Calendar No. 257

109TH CONGRESS
1ST SESSION

S. 1873

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

OCTOBER 17, 2005

Mr. BURR (for himself, Mr. ENZI, Mr. GREGG, Mr. FRIST, Mr. ALEXANDER, and Mrs. DOLE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 24, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 2005".~~

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.

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 AGENCY.

"(a) DEFINITIONS.—In this section:

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

"(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 pro-

curement contracts, grants, and cooperative agreements, including transactions for prototypes, as provided to the Secretary of Defense 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 COUNTERMEASURE AND QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT ADVANCED RESEARCH AND DEVELOPMENT.—

''(A) IN GENERAL.—The term 'qualified countermeasure and qualified pandemic or epidemic product advanced research and development' means any applied research, testing, or evaluation (including those conducted on humans or animals), related to the safety or effectiveness, that is required for approval, clearance, or licensing by the Secretary under this Act or the Federal Food, Drug, and Cosmetic Act, of such countermeasure or pandemic or epidemic product to diagnose, mitigate, prevent, or treat harm from a deliberate, accidental, or natural exposure to a chemical, biological, radiological, or nuclear agent, particularly such ex-

posure resulting from an act of terrorism or potential pandemic infectious disease.

''(B) INCLUSION.—The term under subparagraph (A) includes any investigation to improve the manufacturing, formulation, finish, fill, delivery, or shelf-life of such qualified countermeasures or qualified pandemic or epidemic products.

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

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

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

''(b) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.—

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

‘‘(2) PURPOSE.—It shall be the purpose of the BARDA to coordinate and oversee activities that support and accelerate qualified countermeasure or qualified pandemic or epidemic product (referred to in this section as ‘countermeasure or product’) advanced research and development by—

‘‘(A) directing and coordinating 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) supporting countermeasure and product advanced research and development;

‘‘(C) recommending approaches to modernize and streamline the countermeasure or product development process and reduce regulatory burdens with respect to procurement of security countermeasures and qualified pandemic or epidemic products; and

‘‘(D) supporting 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—

‘‘(A) be appointed by the President, with the advice and consent of the Senate;

‘‘(B) report to the Secretary; and

‘‘(C) serve as the principal advisor to the Secretary on countermeasure and product advanced research and development.

‘‘(4) DUTIES OF DIRECTOR.—

‘‘(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary, acting through the Director, shall—

‘‘(i) increase appropriate communication between the Federal Government and relevant industries, academia, and other interested persons with respect to countermeasure and product advanced research and development by establishing transparent, expeditious, and direct processes to—

‘‘(I) facilitate regular, ongoing communication regarding the processes established under subparagraph

(C)(ii) and new countermeasures or products of interest;

"(II) solicit research and associated data on potential countermeasures and products and related technologies; and

"(III) provide technical assistance with respect to such processes and the Food and Drug Administration approval process;

"(ii) at least annually—

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

"(II) sponsor relevant biodefense countermeasure technology demonstrations;

"(iii) carry out the activities described in subsection (g) of section 2 of the Clayton Act; and

"(iv) encourage and coordinate countermeasure or product advanced research and development, including by convening

working groups as identified in paragraph (5).

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

''(i) conduct continuous searches and support calls for potential countermeasures or products for drugs, biological products, devices, or research tools to diagnose, mitigate, prevent, or treat harm from existing, emerging, or possible chemical, biological, radiological, and nuclear agents or potential pandemic infectious diseases that threaten public health and national security, as identified by the Assistant Secretary for Public Health Emergency Preparedness;

''(ii) direct the countermeasure and product advanced research and development activities of the Department of Health and Human Services, in consultation with the Assistant Secretary for Public Health Emergency Preparedness, the Director of the National Institutes of

Health, the Director of the Centers for the Disease Control and Prevention, and the Commissioner of Food and Drugs; and

"(iii) award contracts, grants, cooperative agreements, and enter into other transactions, to include use of simplified acquisition authorities provided under sections 319F–1 and 319F–2(c)(7)(C)(iii), to public and private persons, including for-profit and nonprofit persons, federally funded research and development centers, and universities, to—

"(I) support the cost of countermeasure and product advanced research and development; and

"(II) ensure accelerated development of countermeasures and products.

"(C) STREAMLINE PROCESSES.—To carry out the purpose described in paragraph (2)(C), the Secretary, acting through the Director, shall—

"(i) receive from the Assistant Secretary for Public Health Emergency Preparedness, requirements for national civil-

~~ian biodefense needs, particularly countermeasures or products and other technologies, to diagnose, mitigate, prevent, or treat harm from existing, emerging, or potential chemical, biological, radiological, or nuclear agents or potential pandemic infectious diseases;~~

~~"(ii) establish transparent, expeditious, and direct processes for selecting promising countermeasures and products, supporting them through advanced research and development and recommending them for procurement;~~

~~"(iii) establish an office within the BARDA, in consultation with the Commissioner of Food and Drugs, to—~~

~~"(I) facilitate regular and ongoing communication between the BARDA and the Food and Drug Administration regarding the status of BARDA advanced research and development activities;~~

~~"(II) ensure that such activities are coordinated with the approval requirements of the Food and Drug Ad-~~

ministration, with the goal of expediting the development and approval of countermeasures and products; and

"(III) connect interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act;

"(iv) coordinate with the Food and Drug Administration to facilitate regulatory review and approval of promising classes of countermeasures or products through the development of research tools; and

"(v) recommend to the Secretary, through the Assistant Secretary for Public Health Emergency Preparedness, procurement of the most promising eligible security countermeasures or qualified pandemic or epidemic products identified in clause (i).

"(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary, acting through the Director, shall award contracts, grants, cooperative

agreements, or enter into other transactions, to include use of simplified acquisition authorities provided under sections 319F–1 and 319F–2(c)(7)(C)(iii), to the entities described in subparagraph (B)(iii), to promote innovation in technologies supporting the advanced research and development and production of qualified or security countermeasures or qualified pandemic or epidemic products, such as research tools, manufacturing, countermeasure administration, storage, and bioinformatics and other devices.

"(E) OTHER DUTIES.—

"(i) IN GENERAL.—The Director may—

"(I) prepare and submit to the President and Congress, an annual budget estimate for qualified countermeasure and pandemic or epidemic product advanced research and development and other BARDA activities, after opportunity for comment by the Secretary; and

"(II) receive from the President and the Office of Management and Budget directly all funds appropriated

by Congress for obligation and expenditure by the BARDA.

"(ii) SECRETARY DUTIES.—The Secretary, acting through the Director, may—

"(I) enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary to carry out the functions of BARDA, without regard to section 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 3324(a) and (b)), (41 U.S.C. 5), with any public agency, any firm, association, corporation, or educational institution, or any other person;

"(II) support advanced research and development and innovation of potential countermeasures or products by highly qualified foreign nationals outside the United States that may inure to the benefit of the American people and collaborative research involving American and foreign participants;

"(III) administer grants using milestone-based awards and payments; and

"(IV) establish 1 or more federally funded research and development centers or university affiliated research centers in accordance with section 253(c)(3) of title 41, United States Code.

"(5) VULNERABLE POPULATIONS.—In carrying out the activities under this section, the Director, in consultation with the Vulnerable Populations Working Group, may give priority to supporting and facilitating advanced research and development of countermeasures or products, and formulations of countermeasures or products, that are likely to be safe and effective for pediatric populations, pregnant women, and other vulnerable populations.

"(6) WORKING GROUPS.—

"(A) IDENTIFICATION OF TECHNOLOGIES.—

"(i) IN GENERAL.—The Director may establish and convene, or enter into a contract with a public or private research institution to convene, one or more working

groups that consists of experts on countermeasure technology to identify innovative technologies that have the potential to be developed as countermeasures or products.

"(ii) MEETINGS.—A working group established under clause (i) shall participate in regular meetings with sponsors of countermeasures, products, or related technologies to—

"(I) review the scientific evidence or concept of such countermeasures, products, or related technologies;

"(II) provide guidance on research protocols or studies; and

"(III) provide guidance on the regulatory approval process for countermeasures, products, and related technologies.

"(iii) RECOMMENDATIONS.—Not later than 30 days after each meeting with a sponsor of a countermeasure, product, or related technology, the working group shall make recommendations to the Director concerning such countermeasure, product, or related technology.

"(iv) CONFIDENTIALITY.—Any commercial confidential or proprietary information that is disclosed to the working group in a meeting under this section shall remain confidential and shall not be disclosed other than to the Secretary or the Director, or their designees.

"(v) CONSTRUCTION.—Nothing in this subparagraph shall be construed to prohibit a sponsor from meeting with the Director to discuss potential countermeasures, products, or related technologies.

"(B) PUBLIC WORKING GROUP.—The Director may establish and convene one or more working groups composed of private citizens and officials of Federal, State, and local governments to advise such Director with respect to the functions of the BARDA and the Director.

"(C) VULNERABLE POPULATIONS WORKING GROUP.—The Director shall establish and convene a Vulnerable Populations Working Group composed of experts on pediatric populations, pregnant women, and other vulnerable

populations to advise such Director with respect to—

"(i) supporting and facilitating advanced research and development of countermeasures, and formulations of countermeasures, that are safe and effective for such populations; and

"(ii) other activities of the BARDA that effect such populations.

"(7) PERSONNEL AUTHORITIES.—

"(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—In hiring personnel for the BARDA, the Director shall have the hiring and management authorities described in section 1101 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (5 U.S.C. 3104 note; Public Law 105–261). With respect to the personnel of the BARDA, the term of appointments for employees referred to under subsection (c)(1) of that section may not exceed 5 years before the granting of any extension under subsection (c)(2) of that section.

"(B) SPECIAL CONSULTANTS.—The Director may accept special consultants as personnel for the BARDA under section 207(f).

"(C) INTERGOVERNMENTAL PERSONNEL ACT.—The Director may accept as personnel for the BARDA, employees under subchapter VI of chapter 33 of subpart B of part III of title 5, United States Code.

"(D) OTHER SERVICES.—The Director may accept voluntary and uncompensated services.

"(c) NATIONAL BIODEFENSE ADVISORY BOARD.—

"(1) IN GENERAL.—

"(A) PURPOSE.—The National Biodefense Advisory Board shall provide expert advice and guidance to the Secretary on the threats, challenges, and opportunities presented by advances in biological and life sciences and the threat from natural infectious diseases and chemical, biological, radiological, and nuclear threats.

"(B) MEMBERSHIP.—There is established the National Biodefense Advisory Board (hereinafter in this section referred to as the 'Board') to be composed of 23 members who represent the Nation's preeminent scientific,

public health, and medical experts on the subject of biological, chemical, nuclear, and radiological threats, whether naturally occurring, accidental, or deliberate, as follows:

"(i) EX OFFICIO.—The following members shall serve on the Board ex officio:

"(I) The Assistant to the President for Homeland Security and Counterterrorism.

"(II) The Director of the Office of Science and Technology Policy.

"(III) The Assistant Secretary for Public Health Emergency Preparedness.

"(IV) The Director of the National Institutes of Health.

"(V) The Director of the Centers for Disease Control and Prevention.

"(VI) The Commissioner of Food and Drugs.

"(VII) The Director of BARDA.

"(VIII) The Assistant Secretary of Defense for Health Affairs.

“(IX) The Assistant Secretary of Homeland Security for Science and Technology.

“(X) The Secretary of Agriculture (or a designee).

“(ii) APPOINTED MEMBERS.—The following individuals, as appointed by the Secretary:

“(I) Four representatives of the pharmaceutical and biotechnology industries.

“(II) Four representatives of academia.

“(III) Five other members as determined appropriate by the Secretary.

“(C) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B)(ii) 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.

“(D) 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.

''(2) DUTIES.—The Board shall—

''(A) advise the Secretary on major biodefense initiatives and review ongoing and proposed biodefense programs, which may include potential activities of the BARDA; and

''(B) in consultation with the Director of BARDA, and in coordination with the Director of National Institute of Allergy and Infectious Diseases, provide to the Secretary, recommendations and findings for an expanded, intensified, and coordinated biodefense research program encompassing the programs of the BARDA and other Federal agencies and related programs of the other research institutes.

''(3) MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually to provide to the Secretary updated assessments, findings, and recommendations of the current trends, challenges, and opportunities posed in biotechnology and genetic engineering.

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

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

"(6) 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.

"(7) PERSONNEL.—

"(A) OFFICERS 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 shall be compensated at a rate equivalent to 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 without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(d) FUND.—

''(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be administered by the Director of the BARDA.

''(2) FUNDS.—

''(A) FIRST FISCAL YEAR.—Of the amounts appropriated to carry out the Project

BioShield Act of 2004 (Public Law 108–276) and not obligated, $1,000,000,000 shall be available to the Fund to carry out this section for fiscal year 2006. Such amounts shall remain available until expended.

''(B) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2007 and each subsequent fiscal year. Such sums shall remain available until expended.

''(c) EFFECT OF SECTION.—Nothing in this section shall be construed to limit any authority of the Department of Health and Human Services, including those authorities provided under the Project BioShield Act of 2004 (Public Law 108–276).

''(f) INAPPLICABILITY OF CERTAIN ACTS.—

''(1) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the duties, activities, working groups, and advisory boards of the BARDA.

''(2) FOIA.—Information that relates to the activities, working groups, and advisory boards of the BARDA shall not be subject to disclosure under section 552 of title 5, United States Code, unless the

Secretary or Director determines that such disclosure would pose no threat to national security. Such a determination shall not be subject to judicial review.

''(3) CERTAIN COST PRINCIPLES AND COST ACCOUNTING STANDARDS.—Notwithstanding any other provision of law, the cost principles set forth under part 31 of title 48, Code of Federal Regulations, the cost accounting standards set forth under chapter 99 of title 48, Code of Federal Regulations, and the requirement for the submission of certified cost and pricing information under section 304A of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254b), shall not apply to any contract, grant, cooperative agreement, or other transaction entered into under the Project BioShield Act of 2004 (Public Law 108–276).''.

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))), device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), or research tool (as that term is defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act) 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 (including organisms that cause an infectious disease) or toxins, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

"(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; or

''(iii) in the case of a research tool, enable the rapid and effective identification, assessment, or development of a drug, biological product, or device to diagnose, mitigate, prevent, or treat harm, as described in clause (i) or (ii).

''(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—

(A) striking ''treat, identify, or prevent'' each place it appears and inserting ''diagnose, mitigate, prevent, or treat''; and

(B) inserting ''agent (including organisms that cause an infectious disease) or toxin'' after ''any biological''.

(c) RESEARCH TOOL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(rr) RESEARCH TOOL.—The term 'research tool' includes the full range of tools and systems that assist in the discovery, development, or manufacture of drugs, biological products (as defined in section 351 of the Public Health Service Act), or devices.''.

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

(a) MARKET EXCLUSIVITY.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUNTERMEASURE PRODUCTS.

''(a) IN GENERAL.—With respect to countermeasure products (as such term is defined in this section), if a countermeasure product is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) shall be 10 years instead of 7 years.

''(b) DEFINITION.—For the purpose of this section, the term 'countermeasure' means a drug or biological product (as such term is defined by section 351(i) of the Public Health Service Act) that the Secretary determines

to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent (including organisms that cause an infectious disease) or toxin identified as a material threat under subsection (c)(2)(A)(ii) of section 319F–2 of the Public Health Service Act.''.

(b) ORPHAN DRUGS.—For purposes of section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) a biological, chemical, radiological, or nuclear agent (including organisms that cause an infectious disease) or toxin identified as a material threat under subsection (c)(2)(A)(ii) of section 319F–2 of the Public Health Service Act shall be considered to be a ''rare disease or condition'' within the meaning of such term in such section 526. The Secretary may designate antibiotics and anti-infective products that treat infectious diseases as designated drugs or biological products under such section 526.

(c) EFFECT OF SECTION.—This section, and the amendments made by this section, shall apply to new drug applications and biological product licenses approved under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act after the date of enactment of this Act.

SEC. 6. LIABILITY PROTECTIONS FOR PANDEMICS, EPIDEMICS, AND COUNTERMEASURES.

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

"SEC. 319F–3. LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

"(a) AUTHORITY.—As provided in subsection (b), and subject to subsection (b)(1)(C), a manufacturer, distibutor, or administrator of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A) or a health care provider shall be immune from suit or liability caused by or arising out of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A).

"(b) LITIGATION MANAGEMENT.—

"(1) LIMITATION ON CAUSE OF ACTION.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—No cause of action shall exist against a person described in subsection (a) for claims for loss of property, personal injury, or death arising out

of, reasonably relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure or qualified pandemic or epidemic product distributed, sold, purchased, donated, dispensed, prescribed, administered, or used in anticipation of and preparation for, in defense against, or in response to, or recovery from an actual or potential public health emergency that is a designated security countermeasure or a qualified pandemic or epidemic product by the Secretary in a declaration described in paragraph (2).

''(ii) RULE OF CONSTRUCTION.—For purposes of this section, the phrase 'arising out of, reasonably relating to, or resulting from' shall not be construed to apply to loss of property, personal injury, or death that has no alleged or potential causal relationship with the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale,

purchase, donation, dispensing, prescribing, administration, or use of a product described in clause (i).

''(B) RULE.—

''(i) SUBSEQUENT INJURY.—The protections set forth in subsection (a) and subparagraph (A) shall apply to all claims identified in subparagraph (A) that involve products distributed, sold, purchased, donated, dispensed, prescribed, administered, or used during the effective period set forth in the designation provided for in paragraph (2), regardless of the date of alleged injury.

''(ii) PRIVATE DONATION OR SALE.—The protections set forth in subsection (a) and subparagraph (A) shall apply to all claims identified in subparagraph (A) that involve security countermeasures or qualified pandemic or epidemic products distributed, sold, purchased, donated, dispensed, prescribed, administered, or used during the effective period set forth in the designation provided for in paragraph (2) by a manufacturer through the commercial

market, provided that the security countermeasures or the qualified pandemic or epidemic product are the security countermeasure or qualified pandemic or epidemic product described in a declaration described in paragraph (2) and the Secretary does not specifically prohibit such private donation or sale in such declaration.

''(C) POTENTIAL LIABILITY UPON DETERMINATION.—

''(i) IN GENERAL.—A manufacturer, distributor, administrator, or health care provider shall not be immune under subsection (a) or exempted from a cause of action under subparagraph (A) if the Secretary makes a determination as provided for in subparagraph (D).

''(ii) INVESTIGATION BY SECRETARY.—A party seeking a determination under subparagraph (D) may petition the Secretary to investigate allegations against a manufacturer, distributor, administrator, or health care provider arising out of, relating to, or resulting from the design, development, clinical testing and investiga-

tion, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of products as provided for in subparagraph (A)(i). The decision to undertake such investigation shall be within the Secretary's discretion and shall not be subject to judicial review.

"(iii) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to abrogate or limit the application of subtitle II of chapter 5 and chapter 7 of title 5, United States Code (commonly known as the Administrative Procedure Act).

"(D) DETERMINATION BY SECRETARY.—

"(i) IN GENERAL.—In making a determination under this subparagraph, the Secretary, acting through an administrative law judge, must find clear and convincing evidence that—

"(I) the manufacturer, distributor, administrator, or health care provider violated a provision of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 301 et seq.) or this Act; and

"(II) in violating such Act, such manufacturer, distributor, administrator, or health care provider acted with willful misconduct.

"(ii) EFFECT OF DETERMINATION.—If the Secretary finds such clear and convincing evidence under clause (i), the Secretary shall examine whether such willful misconduct to violate an Act under such clause—

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

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

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

"(iv) EFFECT OF DETERMINATION.—Subject to subsection (c), the sole exception to the immunity from suit and liability of manufacturers, distributors, administrators, or healthcare providers set forth in subsection (a) and subparagraph (A) shall be for actions against a manufacturer, distributor, administrator, or healthcare provider as provided in subparagraph (A).

"(v) JUDICIAL REVIEW.—At any time prior to the 90th day following a determination by the Secretary under clause (i), any manufacturer, distributor, administrator, or health care provider named in such determination may file a petition with the United States Court District Court for the District of Columbia, for a judicial review of such determination. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose. The Secretary thereupon shall file in the court the record of the findings on which the Secretary based his or her determination. The filing of a peti-

tion under this clause shall automatically stay the Secretary's determination for the duration of the judicial proceeding. The sole parties to the judicial proceeding shall be the Secretary and the petitioner. Intervention by third parties in the judicial proceeding shall not be permitted. No subpoenas shall be issued nor shall other compulsory process apply. The court's review of a determination by the Secretary under this clause shall conform to the procedures for judicial review of administrative orders set forth in paragraphs (2) through (6) of section 701(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(f)) to the extent consistent with this section.

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

"(vii) REGULATORY AUTHORITY.—The Secretary, in consultation with the Attorney General, shall promulgate regulations defining what actions by a manufacturer, distributor, administrator, or healthcare provider of a security countermeasure or a qualified pandemic and epidemic product shall be deemed to constitute 'willful misconduct' for purposes of clause (i). In promulgating such regulations, the Secretary shall consider the nature of the actual or potential public health emergency, the timing and extent of any vaccination or countermeasure program, and any other circumstances they deem significant, so that any civil actions permitted under this subsection will not adversely affect the public health. The Secretary may specify the period of time for which such regulations apply.

"(viii) EVIDENCE REQUIRED.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that require, in order to be a party under

this section, that an individual present evidence that reasonably demonstrates that—

"(I) such individual has suffered a loss as a direct result of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, or administration of a security countermeasure or qualified epidemic or pandemic product; and

"(II) the loss as described in subclause (I) was a direct result of the willful misconduct of the manufacturer, distributor, administrator, or health care provider in violating the Federal Food, Drug, and Cosmetic Act or this Act.

"(E) SCOPE.—Subparagraph (C) shall apply regardless of whether the suit or liability described in subsection (a) or the claim described in subparagraph (A) arises from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, ad-

ministration, or use by the Federal Government or by any person.

''(2) DECLARATION BY SECRETARY.—

''(A) IN GENERAL.—The Secretary may issue a declaration, pursuant to this paragraph, that an actual or potential public health emergency makes advisable the distribution, administration, or use of a security countermeasure or qualified pandemic or epidemic product.

''(B) SECURITY COUNTERMEASURE OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The Secretary shall specify in such declaration the security countermeasures or qualified pandemic or epidemic products to be sold by, purchased from, or donated by a manufacturer or drawn from the Strategic National Stockpile.

''(C) EFFECTIVE PERIOD.—The Secretary shall specify in such declaration the beginning and the ending dates of the effective period of the declaration, which shall be not longer than 6 months. The Secretary may subsequently amend such declaration to shorten or extend such effective period, provided that the new

ending data is after the date on which the declaration is amended.

''(D) PUBLICATION.—The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

''(c) ACTIONS BY THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law.

''(d) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'administrator' means a person employed by the State or local government, or their designee, who supervised or administered a program with respect to the administration, dispensing, distribution, or provision of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, supplied technical or scientific advice or assistance.

''(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a person, including a volunteer, who distributes, prescribes, administers, dispenses, provides a facility to administer, or supervises or oversees the administration of a security

countermeasure or a qualified pandemic or epidemic product, including persons who distribute, prescribe, administer, dispense, or provide a facility to administer in accordance with a designation under subsection (b)(2).

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

''(4) MANUFACTURER.—The term 'manufacturer' includes—

''(A) a contractor or subcontractor of a manufacturer;

''(B) a supplier of any product or service, research tool, or component to the manufacturer; and

''(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

''(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term 'qualified pandemic or epidemic product' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as such term is defined by section 351(i) of this Act) or device (as such term is defined by

section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))) designed, developed, modified, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause or a serious or life-threatening disease or condition caused by such a product, that—

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

"(B) is a product for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the product will qualify for approval or licensing within 8 years after the date the Secretary makes a declaration under paragraph (2); or

"(C) is authorized for emergency use section 564 of the Federal Food, Drug, and Cosmetic Act, except that subsection (b) of such section shall not apply.

"(6) PARTY.— The term 'party' means an individual who can reasonably demonstrate to the Secretary that such individual has suffered a loss (as

defined in paragraph (3)) as a direct result of the willful misconduct of a manufacturer, distributor, administrator, or health care provider.

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

''(8) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2(c)(1)(B).''.

SEC. 7. COMPENSATION.

Title H of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

''PART D—OTHER COMPENSATION PROGRAMS

''SEC. 271. COVERED COUNTERMEASURES PROGRAM.

''(a) IN GENERAL.—If the Secretary issues a Proclamation stating that there is a critical public health need for a covered individual to receive a covered countermeasure during the effective period of the Proclamation, the Secretary shall establish a process to provide compensation to such covered individuals for a covered injury, consistent with the Smallpox Emergency Personnel Protection program under part C.

''(b) DEFINITION.—For purposes of this section:

"(1) COVERED COUNTERMEASURE.—The term 'covered countermeasure' means a qualified pandemic or epidemic (as defined in section 319F–3(c)(5)) or a security countermeasure (as defined in section 319F–2(c)(1)(B)) specified in the Proclamation.

"(2) COVERED INDIVIDUAL.—The term 'covered individual' means an individual—

"(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public health or safety personnel, or support personnel for such occupational specialties;

"(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services emergency response plan approved by the Secretary;

"(C) who has volunteered and been selected to be a member of an emergency response plan; and

"(D) to whom a covered countermeasure is administered pursuant to such approved plan during the effective period of the Proclamation and prior to the time at which the Secretary declares a public health emergency pursuant to

section 319 related to a covered countermeasure specified in the Proclamation.

''(3) COVERED INJURY.—The term 'covered injury' means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined by the Secretary to have been sustained by a covered individual as the direct result of administration to the individual of a covered countermeasure.

''(4) EFFECTIVE PERIOD OF THE PROCLAMATION.—The term 'effective period of the Proclamation' means the effective period specified in the Proclamation, unless extended by the Secretary.

''(5) EMERGENCY RESPONSE PLAN.—The term 'emergency response plan' or 'plan' means a response plan detailing actions to be taken in preparation for a pandemic, epidemic, or biological, chemical, nuclear agent or toxin that presents, or may present, a public health emergency.

''(6) PROCLAMATION.—The term 'Proclamation' means a Proclamation regarding the critical public health need for the administration of a covered countermeasure issued by the Secretary and published in the Federal Register. Such Proclama-

tion shall specify the specific covered countermeasure recommended for administration.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the creation of a compensation program if the covered injuries are only minor injuries consistent with section (b)(3).''.

SEC. 8. REBATES AND GRANTS FOR RESEARCH DEVELOPMENT, AND MANUFACTURING OF VACCINES, QUALIFIED COUNTERMEASURES AND PANDEMIC OR EPIDEMIC PRODUCTS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may award to a person with respect to an investment described in this section (or an amendment made by this section)—

(1) a rebate pursuant to subsection (b); or

(2) a grant pursuant to section 319M of the Public Health Service Act (as added by subsection (c)).

(b) SURGE CAPACITY AND RESEARCH REBATES.—

(1) IN GENERAL.—The Secretary may award rebates out of any money in the Treasury not otherwise appropriated to persons for the expansion of surge capacity for manufacturing vaccines, qualified countermeasures (as defined in 319F–1 of the Pub-

lic Health Service Act, as amended by this Act) or qualified pandemic or epidemic products (as defined in 319F–3(c)(5) of such Act, as added by this Act) (referred to in this section as ''vaccines, countermeasures or products'') and for vaccines, countermeasures, or products research.

(2) VACCINES, COUNTERMEASURES OR PRODUCTS MANUFACTURING FACILITIES INVESTMENT REBATE.—

(A) IN GENERAL.—For purposes of this section, vaccines, countermeasures or products manufacturing facilities investment rebate for any taxable year for a person (as defined with respect to such person for purposes of the Internal Revenue Code of 1986) shall be an amount equal to 20 percent of the qualified investment for such taxable year.

(B) VACCINES, COUNTERMEASURES OR PRODUCTS MANUFACTURING FACILITIES INVESTMENT.—For purposes of subparagraph (A), the qualified investment for any taxable year for a person is the basis of each vaccines, countermeasures or products manufacturing facilities property placed in service by the person during the taxable year involved.

(C) VACCINES, COUNTERMEASURES AND PRODUCTS MANUFACTURING FACILITIES PROPERTY.—For purposes of this subsection, the term ''vaccines, countermeasures and products manufacturing facilities property'' means real and tangible personal property—

(i)(I) the original use of which commences with the person applying for the rebate; or

(II) which is acquired through purchase (as defined by section 179(d)(2) of the Internal Revenue Code of 1986);

(ii) which is depreciable under section 167 of the Internal Revenue Code of 1986;

(iii) which is physically located in a State;

(iv) which is used for the manufacture, distribution, or research and development of vaccines, countermeasures, or products; and

(v) which is in compliance with applicable good manufacturing practice and with any other applicable requirements which are promulgated by the Secretary, the Occupational Safety and Health Ad-

ministration, or the Environmental Protection Agency, and which are applicable to such property.

(D) DENIAL OF DOUBLE BENEFIT FOR MANUFACTURING FACILITIES EXPENSES.—If any portion of the vaccines, countermeasures, and products manufacturing facilities property investment expenses is otherwise allowable as a deduction for the taxable year involved, the Secretary shall only provide a rebate under this section for the portion of such expenses not covered by the rebate determined by such deduction.

(E) ELIGIBILITY.—To be eligible to receive a rebate under this subsection, a manufacturer shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(i) a detailed description and intended use of the facilities that is the basis of application;

(ii) a detailed description of the vaccine, countermeasure, or product being

produced or that may be produced at the facility;

(iii) a detailed accounting of qualified manufacturing facilities investment of the person;

(iv) a certification as to the compliance of the person with clauses (i) through (iv) of subparagraph (C); and

(v) copies of tax returns for the taxable year involved.

(F) EFFECTIVE DATE.—This paragraph shall apply to property placed in service after December 31, 2005.

(G) TERMINATION.—This paragraph shall not apply to any property placed in service after December 31, 2010.

(3) MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES, COUNTERMEASURES OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS REBATE.—

(A) IN GENERAL.—For purposes of this subsection, the research rebate determined under this section for the taxable year involved (as determined as provided for in paragraph (2)(A)) is an amount equal to 35 percent of the vaccines, qualified countermeasures, or qualified

pandemic or epidemic products (referred to in this section as ''vaccine, countermeasure, or product'') research expenses for the taxable year.

(B) VACCINES, COUNTERMEASURES, OR PRODUCTS RESEARCH EXPENSES.—Except as otherwise provided in this paragraph, the term ''vaccines, countermeasures, or products research expenses'' means the amounts which are paid or incurred by the researcher or manufacturer during the taxable year with respect to any research and development of vaccines, countermeasures, or products. Qualified research and development expenses include expenses related to reformulating existing vaccines, countermeasures, or products.

(C) DETERMINING RESEARCH EXPENSES.—Any vaccines, countermeasures, or products research expenses for any taxable year which are qualified research expenses (within the meaning of this subsection) shall be taken into account in determining base period research expenses for purposes of applying this paragraph to subsequent taxable years.

(D) DENIAL OF DOUBLE BENEFIT FOR VACCINES, COUNTERMEASURES, OR PRODUCTS RESEARCH EXPENSES.—If any portion of the vaccines, countermeasures, or products research expenses is otherwise allowable as a deduction for the taxable year involved, the Secretary shall only provide a rebate under this section for the portion of such expenses not covered by any rebate determined by such deduction.

(E) ELIGIBILITY.—To be eligible to receive a rebate under this paragraph, a manufacturer or researcher shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(i) a detailed description of the vaccine, countermeasure, or product being researched or developed;

(ii) a detailed description of the research that is the subject of the rebate;

(iii) a detailed accounting of the qualified research expenses involved;

(iv) an assurance that the researcher or manufacturer is following good laboratory practice, as required by the Secretary

pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.); and

(v) copies of tax returns for the taxable year involved.

(F) EFFECTIVE DATE.—This paragraph shall apply to expenses for taxable years beginning after December 31, 2005.

(4) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The terms ''vaccines, countermeasures, or products manufacturing investment'' and ''qualified research expenses'' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise funded by another person (or any governmental entity).

(c) GRANTS TO EXPAND AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF VACCINES, COUNTERMEASURES OR PRODUCTS.—Part B of title III of the Public Health Service Act is amended by inserting after section 319L, as added by this Act, the following:

"SEC. 319M. GRANTS TO EXPAND AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF VACCINES, QUALIFIED COUNTERMEASURES OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS.

"(a) IN GENERAL.—The Secretary may award grants to a manufacturer to purchase or improve real property and tangible personal property used in the research and development, manufacture, or distribution of a vaccine, qualified countermeasure (as defined in section 319F–1) or qualified pandemic or epidemic product (as defined in section 319F–3(c)(5)).

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a manufacturer shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(1) a detailed description of the planned expansion;

"(2) a detailed description of the equipment, facility, or property involved;

"(3) a certification that such facility or property is physically located in a State;

"(4) a detailed description of the vaccine, qualified countermeasure or qualified pandemic or epidemic product involved;

‘‘(5) a detailed description of the research and development, manufacturer, or distribution involved;

‘‘(6) a description of how such equipment, facility, or property is to be used;

‘‘(7) a description of whether such equipment, facility, or property can be used for the research and development, manufacture, or distribution of a drug, biological product, device or other countermeasure not described in paragraph (4); and

‘‘(8) a certification that the equipment, facility, or property involved complies with all applicable Federal, State, and local laws.

‘‘(c) RECAPTURE.—

‘‘(1) IN GENERAL.—If, at any time prior to the expiration of the 20-year period beginning on the date on which a grant is awarded under this section, the facility or property involved ceases to be used for the purpose for which the grant was awarded, the United States shall be entitled to recover from the manufacturer an amount bearing the same ratio to the value of the facility or property at such time as the amount of the grant bore to the total cost of the purchase or improvement involved. The value of the facility or property at such time may be determined by agreement of the manufacturer and the Sec-

retary, or by order of the United States District Court for the district in which such facility or property is situated.

''(2) LIMITATION.—The Secretary may not recapture the facility or property under this subsection if the Secretary determines, in accordance with regulations promulgated by the Secretary, that there is good cause for the failure of proper use.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.''.

SEC. 9. 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 Practices) 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 products and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.''.

SEC. 10. ANIMAL MODELS FOR CERTAIN DISEASES.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

''SEC. 409J. ANIMAL MODELS FOR CERTAIN DISEASES.

''(a) IN GENERAL.—The Secretary, acting through the Director of NIH, in coordination with the Director of the Biomedical Advanced Research and Development Agency, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs, shall establish and award grants under this section to eligible entities, including other Federal agencies, to study the physiological responses of certain animal species and, where appropriate, juvenile models, to chemical, biological, radiological, or nuclear agents or toxins or potential pandemic infectious disease, and to develop and validate such animal models.

''(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

"(1) provide assurances to the Secretary that the entity—

"(A) has access to an appropriate biosafety laboratory or facility, as determined by the Secretary; and

"(B) will follow good laboratory practices;

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(A) a detailed description of the animal model involved;

"(B) a detailed description of the chemical, biological, radiological, nuclear, or other infectious agents involved;

"(C) a detailed description of how the animal model will be used for the development of a drug, biological product, or device for use as a countermeasure;

"(D) a detailed description of validation methods; and

"(E) an assurance that the entity will follow good laboratory practices; and

"(3) agree to submit the results of the research funded under the grant to the Director of the Bio-

medical Advanced Research and Development Agency and the Director of NIH.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

SEC. 11. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC ADVISORY COMMITTEE.

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

''SEC. 566. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this section, the Secretary shall establish an 11-member advisory committee to be known as the 'Animal Model/Research Tool Scientific Advisory Committee' (referred to in this section as the 'Advisory Committee').

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary shall appoint as members of the Advisory Committee individuals who are technically qualified by training and experience, including in medicine, veterinarian medicine, biology, technology involving the manufacture, eval-

uation, or use of research tools, who are of appropriately diversified professional backgrounds to evaluate the priority animal models and research tools.

''(2) EX OFFICIO MEMBERS.—The Secretary may appoint Federal officials, including at least 1 representative of the Biomedical Advanced Research and Development Agency, to serve as ex officio members of the Advisory Committee.

''(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as the chairperson.

''(c) DUTIES.—The Advisory Committee shall provide advice, information, and recommendations to the Secretary on—

''(1) accepted animal models for diseases and conditions associated with any biological (including organisms that cause infectious diseases), chemical, radiological, or nuclear agent or toxin or potential pandemic infectious disease;

''(2) strategies to accelerate animal model and research tool development and validation; and

''(3) scientific issues raised in applications as requested by the Secretary.

''(d) PRIORITIES.—Priorities for animal models and research tools shall be established by the Secretary.

''(e) COMPENSATION; SUPPORT; FACA.—

''(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged, and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Federal Government service employed intermittently.

''(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

''(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

''(f) PROCEEDINGS.—The Advisory Committee shall make and maintain a transcript of any proceeding of the Committee. The Committee shall delete from any transcript made under this subsection information, which is exempt from disclosure under section 552(b) of title 5, United States Code.''.

SEC. 12. COLLABORATION AND COORDINATION.

Section 2 of the Clayton Act (15 U.S.C. 13) is amended by adding at the end the following:

''(g) LIMITED ANTITRUST EXEMPTION.—

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

''(A) COUNTERMEASURES AND PRODUCTS DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') or the Director of the Biomedical Advanced Research and Development Agency (referred to in this subsection as the 'Director'), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with parties involved in the development of security countermeasures (as defined in section 319F–2 of the

Public Health Service Act) qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act) or qualified pandemic or epidemic products (as defined in section 319F–3(c)(5) of the Public Health Service Act) (referred to in this section as ''countermeasures or products'') for the purpose of the development, manufacture, distribution, purchase, sale, or storage of countermeasures or products consistent with the purposes of this title. The Secretary or Director may convene such meeting or consultation at the request of any person, the Secretary of Homeland Security, the Attorney General, the Chairperson of the Federal Trade Commission, an industry representative or member, or upon initiation by such Secretary. The Secretary or Director shall give notice of such meetings and consultations to the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson') and the Attorney General.

''(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 or Director;

‘‘(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of countermeasures or products, as determined by the Secretary or Director;

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

‘‘(iv) be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures or products, consistent with the purposes of this title; and

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

‘‘(C) LIMITATION.—The Secretary or Director may not require the disclosure of confidential commercial or proprietary information.

‘‘(D) MINUTES.—The Secretary or Director shall maintain minutes of meetings and con-

sultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code, unless such Secretary or Director, in consultation with the Attorney General, determines that disclosure would pose no threat to national security. Such determination shall not be subject to judicial review.

"(E) EXEMPTION.—

"(i) IN GENERAL.—The antitrust laws shall not apply to meetings and consultations under this paragraph.

"(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection.

"(2) WRITTEN AGREEMENTS.—The Secretary or the Director shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing 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 of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

"(E) any other relevant information determined necessary by the Secretary or Director in consultation with the Attorney General and the Chairperson.

"(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement regarding covered activities referred to in paragraph (2) would likely—

"(A) be in compliance with the antitrust laws, and so inform the Secretary or Director and the participating parties; or

"(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, lim-

ited to the performance of the agreement consistent with the purposes of this title.

"(4) ACTION ON REQUEST FOR EXEMPTION.—

"(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 business days of the receipt of such request.

"(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 days. Such additional period may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary or Director and the parties involved.

"(C) DETERMINATION.—In granting an exemption under this paragraph, the Attorney General, in consultation with the Chairperson and the Secretary or Director—

"(i) shall find—

“(I) that the agreement involved is necessary to ensure the availability of countermeasures or products;

“(II) that the exemption from the antitrust laws would promote the public interest; and

“(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

“(ii) may consider any other factors determined relevant by the Attorney General and the Chairperson.

“(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and shall be renewed (with modifications, as appropriate) on the date that is 3 years after the date on which the exemption becomes effective (and at 3-year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

"(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

"(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

"(8) REPORT.—Not later than 1 year after the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

"(9) STATUS OF MEMORANDUMS.—Minutes maintained by the Secretary or Director pursuant to paragraph (1)(D) shall not be disclosed under section 552 of title 5, United States Code, if the exemption is not renewed under paragraph (5), or if meetings are no longer conducted, unless the Secretary or Director, in consultation with the Attorney General, determines that the disclosure would pose

no threat to national security. Such determination shall not be subject to judicial review.

''(h) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemption under this section shall expire at the end of the 6-year period that begins on the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2005.

''(i) 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 this Act, except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) (commonly known as the Robinson-Patman Act), and 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) COVERED ACTIVITIES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, in-

cluding attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

"(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of countermeasures or products;

"(ii) the development or testing of basic engineering techniques necessary to the development of countermeasures or products;

"(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of countermeasures or products;

"(iv) the production, distribution, or marketing of a product, process, or service that is a countermeasures or products;

''(v) the testing in connection with the production of a product, process, or services necessary to the development of countermeasures or products;

''(vi) the collection, exchange, and analysis of research or production information necessary to the development of countermeasures or products; or

''(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

''(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

''(i) Exchanging information among competitors relating to costs, profitability, marketing, or distribution of any product, process, or service if such information is

not reasonably necessary to carry out the purposes of covered activities.

"(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 who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to 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

by a determination under subsection (g)(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 the purpose of 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 so expressly exempted from the antitrust laws by a determination under subsection (g)(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 who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

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

''(3) 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, and any other actions related to preparation of a countermeasure or product.''.

SEC. 13. 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)(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 (as 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 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 up to 3 additional advance payments of 5 per-

cent 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 sole and exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed 15 years, 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 an-

other entity or entities without approval by the Secretary.

''(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 coun-

termeasures to be developed and procured;

''(bb) the amount of funding that will be dedicated by the Secretary for research and development of the countermeasure; and

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

(D) 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 the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 and the

Project BioShield Act of 2004, for the procurement of countermeasures under section 319F–1 or 319F–2.''

SEC. 14. NATIONAL PATHOLOGY CENTER.

(a) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 401(b)(2), by adding at the end the following:

''(H) The National Pathology Center.''; and

(2) by adding at the end of part E (42 U.S.C. 287 et seq.) the following:

''Subpart 7—National Pathology Center

''SEC. 485A. ESTABLISHMENT OF NATIONAL PATHOLOGY CENTER.

''In order to provide pathology consultation for civilian and military health professionals (including Department of Veterans Affairs health professionals) there is established the National Pathology Center (in this subpart referred to as the 'Center'). The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

''SEC. 485B. PURPOSES AND FUNCTIONS OF THE CENTER.

''(a) PURPOSES OF THE CENTER.—The general purposes of the Center are to—

"(1) conduct and support research, education, training, and other programs with respect to the science and clinical practice of pathology;

"(2) maintain and improve a pathology tissue repository; and

"(3) provide pathology consultation services.

"(b) ACTIVITIES OF THE DIRECTOR.—In order to carry out the purposes of the Center described in subsection (a), the Director of the Center—

"(1) shall—

"(A) maintain and improve a comprehensive repository of pathological specimens;

"(B) provide consultations on request regarding clinical cases;

"(C) conduct educational programs and publish educational materials on the science and clinical practice of pathology;

"(D) maintain and improve registries on such clinical conditions as the Director of the Center determines appropriate; and

"(E) conduct and support research on pathology; and

"(2) may—

"(A) collect reasonable and appropriate fees for the activities described in paragraph (1)(B); and

"(B) conduct such other activities as the Director of the Center determines appropriate to carry out the purposes described in subsection (a).

"(c) AUTHORITY FOR EXPERT OPINIONS.—The Director of the Center may enter into memoranda of understanding with officials at the Department of Veterans Affairs and the Department of Defense to provide expert second opinion pathology consultations and pathology education or training if the Secretary of either such Department determines that such provision would be in the best interest of either of their respective departments.

"SEC. 485C. BOARD OF REGENTS.

"(a) MEMBERSHIP.—

"(1) IN GENERAL.—There is established a Board of Regents of the Center (in this subpart referred to as the 'Board') consisting of—

"(A) the Surgeons General of—

"(i) the Public Health Service;

"(ii) the Army;

"(iii) the Navy; and

"(iv) the Air Force;

"(B) the Chief Medical Director of the Department of Medicine and Surgery of the Department of Veterans Affairs;

"(C) the Deputy Director of the National Library of Medicine;

"(D) the Assistant Secretary of Health of the Department of Defense;

"(E) the Dean of the Uniformed Services University of the Health Sciences; and

"(F) 11 members to be appointed by the Secretary from among leaders in pathology research, education and clinical practice.

"(2) EX OFFICIO MEMBERS.—The members of the Board described in subparagraphs (A) through (E) of paragraph (1) shall serve as ex officio members of the Board.

"(3) CHAIRPERSON.—The members of the Board appointed under paragraph (1)(F) shall annually elect one of such members to serve as the Chairperson of the Board until the next election.

"(b) DUTIES OF THE BOARD.—It shall be the duty of the Board to advise, consult with, and make recommendations to the Director of NIH on important matters of policy in regard to the Center, including such matters as the scope, content and organization of the research,

education and consultative services provided by the Center. The Board shall make recommendations to the Director of NIH regarding the rules under which specimens from the tissue repository will be used and under which it's publications, facilities and services will be made available to various kinds of users.

''(c) TERMS OF OFFICE.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within 1 year after the end of the preceding term of such member.

''(d) COMPENSATION.—Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of the Board, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c).

"SEC. 485D. GIFTS TO THE CENTER.

"Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Center or for carrying out any of its functions.

"SEC. 485E. CENTER FACILITIES.

"There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Center. The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.".

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the appropriate committees of Congress that contains—

(1) a review of all functions and duties of the National Pathology Center under subpart 7 of part

E of title IV of the Public Health Service Act,as established by subsection (a);

(2) areas where such functions and duties overlap with the functions and duties of the National Institutes of Health; and

(3) recommendations concerning necessary modifications to the National Pathology Center.

(c) TRANSFER OF THE ARMED FORCES INSTITUTE OF PATHOLOGY.—

(1) IN GENERAL.—

(A) IN GENERAL.—Except as provided in subparagraph (B), there are transferred to the National Pathology Center established under subpart 7 of part E of title IV of the Public Health Service Act all functions, duties, personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations of the Armed Forces Institute of Pathology. The preceding sentence shall not affect any proceedings, pending applications, suits, or other actions pending on the date of enactment of this Act.

(B) EXCEPTIONS.—The following components of the Armed Forces Institute of Pathol-

~~ogy shall not be transferred from the Department of Defense pursuant to subparagraph (A):~~

~~(i) The Armed Forces Medical Examiner.~~

~~(ii) The Department of Defense DNA registry.~~

~~(iii) Accident Investigation Program.~~

~~(iv) The histopathology training program.~~

~~(v) The patient safety center.~~

~~(vi) Department of Legal Medicine.~~

~~(vii) Center for Clinical Laboratory Medicine.~~

~~(viii) Drug Testing and Quality Assurance Program.~~

~~(ix) Subject to the discretion of the Secretary of Defense, medical research programs on the following:~~

~~(I) Body armor.~~

~~(II) Environmental sarcoidosis.~~

~~(III) Depleted uranium.~~

~~(IV) Military working dogs.~~

~~(V) Such other areas of research related to pathology as the Secretary of Defense shall choose to conduct.~~

~~(2) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or relating to the Armed Forces Institute of Pathology shall be deemed to be a reference to the National Pathology Center established under subpart 7 of part E of title IV of the Public Health Service Act.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biodefense and Pandemic Vaccine and Drug Development Act of 2005".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.

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 AGENCY.

"(a) DEFINITIONS.—In this section:

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

"(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, including transactions for prototypes, as provided to the Secretary of Defense 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 COUNTERMEASURE AND QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT ADVANCED RESEARCH AND DEVELOPMENT.—

"(A) IN GENERAL.—The term 'qualified countermeasure and qualified pandemic or epidemic product advanced research and development' means any applied research, testing, or evaluation (including those conducted on hu-

mans or animals), related to the safety or effectiveness, that is required for approval, clearance, or licensing by the Secretary under this Act or the Federal Food, Drug, and Cosmetic Act, of such countermeasure or pandemic or epidemic product to diagnose, mitigate, prevent, or treat harm from a deliberate, accidental, or natural exposure to a chemical, biological, radiological, or nuclear agent, particularly such exposure resulting from an act of terrorism or potential pandemic infectious disease.

"(B) INCLUSION.—The term under subparagraph (A) includes any investigation to improve the manufacturing, formulation, finish, fill, delivery, or shelf-life of such qualified countermeasures or qualified pandemic or epidemic products.

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

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

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

"(b) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.—

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

"(2) PURPOSE.—It shall be the purpose of the BARDA to coordinate and oversee activities that support and accelerate qualified countermeasure or qualified pandemic or epidemic product (referred to in this section as 'countermeasure or 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) supporting countermeasure and product advanced research and development;

"(C) recommending approaches to modernize and streamline the countermeasure or product development process and reduce regulatory burdens with respect to procurement of security countermeasures and qualified pandemic or epidemic products; and

"(D) supporting 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—

"(A) be appointed by the President, with the advice and consent of the Senate;

"(B) report to the Secretary; and

"(C) serve as the principal advisor to the Secretary on countermeasure and product advanced research and development.

"(4) DUTIES OF DIRECTOR.—

"(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary, acting through the Director, shall—

"(i) increase appropriate communication between the Federal Government and relevant industries, academia, and other in-

terested persons with respect to countermeasure and product advanced research and development by establishing transparent, expeditious, and direct processes to—

"(I) facilitate regular, ongoing communication regarding the processes established under subparagraph (C)(ii) and new countermeasures or products of interest;

"(II) solicit research and associated data on potential countermeasures and products and related technologies; and

"(III) provide technical assistance with respect to such processes and the Food and Drug Administration approval process;

"(ii) at least annually—

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

"(II) sponsor relevant biodefense countermeasure technology demonstrations;

"(iii) carry out the activities described in subsection (g) of section 2 of the Clayton Act; and

"(iv) encourage and coordinate countermeasure or product advanced research and development, including by convening working groups as identified in paragraph (5).

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

"(i) conduct continuous searches and support calls for potential countermeasures or products for drugs, biological products, devices, or research tools to diagnose, mitigate, prevent, or treat harm from existing, emerging, or possible chemical, biological, radiological, and nuclear agents or potential pandemic infectious diseases that threaten public health and national security, as identified by the Assistant Sec-

retary for Public Health Emergency Preparedness;

"(ii) direct the countermeasure and product advanced research and development activities of the Department of Health and Human Services, in consultation with the Assistant Secretary for Public Health Emergency Preparedness, the Director of the National Institutes of Health, the Director of the Centers for the Disease Control and Prevention, and the Commissioner of Food and Drugs; and

"(iii) award contracts, grants, cooperative agreements, and enter into other transactions, to include use of simplified acquisition authorities provided under sections 319F–1 and 319F–2(c)(7)(C)(iii), to public and private persons, including for-profit and nonprofit persons, federally funded research and development centers, and universities, to—

"(I) support the cost of countermeasure and product advanced research and development; and

"(II) ensure accelerated development of countermeasures and products.

"(C) STREAMLINE PROCESSES.—To carry out the purpose described in paragraph (2)(C), the Secretary, acting through the Director, shall—

"(i) receive from the Assistant Secretary for Public Health Emergency Preparedness, requirements for national civilian biodefense needs, particularly countermeasures or products and other technologies, to diagnose, mitigate, prevent, or treat harm from existing, emerging, or potential chemical, biological, radiological, or nuclear agents (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) or potential pandemic infectious diseases;

"(ii) establish transparent, expeditious, and direct processes for selecting promising countermeasures and products, supporting them through advanced research and development and recommending them for procurement;

"(iii) establish an office within the BARDA, in consultation with the Commissioner of Food and Drugs, to—

"(I) facilitate regular and ongoing communication between the BARDA and the Food and Drug Administration regarding the status of BARDA advanced research and development activities;

"(II) ensure that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

"(III) connect interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act;

"(iv) coordinate with the Food and Drug Administration to facilitate regulatory review and approval of promising classes of countermeasures or products

through the development of research tools; and

"(v) recommend to the Secretary, through the Assistant Secretary for Public Health Emergency Preparedness, procurement of the most promising eligible security countermeasures or qualified pandemic or epidemic products identified in clause (i).

"(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary, acting through the Director, may award contracts, grants, cooperative agreements, or enter into other transactions, such as prize payments, to include use of simplified acquisition authorities provided under sections 319F–1 and 319F–2(c)(7)(C)(iii), to the entities described in subparagraph (B)(iii), to promote innovation in technologies supporting the advanced research and development and production of qualified or security countermeasures or qualified pandemic or epidemic products, such as research tools, manufacturing, countermeasure administration, storage, and bioinformatics and other devices.

"(E) OTHER DUTIES.—

"(i) IN GENERAL.—The Director may—

"(I) prepare and submit to the President and Congress, an annual budget estimate for qualified countermeasure and pandemic or epidemic product advanced research and development and other BARDA activities, after opportunity for comment by the Secretary; and

"(II) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the BARDA.

"(ii) SECRETARY DUTIES.—The Secretary, acting through the Director, may—

"(I) enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary to carry out the functions of BARDA, without regard to section 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 3324(a) and (b), (41 U.S.C. 5), with any public

agency, any firm, association, corporation, or educational institution, or any other person;

"(II) support advanced research and development and innovation of potential countermeasures or products by highly qualified foreign national persons outside the United States that may inure to the benefit of the American people and collaborative research involving American and foreign participants;

"(III) administer grants using milestone–based awards and payments; and

"(IV) establish 1 or more federally funded research and development centers or university affiliated research centers in accordance with section 253(c)(3) of title 41, United States Code.

"(5) VULNERABLE POPULATIONS.—In carrying out the activities under this section, the Director, in consultation with the Vulnerable Populations Working Group, may give priority to supporting and facili-

tating advanced research and development of countermeasures or products, and formulations of countermeasures or products, that are likely to be safe and effective for pediatric populations, pregnant women, and other vulnerable populations.

"(6) WORKING GROUPS.—

"(A) IDENTIFICATION OF TECHNOLOGIES.—

"(i) IN GENERAL.—The Director may establish and convene, or enter into a contract with a public or private research institution to convene, one or more working groups that consists of experts on countermeasure technology to identify innovative technologies that have the potential to be developed as countermeasures or products.

"(ii) MEETINGS.—A working group established under clause (i) shall participate in regular meetings with sponsors of countermeasures, products, or related technologies to—

"(I) review the scientific evidence or concept of such countermeasures, products, or related technologies;

"(II) provide guidance on research protocols or studies; and

"(III) provide guidance on the regulatory approval process for countermeasures, products, and related technologies.

"(iii) RECOMMENDATIONS.—Not later than 30 days after concluding a meeting with a sponsor of a countermeasure, product, or related technology, the working group shall make recommendations to the Director concerning such countermeasure, product, or related technology.

"(iv) CONFIDENTIALITY.—Any commercial confidential or proprietary information that is disclosed to the working group in a meeting under this section shall remain confidential and shall not be disclosed other than to the Secretary or the Director, or their designees.

"(v) CONSTRUCTION.—Nothing in this subparagraph shall be construed to prohibit a sponsor from meeting with the Director to discuss potential countermeasures, products, or related technologies.

"(B) PUBLIC WORKING GROUP.—The Director may establish and convene one or more work-

ing groups composed of private citizens and officials of Federal, State, and local governments to advise such Director with respect to the functions of the BARDA and the Director.

"(C) VULNERABLE POPULATIONS WORKING GROUP.—The Director shall establish and convene a Vulnerable Populations Working Group composed of experts on pediatric populations, pregnant women, and other vulnerable populations to advise such Director with respect to—

"(i) supporting and facilitating advanced research and development of countermeasures, and formulations of countermeasures, that are safe and effective for such populations; and

"(ii) other activities of the BARDA that effect such populations.

"(7) PERSONNEL AUTHORITIES.—

"(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—In hiring personnel for the BARDA, the Director shall have the hiring and management authorities described in section 9903 of title 5, United States Code (as added by section 1101 of the National Defense Authorization Act for Fiscal Year 2004 (Public

Law 108–136)). With respect to the personnel of the BARDA, the term of appointments for employees referred to under subsection (c)(1) of that section may not exceed 5 years before the granting of any extension under subsection (c)(2) of that section.

"(B) SPECIAL CONSULTANTS.—The Director may accept special consultants as personnel for the BARDA under section 207(f).

"(C) INTERGOVERNMENTAL PERSONNEL ACT.—The Director may accept as personnel for the BARDA, employees under subchapter VI of chapter 33 of subpart B of part III of title 5, United States Code.

"(D) OTHER SERVICES.—The Director may accept voluntary and uncompensated services.

"(c) NATIONAL BIODEFENSE ADVISORY BOARD.—

"(1) IN GENERAL.—

"(A) PURPOSE.—The National Biodefense Advisory Board shall provide expert advice and guidance to the Secretary on the threats, challenges, and opportunities presented by advances in biological and life sciences and the threat from natural infectious diseases and chemical, biological, radiological, and nuclear threats.

"(B) MEMBERSHIP.—There is established the National Biodefense Advisory Board (hereinafter in this section referred to as the 'Board') to be composed of 23 members who represent the Nation's preeminent scientific, public health, and medical experts on the subject of biological, chemical, nuclear, and radiological threats, whether naturally occurring, accidental, or deliberate, as follows:

"(i) EX OFFICIO.—The following members shall serve on the Board ex officio:

"(I) The Assistant to the President for Homeland Security and Counterterrorism.

"(II) The Director of the Office of Science and Technology Policy.

"(III) The Assistant Secretary for Public Health Emergency Preparedness.

"(IV) The Director of the National Institutes of Health.

"(V) The Director of the Centers for Disease Control and Prevention.

"(VI) The Commissioner of Food and Drugs.

"(VII) The Director of BARDA.

"(VIII) The Assistant Secretary of Defense for Health Affairs.

"(IX) The Under Secretary of Homeland Security for Science and Technology.

"(X) The Secretary of Agriculture (or a designee).

"(ii) APPOINTED MEMBERS.—The following individuals, as appointed by the Secretary:

"(I) Four representatives of the pharmaceutical, biotechnology, and device industries.

"(II) Four representatives of academia.

"(III) Five other members as determined appropriate by the Secretary.

"(C) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B)(ii) 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.

"(D) 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.

"(2) DUTIES.—The Board shall—

"(A) advise the Secretary on major biodefense initiatives and review ongoing and proposed biodefense programs, which may include potential activities of the BARDA; and

"(B) in consultation with the Director of BARDA, and in coordination with the Director of National Institute of Allergy and Infectious Diseases, provide to the Secretary, recommendations and findings for an expanded, intensified, and coordinated biodefense research program encompassing the programs of the BARDA and other Federal agencies and related programs of the other research institutes.

"(3) MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually to provide to the Secretary updated assessments, findings, and recommendations of the current trends, challenges, and opportunities posed in life sciences biotechnology and genetic engineering.

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

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

"(6) 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.

"(7) PERSONNEL.—

"(A) OFFICERS 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 shall be compensated at a rate

equivalent to 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.

"(d) FUND.—

"(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be administered by the Director of the BARDA.

"(2) FUNDS.—

"(A) FIRST FISCAL YEAR.—Of the amounts appropriated to carry out the Project BioShield Act of 2004 (Public Law 108–276) and not obligated, $1,000,000,000 shall be available to the Fund to carry out this section for fiscal year 2006. Such amounts shall remain available until expended.

"(B) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2007 and each subsequent fiscal year. Such sums shall remain available until expended.

"(e) EFFECT OF SECTION.—Nothing in this section shall be construed to limit any authority of the Department of Health and Human Services, including those authorities provided under the Project BioShield Act of 2004 (Public Law 108–276).

"(f) INAPPLICABILITY OF CERTAIN ACTS.—

"(1) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the duties, activities, working groups, and advisory boards of the BARDA.

"(2) FOIA.—Information that relates to the activities, working groups, and advisory boards of the

BARDA shall not be subject to disclosure under section 552 of title 5, United States Code, unless the Secretary or Director determines that such disclosure would pose no threat to national security. Such a determination shall not be subject to judicial review.

"(3) CERTAIN COST PRINCIPLES AND COST ACCOUNTING STANDARDS.—Notwithstanding any other provision of law, the cost principles set forth under part 31 of title 48, Code of Federal Regulations, the cost accounting standards set forth under chapter 99 of title 48, Code of Federal Regulations, and the requirement for the submission of certified cost and pricing information under section 304A of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254b), shall not apply to any contract, grant, cooperative agreement, or other transaction entered into under the Project BioShield Act of 2004 (Public Law 108–276).".

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))), device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), or research tool (as that term is defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act) 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 (including organisms that cause an infectious disease) or toxins, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

"(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; or

"(iii) in the case of a research tool, enable the rapid and effective identification, assessment, or development of a drug, biological product, or device to diagnose, mitigate, prevent, or treat harm, as described in clause (i) or (ii).

"(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—

(A) striking "treat, identify, or prevent" each place it appears and inserting "diagnose, mitigate, prevent, or treat"; and

(B) inserting "agent (including organisms that cause an infectious disease) or toxin" after "any biological".

(c) RESEARCH TOOL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(rr) RESEARCH TOOL.—The term 'research tool' includes the full range of tools and systems that assist in the discovery, development, or manufacture of drugs, biological products (as defined in section 351 of the Public Health Service Act), or devices.".

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

(a) MARKET EXCLUSIVITY.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

"SEC. 505C. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUNTERMEASURE PRODUCTS.

"(a) IN GENERAL.—With respect to countermeasure products (as such term is defined in this section), if a countermeasure product is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) shall be 10 years instead of 7 years.

"(b) DEFINITION.—For the purpose of this section, the term 'countermeasure' means a drug or biological product (as such term is defined by section 351(i) of the Public Health Service Act) that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radio-

logical, or nuclear agent (including organisms that cause an infectious disease) or toxin identified as a material threat under subsection (c)(2)(A)(ii) of section 319F–2 of the Public Health Service Act.".

(b) ORPHAN DRUGS.—For purposes of section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) a biological, chemical, radiological, or nuclear agent (including organisms that cause an infectious disease) or toxin identified as a material threat under subsection (c)(2)(A)(ii) of section 319F–2 of the Public Health Service Act shall be considered to be a "rare disease or condition" within the meaning of such term in such section 526. The Secretary may designate antibiotics and anti-infective products that treat infectious diseases as designated drugs or biological products under such section 526.

(c) EFFECT OF SECTION.—This section, and the amendments made by this section, shall apply to new drug applications and biological product licenses approved under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act after the date of enactment of this Act.

SEC. 6. LIABILITY PROTECTIONS FOR PANDEMICS, EPIDEMICS, AND COUNTERMEASURES.

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

"SEC. 319F–3. LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

"(a) AUTHORITY.—As provided in subsection (b), and subject to subsection (b)(1)(C), a manufacturer, distibutor, or administrator of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A) or a health care provider shall be immune from suit or liability caused by or arising out of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A).

"(b) LITIGATION MANAGEMENT.—

"(1) LIMITATION ON CAUSE OF ACTION.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—No cause of action shall exist against a person described in subsection (a) for claims for loss of property, personal injury, or death arising out of, reasonably relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use

of a security countermeasure or qualified pandemic or epidemic product distributed, sold, purchased, donated, dispensed, prescribed, administered, or used in anticipation of and preparation for, in defense against, or in response to, or recovery from an actual or potential public health emergency that is a designated security countermeasure or a qualified pandemic or epidemic product by the Secretary in a declaration described in paragraph (2).

"(ii) RULE OF CONSTRUCTION.—For purposes of this section, the phrase 'arising out of, reasonably relating to, or resulting from' shall not be construed to apply to loss of property, personal injury, or death that has no alleged or potential causal relationship with the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a product described in clause (i).

"(B) RULE.—

"(i) SUBSEQUENT INJURY.—The protections set forth in subsection (a) and subparagraph (A) shall apply to all claims identified in subparagraph (A) that involve products distributed, sold, purchased, donated, dispensed, prescribed, administered, or used during the effective period set forth in the designation provided for in paragraph (2), regardless of the date of alleged injury.

"(ii) PRIVATE DONATION OR SALE.—The protections set forth in subsection (a) and subparagraph (A) shall apply to all claims identified in subparagraph (A) that involve security countermeasures or qualified pandemic or epidemic products distributed, sold, purchased, donated, dispensed, prescribed, administered, or used during the effective period set forth in the designation provided for in paragraph (2) by a manufacturer through the commercial market, provided that the security countermeasures or the qualified pandemic or epidemic product are the security countermeasure or qualified pandemic or epidemic product de-

scribed in a declaration described in paragraph (2) and the Secretary does not specifically prohibit such private donation or sale in such declaration.

"(C) POTENTIAL LIABILITY UPON DETERMINATION.—

"(i) IN GENERAL.—A manufacturer, distributor, administrator, or health care provider shall not be immune under subsection (a) or exempted from a cause of action under subparagraph (A) if the Secretary makes a determination as provided for in subparagraph (D).

"(ii) INVESTIGATION BY SECRETARY.—A party seeking a determination under subparagraph (D) may petition the Secretary to investigate allegations against a manufacturer, distributor, administrator, or health care provider arising out of, relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of products as provided for in subparagraph (A)(i). The deci-

sion to undertake such investigation shall be within the Secretary's discretion and shall not be subject to judicial review.

"(iii) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to abrogate or limit the application of subtitle II of chapter 5 and chapter 7 of title 5, United States Code (commonly known as the Administrative Procedure Act).

"(D) DETERMINATION BY SECRETARY.—

"(i) IN GENERAL.—In making a determination under this subparagraph, the Secretary, acting through an administrative law judge, must find clear and convincing evidence that—

"(I) the manufacturer, distributor, administrator, or health care provider violated a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or this Act; and

"(II) in violating such Act, such manufacturer, distributor, administrator, or health care provider acted with willful misconduct.

"(ii) EFFECT OF DETERMINATION.—If the Secretary finds such clear and convincing evidence under clause (i), the Secretary shall examine whether such willful misconduct to violate an Act under such clause—

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

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

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

"(iii) EFFECT OF DETERMINATION.—Subject to subsection (c), the sole exception to the immunity from suit and liability of manufacturers, distributors, administrators, or health care providers set forth in subsection (a) and subparagraph (A) shall be for actions against a manufacturer, dis-

tributor, administrator, or health care provider as provided in subparagraph (A).

"(iv) JUDICIAL REVIEW.—At any time prior to the 90th day following a determination by the Secretary under clause (i), any manufacturer, distributor, administrator, or health care provider named in such determination may file a petition with the United States Court District Court for the District of Columbia, for a judicial review of such determination. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose. The Secretary thereupon shall file in the court the record of the findings on which the Secretary based his or her determination. The filing of a petition under this clause shall automatically stay the Secretary's determination for the duration of the judicial proceeding. The sole parties to the judicial proceeding shall be the Secretary and the petitioner. Intervention by third parties in the judicial proceeding shall not be permitted. No subpoenas shall

be issued nor shall other compulsory process apply. The court's review of a determination by the Secretary under this clause shall conform to the procedures for judicial review of administrative orders set forth in paragraphs (2) through (6) of section 701(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(f)) to the extent consistent with this section.

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

"(vi) REGULATORY AUTHORITY.—The Secretary, in consultation with the Attorney General, shall promulgate regulations defining what actions by a manufacturer, distributor, administrator, or health care provider of a security countermeasure or a qualified pandemic and epidemic product shall be deemed to constitute 'willful mis-

conduct' for purposes of clause (i). In promulgating such regulations, the Secretary shall consider the nature of the actual or potential public health emergency, the timing and extent of any vaccination or countermeasure program, and any other circumstances they deem significant, so that any civil actions permitted under this subsection will not adversely affect the public health. The Secretary may specify the period of time for which such regulations apply.

"(vii) EVIDENCE REQUIRED.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that require, in order to be a party under this section, that an individual present evidence that reasonably demonstrates that—

"(I) such individual has suffered a loss as a direct result of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, or administration of a security countermeasure or quali-

fied epidemic or pandemic product; and

"(II) the loss as described in subclause (I) was a direct result of the willful misconduct of the manufacturer, distributor, administrator, or health care provider in violating the Federal Food, Drug, and Cosmetic Act or this Act.

"(E) SCOPE.—Subparagraph (C) shall apply regardless of whether the suit or liability described in subsection (a) or the claim described in subparagraph (A) arises from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use by the Federal Government or by any person.

"(2) DECLARATION BY SECRETARY.—

"(A) IN GENERAL.—The Secretary may issue a declaration, pursuant to this paragraph, that an actual or potential public health emergency makes advisable the distribution, administration, or use of a security countermeasure or qualified pandemic or epidemic product.

"(B) SECURITY COUNTERMEASURE OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The Secretary shall specify in such declaration the security countermeasures or qualified pandemic or epidemic products to be sold by, purchased from, or donated by a manufacturer or drawn from the Strategic National Stockpile.

"(C) EFFECTIVE PERIOD.—The Secretary shall specify in such declaration the beginning and the ending dates of the effective period of the declaration, which shall be not longer than 6 months. The Secretary may subsequently amend such declaration to shorten or extend such effective period, provided that the new ending data is after the date on which the declaration is amended.

"(D) PUBLICATION.—The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

"(c) ACTIONS BY THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law.

"(d) DEFINITIONS.—In this section:

"(1) ADMINISTRATOR.—The term 'administrator' means a person employed by the State or local government, or their designee, who supervised or administered a program with respect to the administration, dispensing, distribution, or provision of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, supplied technical or scientific advice or assistance.

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

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

"(4) MANUFACTURER.—The term 'manufacturer' includes—

"(A) a contractor or subcontractor of a manufacturer;

"(B) a supplier of any product or service, research tool, or component to the manufacturer; and

"(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

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

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

"(B) is a product for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the product will qualify for approval or licensing within 8 years after the date the Secretary makes a declaration under paragraph (2); or

"(C) is authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act, except that subsection (b) of such section shall not apply.

"(6) PARTY.— The term 'party' means an individual who can reasonably demonstrate to the Secretary that such individual has suffered a loss (as defined in paragraph (3)) as a direct result of the willful misconduct of a manufacturer, distributor, administrator, or health care provider.

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

"(8) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2(c)(1)(B).".

SEC. 7. COMPENSATION.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"PART D—OTHER COMPENSATION PROGRAMS

"SEC. 271. COVERED COUNTERMEASURES PROGRAM.

"(a) IN GENERAL.—If the Secretary issues a Proclamation stating that there is a critical public health need for a covered individual to receive a covered countermeasure during the effective period of the Proclamation, the Secretary shall establish a process to provide compensation to such covered individuals for a covered injury, consistent with the Smallpox Emergency Personnel Protection program under part C.

"(b) DEFINITION.—For purposes of this section:

"(1) COVERED COUNTERMEASURE.—The term 'covered countermeasure' means a qualified pandemic or epidemic product (as defined in section 319F–3(c)(5)) or a security countermeasure (as defined in section 319F–2(c)(1)(B)) specified in the Proclamation.

"(2) COVERED INDIVIDUAL.—The term 'covered individual' means an individual—

"(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public health or safety personnel, or support personnel for such occupational specialties;

"(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services emergency response plan approved by the Secretary;

"(C) who has volunteered and been selected to be a member of an emergency response plan; and

"(D) to whom a covered countermeasure is administered or used pursuant to such approved plan during the effective period of the Proclamation and prior to the time at which the Secretary declares a public health emergency pursuant to section 319 related to a covered countermeasure specified in the Proclamation.

"(3) COVERED INJURY.—The term 'covered injury' means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined by the Secretary to have been sustained by a covered indi-

vidual as the direct result of administration or use to the individual of a covered countermeasure.

"(4) EFFECTIVE PERIOD OF THE PROCLAMATION.—The term 'effective period of the Proclamation' means the effective period specified in the Proclamation, unless extended by the Secretary.

"(5) EMERGENCY RESPONSE PLAN.—The term 'emergency response plan' or 'plan' means a response plan detailing actions to be taken in preparation for a pandemic, epidemic, or biological, chemical, radiological, nuclear agent or toxin that presents, or may present, a public health emergency.

"(6) PROCLAMATION.—The term 'Proclamation' means a Proclamation regarding the critical public health need for the administration or use of a covered countermeasure issued by the Secretary and published in the Federal Register. Such Proclamation shall specify the specific covered countermeasure recommended for administration.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the creation of a compensation program if the covered injuries are only minor injuries consistent with section (b)(3).".

SEC. 8. REBATES AND GRANTS FOR RESEARCH DEVELOPMENT, AND MANUFACTURING OF VACCINES, QUALIFIED COUNTERMEASURES AND PANDEMIC OR EPIDEMIC PRODUCTS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") may award to a person with respect to an investment described in this section (or an amendment made by this section)—

(1) a rebate pursuant to subsection (b); or

(2) a grant pursuant to section 319M of the Public Health Service Act (as added by subsection (c)).

(b) SURGE CAPACITY AND RESEARCH REBATES.—

(1) IN GENERAL.—The Secretary may award rebates out of any money in the Treasury not otherwise appropriated to persons for the expansion of surge capacity for manufacturing vaccines, qualified countermeasures (as defined in 319F–1 of the Public Health Service Act, as amended by this Act) or qualified pandemic or epidemic products (as defined in 319F–3(c)(5) of such Act, as added by this Act) (referred to in this section as "vaccines, countermeasures or products") and for vaccines, countermeasures, or products research.

(2) VACCINES, COUNTERMEASURES OR PRODUCTS MANUFACTURING FACILITIES INVESTMENT REBATE.—

(A) IN GENERAL.—For purposes of this section, vaccines, countermeasures or products manufacturing facilities investment rebate for any taxable year for a person (as defined with respect to such person for purposes of the Internal Revenue Code of 1986) shall be an amount equal to 20 percent of the qualified investment for such taxable year.

(B) VACCINES, COUNTERMEASURES OR PRODUCTS MANUFACTURING FACILITIES INVESTMENT.—For purposes of subparagraph (A), the qualified investment for any taxable year for a person is the basis of each vaccines, countermeasures or products manufacturing facilities property placed in service by the person during the taxable year involved.

(C) VACCINES, COUNTERMEASURES AND PRODUCTS MANUFACTURING FACILITIES PROPERTY.—For purposes of this subsection, the term "vaccines, countermeasures and products manufacturing facilities property" means real and tangible personal property—

(i)(I) the original use of which commences with the person applying for the rebate; or

(II) which is acquired through purchase (as defined by section 179(d)(2) of the Internal Revenue Code of 1986);

(ii) which is depreciable under section 167 of the Internal Revenue Code of 1986;

(iii) which is physically located in a State;

(iv) which is used for the manufacture, distribution, or research and development of vaccines, countermeasures, or products; and

(v) which is in compliance with applicable good manufacturing practice and with any other applicable requirements which are promulgated by the Secretary, the Occupational Safety and Health Administration, or the Environmental Protection Agency, and which are applicable to such property.

(D) DENIAL OF DOUBLE BENEFIT FOR MANUFACTURING FACILITIES EXPENSES.—If any portion of the vaccines, countermeasures, and products manufacturing facilities property investment expenses is otherwise allowable as a deduction for the taxable year involved, the Secretary shall only provide a rebate under this sec-

tion for the portion of such expenses not covered by the rebate determined by such deduction.

(E) ELIGIBILITY.—To be eligible to receive a rebate under this subsection, a manufacturer shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(i) a detailed description and intended use of the facilities that is the basis of application;

(ii) a detailed description of the vaccine, countermeasure, or product being produced or that may be produced at the facility;

(iii) a detailed accounting of qualified manufacturing facilities investment of the person;

(iv) a certification as to the compliance of the person with clauses (i) through (iv) of subparagraph (C); and

(v) copies of tax returns for the taxable year involved.

(F) EFFECTIVE DATE.—This paragraph shall apply to property placed in service after December 31, 2005.

(G) TERMINATION.—This paragraph shall not apply to any property placed in service after December 31, 2010.

(3) MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES, COUNTERMEASURES OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS REBATE.—

(A) IN GENERAL.—For purposes of this subsection, the research rebate determined under this section for the taxable year involved (as determined as provided for in paragraph (2)(A)) is an amount equal to 35 percent of the vaccines, qualified countermeasures, or qualified pandemic or epidemic products (referred to in this section as "vaccine, countermeasure, or product") research expenses for the taxable year.

(B) VACCINES, COUNTERMEASURES, OR PRODUCTS RESEARCH EXPENSES.—Except as otherwise provided in this paragraph, the term "vaccines, countermeasures, or products research expenses" means the amounts which are paid or incurred by the researcher or manufacturer during the taxable year with respect to any research

and development of vaccines, countermeasures, or products. Qualified research and development expenses include expenses related to reformulating existing vaccines, countermeasures, or products.

(C) DETERMINING RESEARCH EXPENSES.—Any vaccines, countermeasures, or products research expenses for any taxable year which are qualified research expenses (within the meaning of this subsection) shall be taken into account in determining base period research expenses for purposes of applying this paragraph to subsequent taxable years.

(D) DENIAL OF DOUBLE BENEFIT FOR VACCINES, COUNTERMEASURES, OR PRODUCTS RESEARCH EXPENSES.—If any portion of the vaccines, countermeasures, or products research expenses is otherwise allowable as a deduction for the taxable year involved, the Secretary shall only provide a rebate under this section for the portion of such expenses not covered by any rebate determined by such deduction.

(E) ELIGIBILITY.—To be eligible to receive a rebate under this paragraph, a manufacturer or researcher shall submit to the Secretary an application at such time, in such manner, and

containing such information as the Secretary may require, including—

(i) a detailed description of the vaccine, countermeasure, or product being researched or developed;

(ii) a detailed description of the research that is the subject of the rebate;

(iii) a detailed accounting of the qualified research expenses involved;

(iv) an assurance that the researcher or manufacturer is following good laboratory practice, as required by the Secretary pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.); and

(v) copies of tax returns for the taxable year involved.

(F) EFFECTIVE DATE.—This paragraph shall apply to expenses for taxable years beginning after December 31, 2005.

(4) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The terms "vaccines, countermeasures, or products manufacturing investment" and "qualified research expenses" shall not include any amount

to the extent such amount is funded by any grant, contract, or otherwise funded by another person (or any governmental entity).

(c) GRANTS TO EXPAND AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF VACCINES, COUNTERMEASURES OR PRODUCTS.—Part B of title III of the Public Health Service Act is amended by inserting after section 319L, as added by this Act, the following:

"SEC. 319M. GRANTS TO EXPAND AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF VACCINES, QUALIFIED COUNTERMEASURES OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS.

"(a) IN GENERAL.—The Secretary may award grants to a manufacturer to purchase or improve real property and tangible personal property used in the research and development, manufacture, or distribution of a vaccine, qualified countermeasure (as defined in section 319F–1) or qualified pandemic or epidemic product (as defined in section 319F–3(c)(5)).

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a manufacturer shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(1) a detailed description of the planned expansion;

"(2) a detailed description of the equipment, facility, or property involved;

"(3) a certification that such facility or property is physically located in a State;

"(4) a detailed description of the vaccine, qualified countermeasure or qualified pandemic or epidemic product involved;

"(5) a detailed description of the research and development, manufacturer, or distribution involved;

"(6) a description of how such equipment, facility, or property is to be used;

"(7) a description of whether such equipment, facility, or property can be used for the research and development, manufacture, or distribution of a drug, biological product, device or other countermeasure not described in paragraph (4); and

"(8) a certification that the equipment, facility, or property involved complies with all applicable Federal, State, and local laws.

"(c) RECAPTURE.—

"(1) IN GENERAL.—If, at any time prior to the expiration of the 20-year period beginning on the date on which a grant is awarded under this section, the

facility or property involved ceases to be used for the purpose for which the grant was awarded, the United States shall be entitled to recover from the manufacturer an amount bearing the same ratio to the value of the facility or property at such time as the amount of the grant bore to the total cost of the purchase or improvement involved. The value of the facility or property at such time may be determined by agreement of the manufacturer and the Secretary, or by order of the United States District Court for the district in which such facility or property is situated.

"(2) LIMITATION.—The Secretary may not recapture the facility or property under this subsection if the Secretary determines, in accordance with regulations promulgated by the Secretary, that there is good cause for the failure of proper use.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.".

SEC. 9. 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 Practices) 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 products and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.".

SEC. 10. ANIMAL MODELS FOR CERTAIN DISEASES.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409J. ANIMAL MODELS FOR CERTAIN DISEASES.

"(a) IN GENERAL.—The Secretary, acting through the Director of NIH, in coordination with the Director of the Biomedical Advanced Research and Development Agency, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs, shall estab-

lish and award grants under this section to eligible entities, including other Federal agencies, to study the physiological responses of certain animal species and, where appropriate, juvenile models, to chemical, biological, radiological, or nuclear agents or toxins or potential pandemic infectious disease, and to develop and validate such animal models.

"(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

"(1) provide assurances to the Secretary that the entity—

"(A) has access to an appropriate biosafety laboratory or facility, as determined by the Secretary; and

"(B) will follow good laboratory practices;

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(A) a detailed description of the animal model involved;

"(B) a detailed description of the chemical, biological, radiological, nuclear, or other infectious agents involved;

"(C) a detailed description of how the animal model will be used for the development of a

drug, biological product, or device for use as a countermeasure;

"(D) a detailed description of validation methods; and

"(E) an assurance that the entity will follow good laboratory practices; and

"(3) agree to submit the results of the research funded under the grant to the Director of the Biomedical Advanced Research and Development Agency and the Director of NIH.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.".

SEC. 11. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC ADVISORY COMMITTEE.

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

"SEC. 566. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this section, the Secretary shall establish an 11-member advisory committee to be known as the 'Animal Model/Research Tool Scientific Advisory Com-

mittee' (referred to in this section as the 'Advisory Committee').

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Advisory Committee individuals who are technically qualified by training and experience, including in medicine, veterinarian medicine, biology, technology involving the manufacture, evaluation, or use of research tools, who are of appropriately diversified professional backgrounds to evaluate the priority animal models and research tools.

"(2) EX OFFICIO MEMBERS.—The Secretary may appoint Federal officials, including at least 1 representative of the Biomedical Advanced Research and Development Agency, to serve as ex officio members of the Advisory Committee.

"(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as the chairperson.

"(c) DUTIES.—The Advisory Committee shall provide advice, information, and recommendations to the Secretary on—

"(1) accepted animal models for diseases and conditions associated with any biological (including organisms that cause infectious diseases), chemical,

radiological, or nuclear agent or toxin or potential pandemic infectious disease;

"(2) strategies to accelerate animal model and research tool development and validation; and

"(3) scientific issues raised in applications as requested by the Secretary.

"(d) PRIORITIES.—Priorities for animal models and research tools shall be established by the Secretary.

"(e) COMPENSATION; SUPPORT; FACA.—

"(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged, and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Federal Government service employed intermittently.

"(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

"(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

"(f) PROCEEDINGS.—The Advisory Committee shall make and maintain a transcript of any proceeding of the Committee. The Committee shall delete from any transcript made under this subsection information, which is exempt from disclosure under section 552(b) of title 5, United States Code.".

SEC. 12. COLLABORATION AND COORDINATION.

Section 2 of the Clayton Act (15 U.S.C. 13) is amended by adding at the end the following:

"(g) LIMITED ANTITRUST EXEMPTION.—

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

"(A) COUNTERMEASURES AND PRODUCTS DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') or the Director of the Biomedical Advanced Research and Development Agency (re-

ferred to in this subsection as the 'Director'), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with parties involved in the development of security countermeasures (as defined in section 319F–2 of the Public Health Service Act) qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act) or qualified pandemic or epidemic products (as defined in section 319F–3(c)(5) of the Public Health Service Act) (referred to in this section as "countermeasures or products") for the purpose of the development, manufacture, distribution, purchase, sale, or storage of countermeasures or products consistent with the purposes of this title. The Secretary or Director may convene such meeting or consultation at the request of any person, the Secretary of Homeland Security, the Attorney General, the Chairperson of the Federal Trade Commission, an industry representative or member, or upon initiation by such Secretary. The Secretary or Director shall give notice of such meetings and consultations to the Chairperson of the Federal

Trade Commission (referred to in this subsection as the 'Chairperson') and the Attorney General.

"(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 or Director;

"(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of countermeasures or products, as determined by the Secretary or Director;

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

"(iv) be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures or products, consistent with the purposes of this title; and

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

"(C) LIMITATION.—The Secretary or Director may not require the disclosure of confidential commercial or proprietary information.

"(D) MINUTES.—The Secretary or Director shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code, unless such Secretary or Director, in consultation with the Attorney General, determines that disclosure would pose no threat to national security. Such determination shall not be subject to judicial review.

"(E) EXEMPTION.—

"(i) IN GENERAL.—The antitrust laws shall not apply to meetings and consultations under this paragraph.

"(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection.

"(2) WRITTEN AGREEMENTS.—The Secretary or the Director shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is

consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing 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 of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

"(E) any other relevant information determined necessary by the Secretary or Director in consultation with the Attorney General and the Chairperson.

"(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement regarding covered activities referred to in paragraph (2) would likely—

"(A) be in compliance with the antitrust laws, and so inform the Secretary or Director and the participating parties; or

"(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement consistent with the purposes of this title.

"(4) ACTION ON REQUEST FOR EXEMPTION.—

"(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 business days of the receipt of such request.

"(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. Such additional period may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary or Director and the parties involved.

"(C) DETERMINATION.—In granting an exemption under this paragraph, the Attorney General, in consultation with the Chairperson and the Secretary or Director—

"(i) shall find—

"(I) that the agreement involved is necessary to ensure the availability of countermeasures or products;

"(II) that the exemption from the antitrust laws would promote the public interest; and

"(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

"(ii) may consider any other factors determined relevant by the Attorney General and the Chairperson.

"(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and shall be renewed (with modifications, as appropriate) on the date that is 3 years after the date on which the exemption becomes effective (and at 3-year intervals thereafter, if renewed) unless the Attorney General in

consultation with the Chairperson determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

"(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

"(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

"(8) REPORT.—Not later than 1 year after the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

"(9) STATUS OF MEMORANDUMS.—Minutes maintained by the Secretary or Director pursuant to paragraph (1)(D) shall not be disclosed under section 552 of title 5, United States Code, if the exemption is not renewed under paragraph (5), or if meetings

are no longer conducted, unless the Secretary or Director, in consultation with the Attorney General, determines that the disclosure would pose no threat to national security. Such determination shall not be subject to judicial review.

"(h) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemption under this section shall expire at the end of the 6-year period that begins on the date of enactment of the Biodefense and Pandemic Vaccine and Drug Development Act of 2005.

"(i) 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 this Act, except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) (commonly known as the Robinson-Patman Act), and 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) COVERED ACTIVITIES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

"(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of countermeasures or products;

"(ii) the development or testing of basic engineering techniques necessary to the development of countermeasures or products;

"(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of countermeasures or products;

"(iv) the production, distribution, or marketing of a product, process, or service that is a countermeasures or products;

"(v) the testing in connection with the production of a product, process, or services necessary to the development of countermeasures or products;

"(vi) the collection, exchange, and analysis of research or production information necessary to the development of countermeasures or products; or

"(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

"(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

"(i) Exchanging information among competitors relating to costs, profitability, marketing, or distribution of any product, process, or service if such information is not

reasonably necessary to carry out the purposes of covered activities.

"(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 who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to 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 by a determination under subsection (g)(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 the purpose of 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 so expressly exempted from the antitrust laws by a determination under subsection (g)(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 who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

"(vii) Entering into any agreement or engaging in any other conduct restricting or

setting the price at which a product is offered for sale, whether by bid or otherwise.

"(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, and any other actions related to preparation of a countermeasure or product.".

SEC. 13. 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)(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 (as 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 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 up to 3 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 sole and exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed 15 years, 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.

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

ditional 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 research and development of the countermeasure; and

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

(D) 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 the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 and the Project BioShield Act of 2004, for the procurement of countermeasures under section 319F–1 or 319F–2."

SEC. 14. NATIONAL PATHOLOGY CENTER.

(a) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 401(b)(2), by adding at the end the following:

"(H) The National Pathology Center."; and

(2) by adding at the end of part E (42 U.S.C. 287 et seq.) the following:

"Subpart 7—National Pathology Center

"SEC. 485A. ESTABLISHMENT OF NATIONAL PATHOLOGY CENTER.

"In order to provide pathology consultation for civilian and military health professionals (including Department of Veterans Affairs health professionals) there is established the National Pathology Center (in this subpart referred to as the 'Center'). The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

"SEC. 485B. PURPOSES AND FUNCTIONS OF THE CENTER.

"(a) PURPOSES OF THE CENTER.—The general purposes of the Center are to—

"(1) conduct and support research, education, training, and other programs with respect to the science and clinical practice of pathology;

"(2) maintain and improve a pathology tissue repository; and

"(3) provide pathology consultation services.

"(b) ACTIVITIES OF THE DIRECTOR.—In order to carry out the purposes of the Center described in subsection (a), the Director of the Center—

"(1) shall—

"(A) maintain and improve a comprehensive repository of pathological specimens;

"(B) provide consultations on request regarding clinical cases;

"(C) conduct educational programs and publish educational materials on the science and clinical practice of pathology;

"(D) maintain and improve registries on such clinical conditions as the Director of the Center determines appropriate; and

"(E) conduct and support research on pathology; and

"(2) may—

"(A) collect reasonable and appropriate fees for the activities described in paragraph (1)(B); and

"(B) conduct such other activities as the Director of the Center determines appropriate to carry out the purposes described in subsection (a).

"(c) AUTHORITY FOR EXPERT OPINIONS.—The Director of the Center may enter into memoranda of understanding with officials at the Department of Veterans Affairs and the Department of Defense to provide expert second opinion pathology consultations and pathology education or training if the Secretary of either such Department determines that such provision would be in the best interest of either of their respective departments.

"SEC. 485C. BOARD OF REGENTS.

"(a) MEMBERSHIP.—

"(1) IN GENERAL.—There is established a Board of Regents of the Center (in this subpart referred to as the 'Board') consisting of—

"(A) the Surgeons General of—

"(i) the Public Health Service;

"(ii) the Army;

"(iii) the Navy; and

"(iv) the Air Force;

"(B) the Chief Medical Director of the Department of Medicine and Surgery of the Department of Veterans Affairs;

"(C) the Deputy Director of the National Library of Medicine;

"(D) the Assistant Secretary of Health of the Department of Defense;

"(E) the Dean of the Uniformed Services University of the Health Sciences; and

"(F) 11 members to be appointed by the Secretary from among leaders in pathology research, education and clinical practice.

"(2) EX OFFICIO MEMBERS.—The members of the Board described in subparagraphs (A) through (E) of paragraph (1) shall serve as ex officio members of the Board.

"(3) CHAIRPERSON.—The members of the Board appointed under paragraph (1)(F) shall annually elect one of such members to serve as the Chairperson of the Board until the next election.

"(b) DUTIES OF THE BOARD.—It shall be the duty of the Board to advise, consult with, and make recommendations to the Director of NIH on important matters of policy in regard to the Center, including such matters as the scope, content and organization of the research, education and consultative services provided by the Center. The Board shall make recommendations to the Director of NIH regarding the rules under which specimens from the tissue repository will be used and under which publications, facilities and services of the Center will be made available to various kinds of users.

"(c) TERMS OF OFFICE.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within 1 year after the end of the preceding term of such member.

"(d) COMPENSATION.—Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of the Board, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c).

"SEC. 485D. GIFTS TO THE CENTER.

"Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Center or for carrying out any of its functions.

"SEC. 485E. CENTER FACILITIES.

"There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Center. The Administrator of General Services may acquire, by purchase,

condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.''.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the appropriate committees of Congress that contains—

(1) a review of all functions and duties of the National Pathology Center under subpart 7 of part E of title IV of the Public Health Service Act,as established by subsection (a);

(2) areas where such functions and duties overlap with the functions and duties of the National Institutes of Health; and

(3) recommendations concerning necessary modifications to the National Pathology Center.

(c) TRANSFER OF THE ARMED FORCES INSTITUTE OF PATHOLOGY.—

(1) IN GENERAL.—

(A) IN GENERAL.—Except as provided in subparagraph (B), there are transferred to the National Pathology Center established under subpart 7 of part E of title IV of the Public Health Service Act all functions, duties, personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations of the Armed Forces Institute of Pathology. The preceding sentence shall not affect any proceedings, pending applications, suits, or other actions pending on the date of enactment of this Act.

(B) EXCEPTIONS.—The following components of the Armed Forces Institute of Pathology shall not be transferred from the Department of Defense pursuant to subparagraph (A):

(i) The Armed Forces Medical Examiner.

(ii) The Department of Defense DNA registry.

(iii) Accident Investigation Program.

(iv) The histopathology training program.

(v) The patient safety center.

(vi) Department of Legal Medicine.

(vii) Center for Clinical Laboratory Medicine.

(viii) Drug Testing and Quality Assurance Program.

(ix) Subject to the discretion of the Secretary of Defense, medical research programs on the following:

(I) Body armor.

(II) Environmental sarcoidosis.

(III) Depleted uranium.

(IV) Military working dogs.

(V) Such other areas of research related to pathology as the Secretary of Defense shall choose to conduct.

(2) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or relating to the Armed Forces Institute of Pathology shall be deemed to be a reference to the National Pathology Center established under subpart 7 of part E of title IV of the Public Health Service Act.

SEC. 15. 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.

Calendar No. 257

109TH CONGRESS
1ST SESSION

S. 1873

A BILL

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

OCTOBER 24, 2005

Reported with an amendment