

109TH CONGRESS
1ST SESSION

S. 1437

To amend the Public Health Service Act to provide protections for first responders.

IN THE SENATE OF THE UNITED STATES

JULY 20, 2005

Mr. GREGG introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide protections for first responders.

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 “Bioterror and Pan-
5 demic Preparedness Protection Act”.

6 **SEC. 2. LIABILITY PROTECTIONS FOR PANDEMICS,**
7 **EPIDEMICS, AND COUNTERMEASURES.**

8 Part B of title III of the Public Health Service Act
9 is amended by inserting after section 319F–2 (42 U.S.C.
10 247d–6b) the following:

1 “(i) an action may be commenced
2 solely and exclusively against the United
3 States for claims identified in subpara-
4 graph (A) that are against a manufac-
5 turer, distributor, or health care provider;

6 “(ii) no cause of action shall be main-
7 tained against a manufacturer, distributor,
8 or health care provider for claims identified
9 in subparagraph (A); and

10 “(iii) for products subject to designa-
11 tion by the Secretary as provided for in
12 clause (ii) of paragraph (2)(B), the protec-
13 tions set forth in clauses (i) and (ii) shall
14 apply to all claims identified in subpara-
15 graph (A) that involve products sold, pur-
16 chased, donated, dispensed, or adminis-
17 tered during the effective period set forth
18 in the designation provided for in para-
19 graph (2)(F), regardless of the date of al-
20 leged injury.

21 “(C) JURISDICTION.—The United States
22 District Court for the District of Columbia shall
23 have sole and exclusive jurisdiction over any
24 claim for loss of property, personal injury, or
25 death arising out of, relating to, or resulting

1 from the design, development, clinical testing
2 and investigation, manufacture, labeling, dis-
3 tribution, sale, purchase, donation, dispensing,
4 administration, or use of a qualified pandemic
5 or epidemic product or security countermeasure
6 as provided for in clauses (i) and (ii) of para-
7 graph (2)(B).

8 “(2) AFFIRMATIVE DEFENSE.—

9 “(A) IN GENERAL.—There shall be a re-
10 buttable presumption that the Federal Govern-
11 ment is immune from liability in an action de-
12 scribed in subparagraph (B).

13 “(B) ACTION DESCRIBED.—An action de-
14 scribed in this subparagraph is an action that
15 is commenced against the United States for
16 claims arising out of, relating to, or resulting
17 from the design, development, clinical testing
18 and investigation, manufacture, labeling, dis-
19 tribution, sale, purchase, donation, dispensing,
20 administration, or use of—

21 “(i) a security countermeasure that
22 has been procured for the National Stra-
23 tegic Stockpile under section 319F–2 or a
24 qualified pandemic or epidemic product

1 that has been procured by the Secretary;
2 or

3 “(ii) a security countermeasure or
4 qualified pandemic or epidemic product in
5 anticipation of and preparation for, in de-
6 fense against, or in response or recovery to
7 an actual or potential public health emer-
8 gency, that is a security countermeasure or
9 is designated as a qualified pandemic or
10 epidemic product by the Secretary after
11 the Secretary declared a public health
12 emergency as described in paragraph (1)
13 or (2) of section 319(a).

14 “(C) REBUTTABILITY.—

15 “(i) IN GENERAL.—The presumption
16 described in subparagraph (A) shall be
17 overcome by a determination by the Sec-
18 retary as provided for in subparagraph
19 (D).

20 “(ii) INVESTIGATION BY SEC-
21 RETARY.—A party seeking a determination
22 under subparagraph (D) may petition the
23 Secretary to investigate claims against a
24 manufacturer, distributor, dispenser, or
25 health care provider arising out of, relating

1 to, or resulting from the design, develop-
2 ment, clinical testing and investigation,
3 manufacture, labeling, distribution, sale,
4 purchase, donation, dispensing, administra-
5 tion, or use of products as provided for in
6 clauses (i) and (ii) of subparagraph (B).
7 The decision to undertake such investiga-
8 tion shall be within the Secretary's discre-
9 tion and shall not be subject to judicial re-
10 view.

11 “(D) DETERMINATION BY SECRETARY.—

12 “(i) IN GENERAL.—In making a de-
13 termination under this subparagraph, the
14 Secretary must find clear and convincing
15 evidence that the manufacturer, dis-
16 tributor, or health care provider inten-
17 tionally or with willful disregard violated a
18 provision of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 301 et seq.) or
20 this Act and such violation—

21 “(I) caused the product to
22 present a significant risk to health;
23 and

24 “(II) proximately caused the in-
25 jury alleged by the petitioner.

1 “(ii) NOTICE AND HEARING.—Prior to
2 the Secretary’s making a determination
3 under clause (i), the manufacturer, dis-
4 tributor, dispenser, or health care provider
5 shall have notice and a right to a formal
6 hearing in accordance with section 556 of
7 title 5, United States Code.

8 “(iii) JUDICIAL REVIEW.—At any time
9 prior to the 90th day following a deter-
10 mination by the Secretary under clause (i)
11 of this subparagraph, any manufacturer,
12 distributor, or health care provider who
13 will be adversely affected by such deter-
14 mination may file a petition with the
15 United States Court of Appeals for the cir-
16 cuit wherein such person resides or has his
17 principal place of business, for a judicial
18 review of such determination. A copy of
19 the petition shall be forthwith transmitted
20 by the clerk of the court to the Secretary
21 or other officer designated by the Sec-
22 retary for that purpose. The Secretary
23 thereupon shall file in the court the record
24 of the findings on which the Secretary
25 based his or her determination. The filing

1 of a petition under this clause shall auto-
2 matically stay the Secretary's determina-
3 tion for the duration of the judicial pro-
4 ceeding. The sole parties to the judicial
5 proceeding shall be the Secretary and the
6 petitioner. Intervention by third parties in
7 the judicial proceeding shall not be per-
8 mitted. No subpoenas shall be issued nor
9 shall other compulsory process apply. The
10 court's review of a determination by the
11 Secretary under this clause shall conform
12 to the procedures for judicial review of ad-
13 ministrative orders set forth in paragraphs
14 (2) through (6) of section 371(f) of title
15 21, United States Code, to the extent con-
16 sistent with this section.

17 “(E) SCOPE.—The presumption under
18 subparagraph (A) shall apply regardless of
19 whether the claim against the United States
20 arises from the design, development, clinical
21 testing and investigation, manufacture, labeling,
22 distribution, sale, purchase, donation, dis-
23 pensing, administration, or use by the Federal
24 Government or by non-Federal Government
25 customers.

1 “(F) DESIGNATION.—In any declaration of
2 a public health emergency under section 319,
3 the Secretary shall identify the pandemic, epi-
4 demic, or biological, chemical, nuclear agent, or
5 toxin that presents, or may present, a public
6 health emergency and shall designate the secu-
7 rity countermeasure(s) or qualified pandemic or
8 epidemic product(s) to be sold by, purchased
9 from, or donated by a manufacturer or drawn
10 from the National Strategic Stockpile and shall
11 specify in such designation the beginning and
12 ending dates of such sale, purchase, donation,
13 or use from the stockpile. The period so defined
14 shall be the effective period of such qualifica-
15 tion for any products specified in the designa-
16 tion. The declaration shall subsequently be
17 amended to reflect any additional sale, pur-
18 chase, or donation of products specified in the
19 designation.

20 “(c) DEFINITIONS.—In this section:

21 “(1) HEALTH CARE PROVIDER.—The term
22 ‘health care provider’ means a person, including a
23 volunteer, who lawfully prescribes, administers, dis-
24 penses, or provides a facility to administer a security
25 countermeasure or a qualified pandemic or epidemic

1 product, including persons who prescribe, admin-
2 ister, or provide a facility to administer in accord-
3 ance with a designation under subsection (b)(2)(F).

4 “(2) LOSS.—The term ‘loss’ means death, bod-
5 ily injury, or loss of or damage to property, includ-
6 ing business interruption loss.

7 “(3) NON-FEDERAL GOVERNMENT CUS-
8 TOMERS.—The term ‘non-Federal Government cus-
9 tomers’ means any customer of a manufacturer that
10 is not an agency or instrumentality for the United
11 States Government with authority under Public Law
12 85–804 to provide for indemnification under certain
13 circumstances for third-party claims against its con-
14 tractors, including a State, a local authority, a pri-
15 vate entity, a health care provider, or an individual.

16 “(4) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
17 UCT.—The term ‘qualified pandemic or epidemic
18 product’ means a drug (as such term is defined in
19 section 201(g)(1) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 321(g)(1))), biological
21 product (as such term is defined by section 351(i)
22 of this Act) or device (as such term is defined by
23 section 201(h) of the Federal food, Drug and Cos-
24 metic Act (21 U.S.C. 321(h))) designed, developed,
25 modified, or procured to diagnose, mitigate, prevent,

1 treat, or cure a pandemic or epidemic or limit the
2 harm such pandemic or epidemic might otherwise
3 cause or a serious or life-threatening disease or con-
4 dition caused by such a product, that—

5 “(A) is approved or cleared under chapter
6 V of the Federal Food, Drug, and Cosmetic Act
7 or licensed under section 351 of this Act;

8 “(B) is a product for which the Secretary
9 determines that sufficient and satisfactory clin-
10 ical experience or research data (including data,
11 if available, from pre-clinical and clinical trials)
12 support a reasonable conclusion that the coun-
13 termeasure will qualify for approval or licensing
14 within 8 years after the date the Secretary de-
15 clares a public health emergency as described in
16 paragraph (1) or (2) of section 319(a); or

17 “(C) is authorized by the Secretary under
18 this section, except that the Secretary may au-
19 thorize under this section the emergency use of
20 a product only if, after consultation with the
21 Director of the National Institutes of Health
22 and the Director of the Centers for Disease
23 Control and Prevention (to the extent feasible
24 and appropriate given the circumstances of the
25 emergency involved), the Secretary concludes—

1 “(i) that an agent or toxin identified
2 in a declaration described under subsection
3 (b) can cause a serious or life-threatening
4 disease or condition;

5 “(ii) that, based on the totality of the
6 scientific evidence available to the Sec-
7 retary, including data from adequate and
8 well-controlled clinical trials, if available, it
9 is reasonable to believe that—

10 “(I) the product may be effective
11 in diagnosing, mitigating, preventing,
12 treating or curing—

13 “(aa) a pandemic or epi-
14 demic; or

15 “(bb) a serious or life-
16 threatening disease or condition
17 caused by a product; and

18 “(II) the known and potential
19 benefits of the product, when used to
20 diagnose, mitigate, prevent, treat or
21 cure such disease or condition, out-
22 weigh the known and potential risks
23 of the product;

24 “(iii) that there is no adequate, ap-
25 proved, and available alternative to the

1 product for diagnosing, mitigating, pre-
2 venting, treating or curing such disease or
3 condition; and

4 “(iv) that such other criteria as the
5 Secretary may by regulation prescribe are
6 satisfied.

7 “(5) SECURITY COUNTERMEASURE.—The term
8 ‘security countermeasure’ has the meaning given
9 such term in section 319F-2(c)(1)(B).”.

10 **SEC. 3. TECHNICAL AMENDMENT.**

11 Section 319(a)(1) of the Public Health Service Act
12 (42 U.S.C. 247d (a)(1)) is amended by inserting “, or may
13 present,” after “present”.

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