

Public Law 108–20
108th Congress

An Act

Apr. 30, 2003
[H.R. 1770]

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

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

Smallpox
Emergency
Personnel
Protection Act of
2003.
42 USC 201 note.

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

42 USC 239.

“**SEC. 261. GENERAL PROVISIONS.**

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

“(1) **COVERED COUNTERMEASURE.**—The term ‘covered countermeasure’ means a covered countermeasure as specified in a Declaration made pursuant to section 224(p).

“(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 specialities;

“(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 (as defined in paragraph (7)) approved by the Secretary;

“(C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and

“(D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before the enactment of this part).

“(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 covered countermeasure 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 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.

“(b) VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to vaccinate individuals that is approved by the Secretary establishes procedures to ensure, consistent with the Declaration and any applicable guidelines of the Centers for Disease Control and Prevention, that—

“(1) potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part;

“(2) there is voluntary screening provided to potential participants that can identify health conditions relevant to contraindications; and

“(3) there is appropriate post-inoculation medical surveillance that includes an evaluation of adverse health effects that may reasonably appear to be due to such vaccine and prompt referral of, or the provision of appropriate information to, any individual requiring health care as a result of such adverse health event.

Procedures.
Applicability.

42 USC 239a.

Procedures.

“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; and

“(3) whether the covered injury or injuries of an eligible individual 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 files with the Secretary an initial request for benefits or compensation under this part 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 files with the Secretary an initial request for benefits or compensation under this part not later than two years after the date of the first symptom or manifestation of onset of the adverse effect.

“(e) **STRUCTURED SETTLEMENTS AT SECRETARY’S OPTION.**—In any case in which there is a reasonable likelihood that compensation or payment under section 264, 265, or 266(b) will be required for a period in excess of one year from the date an individual is determined eligible for such compensation or payment, the Secretary shall have the discretion to make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total amount of benefits or compensation that the individual is eligible to receive under such section or sections.

“(f) **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. The Secretary shall develop a process by which an individual may file a request for reconsideration of any determination made by the Secretary under this section.

“(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.

42 USC 239b.

“(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.

Regulations.

“(2) AMENDMENTS.—The Secretary may by regulation amend the table established under paragraph (1). An amendment to the table takes effect on the date of the promulgation of the final rule that makes the amendment, and applies to all requests for benefits or compensation under this part that are filed on or after such date or are pending as of such date. In addition, the amendment applies retroactively to an individual who was not with respect to the injury involved an eligible individual under the table as in effect before the amendment but who with respect to such injury is an eligible individual under the table as amended. With respect to a request for benefits or compensation under this part by an individual who becomes an eligible individual as described in the preceding sentence, the Secretary may not provide such benefits or compensation unless the request (or amendment to a request, as applicable) is filed before the expiration of one year after the effective date of the amendment to the table in the case of an individual to whom the vaccine was administered and before the expiration of two years after such effective date in the case of a request based on accidental vaccinia inoculation.

“SEC. 264. MEDICAL BENEFITS.

42 USC 239c.

“(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, including the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation.

“(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.

42 USC 239d.

“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 (based on such income at the time of injury) incurred as a result of a covered injury, at the rate specified in subsection (b).

“(b) AMOUNT OF COMPENSATION.—

“(1) IN GENERAL.—Compensation under subsection (a) shall be at the rate of $66\frac{2}{3}$ percent of the relevant pay period (weekly, monthly, or otherwise), except as provided in paragraph (2).

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

“(3) CONSIDERATION OF OTHER PROGRAMS.—

“(A) IN GENERAL.—The Secretary may consider the provisions of sections 8114, 8115, and 8146a of title 5, United States Code, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

“(B) MINORS.—With respect to an eligible individual who is a minor, the Secretary may consider the provisions of section 8113 of title 5, United States Code, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

“(4) 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.—

“(A) IN GENERAL.—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 or to provide disability or retirement benefits.

“(B) RELATION TO OTHER OBLIGATIONS.—Compensation under subsection (a) shall not be made to an eligible individual to the extent that the total of amounts paid to the individual under such subsection and under the other obligations referred to in subparagraph (A) is an amount that exceeds the rate specified in subsection (b)(1). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this paragraph, be deemed to be received over multiple years rather than

received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

“(2) NO BENEFITS IN CASE OF DEATH.—No payment shall be made under subsection (a) in compensation for loss of employment income subsequent to the receipt, by the survivor or survivors of an eligible individual, of benefits under section 266 for death.

“(3) LIMIT ON TOTAL BENEFITS.—

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

“(i) total compensation paid to an individual under subsection (a) shall not exceed \$50,000 for any year; and

“(ii) the lifetime total of such compensation for the individual may not exceed an amount equal to the amount authorized to be paid under section 266.

“(B) PERMANENT AND TOTAL DISABILITY.—The limitation under subparagraph (A)(ii) does not apply in the case of 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)).

“(4) WAITING PERIOD.—

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

“(B) EXCEPTION.—Subparagraph (A) does not apply if the period of loss of employment income of an eligible individual is 10 or more work days.

“(5) TERMINATION OF BENEFITS.—No payment shall be made under subsection (a) in compensation for loss of employment income once the eligible individual involves reaches the age of 65.

“(d) BENEFIT IN ADDITION TO MEDICAL BENEFITS.—A benefit under subsection (a) shall be in addition to any amounts received by an eligible individual under section 264.

“SEC. 266. PAYMENT FOR DEATH.

42 USC 239e.

“(a) DEATH BENEFIT.—

“(1) IN GENERAL.—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 paragraph (2) to the survivor or survivors in the same manner as death benefits are paid pursuant to the Public Safety Officers’ Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) 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).

“(2) BENEFIT AMOUNT.—

“(A) IN GENERAL.—The amount of the death benefit under paragraph (1) in a fiscal year shall equal the amount of the comparable benefit calculated under the Public Safety Officers’ Benefits Program under subpart 1 of part

L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) in such fiscal year, without regard to any reduction attributable to a limitation on appropriations, but subject to subparagraph (B).

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

“(3) LIMITATIONS.—

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

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

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

“(B) 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 Public Safety Officers’ Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) are reduced because of a limitation on appropriations, and such reduction would affect the amount that would be payable under subparagraph (A) without regard to this subparagraph, benefits shall be available under paragraph (1) to the extent necessary to ensure that the survivor or survivors of such individual receives a total amount equal to the amount described in paragraph (2).

“(b) ELECTION IN CASE OF DEPENDENTS.—

“(1) IN GENERAL.—In the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, if the individual had one or more dependents under the age of 18, the legal guardian of the dependents may, in lieu of the death benefit under subsection (a), elect to receive on behalf of the aggregate of such dependents payments in accordance with this subsection. An election under the preceding sentence is effective in lieu of a request under subsection (a) by an individual who is not the legal guardian of such dependents.

“(2) AMOUNT OF PAYMENTS.—Payments under paragraph (1) with respect to an eligible individual described in such paragraph shall be made as if such individual were an eligible individual to whom compensation would be paid under subsection (a) of section 265, with the rate augmented in accordance with subsection (b)(2) of such section and with such individual considered to be an eligible individual described in subsection (c)(3)(B) of such section.

“(3) LIMITATIONS.—

“(A) AGE OF DEPENDENTS.—No payments may be made under paragraph (1) once the youngest of the dependents involved reaches the age of 18.

“(B) BENEFITS SECONDARY TO OTHER COVERAGE.—

“(i) IN GENERAL.—Any payment under paragraph (1) 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 or to provide disability benefits, retirement benefits, life insurance benefits on behalf of dependents under the age of 18, or death benefits.

“(ii) RELATION TO OTHER OBLIGATIONS.—Payments under paragraph (1) shall not be made to with respect to an eligible individual to the extent that the total of amounts paid with respect to the individual under such paragraph and under the other obligations referred to in clause (i) is an amount that exceeds the rate of payment that applies under paragraph (2). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this subparagraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

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

“SEC. 267. ADMINISTRATION.

42 USC 239f.

“(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. AUTHORIZATION OF APPROPRIATIONS.

42 USC 239g.

“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. The Secretary’s payment of any benefit under section 264, 265, or 266 shall be subject to the availability of appropriations under this section.

“SEC. 269. RELATIONSHIP TO OTHER LAWS.

42 USC 239h.

“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 COUNTER-MEASURES.

(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 exhausted such remedies as are available under part C of this title, except that if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of such part within 240 days after such request was filed, the individual may seek any remedy that may be available under this section.

“(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 request for benefits or compensation under part C of this title.

“(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 42 USC 233 note. November 25, 2002.

Approved April 30, 2003.

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