

**Smallpox Emergency Personnel Protection Act of 2003 (Introduced in House)**  
HR 1413 IH

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

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**A BILL**

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

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the 'Smallpox Emergency Personnel Protection Act of 2003'.

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

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

**'Part C--Smallpox Emergency Personnel Protection**

**'SEC. 261. DEFINITIONS.**

'For purposes of this part:

'(1) VACCINE- The term 'vaccine' or 'smallpox vaccine' means vaccinia (smallpox) vaccines, including the Dryvax vaccine.

'(2) COVERED INDIVIDUAL- The term 'covered individual' means an individual--

'(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other

public safety personnel, or support personnel for such occupational specialties;

`(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan approved by the Secretary; and

`(C) to whom a vaccine is administered pursuant to such approved plan--

`(i) during the effective period of the Declaration (including the portion of such period before the enactment of this part); and

`(ii) not later than the latest of--

`(I) 180 days after the effective date of the initial interim final regulations implementing this part;

`(II) 120 days after becoming an individual in an occupation described in subparagraph (A); or

`(III) 120 days after becoming an individual identified as a member of a smallpox emergency response plan described in subparagraph (B).

`(3) COVERED INJURY- The term 'covered injury' means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 262, to have been sustained by an individual as the direct result of--

`(A) administration to the individual of a vaccine during the effective period of the Declaration; or

`(B) accidental vaccinia inoculation of the individual in circumstances in which--

`(i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;

`(ii) smallpox vaccine has not been administered to the individual; and

`(iii) the individual has resided with, or has been in contact with, an individual who is (or who was accidentally inoculated by) a covered individual.

`(4) DECLARATION- The term 'Declaration' means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003.

`(5) EFFECTIVE PERIOD OF THE DECLARATION- The term 'effective period of the Declaration' means the effective period specified in the Declaration, unless extended by the Secretary.

`(6) ELIGIBLE INDIVIDUAL- The term 'eligible individual' means an individual who is (as determined in accordance with section 262)--

`(A) a covered individual who sustains a covered injury in the manner described in paragraph (3)(A); or

`(B) an individual who sustains a covered injury in the manner described in paragraph (3)(B).

`(7) SMALLPOX EMERGENCY RESPONSE PLAN- The term 'smallpox emergency response plan' or 'plan' means a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

## **`SEC. 262. DETERMINATION OF ELIGIBILITY AND BENEFITS.**

`(a) IN GENERAL- The Secretary shall establish procedures for determining, as applicable with respect to an individual--

`(1) whether the individual is an eligible individual;

`(2) whether an eligible individual has sustained a covered injury or injuries for which medical benefits or compensation may be available under sections 264 and 265, and the amount of such benefits or compensation;

`(3) whether the covered injury or injuries of an eligible individual constitute a compensable disability, or caused the individual's death, for purposes of benefits under section 266.

`(b) COVERED INDIVIDUALS- The Secretary may accept a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures under the Declaration, that an individual is a covered individual.

`(c) CRITERIA FOR REIMBURSEMENT-

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

`(2) OTHER DETERMINATIONS- In making determinations other than those described in paragraph (1) as to the causation or severity of an injury, the Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.

`(d) DEADLINE FOR FILING REQUEST- The Secretary shall not consider any request for a benefit under this part with respect to an individual, unless--

`(1) in the case of a request based on the administration of the vaccine to the individual, the individual provides notice to the Secretary of an adverse effect of the vaccination not later than one year after the date of administration of the vaccine; or

`(2) in the case of a request based on accidental vaccinia inoculation, the individual provides notice to the Secretary of an adverse effect of such vaccination not later than two years after the date of the first symptom or manifestation of onset of the adverse effect.

**“(e) REVIEW OF DETERMINATION-**

“(1) SECRETARY'S REVIEW AUTHORITY- The Secretary may review a determination under this section at any time on the Secretary's own motion or on application, and may affirm, vacate, or modify such determination in any manner the Secretary deems appropriate.

“(2) JUDICIAL AND ADMINISTRATIVE REVIEW- No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this section. No officer or employee of the United States shall review any action by the Secretary under this section (unless the President specifically directs otherwise).

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

**“(a) SMALLPOX VACCINE INJURY TABLE-**

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

“(2) AMENDMENTS- The Secretary may amend by regulation the table established under paragraph (1). Amendments shall apply retroactively to claims pending at the time of promulgation of final amending regulations and to claims filed subsequently. If the effect of such amendment is to permit an individual who was not, before such amendment, eligible for compensation under this part, such individual may file a request for compensation or file an amended request for such compensation not later than one year after the effective date of such amendment in the case of an individual to whom the vaccine was administered and two years in the case of a request for compensation based on accidental vaccinia inoculation.

**“SEC. 264. MEDICAL BENEFITS.**

“(a) IN GENERAL- Subject to the succeeding provisions of this section, the Secretary shall make payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual. The Secretary may consider the Federal Employees Compensation Act (5 U.S.C. 8103) and its implementing regulations in determining the amount of such payment and the circumstances under which such payments are reasonable and appropriate.

“(b) BENEFITS SECONDARY TO OTHER COVERAGE- Payment or reimbursement for services or benefits under subsection (a) shall be secondary to any obligation of the United States or any third party (including any State or

local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits. The Secretary shall have the discretion to establish mechanisms and procedures for providing the secondary benefits under this section.

## **`SEC. 265. COMPENSATION FOR LOST EMPLOYMENT INCOME.**

`(a) IN GENERAL- Subject to the succeeding provisions of this section, the Secretary shall provide compensation to an eligible individual for loss of employment income incurred as a result of a covered injury, at the rate specified in subsection (b).

`(b) AMOUNT OF COMPENSATION-

`(1) IN GENERAL- Compensation under this section shall be at the rate of 66 2/3 percent of monthly employment income. The Secretary may consider the Federal Employees Compensation Act (5 U.S.C. 8114 and 8115) and its implementing regulations in determining the amount of such payment and the circumstances under which such payments are reasonable and appropriate.

`(2) TREATMENT OF SELF-EMPLOYMENT INCOME- For purposes of this section, the term `employment income' includes income from self-employment.

`(c) LIMITATIONS-

`(1) BENEFITS SECONDARY TO OTHER COVERAGE- Any compensation under subsection (a) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income and shall not be made to the extent that compensation for loss of employment income has been made under such other obligations in an amount that equals or exceeds the rate specified in subsection (b)(1).

`(2) NO BENEFITS FOR DEATH OR PERMANENT AND TOTAL DISABILITY- No payment shall be made under this section in compensation for loss of employment income subsequent to the receipt by an eligible individual (or his survivor or survivors) of benefits under section 266 for death or permanent and total disability.

`(3) LIMIT ON TOTAL BENEFITS- Total benefits paid to an individual under this section shall not exceed \$50,000.

`(4) WAITING PERIOD- An eligible individual shall not be provided compensation under this section for the first 5 work days of disability.

## **`SEC. 266. PAYMENT FOR DEATH AND PERMANENT, TOTAL DISABILITY.**

`(a) BENEFIT FOR PERMANENT AND TOTAL DISABILITY- The Secretary shall pay to an eligible individual who is determined to have a covered injury or injuries

meeting the definition of disability in section 216(i) of the Social Security Act (42 U.S.C. 416(i)) an amount determined under subsection (c), in the same manner as disability benefits are paid pursuant to the PSOB program in section 1201(b) of the OCCSSA with respect to an eligible public safety officer (except that payment shall be made to the parent or legal guardian, in the case of an eligible individual who is a minor or is subject to legal guardianship).

`(b) DEATH BENEFIT- The Secretary shall pay, in the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, a death benefit in the amount determined under subsection (c) to the survivor or survivors in the same manner as death benefits are paid pursuant to PSOB program in section 1201 of the OCCSSA with respect to an eligible deceased (except that in the case of an eligible individual who is a minor with no living parent, the legal guardian shall be considered the survivor in the place of the parent).

`(c) BENEFIT AMOUNT-

`(1) IN GENERAL- The amount of the disability or death benefit under subsection (a) or (b) in a fiscal year shall equal the amount of the comparable benefit calculated under the PSOB in such fiscal year, without regard to any reduction attributable to a limitation on appropriations, but subject to paragraph (2).

`(2) REDUCTION FOR PAYMENTS FOR LOST EMPLOYMENT INCOME- The amount of the benefit as determined under paragraph (1) shall be reduced by the total amount of any benefits paid under section 265 with respect to lost employment income.

`(d) BENEFIT IN ADDITION TO MEDICAL BENEFITS- A benefit under this section shall be in addition to any amounts received by an eligible individual under section 264.

`(e) LIMITATIONS-

`(1) DISABILITY BENEFITS- Except as provided in paragraph (3), no benefit is payable under subsection (a) with respect to the disability of an eligible individual if--

`(A) a disability benefit is paid or payable with respect to such individual under the PSOB; or

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

`(2) DEATH BENEFITS- No benefit is payable under subsection (b) with respect to the death of an eligible individual if--

`(A) a disability benefit is paid with respect to such individual under subsection (a) or the PSOB; or

`(B) a death benefit is paid or payable with respect to such individual under the PSOB.

`(3) EXCEPTION IN THE CASE OF A LIMITATION ON APPROPRIATIONS FOR DISABILITY BENEFITS UNDER PSOB- In the event that disability benefits available to an eligible individual under the PSOB program are reduced because of a limitation on appropriations, and such reduction would affect the amount that would be payable under

paragraph (1) or (2) without regard to this paragraph, benefits shall be available under subsection (a) or (b) to the extent necessary to ensure that such individual (or his survivor or survivors) receives a total amount equal to the amount described in subsection (c).

`(f) REFERENCES- References in this section--

`(1) to the Public Safety Officers' Benefits Program or PSOB are references to the program under part L, subpart 1 of title I of the OCCSSA; and

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

## **`SEC. 267. ADMINISTRATION.**

`(a) ADMINISTRATION BY AGREEMENT WITH OTHER AGENCY OR AGENCIES- The Secretary may administer any or all of the provisions of this part through Memorandum of Agreement with the head of any appropriate Federal agency.

`(b) REGULATIONS- The head of the agency administering this part or provisions thereof (including any agency head administering such Act or provisions through a Memorandum of Agreement under subsection (a)) may promulgate such implementing regulations as may be found necessary and appropriate. Initial implementing regulations may be interim final regulations.

## **`SEC. 268. PARTICIPANT EDUCATION REGARDING SMALLPOX EMERGENCY RESPONSE PLANS.**

In reviewing State, local, or Department of Health and Human Services smallpox emergency response plans described in section 261, the Secretary shall ensure that such plans are consistent with guidelines of the Centers for Disease Control and Prevention with respect to the education of individual participants (including information as to the voluntary nature of the program and the availability of potential benefits under this part), and the adequate screening of individuals for vaccine contraindications.

## **`SEC. 269. AUTHORIZATION OF APPROPRIATIONS.**

`For the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007, to remain available until expended, including administrative costs and costs of provision and payment of benefits.

## **`SEC. 270. RELATIONSHIP TO OTHER LAWS.**

`Except as explicitly provided herein, nothing in this part shall be construed to override or limit any rights an individual may have to seek compensation, benefits, or redress under any other provision of Federal or State law.'

### **SEC. 3. AMENDMENTS TO PROVISION REGARDING TORT LIABILITY FOR ADMINISTRATION OF SMALLPOX COUNTERMEASURES.**

(a) AMENDMENT TO ACCIDENTAL VACCINIA INOCULATION PROVISION- Section 224(p)(2)(C)(ii)(II) of such Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is amended by striking 'resides or has resided with' and inserting 'has resided with, or has had contact with,'.

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

(D) ACTS AND OMISSIONS DEEMED TO BE WITHIN SCOPE OF EMPLOYMENT-

(i) IN GENERAL- In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of--

(I) subsection (a); and

(II) section 1346(b) and chapter 171 of title 28, United States Code.

(ii) INDIVIDUALS TO WHOM DEEMING APPLIES- An individual is described by this clause if--

(I) vaccinia vaccine was administered to such individual as provided by subparagraph (B); and

(II) such individual was within a category of individuals covered by a declaration under subparagraph (A)(i).'

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

(3) EXHAUSTION; EXCLUSIVITY; OFFSET-

(A) EXHAUSTION-

(i) IN GENERAL- A person may not bring a claim under this subsection unless such person has received a determination about remedies available under section 262.

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

(iii) CONSTRUCTION- This subsection shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

(B) EXCLUSIVITY- The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or

suit this subsection encompasses, except for a proceeding under part C of this title.

`(C) OFFSET- The value of all compensation and benefits provided under part C of this title for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.'

(d) REQUIREMENT TO COOPERATE WITH UNITED STATES- Section 224(p)(5) of such Act (42 U.S.C. 233(p)(5)) is amended in the caption by striking `DEFENDANT' and inserting `COVERED PERSON'.

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

`(II) used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and'.

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

(1) by striking `includes any person' and inserting `means a person';

(2) in clause (ii)--

(A) by striking `auspices' and inserting `auspices--';

(B) by redesignating `such countermeasure' and all that follows as clause (I) and indenting accordingly; and

(C) by adding at the end the following:

`(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

`(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or

`(IV) an evaluation was made of whether the administration of a countermeasure was effective;'

(3) in clause (iii) by striking `or';

(4) by striking clause (iv) and inserting the following:

`(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to administration of such countermeasures;

`(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual--

`(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such

individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or  
(II) an entity that employs an individual described by clause (I) or where such individual has privileges or is otherwise authorized to provide health care;

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

(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or

(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).'

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

(1) by designating 'is authorized to' and all that follows as clause (i) and indenting accordingly;

(2) by striking 'individual who' and inserting 'individual who--'; and

(3) by striking the period and inserting `; or

(ii) is otherwise authorized by the Secretary to administer such countermeasure.'

(h) DEFINITION OF 'ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE'- Section 224(p)(7) of such Act (42 U.S.C. 233(p)(7)) is amended by adding at the end the following new subparagraph:

(D) ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE- The term 'arising out of administration of a covered countermeasure', when used with respect to a claim or liability, includes a claim or liability arising out of--

(i) determining whether, or under what conditions, an individual should receive a covered countermeasure;

(ii) obtaining informed consent of an individual to the administration of a covered countermeasure;

(iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

(iv) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).'

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

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