

Calendar No. 658109TH CONGRESS
2^D SESSION**S. 3983**

To amend the Public Health Service Act to provide assured compensation for first responders injured by experimental vaccines and drugs and to indemnify manufacturers and health care professionals for the administration of medical products needed for biodefense.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2006

Mr. KENNEDY introduced the following bill; which was read the first time

SEPTEMBER 30 (legislative day, SEPTEMBER 29), 2006

Read the second time and placed on the calendar

A BILL

To amend the Public Health Service Act to provide assured compensation for first responders injured by experimental vaccines and drugs and to indemnify manufacturers and health care professionals for the administration of medical products needed for biodefense.

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 “Responsible Public
5 Readiness and Emergency Preparedness Act”.

1 **SEC. 2. ASSURED COMPENSATION FOR FIRST RESPONDERS**
2 **INJURED BY EXPERIMENTAL VACCINES AND**
3 **DRUGS.**

4 (a) REPEAL.—The Public Readiness and Emergency
5 Preparedness Act (division C of the Department of De-
6 fense, Emergency Supplemental Appropriations to Ad-
7 dress Hurricanes in the Gulf of Mexico, and Pandemic In-
8 fluenza Act, 2006 (Public Law 109–148)) is repealed.

9 (b) NATIONAL BIODEFENSE INJURY COMPENSATION
10 PROGRAM.—

11 (1) ESTABLISHMENT.—Section 224 of the Pub-
12 lic Health Service Act (42 U.S.C. 233) is amended
13 by adding at the end the following:

14 “(q) BIODEFENSE INJURY COMPENSATION PRO-
15 GRAM.—

16 “(1) ESTABLISHMENT.—There is established
17 the Biodefense Injury Compensation Program (re-
18 ferred to in this subsection as the ‘Compensation
19 Program’) under which compensation may be paid
20 for death or any injury, illness, disability, or condi-
21 tion that is likely (based on best available evidence)
22 to have been caused by the administration of a cov-
23 ered countermeasure to an individual pursuant to a
24 declaration under subsection (p)(2).

25 “(2) ADMINISTRATION AND INTERPRETA-
26 TION.—The statutory provisions governing the Com-

1 pensation Program shall be administered and inter-
2 preted in consideration of the program goals de-
3 scribed in paragraph (4)(B)(iii).

4 “(3) PROCEDURES AND STANDARDS.—The Sec-
5 retary shall by regulation establish procedures and
6 standards applicable to the Compensation Program
7 that follow the procedures and standards applicable
8 under the National Vaccine Injury Compensation
9 Program established under section 2110, except that
10 the regulations promulgated under this paragraph
11 shall permit a person claiming injury or death re-
12 lated to the administration of any covered counter-
13 measure to file either—

14 “(A) a civil action for relief under sub-
15 section (p); or

16 “(B) a petition for compensation under
17 this subsection.

18 “(4) INJURY TABLE.—

19 “(A) INCLUSION.—For purposes of receiv-
20 ing compensation under the Compensation Pro-
21 gram with respect to a countermeasure that is
22 the subject of a declaration under subsection
23 (p)(2), the Vaccine Injury Table under section
24 2114 shall be deemed to include death and the
25 injuries, disabilities, illnesses, and conditions

1 specified by the Secretary under subparagraph
2 (B)(ii).

3 “(B) INJURIES, DISABILITIES, ILLNESSES,
4 AND CONDITIONS.—

5 “(i) INSTITUTE OF MEDICINE.—Not
6 later than 30 days after making a declara-
7 tion described in subsection (p)(2), the
8 Secretary shall enter into a contract with
9 the Institute of Medicine, under which the
10 Institute shall, within 180 days of the date
11 on which the contract is entered into, and
12 periodically thereafter as new information,
13 including information derived from the
14 monitoring of those who were administered
15 the countermeasure, becomes available,
16 provide its expert recommendations on the
17 injuries, disabilities, illnesses, and condi-
18 tions whose occurrence in one or more in-
19 dividuals are likely (based on best available
20 evidence) to have been caused by the ad-
21 ministration of a countermeasure that is
22 the subject of the declaration.

23 “(ii) SPECIFICATION BY SEC-
24 RETARY.—Not later than 30 days after the
25 receipt of the expert recommendations de-

1 scribed in clause (i), the Secretary shall,
2 based on such recommendations, specify
3 those injuries, disabilities, illnesses, and
4 conditions deemed to be included in the
5 Vaccine Injury Table under section 2114
6 for the purposes described in subparagraph
7 (A).

8 “(iii) PROGRAM GOALS.—The Insti-
9 tute of Medicine, under the contract under
10 clause (i), shall make such recommenda-
11 tions, the Secretary shall specify, under
12 clause (ii), such injuries, disabilities, ill-
13 nesses, and conditions, and claims under
14 the Compensation Program under this sub-
15 section shall be processed and decided tak-
16 ing into account the following goals of such
17 program:

18 “(I) To encourage persons to de-
19 velop, manufacture, and distribute
20 countermeasures, and to administer
21 covered countermeasures to individ-
22 uals, by limiting such persons’ liability
23 for damages related to death and such
24 injuries, disabilities, illnesses, and
25 conditions.

1 “(II) To encourage individuals to
2 consent to the administration of a
3 covered countermeasure by providing
4 adequate and just compensation for
5 damages related to death and such in-
6 juries, disabilities, illnesses, or condi-
7 tions.

8 “(III) To provide individuals
9 seeking compensation for damages re-
10 lated to the administration of a coun-
11 termeasure with a non-adversarial ad-
12 ministrative process for obtaining ade-
13 quate and just compensation.

14 “(iv) USE OF BEST AVAILABLE EVI-
15 DENCE.—The Institute of Medicine, under
16 the contract under clause (i), shall make
17 such recommendations, the Secretary shall
18 specify, under clause (ii), such injuries,
19 disabilities, illnesses, and conditions, and
20 claims under the Compensation Program
21 under this subsection shall be processed
22 and decided using the best available evi-
23 dence, including information from adverse
24 event reporting or other monitoring of
25 those individuals who were administered

1 the countermeasure, whether evidence from
2 clinical trials or other scientific studies in
3 humans is available.

4 “(v) APPLICATION OF SECTION
5 2115.—With respect to section 2115(a)(2)
6 as applied for purposes of this subsection,
7 an award for the estate of the deceased
8 shall be—

9 “(I) if the deceased was under
10 the age of 18, an amount equal to the
11 amount that may be paid to a sur-
12 vivor or survivors as death benefits
13 under the Public Safety Officers’ Ben-
14 efits Program under subpart 1 of part
15 L of title I of the Omnibus Crime
16 Control and Safe Streets Act of 1968
17 (42 U.S.C. 3796 et seq.); or

18 “(II) if the deceased was 18
19 years of age or older, the greater of—

20 “(aa) the amount described
21 in subclause (I); or

22 “(bb) the projected loss of
23 employment income, except that
24 the amount under this item may
25 not exceed an amount equal to

1 400 percent of the amount that
2 applies under item (aa).

3 “(vi) APPLICATION OF SECTION
4 2116.—Section 2116(b) shall apply to in-
5 juries, disabilities, illnesses, and conditions
6 initially specified or revised by the Sec-
7 retary under clause (ii), except that the ex-
8 ceptions contained in paragraphs (1) and
9 (2) of such section shall not apply.

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

18 “(5) APPLICATION.—The Compensation Pro-
19 gram applies to any death or injury, illness, dis-
20 ability, or condition that is likely (based on best
21 available evidence) to have been caused by the ad-
22 ministration of a covered countermeasure to an indi-
23 vidual pursuant to a declaration under subsection
24 (p)(2).

25 “(6) SPECIAL MASTERS.—

1 “(A) HIRING.—In accordance with section
2 2112, the judges of the United States Claims
3 Court shall appoint a sufficient number of spe-
4 cial masters to address claims for compensation
5 under this subsection.

6 “(B) BUDGET AUTHORITY.—There are ap-
7 propriated to carry out this subsection such
8 sums as may be necessary for fiscal year 2006
9 and each fiscal year thereafter. This subpara-
10 graph constitutes budget authority in advance
11 of appropriations and represents the obligation
12 of the Federal Government.

13 “(7) COVERED COUNTERMEASURE.—For pur-
14 poses of this subsection, the term ‘covered counter-
15 measure’ has the meaning given to such term in sub-
16 section (p)(7)(A).

17 “(8) FUNDING.—Compensation made under the
18 Compensation Program shall be made from the same
19 source of funds as payments made under subsection
20 (p).”.

21 “(2) EFFECTIVE DATE.—This subsection shall
22 take effect as of November 25, 2002 (the date of en-
23 actment of the Homeland Security Act of 2002
24 (Public Law 107–296; 116 Stat. 2135)).

1 **SEC. 3. INDEMNIFICATION FOR MANUFACTURERS AND**
2 **HEALTH CARE PROFESSIONALS WHO ADMIN-**
3 **ISTER MEDICAL PRODUCTS NEEDED FOR**
4 **BIODEFENSE.**

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

7 (1) in the subsection heading by striking
8 “SMALLPOX”;

9 (2) in paragraph (1), by striking “against
10 smallpox”;

11 (3) in paragraph (2)—

12 (A) in the paragraph heading, by striking
13 “AGAINST SMALLPOX”; and

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

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

18 “(3) EXCLUSIVITY; OFFSET.—

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

22 “(i) this subsection;

23 “(ii) subsection (q); or

24 “(iii) part C.

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

1 subparagraph (A) at any one time based on the
2 same incident or series of incidents. An indi-
3 vidual who elects to pursue the remedy under
4 subsection (q) or part C may decline any com-
5 pensation awarded with respect to such remedy
6 and subsequently pursue the remedy provided
7 for under this subsection. An individual who
8 elects to pursue the remedy provided for under
9 this subsection may not subsequently pursue
10 the remedy provided for under subsection (q) or
11 part C.

12 “(C) STATUTE OF LIMITATIONS.—For pur-
13 poses of determining how much time has lapsed
14 when applying statute of limitations require-
15 ments relating to remedies under subparagraph
16 (A), any limitation of time for commencing an
17 action, or filing an application, petition, or
18 claim for such remedies, shall be deemed to
19 have been suspended for the periods during
20 which an individual pursues a remedy under
21 such subparagraph.

22 “(D) OFFSET.—The value of all compensa-
23 tion and benefits provided under subsection (q)
24 or part C of this title for an incident or series
25 of incidents shall be offset against the amount

1 of an award, compromise, or settlement of
2 money damages in a claim or suit under this
3 subsection based on the same incident or series
4 of incidents.”;

5 (5) in paragraph (6)—

6 (A) in subparagraph (A), by inserting “or
7 under subsection (q) or part C” after “under
8 this subsection”; and

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

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

13 “(B) GROSSLY NEGLIGENT, RECKLESS, OR
14 ILLEGAL CONDUCT AND WILLFUL MIS-
15 CONDUCT.—For purposes of subparagraph (A),
16 grossly negligent, reckless, or illegal conduct or
17 willful misconduct shall include the administra-
18 tion by a qualified person of a covered counter-
19 measure to an individual who was not within a
20 category of individuals covered by a declaration
21 under subsection (p)(2) with respect to such
22 countermeasure where the qualified person fails
23 to have had reasonable grounds to believe such
24 individual was within such a category.”; and

25 (D) by adding at the end the following:

1 “(D) LIABILITY OF THE UNITED
2 STATES.—The United States shall be liable
3 under this subsection with respect to a claim
4 arising out of the manufacture, distribution, or
5 administration of a covered countermeasure re-
6 gardless of whether—

7 “(i) the cause of action seeking com-
8 pensation is alleged as negligence, strict li-
9 ability, breach of warranty, failure to warn,
10 or other action; or

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

15 “(E) GOVERNING LAW.—Notwithstanding
16 the provisions of section 1346(b)(1) and chap-
17 ter 171 of title 28, United States Code, as they
18 relate to governing law, the liability of the
19 United States as provided in this subsection
20 shall be in accordance with the law of the place
21 of injury.

22 “(F) MILITARY PERSONNEL AND UNITED
23 STATES CITIZENS OVERSEAS.—

24 “(i) MILITARY PERSONNEL.—The li-
25 ability of the United States as provided in

1 this subsection shall extend to claims
2 brought by United States military per-
3 sonnel.

4 “(ii) CLAIMS ARISING IN A FOREIGN
5 COUNTRY.—Notwithstanding the provisions
6 of section 2680(k) of title 28, United
7 States Code, the liability of the United
8 States as provided for in the subsection
9 shall extend to claims based on injuries
10 arising in a foreign country where the in-
11 jured party is a member of the United
12 States military, is the spouse or child of a
13 member of the United States military, or is
14 a United States citizen.

15 “(iii) GOVERNING LAW.—With regard
16 to all claims brought under clause (ii), and
17 notwithstanding the provisions of section
18 1346(b)(1) and chapter 171 of title 28,
19 United States Code, and of subparagraph
20 (C), as they relate to governing law, the li-
21 ability of the United States as provided in
22 this subsection shall be in accordance with
23 the law of the claimant’s domicile in the
24 United States or most recent domicile with
25 the United States.”; and

1 (6) in paragraph (7)—

2 (A) by striking subparagraph (A) and in-
3 serting the following:

4 “(A) COVERED COUNTERMEASURE.—The
5 term ‘covered countermeasure’, means—

6 “(i) a substance that is—

7 “(I)(aa) used to prevent or treat
8 smallpox (including the vaccinia or
9 another vaccine); or

10 “(bb) vaccinia immune globulin
11 used to control or treat the adverse
12 effects of vaccinia inoculation; and

13 “(II) specified in a declaration
14 under paragraph (2); or

15 “(ii) a drug (as such term is defined
16 in section 201(g)(1) of the Federal Food,
17 Drug, and Cosmetic Act), biological prod-
18 uct (as such term is defined in section
19 351(i) of this Act), or device (as such term
20 is defined in section 201(h) of the Federal
21 Food, Drug, and Cosmetic Act) that—

22 “(I) the Secretary determines to
23 be a priority (consistent with sections
24 302(2) and 304(a) of the Homeland
25 Security Act of 2002) to treat, iden-

1 tify, or prevent harm from any bio-
2 logical, chemical, radiological, or nu-
3 clear agent identified as a material
4 threat under section 319F-
5 2(c)(2)(A)(ii), or to treat, identify, or
6 prevent harm from a condition that
7 may result in adverse health con-
8 sequences or death and may be caused
9 by administering a drug, biological
10 product, or device against such an
11 agent;

12 “(II) is—

13 “(aa) authorized for emer-
14 gency use under section 564 of
15 the Federal Food, Drug, and
16 Cosmetic Act, so long as the
17 manufacturer of such drug, bio-
18 logical product, or device has—

19 “(AA) made all reasonable
20 efforts to obtain applicable ap-
21 proval, clearance, or licensure;
22 and

23 “(BB) cooperated fully with
24 the requirements of the Secretary
25 under such section 564; or

1 “(bb) approved or licensed
2 solely pursuant to the regulations
3 under subpart I of part 314 or
4 under subpart H of part 601 of
5 title 21, Code of Federal Regula-
6 tions (as in effect on the date of
7 enactment of the National Bio-
8 defense Act of 2005); and
9 “(III) is specified in a declaration
10 under paragraph (2).”; and
11 (B) in subparagraph (B)—
12 (i) by striking clause (ii), and insert-
13 ing the following:
14 “(ii) a health care entity, a State, or
15 a political subdivision of a State under
16 whose auspices such countermeasure was
17 administered;”and
18 (ii) in clause (viii), by inserting before
19 the period “if such individual performs a
20 function for which a person described in
21 clause (i), (ii), or (iv) is a covered person”.

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A BILL

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