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109TH CONGRESS
1ST SESSION

H. R. 3970

To amend title 28, United States Code, to provide liability protections for certain pandemics and countermeasures.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 6, 2005

Mr. ISSA introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, 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 amend title 28, United States Code, to provide liability protections for certain pandemics and 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 ''Bioterror and Pandemic Preparedness Protection Act''.

SEC. 2. LIABILITY PROTECTIONS FOR PANDEMICS, EPIDEMICS, AND COUNTERMEASURES.

(a) IN GENERAL.—Part VI of title 28, United States Code, is amended by adding at the end the following new chapter:

"CHAPTER 181—LIABILITY PROTECTION FOR CERTAIN PANDEMICS AND COUNTERMEASURES

"§ 4101. Liability protections for pandemics, epidemics, and security countermeasures

"(a) AUTHORITY.—The Attorney General shall be solely and exclusively responsible for the administration of this section. This section shall apply with respect to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, administration, or use of a security countermeasure or a qualified pandemic or epidemic product.

"(b) LITIGATION MANAGEMENT.—

"(1) FEDERAL CAUSE OF ACTION.—

"(A) IN GENERAL.—There shall exist an exclusive Federal cause of action for all claims for loss of property, personal injury, bodily injury, including mental anguish, or death arising out of, relating to, or resulting from the design,

development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, administration, or use of a qualified pandemic or epidemic product or a security countermeasure as provided for in clauses (i) and (ii) of paragraph (2)(B). Section 1346(b) and Chapter 17 of title 28, United States Code, shall not apply to the cause of action provided for in this paragraph. Such cause of action shall be exclusive of any other civil action or proceeding relating to the same subject matter.

''(B) ACTION.—With respect to the Federal cause of action provided in subparagraph (A)—

''(i) an action may be commenced solely and exclusively against the United States for claims identified in subparagraph (A) that are against a manufacturer, distributor, or health care provider;

''(ii) no cause of action shall be maintained against a manufacturer, distributor, or health care provider for claims identified in subparagraph (A); and

"(iii) if the product is described in paragraph (2)(B)(ii) and is not described in clause (i) of such paragraph, the protections set forth in clauses (i) and (ii) shall apply to all claims identified in subparagraph (A) that involve products sold, purchased, donated, dispensed, or administered during the effective period set forth in the designation provided for in paragraph (2)(F), regardless of the date of alleged injury.

"(C) JURISDICTION.—The United States District Court for the District of Columbia shall have sole and exclusive jurisdiction over any claim for loss of property, personal injury, or death arising out of, relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, administration, or use of a qualified pandemic or epidemic product or security countermeasure as provided for in clauses (i) and (ii) of paragraph (2)(B). The substantive law with respect to a decision in any such action shall be derived from the law, including choice of law principles,

of the State in which such action arose, unless such law is inconsistent with or preempted by Federal law.

''(2) AFFIRMATIVE DEFENSE.—

''(A) IN GENERAL.—Except as provided in subparagraph (C), neither the Federal Government nor a manufacturer, distributor, administrator, or health care provider shall be liable in an action described in subparagraph (B).

''(B) ACTION DESCRIBED.—An action described in this subparagraph is an action that is commenced against the United States for claims arising out of, relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of—

''(i) a security countermeasure that has been procured for or donated to the Strategic National Stockpile under section 319F–2 of the Public Health Service Act or a qualified pandemic or epidemic product that has been procured or donated to the Secretary of Health and Human Services; or

''(ii) a security countermeasure or qualified pandemic or epidemic product distributed, sold, purchased, donated, dispensed, administered, prescribed, or used in anticipation of and preparation for, in defense against, or in response to or recovery from an actual or potential public health emergency, that is a designated security countermeasure or a qualified pandemic or epidemic product by the Secretary of Health and Human Services in a public health emergency as described in paragraph (1) or (2) of section 319(a) of the Public Health Service Act.

''(C) POTENTIAL LIABILITY UPON DETERMINATION.—

''(i) IN GENERAL.—A manufacturer, distributor, administrator, or health care provider may be liable in any action described in subparagraph (B) only if the Attorney General makes a determination as provided for in subparagraph (D).

''(ii) INVESTIGATION BY ATTORNEY GENERAL.—A party seeking a determination under subparagraph (D) may petition

the Attorney General to investigate allegations against a manufacturer, distributor, administrator, or health care provider arising out of, relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, prescribing, dispensing, administration, or use of products as provided for in clauses (i) and (ii) of subparagraph (B). The decision to undertake such investigation shall be within the Attorney General's discretion and shall not be subject to judicial review.

''(D) DETERMINATION BY ATTORNEY GENERAL.—

''(i) IN GENERAL.—In making a determination under this subparagraph, the Attorney General must find clear and convincing evidence that the manufacturer, distributor, administrator, or health care provider intentionally or with willful disregard violated a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act and such violation—

''(I) caused the product to present a significant or unreasonable risk to human health; and

''(II) proximately caused the injury alleged by the party.

''(ii) NOTICE AND HEARING.—Prior to the Attorney General's making a determination under clause (i), the manufacturer, distributor, administrator, or health care provider shall have notice and a right to a formal hearing in accordance with section 556 of title 5, United States Code.

''(iii) EFFECT OF DETERMINATION.—If the Attorney General makes an affirmative determination under clause (i), a case may proceed against a manufacturer, distributor, administrator, or health care provider involved.

''(iv) JUDICIAL REVIEW.—At any time prior to the 90th day following a determination by the Attorney General under clause (i) of this subparagraph, any manufacturer, distributor, administrator, or health care provider named in such determination may file a petition with the

United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such determination. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Attorney General or other officer designated by the Attorney General for that purpose. The Attorney General thereupon shall file in the court the record of the findings on which the Attorney General based his or her determination. The filing of a petition under this clause shall automatically stay the Attorney General's determination for the duration of the judicial proceeding. The sole parties to the judicial proceeding shall be the Attorney General and the petitioner. Intervention by third parties in the judicial proceeding shall not be permitted. No subpoenas shall be issued nor shall other compulsory process apply. The court's review of a determination by the Attorney General under this clause shall conform to the procedures for judicial review of administrative orders set forth in paragraphs (2)

through (6) of section 701(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(f)), to the extent consistent with this section.

''(v) TOLLING OF STATUTE OF LIMITATIONS.—The computation of the statute of limitations for any action against a manufacturer, distributor, administrator, or health care provider described under this subparagraph shall not include any time occurring before the determination by the Attorney General under this subparagraph.

''(E) SCOPE.—Subparagraph (C) shall apply regardless of whether the claim against the United States arises from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use by the Federal Government or by any person.

''(F) DESIGNATION.—In any declaration of a public health emergency under section 319 of the Public Health Service Act, or in a separate declaration under such section, the Secretary of

Health and Human Services may, if necessary, identify the pandemic, epidemic, or biological, chemical, nuclear agent, or toxin that presents, or may present, a public health emergency and shall designate the security countermeasure(s) or qualified pandemic or epidemic product(s) to be sold by, purchased from, or donated by a manufacturer or drawn from the Strategic National Stockpile and shall specify in such designation the beginning and ending dates of such sale, purchase, donation, or use from the stockpile. The period so defined shall be the effective period of such qualification for any products specified in the designation. The declaration shall subsequently be amended to reflect any additional sale, purchase, or donation of products specified in the designation.

''(c) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'administrator' means—

''(A) a person who administers, dispenses, distributes, or otherwise provides a security countermeasure or a qualified pandemic or epidemic product to a person to diagnose, miti-

gate, treat, identify, cure, or prevent harm from—

"(i) a pandemic or epidemic or any biological, chemical, radiological, or nuclear agent; or

"(ii) a serious or life-threatening disease or condition caused by such countermeasure or product; or

"(B) a person that has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to the administration, dispensing, distribution, or provision of a security countermeasure or a qualified pandemic or epidemic product.

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a person, including a volunteer, who lawfully prescribes, administers, dispenses, or provides a facility to administer a security countermeasure or a qualified pandemic or epidemic product, including persons who prescribe, administer, or provide a facility to administer in accordance with a designation under subsection (b)(2)(F).

''(3) LOSS.—The term 'loss' means death, bodily injury, or damage to property, including business interruption loss.

''(4) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term 'qualified pandemic or epidemic product' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as such term is defined by section 351(i) of this Act) or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))) designed, developed, modified, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause or a serious or life-threatening disease or condition caused by such a product, that—

''(A) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act;

''(B) is a product for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials)

support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 8 years after the date the Secretary declares a public health emergency as described in paragraph (1) or (2) of section 319(a) of the Public Health Service Act; or

''(C) is authorized by the Secretary of Health and Human Services under this section, except that the Secretary of Health and Human Services may authorize under thus section the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary of Health and Human Services concludes—

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

''(ii) that, based on the totality of the scientific evidence available to the Secretary of Health and Human Serv-

ices, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

"(I) the product may be effective in diagnosing, mitigating, preventing, treating or curing—

"(aa) a pandemic or epidemic; or

"(bb) a serious or life threatening disease or condition caused by a product;

"(II) the known and potential benefits of the product, when used to diagnose, mitigate, prevent, treat or cure such disease or condition, outweigh the known and potential risks of the product;

"(iii) that there is no adequate, approved, and available alternative to the product for diagnosing, mitigating, preventing, treating, or curing such disease or condition; and

''(iv) that such other criteria as the Secretary of Health and Human Services may by regulation prescribe are satisfied.

''(5) PARTY.—The term 'party' means an individual who can reasonably demonstrate to the Secretary that such individual has suffered a loss (as defined above) as a direct result of the alleged misconduct or illegal activities of a manufacturer, distributor, administrator, or health care provider.

''(6) PERSON.—The term 'person' includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local agency or department.

''(7) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2(c)(1)(B) of the Public Health Service Act.''.

(b) CONFORMING AMENDMENT.—The table of chapters for part VI of title 28, United States Code, is amended by adding after the item relating to chapter 180 the following new item:

''181. Liability protection for certain pandemics and countermeasures ..... 4101''.

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