107TH CONGRESS
1ST SESSION

S. 1635

To ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2001

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

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A BILL

To ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes.

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 ''Pathogen Research, Emergency Preparedness and Response Efforts Act of 2001'' or the ''PREPARE Act''.

SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXVIII—DEVELOPING NEW COUNTERMEASURES AND PROTECTING EXISTING COUNTERMEASURES AGAINST BIOTERRORISM

"SEC. 2801. DEVELOPMENT OF DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES TO COMBAT BIOTERRORISM.

''(a) IDENTIFICATION OF CHEMICAL OR BIOLOGICAL AGENTS OR TOXINS.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense and the Attorney General, shall identify chemical or biological agents or toxins that may be identified, prevented, or treated through—

''(A) the development of new covered products;

''(B) the development of new uses, including pediatric uses, for approved covered products; or

''(C) the manufacture or distribution of covered products that would otherwise not be

manufactured or distributed in sufficient quantities.

''(2) PUBLICATION AND AVAILABILITY.—Not later than 180 days after the date of enactment of this title, and annually thereafter, the Secretary shall publish in the Federal Register, or otherwise make available to manufacturers or potential manufacturers of covered products, a list of the chemical or biological agents and toxins identified under paragraph (1) for which the Secretary desires to encourage the development of, or new uses for, covered products or the manufacture or distribution of such covered products.

''(b) CONSULTATION.—In carrying out this section, the Secretary shall consult with experts in the pharmaceutical, biotechnology, and medical device industries, academic medical centers, and research institutions, including those with pediatric expertise.

''(c) LIMITED ANTITRUST EXEMPTION.—

''(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

''(A) SCHEDULING COUNTERMEASURES DEVELOPMENT MEETINGS.—The antitrust laws shall not apply to meetings or consultations conducted by the Secretary with parties in-

volved in the development of countermeasures for the purpose of the development, manufacture, distribution, and sale of countermeasures that are prioritized under section 2841(c), consistent with the purposes of this title. The Secretary shall give notice to the Assistant Attorney General of Antitrust of meetings scheduled pursuant to this subsection.

''(B) MEETING CONDITIONS.—Any meeting under subparagraph (A)—

''(i) shall be chaired by the Secretary;

''(ii) shall be open to parties involved in the development of countermeasures, as determined by the Secretary;

''(iii) shall be open to the Attorney General and the Federal Trade Commission;

''(iv) shall be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures that are prioritized under section 2841(c); and

''(v) shall be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting.

''(C) MINUTES.—The Secretary shall ensure that minutes of the meeting are maintained.

''(2) APPLYING FOR LIMITED EXEMPTION.—

''(A) FILING PROCEDURES.—As a result of meetings in paragraph (1), the Secretary and participating parties may file a written request with the Attorney General for a limited exemption from the antitrust laws to allow appropriate parties to enter into agreements or engage in conduct relating to the development, manufacture, distribution, or sale of countermeasures prioritized under section 2841(c). Any such request shall set forth the intended purpose of the agreement, including an explanation as to why a cooperative effort among potential competitors is necessary to achieve the objective of the agreement. The request shall state with specificity the substance of the agreement, the methods that will be utilized to achieve the objectives of the agreement, and other relevant information relating to the development and production of countermeasures that are prioritized under section 2841(c).

"(B) GRANT OF EXEMPTION.—The Attorney General, in consultation with the Chairman of the Federal Trade Commission shall grant, deny, grant in part and deny in part, or propose modifications to any request made pursuant to subparagraph (A) for exemption from the antitrust laws. In making the determination to grant, deny, grant in part and deny in part, or propose modifications to any such request, the Attorney General shall consider among other things: whether such agreement would promote the purposes of this Act, whether the exemption from the antitrust laws would promote the public interest, and the competitive impact to areas not directly related to the development and production of countermeasures prioritized under section 2841(c). The Attorney General shall make a determination on a request filed pursuant to subparagraph (A) within 60 days.

"(C) SUNSET.—The authority of the Attorney General to grant a limited antitrust exemption under this section expires at the end of the 2-year period beginning on the date of enactment of the Pathogen Research, Emergency

Preparedness and Response Efforts Act of 2001.

"SEC. 2802. CONTRACTS FOR DEVELOPMENT OF COVERED PRODUCTS.

"(a) AUTHORITY.—The Secretary may enter into contracts, cooperative research and development agreements pursuant to section 11(a) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(a)), material transfer agreements, or other agreements, or agree to the amendment or modification of existing or future contracts or agreements, for the development, manufacture or distribution of covered products for uses or new uses identified by the Secretary pursuant to section 2801(b). A contract or agreement entered into, or amended or modified, under this subsection may address 1 or more aspects of the development, manufacture, or distribution of 1 or more uses of 1 or more covered products. Such contracts or agreements may set forth guaranteed minimum quantities of products and negotiated unit prices.

"(b) TIMING OF CONTRACT.—Notwithstanding any other provision of law, the Secretary may enter into a contract or agreement under subsection (a) even prior to the development, approval, or clearance of the covered product that is the subject of the contract or agreement. Such con-

tract or agreement may provide for the termination of the contract or agreement for the convenience of the Federal Government if the contractor fails to develop the covered product involved.

''(c) PAYMENTS.—Payments under a contract or agreement under subsection (a) may be made from—

''(1) funds obligated for the performance of the contract or agreement involved;

''(2) funds available for the development, manufacture, distribution, or purchase of covered products for uses referred to in section 2801(b); or

''(3) any other funds available to the Secretary.

''(d) CONTRACTS.—In administering the provisions of this section, the Secretary may enter into contracts in advance of appropriations and incur obligations without regard to provisions of law relating to contracts, including sections 1341, 1342, 1349, 1350, and 1351, and subchapter II of chapter 15, of title 31, United States Code.

''SEC. 2803. INDEMNIFICATION.

''The Secretary shall, in any contract or agreement for the manufacture, development, distribution, or the purchase of a covered product intended for a use identified by the Secretary pursuant to section 2801(b), indemnify and hold harmless the contractor consistent with the following principles:

''(1) USES COVERED.—Indemnification only extends to uses of the covered product pursuant to a contract entered into by the Secretary under section 2802.

''(2) ENTITIES COVERED.—The Secretary may indemnify contractors, subcontractors, distributors, persons who administer covered products, or other parties as determined appropriate by the Secretary pursuant to contracts entered into under section 2802.

''(3) LIMITS.—No indemnification shall be provided for intentional torts by the contractor or torts by the contractor involving gross negligence or recklessness.

''SEC. 2804. HIGH QUALITY PRODUCTION.

''The Secretary may, with the agreement of the manufacturer of a drug, biological product, or medical device that is approved, licensed, or cleared (or awaiting approval, licensure or clearance) under section 505, 510, 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or section 351 of this Act, and is a covered product, provide intensive assistance, including on-site assistance, when necessary, in order to facilitate prompt compliance with good manufacturing practice regulations under sections 210, 211, 225, 226, 600, 601, 606, or 820 of title

21, Code of Federal Regulations, in the manufacturing, processing, packing, or holding of the drug, biological product, or medical device.

"SEC. 2805. SECURITY FOR RESEARCH AND PRODUCTION.

"(a) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Defense, may award grants, contracts, or enter into cooperative agreements, and provide technical or nonmonetary assistance, to provide security to facilities that conduct research, development, production, distribution, and storage of covered products.

"(b) BEST PRACTICES.—The Secretary shall develop guidelines and best practices to enable entities eligible for funding under this section to secure their facilities against potential bioterrorist attack.

"SEC. 2806. MOBILITY OF STOCKPILE.

"(a) SPECIAL EVENTS.—In managing the National Pharmaceutical Stockpile, the Secretary, in consultation with State and local government officials, shall take into consideration the timing and location of special events, including designated national security events.

"(b) LOCATION OF CERTAIN STOCKS.—In carrying out subsection (a), the Secretary shall ensure that medical supplies from the National Pharmaceutical Stockpile are

located in appropriate proximity to the site of the special event.

"SEC. 2807. DEFINITIONS.

"In this title:

"(1) ANTITRUST LAWS.—The term 'antitrust laws'—

"(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

"(B) includes any State law similar to the laws referred to in subparagraph (A).

"(2) BIOLOGICAL AGENTS OR TOXINS.—The term 'biological agents or toxins' has the meaning given in section 178 of title 18, United States Code.

"(3) COVERED PRODUCTS.—The term 'covered products' includes drugs, biological products including vaccines, and medical devices including in vitro diagnostics, that may be developed or produced to identify, prevent, or treat disease or harm in humans, including children and other vulnerable popu-

lations, resulting from an attack or threatened attack using chemical or biological agents or toxins.

''(4) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval or clearance, the conduct of post-market or post-approval studies, and any other actions related to preparation of a covered product.''.

SEC. 3. EXPEDITING FDA REVIEW AND APPROVAL.

(a) AMENDMENT.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

''(e) CHEMICAL OR BIOLOGICAL AGENTS OR TOXINS.—

''(1) IN GENERAL.—The Secretary may designate an unapproved covered product identified pursuant to section 2801(b) of the Public Health Service Act as a fast-track product pursuant to this section. Such a designation may be made prior to the submission of—

''(A) a request for designation by the sponsor; or

''(B) an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.''.

''(2) USE OF ANIMAL TRIALS.—An application for a drug for which approval is sought on the basis of evidence of effectiveness that is derived from animal studies under the last sentence of section 505(d) or section 351(a)(1) of the Public Health Service Act may be designated as a fast track product for purposes of this section.''.

(b) REVIEW.—The Secretary shall grant priority review to a submission for a covered product, unless the sponsor has filed an application for review of the product under section 506.

SEC. 4. USE OF ANIMAL TRIALS IN THE APPROVAL OF COVERED PRODUCTS.

(a) NEW DRUGS.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the following: ''In the case of drugs for use against a potentially lethal or permanently disabling toxic chemical or biological agent or toxin, when adequate and well-controlled studies in humans cannot ethically be conducted because the studies would involve administering such an agent or toxin to healthy human volunteers without a proven treatment, and when

adequate field trials assessing the use of the drug (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval, including approval for pediatric populations, based on evidence derived from appropriate studies in animals or other information. The Secretary may use authority under section 506 or other relevant provisions to order post-marketing approval studies. Drugs approved solely under the authority of the preceding two sentences shall be for purposes of identifying, treating, or preventing infection, disease, injury, or other health condition or consequence resulting from a disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the Secretary may determine appropriate.''.

(b) NEW BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) APPROVAL OF CERTAIN PRODUCTS BASED ON ANIMAL TRIALS.—

''(1) IN GENERAL.—In the case of biological products for use against a potentially lethal or permanently disabling toxic chemical, biological, radiological, nuclear, or other agent or toxins, when adequate and well-controlled studies in humans cannot

ethically be conducted because the studies would involve administering such an agent or toxin to human volunteers without a proven treatment, and when adequate field trials assessing the use of the biological product (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval, including approval for pediatric populations, based on evidence derived from appropriate studies in animals or other information.

''(2) POST-APPROVAL STUDIES.—With respect to products described in paragraph (1), the Secretary may use authority under section 506 of the Federal Food, Drug, and Cosmetic Act to order post-marketing approval studies.

''(3) LIMITATIONS.—Biological products approved solely under the authority of this subsection shall be for purposes of identifying, treating, or preventing infection, disease, injury, or other health condition or consequence resulting from a potentially disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the Secretary may determine appropriate.''.

(c) FINAL RULE.—Not later than 60 days after the date of enactment of Pathogen Research, Emergency Preparedness and Response Efforts Act of 2001, the Secretary shall finalize the proposed rule published on October 5, 1999 regarding the use of animal trials in the approval of products.

SEC. 5. CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"PART E—CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS

"SEC. 570. AUTHORITY TO RESTRICT TRANSPORTATION AND USE.

''(a) IN GENERAL.—The Secretary shall undertake a program that, through inspections and other containment procedures, will prohibit the unauthorized shipment or transportation in interstate or foreign commerce, the possession or other use in or affecting commerce, or assistance to another person in such transportation, shipment, or other use by any person of chemical or biological agents or toxins or the receipt of such chemical or biological agents or toxins so shipped or transported.

''(b) DEFINITIONS.—In this section:

''(1) CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The term 'chemical or biological agents and toxins' has the meaning given such term in section 2801(a) of the Public Health Service Act refers to a biological agent or toxin listed as a 'select agent' in section 72.6(j) of title 42, Code of Federal Regulations, which is not exempt under section 72.6(h) or appendix A of such title and which does not include any such biological agent or toxin that is in its naturally-occurring environment and that has not been cultivated, collected, or otherwise extracted from its natural source.

''(2) PERSON.—The term 'person' includes an alien (other than an alien admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that is in effect) that such country has repeatedly provided support for acts of international terrorism.''.

(b) ENFORCEMENT.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(aa) The shipment, transportation, possession or other use, assistance with respect to, or receipt of a biological agent or toxin in violation of section 570.''.

SEC. 6. REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.

(a) REDESIGNATION AND CLARIFICATION OF CHEMICAL OR BIOLOGICAL AGENTS; REGULATORY PROVISIONS OF ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT OF 1996.—

(1) IN GENERAL.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by inserting after section 351, the following:

"SEC. 351A. ENHANCED CONTROL OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.

''(a) REGULATORY CONTROL OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—

''(1) LIST OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (c), establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

''(2) CRITERIA.—In determining whether to include an agent or toxin on the list under subsection (a), the Secretary shall—

''(A) consider—

''(i) the effect on human health of exposure to the agent or toxin;

''(ii) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

''(iii) the availability and effectiveness of pharmacotherapies and immunizations to treat or prevent any illness resulting from infection by the agent or toxin; and

''(iv) any other criteria that the Secretary considers appropriate; and

''(B) consult with scientific experts representing appropriate professional groups.

''(b) REGULATION OF TRANSFERS OF LISTED CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (c), provide for—

''(1) the establishment and enforcement of safety procedures for the transfer of chemical or biological agents and toxins listed pursuant to subsection (a)(1), including measures to ensure—

''(A) proper training and appropriate skills to handle such agents and toxins; and

''(B) proper laboratory facilities to contain and dispose of such agents and toxins;

''(2) safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

''(3) the establishment of procedures to protect the public in the event of a transfer or potential transfer of a biological agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and

''(4) appropriate availability of chemical or biological agents and toxins for research, education and other legitimate purposes.

''(c) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

''(d) DEFINITIONS.—For purposes of this section and section 351B, the term 'biological agent and toxin' shall have the meaning given such term in section 2801(a).''.

(2) CONFORMING AMENDMENT.—Subsections (d), (e), (f), and (g) of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (42 U.S.C. 262 note) are repealed.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect as if incorporated

in the Antiterrorism and Effective Death Penalty Act of 1996.

(b) REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.—

(1) IN GENERAL.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.), as amended by subsection (a)(1), is further amended by inserting after section 351A, the following:

"SEC. 351B. REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.

''(a) IN GENERAL.—

''(1) LIST OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING NATIONAL SECURITY THREAT.—The Secretary shall, through regulations promulgated under subsection (d), establish and maintain a list of those chemical or biological agents and toxins listed pursuant to section 351A(a)(1) that the Secretary determines to be a potential national security threat.

''(2) CRITERIA.—In determining whether to include an agent or toxin on the list under subsection (a), the Secretary shall—

''(A) consider the criteria specified in section 351A(a)(2)(A)(i), and any other criteria that the Secretary considers appropriate; and

''(B) consult with scientific, intelligence, and military experts representing appropriate professional groups.

''(b) REGULATION OF TRANSFERS OF LISTED CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (d), provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of chemical or biological agents and toxins listed pursuant to subsection (a)(1) that are designed to protect public safety and national security, including safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose.

''(c) CIVIL MONEY PENALTIES.—A violation of a requirement imposed by a regulation promulgated under this section shall be subject, in addition to any other applicable civil or criminal sanctions, to a civil money penalty in an amount not to exceed $250,000.

''(d) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

''(e) FREEDOM OF INFORMATION ACT EXEMPTION.—Any information provided to the Secretary pursuant to regulations issued under subsection (d) or under section 351A(c) shall not be disclosed under section 552 of title 5, United States Code.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall take effect as if incorporated in the Antiterrorism and Effective Death Penalty Act of 1996.

SEC. 7. ADMINISTRATION.

In administering the provisions of this Act, the Secretary of Health and Human Services shall—

(1) continue to recognize and honor rights relating to patents, data, and copyrights; and

(2) comply with all applicable provisions of the regulations relating to Federal acquisition, the Federal Trade Secrets Act, and all other laws protecting confidential commercial information, trade secrets, and intellectual property rights, and patent and nonpatent market exclusivity rights.

SEC. 8. COORDINATION OF EFFORTS TO PROTECT AGAINST BIOTERRORISM.

The Secretary of Health and Human Services and the Secretary of Defense shall coordinate in the planning, design, and construction of a Department of Defense govern-

ment-owned, contractor-operated vaccine production facility on a military installation, as appropriate.

SEC. 9. ENHANCEMENT OF PENALTIES FOR ANIMAL ENTERPRISE TERRORISM.

Section 43 of title 18, United States Code, is amended—

(1) in subsection (a), by striking ''one year'' and inserting ''5 years'';

(2) in subsection (b)—

(A) by redesignating paragraph (2) as paragraph (3);

(B) by inserting after paragraph (1) the following:

''(2) EXPLOSIVES OR ARSON.—Whoever in the course of a violation of subsection (a) maliciously damages or destroys, or attempts to damage or destroy, by means of fire or an explosive, any building, vehicle, or other real or personal property used by the animal enterprise shall be imprisoned for not less than 5 years and not more than 20 years, fined under this title, or both.''; and

(C) in paragraph (3), as so redesignated, by striking ''under this title and'' and all that follows through the period and inserting ''under

this title, imprisoned for life or for any term of years,''; and

(3) in subsection (c)—

(A) by striking ''and'' at the end of paragraph (1);

(B) by striking the period at the end of paragraph (2) and inserting ''; and''; and

(C) by adding at the end the following:

''(3) for any other economic damage resulting from the violation of this section.''.

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