the crisis of Hurricane Katrina should not be used to weaken, waive, or roll back Federal public health, environmental, and environmental justice laws and regulations, and for other purposes.

AMENDMENT NO. 1550

At the request of Mr. FEINGOLD, the name of the Senator from Minnesota (Mr. COLEMAN) was added as a cosponsor of amendment No. 1550 intended to be proposed to S. 1042, an original bill to authorize appropriations for fiscal year 2006 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe personnel strengths for such fiscal year for the Armed Forces, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mrs. FEINSTEIN:

S. 1870. a bill to clarify the authorities for the use of certain National Park Services properties within Golden Gate National Recreation Area and San Francisco Maritime National Historical Park, and for other purposes; to the Committee on Energy and Natural Resources.

Mrs. FEINSTEIN. Mr. President, I rise today to introduce a bill which will clarify certain National Park Service authorities for the Golden Gate National Recreation Area and San Francisco Maritime National Historic Park.

I also want to thank Congresswoman PELOSI for introducing a similar bill in the house. As a San Francisco native and a former mayor, I know these parks are extremely popular tourist sites and I believe this bill will allow the National Park Service to restore and renovate these parks in order to maintain their status as top tourist destinations.

The Golden Gate National Recreation Area is one of the largest urban national parks in the world—home to such renowned sites as the Presidio of San Francisco and Alcatraz Island. Additionally, the San Francisco Maritime National Historic Park, located at the west end of San Francisco's Fisherman's Wharf, includes a fleet of landmark vessels and a maritime museum.

Presently, the revenue collected by these parks must be spent in the same fiscal year in which it is collected. Otherwise, any revenue that is not spent is deposited in the National Treasury. This current policy makes it difficult for these two parks to pursue long term, major restoration projects. This bill makes the necessary changes to allow these parks to undertake needed substantive restoration as opposed to smaller, less significant projects allowed under the current revenue system.

The bill also calls for a modest boundary adjustment between the two adjacent parks in order to be consistent with the current administration of San Francisco's Municipal Pier.

I am introducing this bill with the hope that it will allow these two parks to retain the revenue necessary for maintenance in order to continue to attract visitors from around the world to these historic sites of California.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1870

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. GOLDEN GATE NATIONAL RECREATION AREA.

Section 4(f) of Public Law 92–589 (16 U.S.C. 460bb–3) is amended by striking ''Haslett Warehouse, Cliff House Properties and Louis' Restaurant,'' and all that follows and inserting ''Cliff House Properties and Louis' Restaurant, the Secretary may enter into a contract for the management (including rental or lease) of the aforementioned properties with such terms and conditions as will protect the Government's interest. Any proceeds from the use of such properties shall be available until expended, without further appropriation, for the administration, maintenance, repair and related expenses of the properties and for major renovation and park rehabilitation of those buildings included in the Fort Mason Foundation Agreement''.

SEC. 2. SAN FRANCISCO MARITIME NATIONAL HISTORICAL PARK.

Section 3 of Public Law 100–348 (16 U.S.C. 410nn–1) is amended—

(1) by amending the text of subsection (c) to read as follows: ''Notwithstanding any other provision of law, in the administration of any real or personal property (including vessels and heavy marine equipment such as floating drydocks) that is administered as part of the park, the Secretary may enter into a contract for the management (including rental or lease) of such property with such terms and conditions as will protect the Government's interest. Any proceeds from the use of such property shall be available until expended, without further appropriation, for the administration, maintenance, repair, and related expenses of the property.''; and

(2) in the second sentence of subsection (d) by striking ''shall be credited'' and all that follows and by inserting ''shall be available until expended, without further appropriation, for use at the park for purposes of facility maintenance and repair, interpretation, signage, habitat or facility enhancement, resource preservation, annual operations (including fee collection), and law enforcement.''.

SEC. 3. CONFORMING AMENDMENTS.

(a) Section 2(b) of Public Law 100–348 (16 U.S.C. 410nn) is amended—

(1) by striking ''numbered 641/80,053 and dated April 7, 1987'' and inserting ''numbered 350/80,012 and dated June 2004''; and

(2) by striking the third and fourth sentences and inserting the following: ''The Secretary of the Interior'' (hereinafter in this Act referred to as the ''Secretary'') may make minor revisions to the boundary of the park in accordance with section 7(c) of the Land and Water Conservation Act of 1965 (16 U.S.C. 460l–9(c)).

(b) Section 4(e) of Public Law 92–589 (16 U.S.C. 460bb–3) is amended by striking ''and for admission to the sailing vessel Balclutha and other historic vessels of the National Maritime Museum''.

By Mr. BURR (for himself, Mr. ENZI, Mr. GREGG, Mr. FRIST, and Mr. ALEXANDER):

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; to the Committee on Health, Education, Labor, and Pensions.

Mr. BURR. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1873

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 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 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 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 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 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 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, 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.

''(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, 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 investigation, 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.

''(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 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).

''(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 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.

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

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

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

''(bb) the amount of funding that will be dedicated by the Secretary for 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 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.

By Mrs. FEINSTEIN:

S. 1874. A bill to amend title 28, United States Code, to clarify jurisdiction of Federal Courts over a tort action brought by an alien, and for other purposes; to the Committee on the Judiciary.

Mrs. FEINSTEIN. Mr. President, I am pleased to introduce legislation that clarifies the meaning and scope of the Alien Tort Statute.

This 200-year-old law has spawned dozens of legal cases involving U.S. multinational companies, human rights groups, foreign plaintiffs, the State Department, and millions of dollars in litigation costs. Numerous companies in California are in the midst of these lawsuits as defendants and it is my view that legislation can help refine and improve the law.

Judges have grappled in interpreting and applying the statute for years now without a consensus view emerging. I think it would be fair to say that confusion reigns supreme when it comes to alien tort suits.

Given this opaque legal picture, last summer the Supreme Court ruled on a case, Sosa v. Alvarez Machain, in an attempt to reconcile conflicting decisions from judges across the country.

The Court's June 2004 ruling was notable, for embracing certain principles that will help guide the Judiciary branch on alien tort claim issues but for leaving many questions unanswered as well.

It held that a substantive, legal basis exists for foreigners to sue U.S. individuals and corporations over alleged human rights violations occurring in overseas locations. The Court essentially affirmed that a limited, implicit sanction for courts exists to decide certain alien tort claims.

At the same time, the opinion provided a wide berth for what the claims might actually be. The Court hedged on key issues, without clearly demarcating what suits ought to go forward under the statute and which ones should be summarily dismissed.

In particular the ruling did not address: which international law claims by foreigners should be heard in a U.S. district court, and the standard of liability for U.S. companies facing these human rights charges.

To clarify these areas, the Justices wrote that they would welcome ''any congressional guidance'' on the breadth of the statute. During oral arguments a number of the Justices appeared to concur that a legislative approach would make sense. One Justice even commented that ''I just wonder if it isn't wise to . . . let Congress have a look at this thing.''

Those views were echoed by a Washington Post editorial that followed soon after. The paper stated that the

alien tort law has ''formed the basis for litigation against U.S. companies involved with nefarious regimes abroad. And while horrid conduct by an American company ought to be, where proven, grounds for action in American courts, the parameters of such litigation are surely a legislative question, not one for the freewheeling discretion of judges. . . . But the court left open the possibility that at least some of these suits can proceed in the absence of further congressional action.''

The Court's perspective, along with the Post commentary, indicates, at least to me, a sense of caution about imposing by judicial fiat action that is better left to consideration and refinement by the Congress.

The Court's hesitation to legislate from the bench shifts the responsibility to this body, I believe, to pass legislation that settles on a reasonable legal means that plaintiffs and defendants alike can rely on to litigate their differences.

I believe the measure we are introducing today accomplishes this basic and important goal.

Right now, courts are essentially adrift in terms of being able to pinpoint the underlying meaning, scope and intent of this 200-year-old statute. In its entirety, it reads: ''The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.''

The economy of words makes the law abstruse and subject to varying interpretation. And complex, lengthy and unnecessary litigation has burdened the courts as a result.

This new bill will establish a fair, legal basis for filing suit under the Alien Tort Statute (ATS). And it will have the added benefit of explicating the law's dual jurisdictional and substantive nature.

The measure: specifies a legal standard convicting defendants of wrongdoing if they directly participate with specific intent to commit the alleged tort; codifies international claims under the Alien Tort law to include genocide, torture, slavery and slave trade, extrajudicial killing, and piracy; expands on existing statutory law, the Torture Victim Protection Act; states that Federal courts shall not proceed with tort claims when the President adequately certifies that such exercise of jurisdiction will have a negative impact on the foreign policy interests of the U.S.; maintains that every effort should be made to try these cases in the country of origin before granting jurisdiction in U.S. courts; invokes a 10-year statute of limitations on ATS charges filed against U.S. multinational companies; and disallows contingency fee arrangements for legal representatives of plaintiffs or defendants.

The Supreme Court's delineation that the Alien Tort law is jurisdictional in one sense, but recognizes a restricted category of substantive claims encompassed by the law of nations, leaves many unresolved questions.

The historical origins of the ATS, passed by the First Congress as part of the Judiciary Act of 1789, suggest that certain offenses relevant to that period in American history—piracy, infringing the rights of ambassadors, and prevention of safe travel abroad—were meant to be prosecutable. But Justice Souter's Alvarez-Machain opinion notes that a slim legislative history of the statute makes it difficult to surmise the law's true intent.

At the same time, Justice Souter opined: ''Still, the history does tend to support two propositions. First, there is every reason to suppose that the First Congress did not pass the ATS as a jurisdictional convenience to be placed on the shelf for use by a future Congress or state legislature that might, some day, authorize the creation of causes of action or itself decide to make some element of the law of nations actionable for the benefit of foreigners. The anxieties of the preconstitutional period cannot be ignored easily enough to think that the statute was not meant to have a practical effect. . . . The second inference to be drawn from the history is that Congress intended the ATS to furnish jurisdiction for a relatively modest set of actions alleging violations of the law of nations.''

The opinion ranges further, that, such a ''modest set of actions'' indeed applies to current times, not merely offenses grounded in law two hundred years ago. The critical portion reads: ''Accordingly, we think courts should require any claim based on the present-day law of nations to rest on a norm of international character accepted by the civilized world and defined with specificity comparable to the features of the 18th century paradigms we have recognized.''

I am uncomfortable with such a nebulous, open-ended legal approach permitting courts to entertain suits based on a ''norm of international character'' and ''specificity'' consistent with crimes of early American history. Adjudicating cases based on these broad historical and legal precepts is admirable. In practical terms it remains very difficult.

The Congress ought to weigh in and play a constructive role. Without legislation, judges will continue to reach markedly different conclusions under the law, based on arbitrary interpretations of case-specific facts and other considerations.

Let's take the legal mystery out of the statute and what qualifies as an alien tort and replace it with something that is concrete and appropriate for the times.

At the heart of this legislation is codifying a class of violations of international law that will discourage defendant companies from consorting with human rights violators in any respect. They will be held liable if they do so by a specific standard that judges whether they intentionally and directly caused certain violations of human rights.

A plaintiff victim will be able to vindicate their rights by filing an express statutory cause of action based on a half dozen egregious wrongs. Regardless of the foreign policy and trade implications, defendant U.S. companies will be held fully accountable under the bill for bad corporate behavior in their overseas business operations.

That is as it should be. Certain alien torts in violation of the law of nations ought to be cognizable and this legislation ensures that result. Moreover, the fact that specific crimes are made actionable and enforceable will aid human rights organizations in their fight to strengthen the deterrent effect of the law for potential violators.

Regarding the defendant perspective, in one friend of the court brief submitted in the Alvarez Machain case, the argument was made that ''. . . companies face enormous uncertainty regarding the scope of potential claims under the statute. . . . Because ATS cases are based upon an implied cause of action without any clear standards of liability, there may be little companies can do to protect themselves against potential claims, short of simply ceasing to do business in the many nations whose human rights practices come up short against evolving Western ideals.''

The business community ought to embrace this legislation precisely because it wipes away this uncertainty. The best way to encourage U.S. multinationals to invest abroad is: 1. by specifying a universe of the most egregious human rights violations that they may be held liable for and 2. offering a clear, understandable legal standard that judges their actions accordingly. This legislative measure tackles both issues head on.

There are estimates that dozens of existing alien tort suits claim damages—collectively—in excess of $200 billion dollars. That's an extraordinary sum that rightly concerns the U.S. business community, particularly given numerous inconsistent federal courts verdicts handed down in the past two decades.

This legislation deters private plaintiffs from filing sweeping and specious claims simply because a corporation has a U.S. legal nexus and deep pockets. Yet, it expands the basis for foreign plaintiffs pursuing certain international law causes of action in federal court by codifying their rights in a judicious way.

While some in the U.S. business community would prefer that the Alien

Tort statute be deleted from the U.S. Code altogether, I would respectfully disagree. A fair compromise that balances the interests of U.S. companies and human rights organizations is what this legislation seeks to accomplish.

The Congress has waded into this debate before, passing the Torture Victim Protection Act in 1991, and this new legislation contains many similar elements: a statute of limitations, a statutory exhaustion provision, and specifying torture and extrajudicial killing as within the adjudicatory discretion of a district court.

There is precedent, then, for the Legislative branch acting to provide civil redress for victims of torture. Asserting extraterritorial jurisdiction under the ATS, for torture and other jus cogen violations, has a firm footing in American jurisprudence.

The legislative history of the TVPA is important because it spells out the constitutional grounds justifying that statutory law and this new legislation as well.

The Senate Judiciary Committee report on the TVPA states as follows: ''Under article III of the Constitution, the Federal judiciary has the power to adjudicate cases 'arising under' the 'law of the United States.' The Supreme Court has held that the law of the United States includes international law. . . . Congress's ability to enact this legislation also derives from article I, section 8 of the Constitution which authorizes Congress 'to define and punish . . . Offenses against the Law of Nations.' ''

Existing case law confirms the point that Congress has given the federal courts the power to interpret and apply international human rights law. The notable Paquete Habana decision states, in part, that ''international law is part of our law, and must be ascertained and administered by the courts of justice of appropriate jurisdiction, as often as questions of right depending upon it are duly presented for their determination. . . Congress, however, has not only expressed no disagreement with our view of the proper exercise of the judicial power, but has responded to its most notable instance by enacting legislation [the Torture Victim Protection Act] supplementing the judicial determination in some detail.''

The view expressed in the Alvarez Machain case last year was much the same, that no development in the last two centuries has ''categorically precluded federal courts from recognizing a claim under the law of nations as an element of common law.''

Different precedent, Tel Oren v. Libyan Arab Republic, also posits that civil liability should ensue from certain violations of international law, suggesting that the ''limits of section 1350's [the ATS] reach'' be defined by ''a handful of heinous actions—each of which violates definable, universal and obligatory norms.''

This legislation fills that legal vessel with the most egregious crimes: genocide, torture, slavery and slave trading, extrajudicial killing, and piracy. These jus cogen offenses are singled out through 1. stare decisis, 2. the Restatement (Third) of Foreign Relations Law, 3. academic writings, 4. official annual human rights assessments from the State Department and 5. among the writings and publications of many human rights and international law advocacy groups.

Congress is in the best position to make the determination of what falls within the ambit of the statute, not judges across America who lack expertise, time, and resources to assess what constitutes definable, specific, universal, and obligatory norms of international law. The bill, I would submit, represents a good faith effort in permitting these tortious acts, all firmly established and well defined in international law norms, to be prosecuted in U.S. district courts.

I was interested to read the views last year of the head of the National Foreign Trade Council, William Reinsch, that ''these cases are going to end up in the Supreme Court . . . and the Court will over time end up defining what in its judgment constitutes the law of nations and what does not. But that seems to us a fairly circuitous way of doing things.'' I would concur, particularly since the Supreme Court's decision last year in the Alvarez Machain case did not clear up the inherent vagaries in the law.

A significant provision in this legislation creates a standard of liability that requires plaintiffs to show that a defendant directly participated with specific intent in carrying out the alleged tort. In my view, we need to deter legal fishing expeditions, whereby plaintiffs come to the bar with flinty facts backing weak charges. Their real intent, it seems, is to rely on an extensive legal discovery process to uncover matters that embarrass companies and delay their business plans.

In the groundbreaking 1980 Filartiga v. Pena-Irala case, for example, the threshold requirement laid out was that the offense needed to be ''clear and unambiguous'' to be viable under the statute. Succeeding cases have affirmed a standard essentially requiring proof of a defendant aiding and abetting the worst human rights violations. This bill replaces the current aiding and liability standard for good reason: these foreign-based claims demand a particularity of facts that is both strong and specific.

I would submit that the existing ambiguous grant of jurisdiction needs more refinement to provide judges legal bright lines for deciding these cases. My bill offers precise, and fair, treatment for which cases get standing in a U.S. court.

A common theme in dozens of cases alien tort cases is whether the facts and law combine to present a nonjusticiable political question. Each cause of action is obviously different, and whether the matter ought to be under the province of a different branch of government requires careful analysis.

I would certainly agree that certain prudential doctrines, act of state, political question, foreign sovereign immunity, forum non conveniens, and considerations of comity among nations, at times can be appropriately invoked to limit jurisdiction.

Part of that consideration can usefully come from statements of interest and certifications submitted by the Executive branch; for that reason, the legislation I'm offering preserves a suitable role for the Executive branch to weigh in. If a judge determines that a certification offered by the State Department adequately justifies that harm will come to U.S. foreign policy interests if an alien tort suit proceeds, then dismissal is warranted.

In regards to restricting the statute of limitations to ten years, equitable tolling considerations should be explicitly considered in interpreting provisions in the legislation. There are numerous factors that give rise to equitable tolling and long-established judge-made doctrine in this area is not inconsistent with the goals of my bill.

Complementary legislation which I raised earlier, the Torture Victim Protection Act, upholds the principle of equitable tolling. The Judiciary Committee report on that measure notes some common examples:

''The statute of limitation should be tolled during the time the defendant was absent from the United States or from any jurisdiction in which the same or a similar action arising from the same facts may be maintained by the plaintiff, provided that the remedy in that jurisdiction is adequate and available. Excluded also from calculation of the statute of limitations would be the period when a defendant has immunity from suit. The statute of limitations should also be tolled for the period of time in which the plaintiff is imprisoned or otherwise incapacitated.''

I would submit that all of these listed circumstances, and others, are sufficient to suspend the running of the time under my legislation.

Let me conclude by referring back to one of the Supreme Court's foundational points in the Alvarez-Machain case that ''despite considerable scholarly attention, it is fair to say that a consensus understanding of what Congress intended has proven elusive.''

The 33 words contained in the law remain a ''legal Lohengrin'' since ''no one seems to know whence it came''

added a judge hearing a different case some years ago. As a result, costly, complex litigation proceeds forward across the country.

Courts deserve guidance from Congress about how to treat and interpret the statute, particularly in light of the growing importance of international trade and commerce. In a major address Supreme Court Justice O'Connor recently observed that ''international law has emerged in ways that affect all courts, both here and abroad. The reason is globalization. Its importance should not be underestimated. Thirty percent or more of our gross domestic product is internationally derived.'' Yet these particular suits, brought by foreigners for massive monetary damages, threaten the international economic activities that are important to sustaining the American economy.

The suits should be able to go forward, but judges need better legal tools to make heads or tails of the cases that come before them hence the motivation for introducing the Alien Tort Statute Reform Act.

With full understanding of the Supreme Court's admonition to act with judicial caution in framing the alien tort statute, I believe it is time for Congress to bring clarity to the law and this proposed legislation does so.

I look forward to working with colleagues on the Judiciary Committee, through the hearing process and other means, to give this matter serious consideration by the Legislative branch.

I ask unanimous consent that the text of the legislation be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1874

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 ''Alien Tort Statute Reform Act''.

SEC. 2. SUITS BY ALIENS.

Section 1350 of title 28, United States Code, is amended to read as follows:

''§ 1350. Alien's action for tort

''(a) JURISDICTION OF DISTRICT COURTS.—The district courts shall have original and exclusive jurisdiction of any civil action brought by an alien asserting a claim of torture, extrajudicial killing, genocide, piracy, slavery, or slave trading if a defendant is a direct participant acting with specific intent to commit the alleged tort. The district courts shall not have jurisdiction over such civil suits brought by an alien if a foreign state is responsible for committing the tort in question within its sovereign territory.

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

''(1) DEFENDANT.—The term 'defendant' means any person subject to the jurisdiction of the district courts of the United States, including—

''(A) a United States citizen;

''(B) a natural person who is a permanent resident of the United States;

''(C) a natural person who resides in the United States; or

''(D) a partnership, corporation, or other legal entity organized under the laws of the United States or of a foreign state.

''(2) FOREIGN STATE.—The term 'foreign state' has the meaning given that term in section 1603 of title 28, United States Code.

''(3) EXTRAJUDICIAL KILLING.—The term 'extrajudicial killing'—

''(A) means a deliberated killing, which—

''(i) notwithstanding the jurisdictional limitations referred to in subsection (a), is carried out by an individual under actual or apparent authority, or color of law, of any foreign state;

''(ii) is directed against another individual in the offender's custody or physical control; and

''(iii) is not authorized by a previous judgment pronounced by a regularly constituted court affording all the judicial guarantees which are recognized as indispensable by civilized peoples; and

''(B) does not include any such killing that, under international law, is lawfully carried out under the authority of a foreign state.

''(4) GENOCIDE.—The term 'genocide' means, whether in time of peace or in time of war, an act carried out, or an attempt to carry out an act, with the specific intent to destroy, in whole or in substantial part, a national, ethnic, racial, or religious group as such, which—

''(A) kills members of that group;

''(B) causes serious bodily injury to members of that group;

''(C) causes the permanent impairment of the mental faculties of members of the group through drugs, torture, or similar techniques;

''(D) subjects the group to conditions of life that are intended to cause the physical destruction of the group in whole or in part;

''(E) imposes measures intended to prevent births within the group; or

''(F) transfers by force children of the group to another group.

''(5) PIRACY.—The term 'piracy' means—

''(A) any illegal acts of violence or detention, or any act of depredation, committed for private ends by the crew or the passengers of a private ship or a private aircraft, and directed—

''(i) on the high seas, against another ship or aircraft, or against persons or property on board such ship or aircraft; or

''(ii) against a ship, aircraft, persons, or property in a place outside the jurisdiction of any country;

''(B) any act of voluntary participation in the operations of a ship or of an aircraft with knowledge of facts making it a pirate ship or aircraft; or

''(C) any act of inciting or of intentionally facilitating an act described in subparagraph (A) or (B).

''(6) SLAVE TRADING.—The term 'slave trading' includes—

''(A) all acts involved in the capture, acquisition, or disposal of a person with intent to reduce such person to slavery;

''(B) all acts involved in the acquisition of a slave with a view to selling or exchanging such slave;

''(C) all acts of disposal by sale or exchange of a slave acquired with a view to being sold or exchanged; and

''(D) in general, every act of trade or transport of slaves.

''(7) SLAVERY.—The term 'slavery' means the status or condition of a person over whom any or all of the powers attaching to the right of ownership are exercised.

''(8) TORTURE.—

''(A) IN GENERAL.—Notwithstanding the jurisdictional limitations referred to in subsection (a), the term 'torture' means any act, carried out by an individual under actual or apparent authority, or color of law, of any foreign state, directed against another individual in the offender's custody or physical control, by which severe pain or suffering (other than pain or suffering arising only from or inherent in, or incidental to, lawful sanctions), whether physical or mental, is intentionally inflicted on that individual for such purposes as obtaining from that individual or a third person information or a confession, punishing that individual for an act that individual or a third person has committed or is suspected of having committed, intimidating or coercing that individual or a third person, or for any reason based on discrimination of any kind.

''(B) MENTAL PAIN OR SUFFERING.—In subparagraph (A), mental pain or suffering refers to prolonged mental harm caused by or resulting from—

''(i) the intentional infliction or threatened infliction of severe physical pain or suffering;

''(ii) the administration or application, or threatened administration or application, of mind altering substances, or other procedures calculated to disrupt profoundly the senses or the personality;

''(iii) the threat of imminent death; or

''(iv) the threat that another individual will imminently be subjected to death, severe physical pain or suffering, or the administration or application of mind altering substances or other procedures calculated to disrupt profoundly the senses or personality.

''(c) LIABILITY FOR DAMAGES.—Any defendant who is a direct participant acting with specific intent to commit a tort referred to in subsection (a) against an alien shall be liable for damages to that alien or to any person who may be a claimant in an action for the wrongful death of that alien.

''(d) EXHAUSTION OF REMEDIES.—A district court shall abstain from the exercise of jurisdiction over a civil action described in subsection (a) if the claimant has not exhausted adequate and available remedies in the place in which the injury occurred. Adequate and available remedies include those available through local courts, claims tribunals, and similar legal processes.

''(e) FOREIGN POLICY INTERESTS OF THE UNITED STATES.—No court in the United States shall proceed in considering the merits of a claim under subsection (a) if the President, or a designee of the President, adequately certifies to the court in writing that such exercise of jurisdiction will have a negative impact on the foreign policy interests of the United States.

''(f) PROCEDURAL REQUIREMENTS.—

''(1) SPECIFICITY.—In any action brought under this section, the complaint shall state with particularity specific facts that—

''(A) describe each tort alleged to have been committed and demonstrate the reason or reasons why the tort action may be brought under this section, provided that if an allegation is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed; and

''(B) demonstrate that the defendant had the specific intent to commit the tort alleged to have been committed.

''(2) MOTION TO DISMISS.—In any action brought under this section, the court shall, on the motion of any defendant, dismiss the

complaint if the requirements of subparagraphs (A) and (B) of paragraph (1) are not met.

''(3) STAY OF DISCOVERY.—In any action brought under this section, all discovery related to the merits of the claim and other proceedings shall be stayed during the pendency of any motion to dismiss, unless the court finds upon the motion of any party that particularized discovery is necessary to preserve evidence or to prevent undue prejudice to that party.

''(4) PLAINTIFF IDENTITY.—

''(A) REQUIREMENT.—Subject to subparagraph (B), in any action brought under this section, the first and last names of all plaintiffs shall be disclosed in the complaint filed with the court.

''(B) EXCEPTION.—A court may permit an anonymous filing of a complaint if a plaintiff's life or safety would be endangered by publicly disclosing the plaintiff's identity.

''(g) FEES.—Contingency fee arrangements are prohibited in any action brought under the jurisdiction provided in this section.

''(h) STATUTE OF LIMITATIONS.—No action shall be maintained under this section unless it is commenced not later than 10 years from the date the injury occurred.

''(i) APPLICATION OF OTHER LAWS.—Nothing in this section may be construed to waive or modify the application of any provision of the Class Action Fairness Act of 2005 (Public Law 109–2; 119 Stat. 4) and any amendment made by that Act, or of title 28, United States Code, to any class action law suit brought under this section.''.

By Mr. BINGAMAN:

S. 1875. A bill to provide financial aid to local law enforcement officials along the Nation's borders, and for other purposes; to the Committee on the Judiciary.

Mr. BINGAMAN. Mr. President, I rise today to introduce the Border Law Enforcement Relief Act of 2005. This bill will provide local law enforcement in border communities with much needed assistance in combating border-related criminal activity. For far too long, law enforcement agencies operating along the border have had to incur significant costs due to the inability of the Federal Government to secure our Nation's borders. It is time that the Federal Government recognizes that border communities should not have to bear this burden alone.

The bill I am introducing today is aimed at enhancing security in the border region by giving law enforcement agencies the manpower and resources they need to combat border-related crimes. Specifically, the bill would establish a competitive grant program within the Department of Homeland Security to help local law enforcement situated along the border cover some of the costs they incur as a result of dealing with illegal immigration, drug trafficking, stolen vehicles, and other border-related crimes, and authorizes $30 million a year to carry out the program. Funds allocated under the grant program could be used to hire additional personnel, obtain necessary equipment, upgrade law enforcement technology, and cover overtime and transportations costs.

Law enforcement agencies serving communities within 100 miles of the U.S. border with Mexico or Canada, as well as any other agencies located outside of this geographical limit located in an area which has been designated by the Secretary of Homeland Security as a ''High Impact Area,'' would be eligible to apply for the grants. Priority in awarding grants would go to law enforcement agencies serving communities with populations under 50,000. Two-thirds of the funds would be set aside for the six states with the highest alien apprehension rates and one-third for areas designated as ''High Impact Areas.''

It is the responsibility of the Federal Government to adequately secure the Nation's borders and prevent the flow of undocumented persons and illegal drugs into the country. Despite the fact that the Border Patrol apprehends over 1 million people each year trying to illegally enter the United States, the number of illegal aliens in the United States continues to rise as thousands of individuals enter the country through our porous borders. The border region is also a major corridor for the shipment of drugs—according to the El Paso Intelligence Center, 65 percent of the narcotics that are sold in the United States enter the country through the Southwest border.

By virtue of their proximity to an international border, many of adverse consequences of the failure of the Federal Government to adequately secure the border fall on the border communities. In traveling around the New Mexico-Mexico border region, I have heard repeatedly how drug trafficking, kidnappings, human smuggling, and the destruction of private property, such as the tearing down ranchers' cattle fences, are impacting our communities.

The United States shares 5,525 miles of border with Canada and 1,989 miles with Mexico. Many of the local law enforcement agencies located along the border are small, rural departments charged with patrolling large areas of land with few officers and very limited resources. Counties along the Southwest border are some of the poorest in the country and are not in the position to cover the additional costs associated with illegal immigration, drug trafficking, and other border-related crimes.

According to a 2001 study by the United States-Mexico Border Counties Coalition, local law enforcement and criminal justice costs associated with illegal immigration exceed $89 million every year. The States of Arizona and New Mexico have declared states of emergency in order to provide local law enforcement with immediate assistance in addressing criminal activity along the border. It is time that the Federal Government step up and share some of this burden.

We are making some headway in terms of increasing the number of Border Patrol agents along the border. Despite the fact that the administration only requested funding to hire an additional 210 Border Patrol agents in its 2006 Budget Request, Congress has appropriated enough funding to hire and train an additional 1,500 agents. We are making some progress, and I am pleased that additional agents have been sent to New Mexico, but we must face the reality that much more needs to be done and we are a long way off from securing our borders and preventing the illegal flow of drugs and undocumented person into this country. I believe that this is an area that Congress can, and should, be doing more.

We need more Border Patrol agents, better technology, and a comprehensive strategy to meet our security needs. We also need to reform our broken immigration system so we are able to more effectively target those who pose a threat to our country. However, we must also remember the role local law enforcement play in responding to criminal activity that occurs in the border region. Increasing funding for local law enforcement will help border communities alleviate some of these problems and enhance security in the border region.

Federal assistance is desperately needed to help border law enforcement agencies address the unique challenges that arise from being situated along an international border and the lack of overall border security. I urge my colleagues to lend their support to this important bill and give law enforcement the resources they need to meet these challenges.

By Mr. AKAKA:

S. 1878. A bill to prohibit predatory payday loans, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. AKAKA:

S. 1879. A bill to amend title 11, United States Code, to limit claims in bankruptcy by certain unsecured creditors; to the Committee on the Judiciary.

BANKRUPTCY REFORM IMPLEMENTATION

Mr. AKAKA. Mr. President, I opposed the bankruptcy reform bill because it was an outdated bill that failed to include adequate consumer protections. We saw a record number of consumer bankruptcy filing prior to the October 17 implementation deadline for the harsh new bankruptcy. Not enough was included in the legislation to protect consumers from predatory lenders or to make credit counseling a viable alternative to bankruptcy or to better inform over extended consumers about the true costs of their debts. I was disappointed that the Senate failed to effectively address these issues in a

meaningful way, and instead, passed an outdated bill that forces working families into more costly and difficult bankruptcy proceedings. I am committed to making improvements in this flawed law.

Today, I am introducing two bills that address flaws in the bankruptcy reform law. The first bill is the Predatory Payday Loan Prohibition Act. This bill would prevent federally-insured financial institutions from originating predatory payday loans. Payday loans are small cash loans repaid by borrowers' postdated checks or borrowers' authorizations to make electronic debits against existing financial accounts. Payday loan amounts are usually in the range of $100 to $500 with full payment due in 2 weeks. Finance charges on payday loans are typically in the range of $15 to $30 per $100 borrowed, which translates into triple digit interest rates in the range of 390 percent to 780 percent when expressed as an annual percentage rate. Loan flipping, which is a common practice, is the renewing of loans at maturity by paying additional fees without any principal reduction. Loan flipping often leads to instances where the fees paid for a payday loan well exceed the principal borrowed. This situation often creates a cycle of debt that is hard to break.

Industry analysts conservatively estimate that more than 15,000 payday advance locations across America extend about $25 billion in short-term credit to millions of households experiencing cash-flow shortfalls. Too many of its customers are low-income, working families. More and more customers are the financially stretched middle class, including people who have maxed out their credit cards, people perhaps who have lost a job, or people with no savings to fall back on during a situation that causes a cash-flow shortfall, such as a medical emergency.

Payday lending is also rampant in the military. One in five servicemembers have used payday lenders in the last year, according to the report, ''Payday Lenders Target the Military,'' by the Center for Responsible Lending. Payday lenders exploit people in financial need and profit enormously from these loans. We must act to protect vulnerable consumers from these predatory lenders.

In addition, I previously introduced S. 1347, the Low-Cost Alternatives to Payday Loans Act. This bill would authorize award demonstration project grants for eligible entities to provide consumers with low-cost, small loan alternatives to more costly and predatory payday loans. Loan alternatives that meet the needs of consumers and are at a fair price must be developed.

Today, I am also introducing the Bankruptcy Prevention Credit Counseling Act. The new bankruptcy reform law does not allow consumers to declare personal bankruptcy in either chapter 7 or chapter 13, unless they receive a briefing from an approved nonprofit credit counseling agency within 6 months of filing. The credit counseling instructional course requirement is intended to provide financial education to consumers who declare bankruptcy so they can attempt to avoid future financial problems.

About one in three consumers in credit counseling enter a debt management plan. In exchange, creditors may agree to concessions so that consumers pay off as much of their outstanding debt as possible. Examples of concessions can include a reduced interest rate on the amount they owe and the elimination of fees. Unfortunately, most credit card companies have become increasingly unwilling to significantly reduce interest rates for consumers in credit counseling.

The Bankruptcy Prevention Credit Counseling Act would prevent unsecured creditors, primarily credit card issuers, from attempting to collect accruing interest and additional fees from consumers in bankruptcy, if the creditor does not have a policy of waiving interest and fees for debtors who enter a consolidated payment plan at a credit counseling agency. Since the new bankruptcy law requires that consumers enter credit counseling before filing for bankruptcy, we must ensure that consumers are given a fair chance at reducing their debt burden.

I also offered the text of the amendment of my bill, S. 393, the Credit Card Minimum Payment Warning Act, as an amendment to the bankruptcy bill. My amendment, intended to provide consumers with adequate, timely, and meaningful disclosures, was unfortunately defeated. As the bankruptcy reform law makes it more difficult for consumers to discharge their debts in bankruptcy, we have a responsibility to provide meaningful additional information so that consumers can make better informed debt management decisions. The bankruptcy reform law includes a requirement that credit card issuers provide a generic warning about the consequences of only making the minimum payment. This requirement fails to provide consumers the detailed information that my amendment would have provided, which means detailed, personalized information necessary for them to make better informed choices about their credit card use and repayment. My amendment would have required companies to inform consumers of how many years and months it would take to repay their entire balance, and the total cost in interest and principal, if the consumer makes only the minimum payment. My legislation would also have required consumers to be provided with the amount they would need to pay to eliminate their outstanding balance in 36 months. Finally, my legislation would have required that creditors establish a toll-free number so that consumers can access trustworthy credit counselors. In response to criticisms that my amendment was not feasible, I, along with Senator SARBANES, requested that the Government Accountability Office study the issue. I am hopeful the report will provide helpful information as we must continue to improve meaningful and understandable disclosures that will help Americans better manage their credit card debts.

I want to take a moment to thank Senator SARBANES, and his Banking Committee staff, for working with me on this and many other financial literacy related issues. In addition, I also want to thank Senator LEAHY and the staff of the Judiciary Committee for all of their efforts to try and improve the flawed bankruptcy legislation.

I fear that the bankruptcy reform law will significantly harm families who have suffered financially due to illnesses, the loss of a job, or the death of a loved one. I remain committed to working with all of my colleagues to better protect and inform consumers and to hold the credit card industry accountable for its aggressive marketing of credit to our debt burdened society.

Mr. AKAKA. Mr. President, I rise to introduce the Predatory Payday Loan Prohibition Act of 2005. Currently, federal law authorizes insured depository institutions to export interest rates, as provided under the laws of the state where the bank or credit union is located, to out-of-state borrowers. My bill would effectively eliminate the ability of financial institutions to do this by prohibiting federally-insured financial institutions from originating predatory payday loans.

What constitutes a payday loan? These are small cash loans repaid by borrowers' postdated checks or borrowers' authorizations to make electronic debits against existing financial accounts. Payday loan amounts are usually in the range of $100 to $500 with payment in full due in two weeks. Finance charges on payday loans are typically in the range of $15 to $30 per $100 borrowed, which translates into triple digit interest rates in the range of 390 percent to 780 percent when expressed as an annual percentage rate. Loan flipping, which is a common practice, is the renewing of loans at maturity by paying additional fees without any principal reduction. Loan flipping often leads to instances where the fees paid for a payday loan well exceed the principal borrowed. This situation often creates a cycle of debt that is hard to break. Today, industry analysts conservatively estimate that more than 15,000 payday advance locations across America extend about $25 billion in short-term credit to millions of households experiencing cash-flow shortfalls.

I am appalled that the payday lending industry is portrayed as a legitimate business. Too many of its customers are low-income, working families. More and more customers are the financially stretched middle class including people who have maxed out their credit cards, people perhaps who have lost a job, or people with no savings to fall back on during a situation that causes a cash-flow shortfall, such as a medical emergency. Payday lending is also rampant in the military. One in five servicemembers have used payday lenders in the last year, according to the report, ''Payday Lenders Target the Military,'' by the Center for Responsible Lending. Payday lenders are concentrated around military bases, such as the Navy bases in Norfolk, Virginia, the Army's Fort Lewis in Washington State, and the Marine Corps base at Camp Pendleton in California. The Department of Defense confirms the Center's report by listing payday lending as one of the top 10 priority issues facing military families, according to Dr. David Chu, the Under Secretary of Defense for Personnel and Readiness. To the predatory lenders, our military personnel's government paychecks represent a reliable source of fees. Also, payday lenders can be relatively confident that borrowers will continue to pay, because military personnel face harsh consequences, such as court martial or dishonorable discharge, for not repaying their debts. I am pleased that in my home state a local credit union, Windward Community Federal Credit Union, Kailua, Hawaii, has developed an affordable, alternative product to offer the many Marines who live in its service area. Earlier this year I introduced another bill to encourage replication of such practices. S. 1347, the Low-Cost Alternatives to Payday Loans Act, would authorize demonstration project grants to eligible entities to provide low-cost, small loans to consumers that would provide alternatives to more costly, predatory payday loans so that more people could have access to payday loan alternatives.

Payday loan providers claim that they are offering a simple financial product that addresses an emergency or temporary credit need that usually cannot be met by traditional financial institutions. An analysis of payday lending statistics by the Center for Responsible Lending indicates that the majority of payday loan borrowers have multiple loans each year with two thirds having five or more payday loans annually and half of these borrowers having 12 or more payday loans annually. Some borrowers seek loans from two or more payday lenders, multiplying the potential for getting trapped in debt. Research by the Community Financial Services Association of America, the payday loan industry's national trade association, found that 40 percent of payday loan customers renew their payday loans a staggering five times or more.

The payday loan industry exploits people that are in financial need. Congress has failed to act to prevent the exploitation of working families that are short on cash due to unexpected medical expenses or other needs. We must act to protect consumers from these unscrupulous lenders. I remain committed to restricting all forms of predatory lending, including payday loans, and I encourage my colleagues to support this legislation.

Mr. President, I ask unanimous consent that the text of the bill and a letter of support be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 1878

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 ''Predatory Payday Loan Prohibition Act of 2005''.

SEC. 2. PROHIBITION ON CREDITORS MAKING PAYDAY LOANS.

The Truth in Lending Act (15 U.S.C. 1601 et seq.) is amended by inserting after section 109 the following:

''SEC. 110. PROHIBITION ON PAYDAY LOANS.

''(a) IN GENERAL.—A creditor may not make a payday loan to any person, if the creditor knows or has reasonable cause to believe that—

''(1) the personal check or share draft that the creditor receives from the person in exchange for the loan is drawn on an insured depository institution or an insured credit union; or

''(2) the account that will be debited in exchange for the loan is a transaction account or share draft account at an insured depository institution or an insured credit union.

''(b) DEFINITIONS.—In this section, the following definitions shall apply:

''(1) INSURED INSTITUTIONS.—The terms 'insured depository institution' and 'insured credit union' have the meanings given those terms in section 3 of the Federal Deposit Insurance Act and section 101 of the Federal Credit Union Act, respectively.

''(2) PAYDAY LOAN.—The term 'payday loan' means any transaction in which a short-term cash advance is made to a consumer in exchange for—

''(A) the personal check or share draft of the consumer, in the amount of the advance plus a fee, where presentment or negotiation of such check or share draft is deferred by agreement of the parties until a designated future date; or

''(B) the authorization of a consumer to debit the transaction account or share draft account of the consumer, in the amount of the advance plus a fee, where such account will be debited on or after a designated future date.''.

SEC. 3. PROHIBITION ON INSURED DEPOSITORY INSTITUTIONS MAKING PAYDAY LOANS.

Section 18 of the Federal Deposit Insurance Act (12 U.S.C. 1828) is amended by adding at the end the following:

''(x) PROHIBITION ON CERTAIN UNSAFE AND UNSOUND BANKING PRACTICES.—

''(1) IN GENERAL.—An insured depository institution may not—

''(A) make any payday loan, either directly or indirectly; or

''(B) make any loan to any other lender for purposes of financing a payday loan or refinancing or extending any payday loan.

''(2) PAYDAY LOAN DEFINED.—For purposes of this subsection, the term 'payday loan' means any transaction in which a short-term cash advance is made to a consumer in exchange for—

''(A) the personal check or share draft of the consumer, in the amount of the advance plus a fee, where presentment or negotiation of such check or share draft is deferred by agreement of the parties until a designated future date; or

''(B) the authorization of the consumer to debit the transaction account or share draft account of the consumer, in the amount of the advance plus a fee, where such account will be debited on or after a designated future date.''.

OCTOBER 6, 2005.

Hon. DANIEL K. AKAKA,
U.S. Senate,
Washington, DC.

DEAR SENATOR AKAKA: Consumer Federation of America, Community Reinvestment Association of NC, Consumer Action, Consumers Union, National Community Reinvestment Coalition, National Consumer Law Center and U.S. PIRG applaud you for sponsoring legislation to prohibit lending based on checks or debits drawn on federally insured depository institutions. You have recognized that it is an unsafe banking practice for consumers to be enticed by payday lenders to write checks or authorize debits when there is no money on deposit to cover these cash advances. We are also pleased that your bill would prohibit banks from partnering with payday lenders, a tactic used by storefront lenders to evade state small loan and usury laws.

The ''Predatory Payday Loan Prohibition Act of 2005'' prohibits the relatively new practice of holding a check as security for a loan. Using the check as security for the payment of a payday loan is the key to the coercive collection tactics used by the lenders. As the lender holds the check, at the end of the short term loan, the consumer is generally forced to choose among three untenable options: 1) allowing the check to be debited from their bank account where it will deplete money needed for food and other living necessities, 2) allowing the check to bounce, exposing the borrower to coercive collection tactics when lenders threaten civil or criminal liability for unpaid checks, and from the risk of losing their bank account or checkwriting privileges, or 3) renewing the loan at the original high cost. Loans based on personal checks drawn on the borrower's bank account that will be deposited to repay the loan on the next payday is the modern version of lending secured by wage assignments, a credit practice long recognized as inherently unfair which violates FTC rules.

Your legislation also stops payday lenders from partnering with federally insured depository institutions to evade state usury or small loan rate caps. A few federally insured state chartered banks persist in ''renting'' their charters to payday lenders, a practice curtailed by most federal bank regulators, to make loans in states that enforce their usury or small loan laws.

Although payday lender-bank charter renting has been curtailed by regulatory action,

only legislation will create a clear prohibition to stop this practice that undermines state small loan regulation.

Sincerely,

JEAN ANN FOX,
Director of Consumer Protection, Consumer Federation of America.
PETER SKILLERN,
Executive Director, Community Reinvestment Association of NC.
LINDA SHERRY,
Director, National Priorities, Consumer Action.
SUSANNA MONTEZEMOLO,
Policy Analyst, Consumers Union.
MONICA GONZALES,
Vice President of Legislation and Regulatory Affairs, National Community Reinvestment Coalition.
MARGOT SAUNDERS,
Of Counsel, National Consumer Law Center.
ED MIERZWINSKI,
Consumer Program Director, U.S. Public Interest Research Group (U.S. PIRG).

Mr. AKAKA. Mr. President, I rise to introduce the Bankruptcy Prevention Credit Counseling Act. The new bankruptcy reform law does not allow consumers to declare personal bankruptcy in either Chapter 7 or Chapter 13, unless they receive a briefing from an approved nonprofit credit counseling agency within 6 months of filing. The credit counseling instructional course requirement is intended to provide financial education to consumers who declare bankruptcy so they can attempt to avoid future financial problems.

About one in three consumers in credit counseling enter a debt management plan. In exchange, creditors may agree to concessions so that consumers pay off as much of their outstanding debt as possible. Concessions can include a reduced interest rate on the amount they owe and the elimination of fees. Unfortunately, most credit card companies have become increasingly unwilling to significantly reduce interest rates for consumers in credit counseling. A study by the National Consumer Law Center and the Consumer Federation of America revealed that 5 of 13 credit card issuers increased the interest rates they offered to consumers in credit counseling between 1999 and 2003. American Express and Wells Fargo completely waive all interest for consumers in credit counseling. However, the majority of credit card issuers charge interest rates above 9 percent for account holders that enter into credit counseling, with several charging more than 15 percent.

My bill would prevent unsecured creditors, primarily credit card issuers, from attempting to collect accruing interest and additional fees from consumers in bankruptcy, if the creditor does not have a policy of waiving interest and fees for debtors who enter a consolidated payment plan at a credit counseling agency.

Since the new bankruptcy law requires that consumers enter credit counseling before filing for bankruptcy, we must ensure that credit counseling is truly effective and a viable alternative to bankruptcy. Credit card issuers undermine the good intentions of those consumers. They have sharply curtailed the concessions they offer to consumers in credit counseling, contributing to increased bankruptcy filings. According to a survey by VISA USA, 33 percent of consumers who failed to complete a debt management plan in credit counseling said they would have stayed on the plan if creditors had lowered interest rates or waived fees. Credit card companies have an obligation to ensure that effective alternatives are readily available to the consumers they aggressively pursue.

We must make sure that credit counseling is an effective tool to help consumers avoid bankruptcy. In order to do this, credit card issuers should waive the amount owed in interest and fees for consumers who enter a consolidated payment plan. Successful completion of a debt management plan benefits both creditors and consumers. Mr. President, for many consumers, paying off their debt is not easy. My bill will help people who are struggling to repay their obligations. I encourage all of my colleagues to support this legislation to help consumers enrolled in debt management plans to successfully repay their creditors, free themselves from debt, and avoid bankruptcy.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1879

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 ''Bankruptcy Prevention Credit Counseling Act of 2005''.

SEC. 2. REDUCTION OF UNSECURED CLAIMS.

Section 502(b) of title 11, United States Code, is amended—

(1) in paragraph (8), by striking ''or'' at the end;

(2) in paragraph (9), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(10) such consumer debt is an unsecured claim arising from a debt to a creditor that does not have, as of the date of the order for relief, a policy of waiving additional interest for all debtors who participate in a debt management plan administered by a nonprofit budget and credit counseling agency described in section 111(a).''.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 273—EXPRESSING THE SENSE OF THE SENATE THAT THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS SHALL NOT BE ALLOWED TO EXERCISE CONTROL OVER THE INTERNET

Mr. COLEMAN submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 273

Whereas market-based polices and private sector leadership have allowed the Internet the flexibility to evolve;

Whereas given the importance of the Internet to the global economy, it is essential that the underlying domain name system and technical infrastructure of the Internet remain stable and secure;

Whereas the Internet was created in the United States and has flourished under United States supervision and oversight, and the Federal Government has followed a path of transferring Internet control from the defense sector to the civilian sector, including the Internet Corporation for Assigned Names and Numbers (ICANN) with the goal of full privatization;

Whereas the developing world deserves the access to knowledge, services, commerce, and communication, the accompanying benefits to economic development, education, health care, and the informed discussion that is the bedrock of democratic self-government that the Internet provides;

Whereas the explosive and hugely beneficial growth of the Internet did not result from increased government involvement but from the opening of the Internet to commerce and private sector innovation;

Whereas, on June 30, 2005, President George W. Bush announced that the United States intends to maintain its historic role over the master ''root zone'' file of the Internet, which lists all authorized top-level Internet domains;

Whereas the recently articulated principles of the United States on the domain name and addressing system of the Internet (DNS) are that the Federal Government will preserve the security and stability of the DNS, will take no action with the potential to adversely affect the effective and efficient operation of the DNS, and will maintain the historic role of the United States regarding modifications to the root zone file, that governments have a legitimate interest in the management of country code top level domains (ccTLD), and the United States is committed to working with the international community to address the concerns of that community in accordance with the stability and security of the DNS, that ICANN is the appropriate technical manager of the Internet, and the United States will continue to provide oversight so that ICANN maintains focus and meets its core technical mission, and that dialogue relating to Internet governance should continue in multiple relevant fora, and the United States encourages an ongoing dialogue with all stakeholders and will continue to support market-based approaches and private sector leadership;

Whereas the final report issued by the Working Group on Internet Governance (WGIG) of the United Nations indicates that