2902(d)(5).”.

14 **SEC. 3. HEALTH CARE FOR HEALTH CARE WORKERS AND**
15 **FIRST RESPONDERS SUFFERING ADVERSE**
16 **REACTIONS OR COMPLICATIONS FROM**
17 **SMALLPOX VACCINE; CONTINUED INSUR-**
18 **ANCE COVERAGE.**

19 (a) PAYMENTS FOR PROVISION OF MEDICAL ASSIST-
20 ANCE.—Title XXIX of the Public Health Service Act (as
21 added by section 2) is amended by adding at the end the
22 following:

1 **“SEC. 2907. HEALTH CARE FOR INDIVIDUALS SUFFERING**
2 **ADVERSE REACTIONS OR COMPLICATIONS**
3 **FROM SMALLPOX VACCINE.**

4 “(a) PAYMENT.—

5 “(1) IN GENERAL.—The Secretary shall pay to
6 each State with an agreement described in sub-
7 section (b) an amount equal to the costs incurred by
8 that State to provide medical assistance described in
9 subsection (b)(1), subject to paragraph (2).

10 “(2) LIMITATION ON PAYMENT.—The Secretary
11 shall not make any payment under paragraph (1)
12 for costs for medical assistance insofar as such costs
13 may reasonably be reimbursed from a third party
14 under the terms of the agreement described in sub-
15 section (b)(2). Any payment under this section to a
16 State with respect to medical assistance shall be con-
17 ditioned on reimbursement to the Secretary when
18 notice or other information is received that payment
19 for such medical assistance has been or could be
20 made by a third party under subsection (b)(2).

21 “(b) AGREEMENT.—An agreement described in this
22 subsection is an agreement between a State and the Sec-
23 retary in which the State—

24 “(1) agrees to provide such medical assistance
25 as may be medically necessary to—

1 “(A) any health care worker or first re-
2 sponder who—

3 “(i) has suffered any adverse reaction
4 or complication as a result of a covered
5 countermeasure against smallpox or expo-
6 sure to vaccinia virus or any other sub-
7 stance administered for the prevention or
8 treatment of smallpox; and

9 “(ii) has not received compensation
10 under the National Smallpox Vaccine In-
11 jury Compensation Program established
12 under section 224; and

13 “(B) any individual who—

14 “(i) has suffered any adverse reaction
15 or complication as a result of contact with
16 another person who received a covered
17 countermeasure; and

18 “(ii) has not received compensation
19 under the National Smallpox Vaccine In-
20 jury Compensation Program established
21 under section 224; and

22 “(2) agrees to take all reasonable measures to
23 obtain reimbursement for the costs of providing such
24 assistance from any third party (including health in-

1 surers and group health plans (as defined in section
2 2791)) with responsibility for such costs.

3 “(c) STATE ENTITLEMENT.—This section constitutes
4 budget authority in advance of appropriations Acts and
5 represents the obligation of the Federal Government to
6 provide for the payment to States of amounts provided
7 under this section.

8 “(d) RULE OF CONSTRUCTION.—

9 “(1) INSURANCE COVERAGE.—Nothing in this
10 section shall be construed to invalidate or otherwise
11 abridge any provision of law or any contractual obli-
12 gation that otherwise obligates a health insurance
13 issuer to provide reimbursement or otherwise defray
14 the cost to an individual of health care needed to
15 treat the health consequences of the administration
16 of or exposure to a covered countermeasure against
17 smallpox or exposure to vaccinia virus.

18 “(2) HEALTH CARE FACILITIES.—Nothing in
19 this section shall be construed to invalidate or other-
20 wise abridge any provision of law or any contractual
21 obligation that otherwise obligates a health care fa-
22 cility to provide health care or other health services
23 to an individual that are needed to treat the health
24 consequences of the administration of a covered

1 countermeasure against smallpox or exposure to
2 vaccinia virus.

3 “(3) EMPLOYERS.—Nothing in this section
4 shall be construed to invalidate or otherwise abridge
5 any provision of law or any contractual obligation
6 that otherwise obligates an employer to provide
7 leave, wages, vacation time, or any other benefit to
8 an individual.

9 “(4) STATE OR LOCAL GOVERNMENTS.—Noth-
10 ing in this section shall be construed to invalidate or
11 otherwise abridge any provision of law or any con-
12 tractual obligation that otherwise obligates a State
13 or local government to provide health care, workers’
14 compensation, or any other benefit to an individual.

15 “(e) AUTHORIZING UTILIZATION OF MEDICAID IN
16 PROVIDING MEDICAL ASSISTANCE.—Nothing in this sec-
17 tion shall be construed to prevent a State from utilizing
18 its medicaid program under title XIX of the Social Secu-
19 rity Act in order to provide medical assistance under this
20 section. The Secretary shall waive such provisions of such
21 Act as are necessary to permit a State to so utilize such
22 program under this subsection.”.

23 (b) CONTINUED COVERAGE OF BENEFITS FOR
24 SMALLPOX VACCINE SIDE EFFECTS.—

1 (1) STATE MAINTAINED PLANS.—Section 2907
2 of the Public Health Service Act (as added by sub-
3 section (a)) is amended by adding at the end the fol-
4 lowing:

5 “(f) CONTINUED COVERAGE OF BENEFITS FOR
6 SMALLPOX VACCINE SIDE EFFECTS.—

7 “(1) IN GENERAL.—In accordance with regula-
8 tions which the Secretary shall prescribe, each group
9 health plan that is maintained by any State that re-
10 ceives funds under this Act, by any political subdivi-
11 sion of such State, or by any agency or instrumen-
12 tality of such State or political subdivision, shall pro-
13 vide coverage of benefits for side effects resulting
14 from covered countermeasures against smallpox at
15 the level of such coverage it provided as of Sep-
16 tember 10, 2001.

17 “(2) ENFORCEMENT.—For purposes of section
18 2207, the requirement of paragraph (1) is deemed a
19 requirement of title XXII.”.

20 (2) PRIVATE PLANS.—

21 (A) AMENDMENT TO TAX CODE.—

22 (i) IN GENERAL.—Paragraph (1) of
23 section 4980B(f) of the Internal Revenue
24 Code of 1986 is amended by inserting be-
25 fore the period at the end the following: “,

1 and (C) only if the coverage of the side ef-
2 fects from covered countermeasures
3 against smallpox (as such term is defined
4 in section 224(p) of the Public Health
5 Service Act) is not less than the level of
6 coverage provided by the plan as of Sep-
7 tember 10, 2001”.

8 (ii) CONFORMING AMENDMENTS.—
9 Section 4980B(f)(1) of such Code is
10 amended—

11 (I) by inserting “(A)” before
12 “only if” the first place it appears,
13 and

14 (II) by striking “and only if” and
15 inserting “, (B) only if”.

16 (iii) EFFECTIVE DATE.—The amend-
17 ments made by this section shall apply to
18 covered countermeasures against smallpox
19 taken after the date of the enactment of
20 this Act.

21 (B) AMENDMENT TO ERISA.—Section
22 609 of the Employee Retirement Income Secu-
23 rity Act of 1974 (29 U.S.C. 1169) is amend-
24 ed—

1 (i) by redesignating subsection (e) as
 2 subsection (f); and
 3 (ii) by inserting after subsection (d)
 4 the following:

5 “(e) CONTINUED COVERAGE OF BENEFITS FOR
 6 SMALLPOX VACCINE SIDE EFFECTS.—A group health
 7 plan shall provide coverage of the side effects from covered
 8 countermeasures against smallpox (as such term is defined
 9 in section 224(p) of the Public Health Service Act) at the
 10 level of coverage provided by the plan as of September 10,
 11 2001.”.

12 **SEC. 4. NATIONAL SMALLPOX VACCINE INJURY COMPENSA-**
 13 **TION PROGRAM.**

14 (a) ESTABLISHMENT.—Section 224 of the Public
 15 Health Service Act (42 U.S.C. 233), as amended by sec-
 16 tion 304(c) of Public Law 107–296 (116 Stat. 2135), is
 17 amended by adding at the end the following:

18 “(q) NATIONAL SMALLPOX VACCINE INJURY COM-
 19 PENSATION PROGRAM.—

20 “(1) ESTABLISHMENT.—The Secretary shall es-
 21 tablish the National Smallpox Vaccine Injury Com-
 22 pensation Program (referred to in this subsection as
 23 the ‘Smallpox Program’) under which compensation
 24 may be paid for injury or death related to the ad-

1 ministration of any covered countermeasure against
2 smallpox.

3 “(2) PROCEDURES AND STANDARDS.—The Sec-
4 retary shall by regulation establish procedures and
5 standards applicable to the Smallpox Program that
6 follow the procedures and standards applicable
7 under the National Vaccine Injury Compensation
8 Program established under section 2110, except for
9 the following:

10 “(A) A person may not file a civil action
11 under subsection (p) unless the person has first
12 filed a petition for compensation under the
13 Smallpox Program under section 2111.

14 “(B) After filing a petition under section
15 2111, a person may elect to instead bring a
16 civil action under subsection (p) if the person
17 would be authorized under clause (i) or (ii) of
18 section 2111(a)(2)(A) and under section 2121
19 to elect to bring a civil action.

20 “(C) Notwithstanding section
21 2111(c)(1)(A), a person who did not receive a
22 covered countermeasure against smallpox or
23 any other substance administered for the pre-
24 vention or treatment of smallpox (including
25 vaccinia virus) may receive compensation under

1 the Smallpox Program if the person was injured
2 as a result of contact with another person who
3 received such a countermeasure or substance.

4 “(D) Section 2111(c)(1)(D) (requiring pe-
5 titioner to demonstrate death, residual effects
6 for more than 6 months, or inpatient hos-
7 pitalization and surgical intervention) shall not
8 apply.

9 “(E) Notwithstanding section 2115(a)(2),
10 in the event of a death related to the adminis-
11 tration of vaccinia virus or other substance or
12 medication administered for the purpose of pre-
13 venting or treating smallpox (including any cov-
14 ered countermeasure against smallpox), com-
15 pensation under the Smallpox Program shall in-
16 clude an award for the estate of the deceased
17 of \$850,000, in addition to any other com-
18 pensation to which the petitioner is entitled
19 under this section.

20 “(3) VACCINE INJURY TABLE.—

21 “(A) INCLUSION.—For purposes of receiv-
22 ing compensation under the Smallpox Program,
23 the Vaccine Injury Table under section 2114 is
24 deemed to include the following table of inju-
25 ries, disabilities, illnesses, conditions, and

1 deaths resulting from the administration of the
 2 smallpox vaccine, and the time period in which
 3 the first symptom or manifestation of onset or
 4 of significant aggravation of such injuries, dis-
 5 abilities, illnesses, conditions, and deaths is to
 6 occur after administration of vaccinia virus or
 7 other substance or medication administered for
 8 the purpose of preventing or treating smallpox
 9 (including a covered countermeasure against
 10 smallpox):

“Adverse event:

Time period for first symptom or mani-
 festation of onset or of significant aggra-
 vation after administration of vaccinia
 virus or other substance or medication
 administered for the purpose of pre-
 venting or treating smallpox (including a
 covered countermeasure against small-
 pox):

| | |
|---|----------------|
| A. Anaphylaxis or anaphylactic shock | 0–4 hours |
| B. Eczema vaccinatum (including in a con- tact case) | any |
| C. Accidental inoculation (including in a contact case) | any |
| D. Progressive vaccinia | any |
| E. Encephalopathy (or encephalitis) | 0–21 days |
| F. Stevens-Johnson syndrome | 3–21 days |
| G. Generalized vaccinia | 0–60 days |
| H. Any acute complication or sequela (in- cluding death) of an illness, disability, in- jury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed .. | Not applicable |

11 “(B) RULE OF CONSTRUCTION.—Section
 12 13632 (a)(3) of Public Law 103–66 (107 Stat.
 13 646) (making revisions by Secretary to the Vac-
 14 cine Injury Table effective on the effective date
 15 of a corresponding tax) shall not be construed
 16 to apply to the revision to the Vaccine Injury
 17 Table made by this paragraph.

1 “(4) PROHIBITION.—The Secretary may not
2 provide any compensation under the Smallpox Pro-
3 gram for any minor scarring or minor local reaction.

4 “(5) APPLICATION.—The Smallpox Program
5 applies to any injury or death associated with the
6 administration of any covered countermeasure on or
7 after November 25, 2002.

8 “(6) REIMBURSEMENT.—Notwithstanding para-
9 graph (4), the Secretary may reimburse under this
10 section an employer who seeks reimbursement pur-
11 suant to section 2904.

12 “(7) SPECIAL MASTERS.—

13 “(A) HIRING.—In accordance with section
14 2112, the judges of the United States Claims
15 Court shall appoint a sufficient number of spe-
16 cial masters to address claims for compensation
17 under this subsection.

18 “(B) BUDGET AUTHORITY.—There are ap-
19 propriated to carry out this paragraph such
20 sums as may be necessary for fiscal year 2003
21 and each fiscal year thereafter. This subpara-
22 graph constitutes budget authority in advance
23 of appropriations and represents the obligation
24 of the Federal Government.

1 “(8) COVERED COUNTERMEASURE.—For pur-
 2 poses of this subsection, the terms ‘covered counter-
 3 measure’ and ‘covered countermeasure against
 4 smallpox’ have the meanings given to those terms in
 5 subsection (p)(7)(A).

6 “(9) FUNDING.—Compensation made under the
 7 Smallpox Program shall be made from the same
 8 source of funds as payments made under subsection
 9 (p).”.

10 (b) RELATION TO FEDERAL TORT CLAIMS ACT.—
 11 Paragraph (3) of section 224(p) of the Public Health
 12 Service Act (42 U.S.C. 233(p)) is amended to read as fol-
 13 lows:

14 “(3) EXHAUSTION; EXCLUSIVITY.—

15 “(A) NATIONAL SMALLPOX VACCINE IN-
 16 JURY COMPENSATION PROGRAM.—A person
 17 may not bring a claim under this subsection un-
 18 less the person has first filed a petition for
 19 compensation under the program established
 20 under subsection (q) and made a proper elec-
 21 tion under sections 2111(a)(2)(A) and 2121.

22 “(B) EXCLUSIVITY.—Except for filing a
 23 petition for compensation under the program
 24 established under subsection (q), the remedy
 25 provided by subsection (a) shall be exclusive of

1 any other civil action or proceeding for any
2 claim or suit this subsection encompasses, dur-
3 ing the effective period of a declaration by the
4 Secretary under paragraph (2)(A).”.

5 (c) PERSONS SUSCEPTIBLE TO VACCINE-RELATED
6 INJURY.—Subsection (b) of section 2114 of the Public
7 Health Service Act (42 U.S.C. 300aa–14) is amended by
8 adding at the end the following:

9 “(5) A petitioner shall be considered to have
10 suffered an injury related to the administration of a
11 covered countermeasure even if the petitioner might
12 not have suffered the injury absent an infection, dis-
13 ease, or other condition that made him or her more
14 susceptible to the injury.”.

15 **SEC. 5. TECHNICAL MODIFICATION.**

16 (a) CIRCUMSTANCES IN WHICH PRESUMPTION IN
17 CASES OF ACCIDENTAL VACCINIA INOCULATION AP-
18 PLIES.—Section 224(p)(2)(C)(ii)(II) of the Public Health
19 Service Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is amended
20 by striking “resides or has resided with” and inserting
21 “has had close contact with”.

22 (b) COVERED COUNTERMEASURE.—Subparagraph
23 (A) of section 224(p)(7) of the Public Health Service Act
24 (42 U.S.C. 233(p)(7)(A)) is amended to read as follows:

1 “(A) COVERED COUNTERMEASURE.—The
2 term ‘covered countermeasure’, or ‘covered
3 countermeasure against smallpox’, means a sub-
4 stance specified in a declaration under para-
5 graph (2) that is—

6 “(i) a substance used to prevent or
7 treat smallpox (including vaccinia or an-
8 other vaccine); or

9 “(ii) a substance (including vaccinia
10 immune globulin and cidofovir) used to
11 control or treat the adverse effects of
12 vaccinia inoculation or administration of
13 any other countermeasure against small-
14 pox.”.

15 (c) COVERED PERSON.—Section 224(p)(7)(B)(ii) of
16 the Public Health Service Act (42 U.S.C.
17 233(p)(7)(B)(ii)) is amended to read as follows:

18 “(ii) a health care entity, a State, or
19 a political subdivision of a State under
20 whose auspices such countermeasure was
21 administered;”.

22 (d) EFFECTIVE DATE.—This section shall take effect
23 as of November 25, 2002 (the date of enactment of the

- 1 Homeland Security Act of 2002 (Pub. L. 107–296; 116
- 2 Stat. 2135)).

