109TH CONGRESS
2D SESSION

S. 2291

To provide for the establishment of a biodefense injury compensation program and to provide indemnification for producers of countermeasures.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2006

Mr. KENNEDY (for himself, Mr. DODD, Mr. HARKIN, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To provide for the establishment of a biodefense injury compensation program and to provide indemnification for producers of countermeasures.

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 ''Responsible Public Readiness and Emergency Preparedness Act''.

SEC. 2. REPEAL.

The Public Readiness and Emergency Preparedness Act (division C of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in

the Gulf of Mexico, and Pandemic Influenza Act, 2006 (Public Law 109–148)) is repealed.

SEC. 3. NATIONAL BIODEFENSE INJURY COMPENSATION PROGRAM.

(a) ESTABLISHMENT.—Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

''(q) BIODEFENSE INJURY COMPENSATION PROGRAM.—

''(1) ESTABLISHMENT.—There is established the Biodefense Injury Compensation Program (referred to in this subsection as the 'Compensation Program') under which compensation may be paid for death or any injury, illness, disability, or condition that is likely (based on best available evidence) to have been caused by the administration of a covered countermeasure to an individual pursuant to a declaration under subsection (p)(2).

''(2) ADMINISTRATION AND INTERPRETATION.—The statutory provisions governing the Compensation Program shall be administered and interpreted in consideration of the program goals described in paragraph (4)(B)(iii).

''(3) PROCEDURES AND STANDARDS.—The Secretary shall by regulation establish procedures and

standards applicable to the Compensation Program that follow the procedures and standards applicable under the National Vaccine Injury Compensation Program established under section 2110, except that the regulations promulgated under this paragraph shall permit a person claiming injury or death related to the administration of any covered countermeasure to file either—

''(A) a civil action for relief under subsection (p); or

''(B) a petition for compensation under this subsection.

''(4) INJURY TABLE.—

''(A) INCLUSION.—For purposes of receiving compensation under the Compensation Program with respect to a countermeasure that is the subject of a declaration under subsection (p)(2), the Vaccine Injury Table under section 2114 shall be deemed to include death and the injuries, disabilities, illnesses, and conditions specified by the Secretary under subparagraph (B)(ii).

''(B) INJURIES, DISABILITIES, ILLNESSES, AND CONDITIONS.—

"(i) INSTITUTE OF MEDICINE.—Not later than 30 days after making a declaration described in subsection (p)(2), the Secretary shall enter into a contract with the Institute of Medicine, under which the Institute shall, within 180 days of the date on which the contract is entered into, and periodically thereafter as new information, including information derived from the monitoring of those who were administered the countermeasure, becomes available, provide its expert recommendations on the injuries, disabilities, illnesses, and conditions whose occurrence in one or more individuals are likely (based on best available evidence) to have been caused by the administration of a countermeasure that is the subject of the declaration.

"(ii) SPECIFICATION BY SECRETARY.—Not later than 30 days after the receipt of the expert recommendations described in clause (i), the Secretary shall, based on such recommendations, specify those injuries, disabilities, illnesses, and conditions deemed to be included in the

Vaccine Injury Table under section 2114 for the purposes described in subparagraph (A).

''(iii) PROGRAM GOALS.—The Institute of Medicine, under the contract under clause (i), shall make such recommendations, the Secretary shall specify, under clause (ii), such injuries, disabilities, illnesses, and conditions, and claims under the Compensation Program under this subsection shall be processed and decided taking into account the following goals of such program:

''(I) To encourage persons to develop, manufacture, and distribute countermeasures, and to administer covered countermeasures to individuals, by limiting such persons' liability for damages related to death and such injuries, disabilities, illnesses, and conditions.

''(II) To encourage individuals to consent to the administration of a covered countermeasure by providing adequate and just compensation for

damages related to death and such injuries, disabilities, illnesses, or conditions.

"(III) To provide individuals seeking compensation for damages related to the administration of a countermeasure with a non-adversarial administrative process for obtaining adequate and just compensation.

"(iv) USE OF BEST AVAILABLE EVIDENCE.—The Institute of Medicine, under the contract under clause (i), shall make such recommendations, the Secretary shall specify, under clause (ii), such injuries, disabilities, illnesses, and conditions, and claims under the Compensation Program under this subsection shall be processed and decided using the best available evidence, including information from adverse event reporting or other monitoring of those individuals who were administered the countermeasure, whether evidence from clinical trials or other scientific studies in humans is available.

"(v) APPLICATION OF SECTION 2115.—With respect to section 2115(a)(2) as applied for purposes of this subsection, an award for the estate of the deceased shall be—

"(I) if the deceased was under the age of 18, an amount equal to the amount that may be paid to a survivor or survivors as death benefits 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) if the deceased was 18 years of age or older, the greater of—

"(aa) the amount described in subclause (I); or

"(bb) the projected loss of employment income, except that the amount under this item may not exceed an amount equal to 400 percent of the amount that applies under item (aa).

''(vi) APPLICATION OF SECTION 2116.—Section 2116(b) shall apply to injuries, disabilities, illnesses, and conditions initially specified or revised by the Secretary under clause (ii), except that the exceptions contained in paragraphs (1) and (2) of such section shall not apply.

''(C) RULE OF CONSTRUCTION.—Section 13632 (a)(3) of Public Law 103–66 (107 Stat. 646) (making revisions by Secretary to the Vaccine Injury Table effective on the effective date of a corresponding tax) shall not be construed to apply to any revision to the Vaccine Injury Table made under regulations under this paragraph.

''(5) APPLICATION.—The Compensation Program applies to any death or injury, illness, disability, or condition that is likely (based on best available evidence) to have been caused by the administration of a covered countermeasure to an individual pursuant to a declaration under subsection (p)(2).

''(6) SPECIAL MASTERS.—

''(A) HIRING.—In accordance with section 2112, the judges of the United States Claims

Court shall appoint a sufficient number of special masters to address claims for compensation under this subsection.

''(B) BUDGET AUTHORITY.—There are appropriated to carry out this subsection such sums as may be necessary for fiscal year 2006 and each fiscal year thereafter. This subparagraph constitutes budget authority in advance of appropriations and represents the obligation of the Federal Government.

''(7) COVERED COUNTERMEASURE.—For purposes of this subsection, the term 'covered countermeasure' has the meaning given to such term in subsection (p)(7)(A).

''(8) FUNDING.—Compensation made under the Compensation Program shall be made from the same source of funds as payments made under subsection (p).''.

(b) EFFECTIVE DATE.—This section shall take effect as of November 25, 2002 (the date of enactment of the Homeland Security Act of 2002 (Public Law 107–296; 116 Stat. 2135)).

SEC. 4. INDEMNIFICATION FOR MANUFACTURERS AND HEALTH CARE PROFESSIONALS WHO ADMINISTER MEDICAL PRODUCTS NEEDED FOR BIODEFENSE.

Section 224(p) of the Public Health Service Act (42 U.S.C. 233(p)) is amended—

(1) in the subsection heading by striking ''SMALLPOX'';

(2) in paragraph (1), by striking ''against smallpox'';

(3) in paragraph (2)—

(A) in the paragraph heading, by striking ''AGAINST SMALLPOX''; and

(B) in subparagraph (B), by striking clause (ii);

(4) by striking paragraph (3) and inserting the following:

''(3) EXCLUSIVITY; OFFSET.—

''(A) EXCLUSIVITY.—With respect to an individual to which this subsection applies, such individual may bring a claim for relief under—

''(i) this subsection;

''(ii) subsection (q); or

''(iii) part C.

''(B) ELECTION OF ALTERNATIVES.—An individual may only pursue one remedy under

subparagraph (A) at any one time based on the same incident or series of incidents. An individual who elects to pursue the remedy under subsection (q) or part C may decline any compensation awarded with respect to such remedy and subsequently pursue the remedy provided for under this subsection. An individual who elects to pursue the remedy provided for under this subsection may not subsequently pursue the remedy provided for under subsection (q) or part C.

''(C) STATUTE OF LIMITATIONS.—For purposes of determining how much time has lapsed when applying statute of limitations requirements relating to remedies under subparagraph (A), any limitation of time for commencing an action, or filing an application, petition, or claim for such remedies, shall be deemed to have been suspended for the periods during which an individual pursues a remedy under such subparagraph.

''(D) OFFSET.—The value of all compensation and benefits provided under subsection (q) or 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.'';

(5) in paragraph (6)—

(A) in subparagraph (A), by inserting ''or under subsection (q) or part C'' after ''under this subsection''; and

(B) by redesignating subparagraph (B) as subparagraph (C);

(C) by inserting after subparagraph (A), the following:

''(B) GROSSLY NEGLIGENT, RECKLESS, OR ILLEGAL CONDUCT AND WILLFUL MISCONDUCT.—For purposes of subparagraph (A), grossly negligent, reckless, or illegal conduct or willful misconduct shall include the administration by a qualified person of a covered countermeasure to an individual who was not within a category of individuals covered by a declaration under subsection (p)(2) with respect to such countermeasure where the qualified person fails to have had reasonable grounds to believe such individual was within such a category.''; and

(D) by adding at the end the following:

''(D) LIABILITY OF THE UNITED STATES.—The United States shall be liable under this subsection with respect to a claim arising out of the manufacture, distribution, or administration of a covered countermeasure regardless of whether—

''(i) the cause of action seeking compensation is alleged as negligence, strict liability, breach of warranty, failure to warn, or other action; or

''(ii) the covered countermeasure is designated as a qualified anti-terrorism technology under the SAFETY Act (6 U.S.C. 441 et seq.).''

''(E) GOVERNING LAW.—Notwithstanding the provisions of section 1346(b)(1) and chapter 171 of title 28, United States Code, as they relate to governing law, the liability of the United States as provided in this subsection shall be in accordance with the law of the place of injury.

''(F) MILITARY PERSONNEL AND UNITED STATES CITIZENS OVERSEAS.—

''(i) MILITARY PERSONNEL.—The liability of the United States as provided in

this subsection shall extend to claims brought by United States military personnel.

''(ii) CLAIMS ARISING IN A FOREIGN COUNTRY.—Notwithstanding the provisions of section 2680(k) of title 28, United States Code, the liability of the United States as provided for in the subsection shall extend to claims based on injuries arising in a foreign country where the injured party is a member of the United States military, is the spouse or child of a member of the United States military, or is a United States citizen.

''(iii) GOVERNING LAW.—With regard to all claims brought under clause (ii), and notwithstanding the provisions of section 1346(b)(1) and chapter 171 of title 28, United States Code, and of subparagraph (C), as they relate to governing law, the liability of the United States as provided in this subsection shall be in accordance with the law of the claimant's domicile in the United States or most recent domicile with the United States.''; and

(6) in paragraph (7)—

(A) by striking subparagraph (A) and inserting the following:

"(A) COVERED COUNTERMEASURE.—The term 'covered countermeasure', means—

"(i) a substance that is—

"(I)(aa) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

"(bb) vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and

"(II) specified in a declaration under paragraph (2); or

"(ii) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act), biological product (as such term is defined in section 351(i) of this Act), or device (as such term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) that—

"(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to treat, iden-

tify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

''(II) is—

''(aa) authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act, so long as the manufacturer of such drug, biological product, or device has—

''(AA) made all reasonable efforts to obtain applicable approval, clearance, or licensure; and

''(BB) cooperated fully with the requirements of the

Secretary under such section 564; or

"(bb) approved or licensed solely pursuant to the regulations under subpart I of part 314 or under subpart H of part 601 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the National Biodefense Act of 2005); and

"(III) is specified in a declaration under paragraph (2)."; and

(B) in subparagraph (B)—

(i) by striking clause (ii), and inserting the following:

"(ii) a health care entity, a State, or a political subdivision of a State under whose auspices such countermeasure was administered;" and

(vi) in clause (viii), by inserting before the period "if such individual performs a function for which a person described in clause (i), (ii), or (iv) is a covered person".

○