AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5533

OFFERED BY _____

Strike all after the enacting clause and insert the following:

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.

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) 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.—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 authorized 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 procuring 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 6 of the Biodefense and Pandemic Vaccine and Drug Development Act of 2006.

''(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose de-

scribed 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 au-

thority 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 may require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of para-

graph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, relevant 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 Secretary 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 and are consistent with National security.

''(F) ESTABLISHMENT OF ADVANCED 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)), provided that such centers are consistent and complementary with the duties described in paragraph (4), and are consistent and complementary with, and deemed necessary after considering the availability of, existing federally-supported basic research programs.

''(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 the emergency health security needs of children 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.

''(c) 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 determine 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.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out advanced research and develop-

ment under this section, there are authorized to be appropriated $160,000,000 for each of the fiscal years 2007 and 2008. Such authorizations are in addition to other authorizations of appropriations that are available for such purpose. Amounts appropriated under the preceding sentence are available until expended.

''(e) DEFINITIONS.—For purposes of this section:

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

''(2) 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.

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

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

''(5) 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.

''(6) RESEARCH TOOL.—The term 'research tool' means a device, technology, biological material, 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.

''(7) 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.

''(8) 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.

''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 to biodefense or public health security 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) 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.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,000,000 to carry out this section for each of the fiscal years 2007 and 2008.''.

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

(a) QUALIFIED COUNTERMEASURES.—Section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2)) is amended—

(1) by amending subparagraph (A) to read as follows:

''(A) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, or from any chemical, radiological, or nuclear agent, that may cause a public health emergency affecting national security; or'';

(2) in subparagraph (B), by striking ''treat, identify, or prevent harm'' and inserting ''diagnose, mitigate, prevent, or treat harm''; and

(3) by adding after and below subparagraph (B) the following:

''If through publication in the Federal Register the Secretary makes a determination that there is credible evidence that a biological agent has the potential to cause an epidemic or pandemic that may constitute a public health emergency, a countermeasure to such agent shall, without further administrative action, be considered a qualified countermeasure within the meaning of this paragraph.''.

(b) SECURITY COUNTERMEASURES.—Section 319F–2(c)(1)(B)(i)(I) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(1)(B)(i)(I)) is amended by striking ''to treat'' the first place such term appears and all that follows through ''from a condition'' and inserting the following: ''to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin or from any chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition''.

SEC. 5. 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. 6. 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 signifi-

cant 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 advance 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 Regu-

lation) relating to the termination of contracts for the convenience of the Government.''; and

(ii) by adding at the end the following:

''(VII) PROCUREMENT OF MULTIPLE PRODUCTS AND TECHNOLOGIES.—The Secretary may enter into multiple transactions for the procurement of multiple technologies and products from multiple manufacturers of security countermeasures in order to mitigate against the risks associated with dependence on a single supplier or technology.

''(VIII) 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)).

''(IX) 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.

''(X) ADDITIONAL 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 acquisition 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: ''In the case of such agreements by the Secretary, the Secretary may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established

by the Secretary, and 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.''.