II

109TH CONGRESS
2D SESSION

S. 2564

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 6, 2006

Mr. BURR (for himself, Mr. FRIST, Mr. ENZI, Mr. GREGG, Mr. ALEXANDER, and Mrs. DOLE) 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 prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, 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 ''Biodefense and Pandemic Vaccine and Drug Development Act of 2006''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY; NATIONAL BIODEFENSE SCIENCE BOARD.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319K the following:

"SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

''(a) DEFINITIONS.—In this section:

''(1) BARDA.—The term 'BARDA' means the Biomedical Advanced Research and Development Authority.

''(2) FUND.—The term 'Fund' means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

''(3) OTHER TRANSACTIONS.—The term 'other transactions' means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code.

''(4) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' has the meaning given such term in section 319F–1.

''(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term 'qualified pandemic or epidemic product' has the meaning given the term in section 319F–3.

''(6) ADVANCED RESEARCH AND DEVELOPMENT.—

''(A) IN GENERAL.—The term 'advanced research and development' means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

''(i) are conducted after basic research and preclinical development of the product; and

''(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

''(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

''(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

''(ii) design and development of tests or models, including animal models, for such testing;

''(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

''(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

''(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the

product for such use and as are specified by the Secretary.

''(7) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2.

''(8) RESEARCH TOOL.—The term 'research tool' means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

''(9) PROGRAM MANAGER.—The term 'program manager' means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

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

''(b) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—

''(1) IN GENERAL.—Not later than 6 months after the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products.

''(2) CONTENT.—The strategic plan under paragraph (1) shall guide—

''(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

''(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as 'coun-

termeasure and product advanced research and development'); and

''(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

''(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

''(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

''(2) IN GENERAL.—Based upon the strategic plan described in subsection (b), the Secretary shall coordinate and oversee the acceleration of countermeasure and product advanced research and development by—

''(A) facilitating collaboration among the Department of Health and Human Services, other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

''(B) promoting countermeasure and product advanced research and development;

''(C) facilitating contacts between interested persons and the offices or employees au-

thorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

''(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

''(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the 'Director') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

''(4) DUTIES.—

''(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

''(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

''(I) facilitating such communication regarding the processes for pro-

curing such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

''(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

''(ii) at least annually—

''(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

''(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

''(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine

are necessary to carry out this section; and

''(iii) carry out the activities described in section 7 of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

''(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

''(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

''(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

''(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development and innovation in such areas as the Secretary may identify as priority unmet need areas; and

"(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

"(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

"(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

"(ii) ensure that, with respect to persons performing countermeasure and product advanced research and development funded under this section, such offices or employees provide such advice in a manner that is ongoing and that is otherwise designated to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products

that may achieve such approval, clearance, or licensure.

''(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

''(i) innovation in technologies that may assist countermeasure and product advanced research and development;

''(ii) research on and development of research tools and other devices and technologies; and

''(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

''(5) TRANSACTION AUTHORITIES.—

''(A) OTHER TRANSACTIONS.—In carrying out the functions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have authority to enter into other transactions for countermeasure and product advanced research and development.

''(B) EXPEDITED AUTHORITIES.—

''(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F–1.

''(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F–1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

''(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F–1(b)(1)(D) to this paragraph, the phrase 'BioShield Program under the Project BioShield Act of 2004' shall be

deemed to mean the countermeasure and product advanced research and development program under this section.

"(iv) AVAILABILITY OF DATA.—The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

"(C) ADVANCE PAYMENTS; ADVERTISING.—The authority of the Secretary to enter into contracts under this section shall not be limited by section 3324(a) of title 31, United States Code, or by section 3709 of the Revised Statutes of the United States (41 U.S.C. 5).

"(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Sec-

retary may use milestone-based awards and payments.

"(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

"(F) ESTABLISHMENT OF RESEARCH CENTERS.—The Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)).

"(6) VULNERABLE POPULATIONS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, and other vulnerable populations.

''(7) PERSONNEL AUTHORITIES.—

''(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—In addition to any other personnel authorities, the Secretary may—

''(i) without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

''(ii) compensate them in the same manner in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

''(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may—

''(i) appoint special consultants pursuant to section 207(f); and

''(ii) accept voluntary and uncompensated services.

''(d) FUND.—

''(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section.

''(2) FUNDS.—

''(A) FIRST FISCAL YEAR.—

''(i) AUTHORIZATION AND APPROPRIATION.—There are authorized to be appropriated and there are appropriated to the Fund $340,000,000 to carry out this section for fiscal year 2007. Such funds shall remain available until expended.

''(ii) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, in addition to the amounts appropriated under clause (i), $160,000,000 to carry out this section for fiscal year 2007. Such funds shall remain available until expended.

''(B) SUBSEQUENT FISCAL YEARS.—

''(i) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(I) $500,000,000 for fiscal year 2008; and

''(II) such sums as may be necessary for fiscal years 2009 through 2012.

''(ii) AVAILABILITY OF FUNDS.—Such sums authorized under clause (i) shall remain available until expended.

''(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

''(1) DISCLOSURE.—

''(A) IN GENERAL.—The Secretary shall withhold from disclosure under section 552 of title 5, United States Code, specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development funded by the Secretary that reveal vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

''(B) OVERSIGHT.—Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years to de-

termine the relevance or necessity of continued nondisclosure.

''(2) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to a working group of BARDA or to the National Biodefense Science Board under section 319M.

"SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND WORKING GROUPS.

''(a) IN GENERAL.—

''(1) ESTABLISHMENT AND FUNCTION.—The Secretary shall establish the National Biodefense Science Board (referred to in this section as the 'Board') to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

''(2) MEMBERSHIP.—The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

''(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

''(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

''(C) four individuals representing academia; and

''(D) five other members as determined appropriate by the Secretary.

''(3) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

''(4) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

''(5) DUTIES.—The Board shall—

''(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life

sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

''(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b); and

''(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities.

''(6) MEETINGS.—

''(A) INITIAL MEETING.—Not later than one year after the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006, the Secretary shall hold the first meeting of the Board.

''(B) SUBSEQUENT MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually.

''(7) VACANCIES.—Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

''(8) CHAIRPERSON.—The Secretary shall appoint a chairperson from among the members of the Board.

''(9) POWERS.—

''(A) HEARINGS.—The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

''(B) POSTAL SERVICES.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

''(10) PERSONNEL.—

''(A) EMPLOYEES OF THE FEDERAL GOVERNMENT.—A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

''(B) OTHER MEMBERS.—A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate

of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

''(C) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

''(D) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(b) OTHER WORKING GROUPS.—The Secretary may establish a working group of experts, or may use an existing working group or advisory committee, to—

''(1) identify innovative research with the potential to be developed as a qualified countermeasure or a qualified pandemic or epidemic product;

''(2) identify accepted animal models for particular diseases and conditions associated with any biological, chemical, radiological, or nuclear agent, any toxin, or any potential pandemic infectious disease, and identify strategies to accelerate animal model and research tool development and validation; and

''(3) obtain advice regarding supporting and facilitating advanced research and development related to qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, and other vulnerable populations, and other issues regarding activities under this section that affect such populations.

''(c) DEFINITIONS.—Any term that is defined in section 319L and that is used in this section shall have the same meaning in this section as such term is given in section 319L.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,000,000 to carry out this section for fiscal year 2007 and each fiscal year thereafter.''.

(b) OFFSET OF FUNDING.—The amount appropriated under the subheading ''Biodefense Counter-

measures'' under the heading ''Emergency Preparedness and Response'' in title III of the Department of Homeland Security Appropriations Act, 2004 (Public Law 108–90) shall be decreased by $340,000,000.

SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED BY PROJECT BIOSHIELD.

(a) QUALIFIED COUNTERMEASURE.—Section 319F–1(a) of the Public Health Service Act (42 U.S.C. 247d–6a(a)) is amended by striking paragraph (2) and inserting the following:

''(2) DEFINITIONS.—In this section:

''(A) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to—

''(i) diagnose, mitigate, prevent, or treat harm from any biological agent (in-

cluding organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

''(ii) diagnose, mitigate, prevent, or treat 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 that is used as described in this subparagraph.

''(B) INFECTIOUS DISEASE.—The term 'infectious disease' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.''.

(b) SECURITY COUNTERMEASURE.—Section 319F–2(c)(1)(B) is amended by striking ''treat, identify, or prevent'' each place it appears and inserting ''diagnose, mitigate, prevent, or treat''.

(c) LIMITATION ON USE OF FUNDS.—Section 510(a) of the Homeland Security Act of 2002 (6 U.S.C. 320(a)) is amended by adding at the end the following: ''None of the funds made available under this subsection shall be

used to procure countermeasures to diagnose, mitigate, prevent, or treat harm resulting from any naturally occurring infectious disease.''.

SEC. 5. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUNTERMEASURE PRODUCTS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by adding at the end the following:

''(e) MARKET EXCLUSIVITIES FOR COUNTERMEASURES, ANTIBIOTICS, AND ANTIINFECTIVES.—

''(1) IN GENERAL.—Except as provided in paragraph (2), with respect to a drug that is designated under section 526 for a rare disease or condition, the period referred to in this section is deemed to be 10 years in lieu of 7 years if—

''(A) such rare disease or condition is directly caused by a—

''(i)(I) biological agent (including an organism that causes infectious disease);

''(II) toxin; or

''(III) chemical, radiological, or nuclear agent; and

''(ii) such biological agent (including an organism that causes an infectious disease), toxin, or chemical, radiological or

nuclear agent, is identified as a material threat under subsection (c)(2)(A)(ii) of section 319F–2 of the Public Health Service Act;

''(B) such drug is determined by the Secretary to be a security countermeasure under subsection (c)(1)(B) of such section 319F–2 with respect to such agent or toxin;

''(C) no active ingredient (including a salt or ester of the active ingredient) of the drug has been approved under an application under section 505(b) prior to the submission of the request for designation of the new drug under section 526; and

''(D) notice respecting the designation of a drug under section 526 has been made available to the public.

''(2) APPLICATION OF PROVISION.—Paragraph (1) shall apply with respect to an antibiotic drug or antiinfective drug designated under section 526 only if—

''(A) no active ingredient (including a salt or ester of the active ingredient) of such drug has been approved as a feed or water additive for an animal in the absence of any clinical sign

of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose;

''(B) no active ingredient (including a salt or ester of the active ingredient) of such drug has been approved for use in humans under section 505 or approved for human use under section 507 (as in effect prior to November 21, 1997) prior to the submission of the request for designation of the new drug under section 526;

''(C) the Secretary has made a determination that—

''(i) such drug is not a member of a class of antibiotics that is particularly prone to creating antibiotic resistance;

''(ii) sufficient antibiotics do not already exist in the same class;

''(iii) such drug represents a significant clinical improvement over other antibiotic drugs;

''(iv) such drug is for a serious or life-threatening disease or conditions; and

''(v) such drug is for a countermeasure use; and

''(D) notice respecting the designation of a drug under section 526 has been made available to the public.

''(3) RULE OF CONSTRUCTION.—With respect to a drug to which this subsection applies, and which is also approved for additional uses to which this subsection does not apply, nothing in section 505(b)(2) or 505(j) shall prohibit the Secretary from approving a drug under section 505(b)(2) or 505(j) with different or additional labeling for the drug as the Secretary deems necessary to ensure that the drug is safe and effective for the uses to which this subsection does not apply.

''(4) STUDY AND REPORT.—Not later than January 1, 2011, the Comptroller General of the United States shall conduct a study and submit to Congress a report concerning the effect of and activities under this subsection. Such study and report shall examine all relevant issues including—

''(A) the effectiveness of this subsection in improving the availability of novel countermeasures for procurement under section 319F–2 of the Public Health Service Act;

''(B) the effectiveness of this subsection in improving the availability of drugs that treat

serious or life threatening diseases or conditions and offer significant clinical improvements;

''(C) the continued need for additional incentives to create more antibiotics and antiinfectives;

''(D) the economic impact of the section on taxpayers and consumers, including—

''(i) the economic value of additional drugs provided for under this subsection, including the impact of improved health care and hospitalization times associated with treatment of nosocomial infections; and

''(ii) the economic cost of any delay in the availability of lower cost generic drugs on patients, the insured, and Federal and private health plans;

''(E) the adequacy of limits under subparagraphs (A) and (B) of paragraph (2) to maximize the useful period during which antibiotic drugs or antiinfective drugs remain therapeutically useful treatments; and

''(F) any recommendations for modifications to this subsection that the Comptroller determines to be appropriate.

''(5) EFFECTIVE DATE.—This subsection shall apply only to products for which an applicant has applied for designation under section 526 after the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

''(6) SUNSET.—This subsection shall not apply with respect to any designation of a drug under section 526 made by the Secretary on or after October 1, 2011.''.

SEC. 6. TECHNICAL ASSISTANCE.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 565. TECHNICAL ASSISTANCE.

''The Secretary, in consultation with the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act), security countermeasures (as defined in section 319F–2 of such Act), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines

that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.''.

SEC. 7. COLLABORATION AND COORDINATION.

(a) LIMITED ANTITRUST EXEMPTION.—

(1) MEETINGS AND CONSULTATIONS TO DISCUSS SECURITY COUNTERMEASURES, QUALIFIED COUNTERMEASURES, OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DEVELOPMENT.—

(A) AUTHORITY TO CONDUCT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary''), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with persons engaged in the development of a security countermeasure (as defined in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act), a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of

the Public Health Service Act (42 U.S.C. 247d–6d)) for the purpose of the development, manufacture, distribution, purchase, or storage of a countermeasure or product. The Secretary may convene such meeting or consultation at the request of the Secretary of Homeland Security, the Attorney General, the Chairman of the Federal Trade Commission (referred to in this section as the ''Chairman''), or any interested person, or upon initiation by the Secretary. The Secretary shall give prior notice of any such meeting or consultation, and the topics to be discussed, to the Attorney General, the Chairman, and the Secretary of Homeland Security.

(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

(ii) be open to persons involved in the development, manufacture, distribution, purchase, or storage of a countermeasure or product, as determined by the Secretary;

(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairman;

(iv) be limited to discussions involving covered activities; and

(v) be conducted in such manner as to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting or consultation.

(C) LIMITATION.—The Secretary may not require participants to disclose confidential commercial or proprietary information.

(D) TRANSCRIPT.—The Secretary shall maintain a complete verbatim transcript of each meeting or consultation conducted under this subsection, which shall not be disclosed under section 552 of title 5, United States Code, unless such Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, determines that disclosure would pose no threat to national security. The determination regarding possible threats to national security shall not be subject to judicial review.

(E) EXEMPTION.—

(i) IN GENERAL.—Subject to clause (ii), it shall not be a violation of the antitrust laws for any person to participate in a meeting or consultation conducted in accordance with this paragraph.

(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that is not covered by an exemption granted under paragraph (4).

(2) SUBMISSION OF WRITTEN AGREEMENTS.—The Secretary shall submit each written agreement regarding covered activities that is made pursuant to meetings or consultations conducted under paragraph (1) to the Attorney General and the Chairman for consideration. In addition to the proposed agreement itself, any submission shall include—

(A) an explanation of the intended purpose of the agreement;

(B) a specific statement of the substance of the agreement;

(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

(D) an explanation of the necessity for a cooperative effort among the particular participating persons to achieve the objectives of the agreement; and

(E) any other relevant information determined necessary by the Attorney General, in consultation with the Chairman and the Secretary.

(3) EXEMPTION FOR CONDUCT UNDER APPROVED AGREEMENT.—It shall not be a violation of the antitrust laws for a person to engage in conduct in accordance with a written agreement to the extent that such agreement has been granted an exemption under paragraph (4), during the period for which the exemption is in effect.

(4) ACTION ON WRITTEN AGREEMENTS.—

(A) IN GENERAL.—The Attorney General, in consultation with the Chairman, shall grant, deny, grant in part and deny in part, or propose modifications to an exemption request regarding a written agreement submitted under paragraph (2), in a written statement to the Secretary, within 15 business days of the receipt of such request. An exemption granted

under this paragraph shall take effect immediately.

(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 business days.

(C) DETERMINATION.—An exemption shall be granted regarding a written agreement submitted in accordance with paragraph (2) only to the extent that the Attorney General, in consultation with the Chairman and the Secretary, finds that the conduct that will be exempted will not have any substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure or product involved.

(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and such exemption shall be renewed (with modifications, as appropriate, consistent with the finding described in paragraph (4)(C)), on the date that is 3 years after the date on which the exemption is granted unless the Attorney General in consultation with the Chairman determines that the exemption should not be

renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

(6) AUTHORITY TO OBTAIN INFORMATION.—Consideration by the Attorney General for granting or renewing an exemption submitted under this section shall be considered an antitrust investigation for purposes of the Antitrust Civil Process Act (15 U.S.C. 1311 et seq.).

(7) LIMITATION ON PARTIES.—The use of any information acquired under an agreement for which an exemption has been granted under paragraph (4), for any purpose other than specified in the exemption, shall be subject to the antitrust laws and any other applicable laws.

(8) REPORT.—Not later than one year after the date of enactment of this Act and biannually thereafter, the Attorney General and the Chairman shall report to Congress on the use of the exemption from the antitrust laws provided by this subsection.

(b) SUNSET.—The applicability of this section shall expire at the end of the 6-year period that begins on the date of enactment of this Act.

(c) DEFINITIONS.—In this section:

(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) COUNTERMEASURE OR PRODUCT.—The term ''countermeasure or product'' refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

(3) COVERED ACTIVITIES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term ''covered activities'' includes any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

(B) EXCEPTION.—The term ''covered activities'' shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection

(a)(4), the following activities involving 2 or more persons:

(i) Exchanging information among competitors relating to costs, profitability, or distribution of any product, process, or service if such information is not reasonably necessary to carry out covered activities—

(I) with respect to a countermeasure or product regarding which such meeting or consultation is being conducted; or

(II) that are described in the agreement as exempted.

(ii) Entering into any agreement or engaging in any other conduct—

(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

(II) to restrict or require participation, by any person participating in such covered activities, in other re-

search and development activities, except as reasonably necessary to prevent the misappropriation of proprietary information contributed by any person participating in such covered activities or of the results of such covered activities.

(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws under subsection (a)(4).

(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out such covered activities.

(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not expressly exempted from the antitrust laws under subsection (a)(4).

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

SEC. 8. PROCUREMENT.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in the section heading, by inserting ''**AND SECURITY COUNTERMEASURE PROCUREMENTS**'' before the period; and

(2) in subsection (c)—

(A) in the subsection heading, by striking ''BIOMEDICAL'';

(B) in paragraph (5)(B)(i), by striking ''to meet the needs of the stockpile'' and inserting ''to meet the stockpile needs'';

(C) in paragraph (7)(B)—

(i) by striking the subparagraph heading and all that follows through ''Homeland Security Secretary'' and inserting the following: ''INTERAGENCY AGREEMENT; COST.—The Homeland Security Secretary''; and

(ii) by striking clause (ii);

(D) in paragraph (7)(C)(ii)—

(i) by amending clause (I) to read as follows:

''(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project,

the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract. Provided that the specified milestones are reached, these advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.''; and

(ii) by adding at the end the following:

"(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

"(VIII) SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that

additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

''(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section, may specify—

''(aa) the dosing and administration requirements for countermeasures to be developed and procured;

''(bb) the amount of funding that will be dedicated by the Secretary for development and ac-

quisition of the countermeasure; and

''(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section.''; and

(E) in paragraph (8)(A), by adding at the end the following: ''Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this section for the procurement of countermeasures.''.

SEC. 9. RULE OF CONSTRUCTION.

Nothing in this Act, or any amendment made by this Act, shall be construed to affect any law that applies to the National Vaccine Injury Compensation Program under

title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.), including such laws regarding—

(1) whether claims may be filed or compensation may be paid for a vaccine-related injury or death under such Program;

(2) claims pending under such Program; and

(3) any petitions, cases, or other proceedings before the United States Court of Federal Claims pursuant to such title.

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