109TH CONGRESS
1ST SESSION

S. 3

To strengthen and protect America in the war on terror.

IN THE SENATE OF THE UNITED STATES

JANUARY 24, 2005

Mr. GREGG (for himself, Mr. FRIST, Mr. SESSIONS, Mr. DEWINE, Mr. ALLEN, Mr. SANTORUM, Mr. MCCONNELL, and Mr. DEMINT) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To strengthen and protect America in the war on terror.

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

SECTION 1. SHORT TITLE.

(a) SHORT TITLE.—This Act may be cited as the ''Protecting America in the War on Terror Act of 2005''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—BIOPREPAREDNESS

SEC. 101. SHORT TITLE.

This title may be cited as the ''Biopreparedness Act of 2005''.

Subtitle A—Product Development

CHAPTER 1—PARTNERING WITH THE PRIVATE SECTOR

SEC. 111. EXPANSION OF COUNTERMEASURES COVERED BY BIOSHIELD.

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))), detection technology, or research tool 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) treat, identify, detect or prevent harm from any biological (including an infectious disease), chemical, radiological, or

nuclear agent that may cause a public health emergency affecting national security; or

"(ii) treat, identify, detect or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, device, detection technology or research tool that is used as described in this subparagraph.

"(B) DETECTION TECHNOLOGY.—The term 'detection technology' means a technology device and its use for the detection of the presence, concentration, or characteristics of a biological (including an infectious disease), chemical, or radiological agent in environmental or field samples.

"(C) RESEARCH TOOL.—The term 'research tool' includes the full range of tools that scientists may use in the laboratory to enable the rapid and effective development of countermeasures, including diagnostics, vaccines, and drugs.

"(D) INFECTIOUS DISEASE.—

''(i) IN GENERAL.—The term 'infectious disease' means a disease in humans caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(ii) CLARIFICATION.—The term 'infectious disease' includes a pathogenic organism whether or not such pathogenic organism is acquired by an individual through human-to-human contact or if the individual is initially symptomatic of the disease.''.

SEC. 112. ENHANCING AVAILABILITY OF PRIVATE AND INTERNATIONAL SECTOR FINANCING.

Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress recommendations concerning the necessity and feasibility of establishing mechanisms through which the United States may accept contributions or guarantees from private organizations, international health agencies, and nongovernmental organizations to enhance the procurement or development of qualified countermeasures (as such

term is defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a(a)).

SEC. 113. RESTORATION OF PATENT TERM.

(a) PURPOSE.—The purpose of this section is to provide patent incentives to certain entities to protect inventions from expropriation by competitors and to provide an incentive for capital formation to fund countermeasures and vaccine research.

(b) LIMITATION.—A private entity may utilize the patent term protection and exclusive marketing provisions described in this title for countermeasures if such private entity is an entity certified under section 1812(d) of the Homeland Security Act of 2002.

(c) RESTORATION OF PATENT TERMS RELATING TO COUNTERMEASURES AND VACCINES.—

(1) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by inserting after section 156 the following:

"§ 156a. Restoration of patent terms relating to countermeasures and vaccines

''(a) DEFINITIONS.—In this section, the term—

''(1) 'countermeasure product' means a countermeasure, as that term is defined in section 319F–1 of the Public Health Service Act, that is also a new drug, antibiotic drug, human biological product

or medical device, as those terms are used in 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.));

''(2) 'regulatory review period' means the period of time that—

''(A) starts on the date that is the later of—

''(i) the date that an eligible patent sought to be extended under this section is issued;

''(ii) the date that an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective for the product; or

''(iii) the date on which an investigational device exemption is approved pursuant to section 501 of the Federal Food, Drug and Cosmetic Act;

''(B) ends on the date that is—

''(i) in the case of a drug or antibiotic drug, the date on which an application submitted for such drug or antibiotic under section 505(b) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355(b)) is approved;

''(ii) in the case of a biologic, the date on which an application submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) is approved; or

''(iii) in the case of a medical device, the date on which an application submitted for such device under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is approved; and

''(3) 'eligible patent' means a patent that—

''(A)(i) claims a countermeasure product that has been successfully developed as specified by section 1812(e) of the Homeland Security Act of 2002, or claims an active ingredient of such countermeasure product, or a process of making or using the countermeasure product or an active ingredient of such countermeasure product, and

''(ii) is owned by or licensed to an entity that has successfully developed the countermeasure and has been certified under section 1812(d) of the Homeland Security Act of 2002, or

''(B) claims a vaccine that has been successfully developed.

''(b) PATENT TERM EXTENSION.—The term of an eligible patent shall be extended by a period equal to the number of days in the regulatory review period if:

''(1) An application in conformance with the requirements of section (c) is submitted to the Director by either the owner of record of the patent or its agent on or before the date specified in subsection (c)(3), or within 45 days from the date of issuance of the patent, whichever date is later.

''(2) The patent that is the basis of the application has not been previously extended under this section, or under sections 156 or 158 of this title.

''(3) The term of the patent that is the basis of the application has not expired before the date that the application is submitted under section (c).

''(4) The regulatory review period for the countermeasure product or vaccine has not been relied upon to support an application to extend the term of another patent under this section or under section 156 of this title.

''(c) ADMINISTRATIVE PROVISIONS.—

''(1) IN GENERAL.—To obtain an extension of the term of a patent under this section, the assigner

of record and licensee of record of the patent or the agent of the assigner of record and licensee shall submit an application to the Director.

''(2) CONTENT.—The application shall contain—

''(A) a description of the approved countermeasure product or vaccine and the Federal statute under which regulatory review occurred;

''(B) the identity of the patent for which an extension is sought under this section; and

''(C) such other information as the Director may require including to establish that the applicant meets the requirements of this section.

''(3) SUBMISSION OF APPLICATION FOR A COUNTERMEASURE.—An application for a countermeasure under this section shall be submitted to the Director within the 60-day period beginning on the date the product became eligible for purchase under a contract for procurement under section 319F–1 or 319F–2 of the Public Health Service Act.

''(4) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A pat-

ent that has been the basis of an application made under this section may not be the subject of an application made under sections 156 or 158 of this title.

''(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit an extension of the term of a patent relating to a countermeasure product that, before the effective date of this section was approved for commercial marketing for non-countermeasure uses.

''(d) LIMITATION.—A patent may not be extended under this section where—

''(1) the regulatory review period for the countermeasure product was concluded before the date of enactment of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act; or

''(2) the patent that is the basis of the application under this section expired before the date of enactment of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by inserting after the item relating to section 156 the following:

''156a. Restoration of patent terms relating to countermeasures for certain biological or chemical agents or toxins.''.

(d) GENERAL EXTENSION OF CERTAIN PATENT TERMS FOR PATENTS HELD BY ENTITIES THAT HAVE SUCCESSFULLY DEVELOPED COUNTERMEASURES.—

(1) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"§ 158. Patent term for patents held by entities with certain research certifications

''(a) DEFINITIONS.—In this section, the term—

''(1) 'countermeasure product' means a countermeasure, as that term is defined in section 319F–1 of the Public Health Service Act, that is also a new drug, antibiotic drug, human biological product or medical device, as those terms are used in 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.);

''(2) 'eligible patent' means an issued patent that, at least 1 year before the date on which an eligible entity was certified under section 1812(d) of the Homeland Security Act of 2002, was owned by or licensed to that eligible entity; and

''(3) 'eligible entity' means a natural or legal person that has—

''(A) alone or with others, successfully developed a countermeasure product;

''(B) been certified under section 1812(d) of the Homeland Security Act of 2002;

''(C) entered into a contract for the sale of the countermeasure product under section 319F–1 or section 319F–2 of the Public Health Service Act;

''(4) 'Research Act' means the Biological, Chemical, and Radiological Weapons Countermeasures Research Act.

''(b) SPECIAL PATENT TERM EXTENSION.—The term of a eligible patent shall be extended for a period as specified by regulations to be promulgated by the Secretary of Health and Human Services, in addition to the term which would otherwise apply except for this section, if:

''(1) An application in conformance with the requirements of subsection (c) is submitted to the Director by either the owner of record of the patent or its agent on or before the date specified in subsection (c)(3).

''(2) The patent that is the basis of the application has not been previously extended under this section, or under sections 156 or 156a of this title.

''(3) The term of the patent that is the basis of the application has not expired before the date that the application is submitted under subsection (c).

''(4) The term of no other patent has been extended based on the certification under section 1812(d) of the Homeland Security Act of 2002 of the eligible entity.

''(c) ADMINISTRATIVE PROVISIONS.—

''(1) IN GENERAL.—To obtain an extension of the term of a patent under this section, the owner of record of the patent or the agent of the owner shall submit an application to the Director.

''(2) CONTENT.—An application under this section shall contain—

''(A) a description of the approved countermeasure product and the Federal statute under which regulatory review occurred;

''(B) the identity of the patent for which an extension is sought under this section;

''(C) the identity of the eligible entity and the applicant; and

''(D) such other information as the Director may require including to establish that the

applicant meets the requirements of this section.

''(3) SUBMISSION OF APPLICATION.—An application under this section shall be submitted to the Director within the 60-day period beginning on the date the countermeasure product became eligible for purchase under a contract for procurement under section 319F–1 or 3199F–2 of the Public Health Service Act.

''(d) LIMITATIONS AND CONDITIONS.—

''(1) PERIOD OF EXTENSION.—The Secretary of Health and Human Services shall promulgate regulations specifying the duration of extensions to be granted under the authority of this section. The extension to be granted to an application shall be that specified by such regulations in effect on the date that an application for certification under section 1812(d) of the Homeland Security Act of 2005 is made by the eligible entity. In no case, shall any extension granted under this section exceed 2 years, or be less than 6 months.

''(2) CRITERIA FOR EXTENSION.—The Secretary of Health and Human Services, in determining the period of extensions to be granted under the authority of this section, shall consider—

''(A) the nature of the threat to be countered and the importance of developing countermeasures to respond to such threat;

''(B) the difficulty, risk, and expense likely to be associated with the development of such countermeasure; and

''(C) the impact of the patent extension on consumers and healthcare providers.

''(3) LIMITATION.—No patent may be extended under the authority of this subsection more than once.

''(4) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A patent that has been the basis of an application made under this section may not be the subject of an application made under sections 156 or 156a of this title.''

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by adding at the end the following:

''158. Patent term for patents held by entities with certain research certifications.''.

(e) LICENSING.—

(1) DISCRETION TO WAIVE MARCH-IN RIGHTS.—Notwithstanding sections 200, 203, and 209 of title 35, United States Code, an entity that holds a certification under section 1812(d) of the Homeland Security Act of 2002 with respect to a product that is a countermeasure, detection equipment, diagnostic, research tool, or drug intended to prevent or treat an infectious disease may license such patented product.

(2) FEDERALLY OWNED INVENTIONS.—Section 209 of title 35, United States Code, is amended—

(A) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively; and

(B) by inserting after subsection (d) the following:

''(e) TERMS AND CONDITIONS OF LICENSE.—Each license granted under section 207(a)(2) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to any patent for the licensed invention for purposes of extending a patent under section 156a or 158.''.

(3) COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.—Section 12(b) of the Stevenson-Wydler Technology Innovation Act of 1980 (15

U.S.C. 3710a(b)) is amended by adding at the end the following:

''(7) Each license for a patent granted under an agreement entered into under subsection (a)(1) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to that patent for purposes of extending a patent under section 156a or 158 of title 35, United States Code.''.

(4) APPLICABLE LICENSES.—The amendments made by paragraphs (2) and (3) shall apply only to licenses granted on or after 60 days after the date of enactment of this Act.

(f) ADDITIONAL INTELLECTUAL PROPERTY PROTECTIONS.—Not later than 12 months after the date of enactment of this Act, the Secretary of Commerce in consultation with the Secretary of Health and Human Services shall submit to the appropriate committees of Congress recommendations concerning additional intellectual property incentives and protections that may be necessary to accelerate efforts to develop or enhance qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a(a)) or preparedness pools.

SEC. 114. INTERNATIONAL HARMONIZATION OF REGULATIONS.

The Secretary of Health and Human Services shall provide an annual report to the appropriate committees of Congress describing the activities undertaken, progress made, and barriers to the implementation by the Department of Health and Human Services with respect to the international harmonization of regulations, including the International Conference on Harmonization, the Global Harmonization Task Force, and efforts to establish international standards for data exclusivity.

SEC. 115. DEVELOPMENT OF ADDITIONAL ANIMAL MODELS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319J the following:

"SEC. 319K. ANIMAL MODELS FOR CERTAIN DISEASES.

''(a) IN GENERAL.—The Secretary, in coordination with the Director of the National Institute on Allergy and Infectious Diseases and the Director of the Centers for Disease Control and Prevention, shall establish and award grants under this section to eligible entities to study the physiological responses of certain animal species to bioterrorism agents and other infectious agents.

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

''(1) provide assurances to the Secretary that the entity has access to a biosafety level 3 or 4 facility;

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

''(3) agree to submit the results of the research funded under the grant to the Director of the National Institute on Allergy and Infectious Diseases.''.

SEC. 116. 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) COUNTERMEASURES DEVELOPMENT MEETINGS AND CONSULTATIONS.—

''(A) COUNTERMEASURES DEVELOPMENT MEETING AND CONSULTATIONS.—The Secretary may conduct meetings and consultations with parties involved in the development of priority countermeasures for the purpose of the development, manufacture, distribution, purchase, or sale of priority countermeasures consistent with the purposes of this title. The Secretary shall give notice of such meetings and consultations to the Attorney General and the

Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

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

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

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

''(iii) be open to the Attorney General and the Chairperson;

''(iv) be limited to discussions involving the development, manufacture, distribution, or sale of priority countermeasures, 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) MINUTES.—The Secretary shall maintain minutes of meetings and consultations

under this subsection, which shall not be disclosed under section 552 of title 5, United States Code.

''(D) EXEMPTION.—The antitrust laws shall not apply to meetings and consultations under this paragraph, except that any agreement or conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection shall be subject to the antitrust laws.

''(2) WRITTEN AGREEMENTS.—The Secretary 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 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 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 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 and the parties involved.

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

"(i) must find—

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

''(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 expire 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 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 Biopreparedness 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) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemption under this subsection shall expire at the end of the 6-year period that begins on the date of enactment of the Biopreparedness Act of 2005.

''(h) DEFINITIONS.—In this section and title XXVIII of the Public Health Service Act:

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

''(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes 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 priority countermeasures;

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

"(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 priority countermeasures;

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

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

''(vi) the collection, exchange, and analysis of research or production information necessary to the development of priority countermeasures; 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, sales, profitability, prices, 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 activi-

ties, 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 (i)(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 (i)(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.

"(3) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure.

"(4) PERSON.—The term 'person' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).

"(5) PRIORITY COUNTERMEASURES.—The term 'priority countermeasure' means a countermeasure, including a drug, medical device, biological product, or diagnostic test to treat, identify, or prevent infection by a biological agent or toxin on the list developed under section 351A(a)(1) of the Public Health Service Act and prioritized under subsection (a)(1).".

CHAPTER 2—ENSURING REGULATORY EFFICIENCY

SEC. 121. COMMISSION ON COUNTERMEASURE AND VACCINE REGULATION.

(a) ESTABLISHMENT.—There shall be established a commission to be known as the Commission on Countermeasure and Vaccine Regulation (referred to in this section referred to as the ''Commission'').

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 7 members to be appointed by the Secretary of Health and Human Services in accordance with this subsection.

(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with expertise and experience in the manufacture, regulation, distribution, and use of vaccines, of which—

(A) at least 2 members of the Commission shall have experience qualified by training and experience to inspect vaccine manufacturing facilities and may be employees of the Department of Health and Human Services;

(B) at least 2 members of the Commission shall represent manufacturers of vaccine products; and

(C) at least 1 member of the Commission shall be a representative of vaccine consumers.

(3) CHAIRPERSON.—The Secretary shall appoint an individual to serve as the Chairperson of the Commission. Such individual shall not be an employee of the Department of Health and Human Services.

(c) FUNCTIONS.—The Commission shall conduct a study of the statutes, regulations, guidelines, and compliance, inspection, and enforcement practices and policies of the Department of Health and Human Services and of the Food and Drug Administration that are applicable to vaccines intended for human use that are in periodic short supply in the United States.

(d) REQUIREMENTS.—The study under subsection (c) shall include a review of the regulatory requirements, guidelines, practices, and policies—

(1) for the development and licensing of vaccines and the licensing of vaccine manufacturing facilities;

(2) for inspections and other activities for maintaining compliance and enforcement of the requirements applicable to such vaccines and facilities: and

(3) that may have contributed to temporary or long-term shortages of vaccines.

(e) REPORT AND RECOMMENDATIONS.—Not later than 6 months after the date of enactment of this Act, the Commission shall submit to the Secretary of Health and Human Services, the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains—

(1) the results of the study conducted under subsection (a); and

(2) recommendations for modifications to the regulatory requirements, guidelines and practices, and policies described in subsection (b) to reduce waste, increase efficiency, and ensure the rapid availability of safe and effective products.

SEC. 122. 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, at the request of

the manufacturer, to the manufacturers of vaccines or other biological products regulated under this act or section 351 of the Public Health Service Act 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. 123. REQUIREMENT TO FULLY INFORM.

(a) IN GENERAL.—Subchapter E of Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by section 122, is further amended by adding at the end the following:

''SEC. 566. REQUIREMENT TO FULLY INFORM.

''Notwithstanding any other provision of law, a manufacturer of a drug that is subject to Food and Drug Administration regulation shall promptly submit to the Food and Drug Administration all communications between the manufacturer and the regulatory body of a foreign government if the content of such communications may impact the introduction of a drug into the interstate commerce of the United States.''.

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

''(hh) The knowing failure or refusal by a manufacturer of a drug or vaccine to provide any communication required by this chapter.''.

SEC. 125. ACCELERATED APPROVAL OF COUNTERMEASURES OR VACCINES.

(a) IN GENERAL.—The Secretary of Health and Human Services may designate a countermeasure or vaccine as a fast-track product pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356). Such a designation may be made for countermeasures or vaccines that demonstrate the potential to improve upon countermeasures or vaccines available at the time of such declaration. Such a designation may be made prior to the submission of—

(1) a request for designation by the sponsor or applicant; or

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

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a sponsor or applicant from declining a designation under subsection (a).

SEC. 126. NATIONAL UNIFORMITY FOR APPROVED PRODUCTS.

(b) OTHER PRODUCTS.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter H—National Uniformity for Approved Products

"SEC. 761. NATIONAL UNIFORMITY FOR DRUGS, VACCINES, AND OTHER BIOLOGICAL PRODUCTS.

"(a) IN GENERAL.—Except as provided in section 763, no State, political subdivision of a State, or judicial system of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug intended for use by humans (including a vaccine or other biological product); and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and the administrative implementation of such Acts.

"(b) REQUIREMENT RELATING TO REGULATIONS.—For purposes of this section, a requirement relating to the regulation of a drug, vaccine, or other biological product shall be deemed to include any requirement relating to the

subject matter in any provision of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), but shall not include any requirement relating to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"SEC. 762. WARNING UNIFORMITY.

''(a) IN GENERAL.—Except as provided in this section, no State or political subdivision of a State may, directly or indirectly, establish or continue in effect under any authority any notification requirement for a drug, vaccine, or other biological product intended for use by humans that provides for a warning concerning the safety of the drug, vaccine, or biological product or any component or package thereof, unless such notification requirement has been prescribed under the authority of this Act and the State or political subdivision notification requirement is identical to the notification requirement prescribed under the authority of this Act.

''(b) DEFINITIONS.—In this section:

''(1) NOTIFICATION REQUIREMENT.—The term 'notification requirement' includes any mandatory disclosure requirement relating to the dissemination of information about a drug, vaccine, or biological

product in any manner, such as labels, labeling, posters, public notices, advertising, or any other means of communication.

''(2) WARNING.—The term 'warning' with respect to a drug, vaccine, or other biological product means any statement, vignette, or other representation which indicates, directly or by implication, that the drug, vaccine or biological product presents or may present a hazard to human health or safety.

''SEC. 763. EXEMPTIONS FROM UNIFORMITY.

''Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from section 761 or 762, under such conditions as the Secretary may impose, a State requirement that—

''(1) is justified by compelling and unique local conditions;

''(2) protects an important public interest that would otherwise be unprotected;

''(3) would not cause any drug, vaccine, or other biological product to be in violation of any applicable requirement or prohibition under Federal law; and

''(4) would not unduly burden interstate commerce.''.

Subtitle B—Litigation Reform

CHAPTER 1—PROTECTION FOR COUNTERMEASURES AND PRODUCTS PROTECTING AGAINST PANDEMICS, EPIDEMICS, AND BIOTERRORISM

SEC. 131. 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 PANDEMICS, EPIDEMICS, AND COUNTERMEASURES.

''(a) AUTHORITY.—The Secretary shall be responsible for the administration of this section. This section shall apply with respect to both Federal and non-Federal sales and purchases of qualified countermeasures within the meaning of section 319F–1 of the Public Health Service Act, or qualified pandemic or epidemic technologies.

''(b) LITIGATION MANAGEMENT.—

''(1) FEDERAL CAUSE OF ACTION.—

''(A) IN GENERAL.—There shall exist an exclusive Federal cause of action for claims arising out of, relating to, or resulting from the use of a qualified pandemic or epidemic technology or qualified countermeasure. The sub-

stantive law for decision in any such action shall be derived from the law, including choice of law principles, of the State in which such cases of pandemic occur, unless such law is inconsistent with or preempted by Federal law. Such Federal cause of action shall be brought only for claims for injuries that are proximately caused by manufacturers, distributors, or health care providers that provide qualified pandemic or epidemic technology or qualified countermeasure to Federal and non-Federal Government customers.

''(B) JURISDICTION.—Such appropriate district court of the United States shall have original and exclusive jurisdiction over all actions for any claim for loss of property, personal injury, or death arising out of, relating to, or resulting from when a qualified pandemic technology has been deployed in defense against or response or recovery and such claims result or may result in loss to the manufacturer, distributor, or health care provider.

''(2) SPECIAL RULES.—In an action brought under this section for damages the following provisions shall apply:

"(A) PUNITIVE DAMAGES.—No punitive damages intended to punish or deter, exemplary damages, or other damages not intended to compensate a plaintiff for actual losses may be awarded, nor shall any party be liable for interest prior to the judgment.

"(B) NONECONOMIC DAMAGES.—

"(i) IN GENERAL.—Noneconomic damages may be awarded in an amount not to exceed $250,000 against a defendant only in an amount directly proportional to the percentage of responsibility of such defendant for the harm to the plaintiff, and no plaintiff may recover noneconomic damages unless the plaintiff suffered physical harm.

"(ii) DEFINITION.—For purposes of clause (i), the term 'noneconomic damages' means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to rep-

utation, and any other nonpecuniary losses.

''(3) COLLATERAL SOURCES.—Any recovery by a plaintiff in an action under this section shall be reduced by the amount of collateral source compensation, if any, that the plaintiff has received or is entitled to receive that result or may result in loss to the manufacturer, distributor, or health care provider.

''(4) GOVERNMENT CONTRACTOR DEFENSE.—

''(A) IN GENERAL.—Should a product liability or other lawsuit be filed for claims arising out of, relating to, or resulting from the use of a qualified countermeasure, or qualified pandemic or epidemic technology in anticipation of and preparation for, in defense against or response or recovery and such claims result or may result in loss to the manufacturer, distributor, or health care provider there shall be a rebuttable presumption that the government contractor defense applies in such lawsuit. This presumption shall only be overcome by evidence showing that the manufacturer, distributor or health care provider acted fraudulently or with willful misconduct. This presumption of the

government contractor defense shall apply regardless of whether the claim against the manufacturer, distributor or health care provider arises from a sale of the product to Federal Government or non-Federal Government customers.

''(B) PRODUCT APPROVAL.—A defendant may assert the defense under subparagraph (A), if the qualified countermeasure or qualified pandemic or epidemic technology involved—

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

''(ii) is a countermeasure 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 countermeasure will qualify for approval or licensing within 8 years after the date of a determination under section 319F–2; or

''(iii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

''(c) DEFINITIONS.—In this section:

''(1) QUALIFIED PANDEMIC OR EPIDEMIC TECHNOLOGY.—The term 'qualified pandemic or epidemic technology' means any product (including drugs, vaccines, and other biologics), equipment, service (including support services), device, or technology (including information technology) designed, developed, modified, or procured for the specific purpose of preventing, detecting, identifying, or preventing a pandemic or epidemic or limiting the harm such pandemic or epidemic might otherwise cause, that is designated as such by the Secretary after the Secretary declares a public health emergency as described in section 319.

''(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a person who lawfully prescribes, administers, or provide a facility to administer a qualified countermeasure or a qualified pandemic or epidemic technology.

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

''(4) NON-FEDERAL GOVERNMENT CUSTOMERS.—The term 'non-Federal Government customers' means any customer of a manufacturer that is not an agency or instrumentality of the United States Government with authority under Public Law 85–804 to provide for indemnification under certain circumstances for third-party claims against its contractors, including but not limited to State and local authorities and private entities.''.

CHAPTER 2—VACCINE INJURY COMPENSATION PROGRAM

SEC. 141. VACCINE INJURY COMPENSATION AND VACCINE LITIGATION REFORM.

(a) FINDINGS.—Congress finds that—

(1) there are shortcomings in the Vaccine Injury Compensation Program and loopholes in that program that have been exploited in a manner that has contributed to a decline in the availability of vaccines generally in the United States and a decline in the number of manufacturers able to supply vaccines; and

(2) the condition described in paragraph (1) presents a barrier to the development of vaccines needed for bioterror countermeasures.

(b) RECOMMENDATIONS.—After considering recent changes in the litigation environment with respect to vaccines as well as recent scientific evidence and reports by the Institute of Medicine and others with respect to the safety of vaccines and their components and ingredients, the Secretary of Health and Human Services and the Attorney General shall, not later than 6 months after the date of enactment of this Act, jointly submit recommendations to the appropriate committees of Congress concerning necessary modifications to the Vaccine Injury Compensation Program and Federal rules regarding litigation involving vaccines.

SEC. 142. MODIFICATIONS TO VACCINES FOR CHILDREN PROGRAM.

(a) EXPANSION OF DEFINITION OF FEDERALLY VACCINE-ELIGIBLE CHILD.—Section 1928(b)(2)(A)(iii) of the Social Security Act (42 U.S.C.1396s(b)(2)(A)(iii)) is amended to read as follows:

> ''(iii) A child who (I) is administered a qualified pediatric vaccine by a federally-qualified health center (as defined in section 1905(l)(2)(B)), a rural health clinic (as defined in section 1905(l)(1)), or a State or local public health clinic, and (II)

is not insured with respect to the vaccine.''.

(b) REPEAL OF PRICE CAP FOR PRE-1983 VACCINES.—

(1) IN GENERAL.—Section 1928(d)(3)(E) of such Act (42 U.S.C.1396s(d)(3)(B)) is repealed.

(2) CONFORMING AMENDMENT.—Section 1928(d)(3) of such Act (42 U.S.C. 1396s(d)(3)) is amended by re-designating subparagraph (C) as subparagraph (B).

(c) SIMPLIFIED ADMINISTRATION OF VACCINE SUPPLY.—Section 1928(d)(6) of such Act (42 U.S.C. 1396s(d)(6)) is amended by inserting before the last sentence the following: ''The Secretary may sell such quantities of vaccines from such supply as the Secretary determines appropriate. Proceeds received from such sales shall be available to the Secretary only for the purposes of procuring pediatric vaccine stockpiles under this section and shall remain available until expended.''.

CHAPTER 3—ENCOURAGING VACCINE AND COUNTERMEASURE PRODUCTION CAPACITY

SEC. 151. INCENTIVES FOR THE CONSTRUCTION OF VACCINE AND COUNTERMEASURE MANUFACTURING FACILITIES.

(a) VACCINE AND COUNTERMEASURES MANUFACTURING FACILITIES INVESTMENT TAX CREDIT.—

(1) ALLOWANCE OF CREDIT.—Section 46 of the Internal Revenue Code of 1986 (relating to amount of investment credit) is amended by striking ''and'' at the end of paragraph (1), by striking the period at the end of paragraph (2) and inserting '', and'', and by adding at the end the following new paragraph:

''(3) the vaccine and countermeasures manufacturing facilities investment credit.''.

(2) AMOUNT OF CREDIT.—Section 48 of such Code is amended by adding at the end the following new subsection:

''(c) VACCINE AND COUNTERMEASURES MANUFACTURING FACILITIES INVESTMENT CREDIT.—

''(1) IN GENERAL.—For purposes of section 46, the vaccine and countermeasures manufacturing facilities investment credit for any taxable year is an

amount equal to 20 percent of the qualified investment for such taxable year.

''(2) QUALIFIED INVESTMENT.—For purposes of paragraph (1), the qualified investment for any taxable year is the basis of each vaccine manufacturing facilities property placed in service by the taxpayer during such taxable year.

''(3) VACCINE OR COUNTERMEASURES MANUFACTURING FACILITIES PROPERTY.—For purposes of this subsection, the term 'vaccine or countermeasures manufacturing facilities property' means real and tangible personal property—

''(A)(i) the original use of which commences with the taxpayer, or

''(ii) which is acquired through purchase (as defined by section 179(d)(2)),

''(B) which is depreciable under section 167,

''(C) which is used for the manufacture, distribution, or research and development of vaccines or qualified countermeasures (as such term is defined in section 319F–1 of the Public Health Service Act), and

''(D) which is in compliance with any standards and regulations which are promul-

gated by the Food and Drug Administration, the Occupational Safety and Health Administration, or the Environmental Protection Agency and which are applicable to such property.

''(4) CERTAIN PROGRESS EXPENDITURE RULES MADE APPLICABLE.—Rules similar to rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this subsection.

''(5) TERMINATION.—This subsection shall not apply to any property placed in service after December 31, 2009.''.

(b) TECHNICAL AMENDMENTS.—

(1) Subparagraph (C) of section 49(a)(1) of such Code is amended by striking ''and'' at the end of clause (ii), by striking the period at the end of clause (iii) and inserting '', and'', and by adding at the end the following new clause:

''(iv) the basis of any vaccine or countermeasures manufacturing facilities property.''.

(2) Subparagraph (E) of section 50(a)(2) of such Code is amended by inserting ''or 48(c)(4)'' before the period.

(3)(A) The section heading for section 48 of such Code is amended to read as follows:

"SEC. 48. OTHER CREDITS.".

(B) The table of sections for subpart E of part IV of subchapter A of chapter 1 of such Code is amended by striking the item relating to section 48 and inserting the following:

"Sec. 48. Other credits.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after December 31, 2004, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of enactment of the Revenue Reconciliation Act of 1990).

SEC. 152. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES OR COUNTERMEASURES.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business-related credits), as amended by this Act, is amended by adding at the end the following new section:

"SEC. 45L. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES OR COUNTERMEASURES.

"(a) GENERAL RULE.—For purposes of section 38, the vaccine research credit determined under this section for the taxable year is an amount equal to 35 percent of the qualified vaccine or countermeasures research expenses for the taxable year.

"(b) QUALIFIED VACCINE OR COUNTERMEASURES RESEARCH EXPENSES.—For purposes of this section—

"(1) QUALIFIED VACCINE OR COUNTERMEASURES RESEARCH EXPENSES.—Except as otherwise provided in this subsection, the term 'qualified vaccine or countermeasures research expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year with respect to any research and development of vaccines or qualified countermeasures (as such term is defined in section 319F–1 of the Public Health Service Act) which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in paragraph (2).

"(2) MODIFICATIONS; INCREASED INCENTIVE FOR CONTRACT RESEARCH PAYMENTS.—For purposes of paragraph (1), subsection (b) of section 41 shall be applied—

"(A) by substituting 'qualified vaccine research' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection,

"(B) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection, and

"(C) in a manner so that qualified research and development expenses include expenses related to re-formulating existing vaccines.

"(3) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified vaccine research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any qualified vaccine or countermeasures research expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified vaccine or countermeasures research expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) SPECIAL RULES.—

''(1) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(2) COORDINATION WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any qualified vaccine or countermeasures research expense for a taxable year shall not be taken into account for purposes of determining the credit allowable under section 45C for such taxable year.

''(3) COORDINATION WITH CREDIT FOR COUNTERMEASURES RESEARCH.—Any qualified vaccine or countermeasures research expense for a taxable year shall not be taken into account for purposes of de-

termining the credit allowable under section 45K for such taxable year.''.

(b) INCLUSION IN GENERAL BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986, as amended by this Act, is amended by striking ''plus'' at the end of paragraph (21), by striking the period at the end of paragraph (22) and inserting '', plus'', and by adding at the end the following new paragraph:

''(23) the vaccine or countermeasures research credit determined under section 45L.''.

(c) DENIAL OF DOUBLE BENEFIT.—Section 280C of the Internal Revenue Code of 1986 (relating to certain expenses for which credits are allowable), as amended by this Act, is amended by adding at the end the following new subsection:

''(g) CREDIT FOR QUALIFIED VACCINE OR COUNTERMEASURES RESEARCH EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified vaccine or countermeasures research expenses (as defined in section 45L(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45L(a).

''(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.''.

(d) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of the Internal Revenue Code of 1986 (defining qualified business credits), as amended by this Act, is amended by striking ''and'' at the end of paragraph (14), by striking the period at the end of paragraph (15) and inserting '', and'', and by adding at the end the following new paragraph:

''(16) the vaccine or countermeasures research credit determined under section 45L(a) (other than such credit determined under the rules of section 280C(g)(2)).''.

(e) TECHNICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986, as amended by this Act, is amended by adding at the end the following new item:

''Sec. 45L. Credit for medical research related to developing vaccines or countermeasures.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2004.

SEC. 153. GRANTS TO CONSTRUCT AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF COUNTERMEASURES OR VACCINES.

Part B of title III of the Public Health Service Act is amended by inserting after section 519K (as added by section 115) the following:

"SEC. 319L. GRANTS TO CONSTRUCT AND IMPROVE RESEARCH AND DEVELOPMENT AND MANUFACTURING OF COUNTERMEASURES OR VACCINES.

''(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 countermeasure or vaccine.

''(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 equipment, facility, or property involved;

''(2) a detailed description of the countermeasure or vaccine involved;

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

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

''(5) 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, vaccine, medical device or other countermeasure not described in paragraph (2); and

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

''(c) RECAPTURE.—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 equipment, facility, or property involved shall cease to be used for the purposes 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 current value of the facility (at the time of the determination) as the amount the grant bore to the total cost of the purchase or improvement involved. Such current value 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 is situated. The Sec-

retary may not recapture the equipment, facility, or property, in accordance with regulations, if the Secretary determines 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. 154. REVENUE RECOGNITION FOR ADULT AND PEDIATRIC VACCINES AND OTHER COUNTERMEASURES AGAINST POTENTIAL ACTS OF TERRORISM.

Notwithstanding any other Federal or State law (including general accounting guidelines of the Securities and Exchange Commission), the revenue derived under a Federal Government contract from the stockpiling, holding, storing, rotating, or other management of an inventory of vaccines or countermeasures shall be deemed as income to the manufacturer or other legal entity at the time such manufacturer or entity receives such revenue, except for any revenue credited back or returned to such agency or for inventories subsequently sold by such manufacturer or entity to a third party.

Subtitle C—Public Health Preparedness

CHAPTER 1—CAPACITY TO RESPOND

SEC. 171. PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN.

(a) IN GENERAL.—In implementing out the Pandemic Influenza Preparedness and Response Plan of the Centers for Disease Control and Prevention, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall ensure funding for the following activities:

(1) RESEARCH.—The Secretary shall provide funding to carry out research to develop improved influenza vaccines.

(2) EDUCATION AND OUTREACH.—The Secretary shall carry out activities to increase public awareness on the need to be vaccinated, particularly in priority or high-risk populations.

(3) SURVEILLANCE.—The Secretary shall—

(A) carry out activities to improve international and State influenza surveillance capacity;

(B) conduct influenza vaccine safety and efficacy data collection; and

(C) provide for the conduct of epidemiological studies and research concerning novel influenza viruses.

(4) IMPROVE COMMUNICATION.—In the case of a vaccine production delay or shortage or an influenza pandemic or epidemic, the Secretary shall—

(A) identify those priority sub-groups that should be vaccinated first;

(B) provide the information determined under subparagraph (A) to State and local health department; and

(C) identify which priority sub-group each State or local health department should have responsibility for vaccinating.

(b) DIRECT DISTRIBUTION.—Notwithstanding any other provision of law, if the Secretary determines that an influence pandemic or epidemic has occurred, or is imminent, the Secretary shall have the authority to—

(1) determine which health care providers should receive priority in the allotment of influenza vaccine; and

(2) require manufactures or distributors of such vaccine to provide such vaccine to the providers identified under paragraph (1).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2006, and such sums as may be necessary for each of fiscal years 2007 through 2011.

SEC. 172. NATIONAL NOTIFIABLE DISEASE SURVEILLANCE PROGRAM.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended—

(1) by striking section 314; and

(2) by inserting after section 311, the following:

"SEC. 311A. NATIONAL NOTIFIABLE DISEASE SURVEILLANCE PROGRAM.

''(a) IN GENERAL.—The Secretary is authorized to develop a real-time surveillance program for collecting and reporting information on notifiable diseases and conditions.

''(b) NOTIFIABLE DISEASES.—Not later than 180 days after the date of enactment of the Public Health Security Act of 2005, and annually thereafter, the Secretary, in consultation with State and local health authorities and appropriate private professional societies, shall certify a list of infectious diseases, environmental exposures or poisons, and other conditions, the real-time surveillance and control of which, in each State and territory of the United States, constitute a critical public health need. For pur-

poses of this part, the term 'notifiable disease' means a disease, exposures or poison, or other condition that appears on the list under this section.

''(c) FEDERAL INFORMATICS ACTIVITIES.—

''(1) IN GENERAL.—In order to meet the urgent need for critical electronic surveillance of notifiable diseases, the Director of the Centers for Disease Control and Prevention, in consultation with State and local health authorities, shall, not later than 1 year after the date of enactment of the Public Health Security Act of 2005, establish and maintain a national electronic surveillance program that includes the following components:

''(A) Procedures to provide for the collection (in a standardized form) and analysis of data on all notifiable diseases and on certain other conditions that States or regions elect to report to the program.

''(B) A procedure to enable all major public and private clinical laboratories to automatically report data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, to the program concerning notifiable diseases, antimicrobial resistance test-

ing, and other data determined appropriate by the Director.

''(C) A procedure to provide for syndromic and disease-specific surveillance by monitoring, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, of private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data).

''(D) A procedure to enable States to report data on suspicious cases of conditions that are not on the notifiable disease list but that may warrant further investigation.

''(E) A procedure to enable the program to automatically identify certain trends and suspicious patterns with respect to data reported to the program.

''(F) A procedure to enable the program to provide regular reports to regional, State, and local government entities concerning disease trends, suspicious disease patterns, incidence and prevalence of diseases, laboratory data, and other information determined appropriate. Such

information shall include data on comparative national disease trends.

''(G) A procedure to enable the program to collect and analyze data from certain seminal veterinary and environmental sources where appropriate.

''(H) A procedure to enable the program to export data in a form appropriate for aggregation, statistical analysis, and reporting.

''(I) A procedure to enable the program to receive and report data relating to non-notifiable diseases, including vital records, registries, chronic disease, and maternal and child health data.

''(2) TIMELINESS OF REPORTING.—The procedures developed under paragraph (1) for the reporting of data shall ensure that such data are reported in a timely manner.

''(3) PRIVATE SECTOR RESOURCES.—To meet the deadline described in paragraph (1), the Director of the Centers for Disease Control and Prevention may, on a temporary or permanent basis, implement systems or products developed by the private sector.

''(4) AUTHORITY FOR CONTRACTS.—In carrying out this subsection, the Director of the Centers for

Disease Control and Prevention may enter into contracts with public and private entities.

''(d) NATIONAL BIOINTELLIGENCE UNIT.—The Director of the Centers for Disease Control and Prevention shall analyze data maintained by the national electronic surveillance program under subsection (b), and data from other sources, to report on the prevalence and incidence of notifiable diseases and conditions, trends and patterns in public health, emerging health problems, regional differences, and other analyses determined appropriate by the Director of the Centers for Disease Control and Prevention.

''(e) FEDERAL TECHNICAL ASSISTANCE, COMMUNICATION, AND COORDINATION.—

''(1) IN GENERAL.—In carrying out this section, the Secretary shall provide technical assistance to, and provide for appropriate communications to the public, scientific, public health and medical communities, and other key stakeholders, and to provide for the coordination of the activities of—

''(A) State and local health authorities to integrate State and local surveillance activities and systems with the national notifiable disease surveillance program developed under this section and to generally improve State and local

notifiable disease reporting and communications; and

''(B) private corporations, professional associations, or other entities that may have sources of surveillance data or access to health care providers, health officials, or other individuals who would need to participate in a surveillance program.

''(2) FINANCIAL ASSISTANCE.—Assistance provided under paragraph (1)(B) may include financial assistance for the purpose of formatting or translating data into a form that is most compatible and appropriate for use in the national notifiable disease surveillance program developed under this section.

''(3) HEALTH ALERT REGISTRATION AND INFORMATION.—

''(A) REGISTRATION.—Each health care provider and facility that receives funds under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or that receives funds under a State program under title XIX of such Act (42 U.S.C. 1396 et seq.) shall annually submit to the Secretary a registration that contains the e-mail address or fax number of the provider or facility for purposes of enabling the

Secretary to provide health alerts in the case of a public health emergency or other circumstance requiring active surveillance.

''(B) ESTABLISHMENT OF SYSTEM.—The Secretary shall establish a system to maintain the information provided by providers and facilities under subparagraph (A). Such system shall be designed—

''(i) to enable providers and facilities—

''(I) to provide and update information contained in the system; and

''(II) to request information or to elect to receive additional types of non-emergency health alerts or communications; and

''(ii) to enable the Director of the Centers for Disease Control and Prevention to provide updated contact information for providers and facilities to State and local health authorities for the purpose of emergency health communications.

''(f) GRANTS TO STATES FOR DISEASE REPORTING.—

''(1) GRANTS.—The Secretary shall award grants to States to enable such States to conduct passive, active, and when appropriate syndromic surveillance, and timely reporting activities with respect to notifiable diseases.

''(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

''(A) a description of the manner in which grants funds will be used to enhance the timeliness and comprehensiveness of the State's effort to report notifiable diseases to the program under subsection (c); and

''(B) a plan for identifying and reporting to the Secretary the identity of health care providers and facilities that consistently fail to report to the State instances of notifiable diseases in a timely manner.

''(3) ENHANCED GRANT.—In the case of a State that submits a plan, as part of the application under paragraph (2), to transition State and local reporting of notifiable diseases to an electronic system that is compatible with the program under sub-

section (c), the amount of the grant awarded to a State under paragraph (1) shall be increased by an amount determined by the Secretary to be necessary to complete such transition.

''(4) SUPPLEMENT NOT SUPPLANT FUNDS FOR ACTIVITIES.—A State shall use amounts received under a grant under this subsection to supplement and not supplant other funds made available by the State for the conduct of reporting activities with respect to notifiable diseases.

''(5) REDUCTION IN BLOCK GRANT FUNDING.—For fiscal year beginning with fiscal year 2008, if the Secretary determines that a State is not reporting all notifiable diseases to the program established under subsection (c) in a timely manner through the use of an electronic system that is compatible with the program, the State shall not be eligible to receive a grant under part A of title XIX for such fiscal year.

''(6) FAILURE TO REPORT.—A health care provider or facility shall not be eligible to receive funds under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State program under title XIX of such Act (42 U.S.C. 1396 et seq.) if the Secretary determines, based on a State

notification received under the plan described in paragraph (2)(B), that such provider or facility has consistently failed to report, in a timely manner, instances of notifiable diseases to the State for submission to the program under subsection (c).

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

SEC. 173. ENHANCING CRITICAL CAPACITY FOR ILLNESS DETECTION.

Section 319C(c) of the Public Health Service Act (42 U.S.C. 247d–3(c)) is amended—

(1) in paragraph (3), by striking ''and'' at the end;

(2) in paragraph (4), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(5) develop benchmarks for meeting critical capacity for food or water borne disease detection and response.''.

SEC. 174. EVALUATION OF PUBLIC HEALTH CAPACITY OUTCOMES.

Section 319C–1(b) of the Public Health Service Act (42 U.S.C. 247d–3a(b)) is amended by adding at the end the following:

''(3) EVALUATION OF PUBLIC HEALTH CAPACITY OUTCOMES.—The Director of the Centers for Disease Control and Prevention shall enter into contracts with independent entities for the periodic evaluation of the progress made by State and local governments in meeting the benchmarks established in the plan under paragraph (1)(A)(ii)(V).''.

SEC. 175. NONIMMIGRANT HEALTH SCREENING.

(a) PARITY IN SCREENING FOR NON-IMMIGRANTS.—Section 212(a)(1) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)) is amended by adding at the end the following:

''(D) APPLICATION OF REGULATIONS.—Determinations under subparagraph (A) shall be made based upon regulations promulgated by the Secretary of Health and Human Services under clause (i) of such subparagraph regardless of whether the alien involved is applying for permanent admission or for a visa for a stay of 6 months or longer (including aliens seeking a temporary work visa or student visa). The health-related requirements under such regulations shall be applied in the same manner to all such aliens.''.

(b) PANEL PHYSICIAN QUALITY CONTROL.—Section 361 of the Public Health Service Act (42 U.S.C. 264) is amended by adding at the end the following:

''(f) Where the United States enters into agreements or contracts (or other arrangements) with physicians or other health care providers and laboratories in foreign nations for the purpose of conducting health screening of aliens seeking temporary or permanent residence in the United States, the Secretary shall evaluate each such physician or provider on an annual basis to determine (and certify) that the physician or provider adequately complies with applicable regulations governing the medical screening of applicants for entry into the United States.''.

SEC. 176. INSPECTION, SCREENING, AND QUARANTINING OF LIVE ANIMALS.

Section 362 of the Public Health Service Act (42 U.S.C. 265) is amended by adding at the end the following: The Secretary shall establish procedures for the appropriate inspection, screening, and quarantine of live animals entering the United States for commercial purposes, including procedures to protect domestic animal and human populations from diseases carried by imported live animals.''.

SEC. 177. AUTHORITY TO PROCURE AIRCRAFT.

Section 301 of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''(e) The Secretary may procure and maintain aircraft for the purpose of transporting personnel, equipment, biological or environmental specimens, or humans or animals requiring advanced biohazard protection in a timely fashion in the event of an outbreak of infectious disease or another public health emergency. In lieu of procuring an aircraft under the preceding sentence, the Secretary may enter into a contract for air transportation that achieves the purpose described in such sentence.''.

CHAPTER 2—PUBLIC HEALTH WORKFORCE

SEC. 181. PUBLIC HEALTH WORKFORCE SCHOLARSHIP AND LOAN REPAYMENT PROGRAM.

Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.) is amended by adding at the end the following:

"Subpart 3—Public Health Workforce Scholarship and Loan Repayment Program

"SEC. 780. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Loan Repayment Pro-

gram (referred to in this section as the 'Program') to assure an adequate supply of public health professionals to eliminate critical public health preparedness workforce shortages in Federal, State, local, and tribal public health agencies.

''(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

''(1)(A) be accepted for enrollment, or be enrolled, as a full-time or part-time student in an accredited academic educational institution in a State or territory in the final year of a course of study or program offered by that institution leading to a health professions or medical degree or certificate, which may include a degree (graduate, undergraduate, or associate) or certificate relating to public health, laboratory sciences, or epidemiology; or

''(B) have graduated, within 5 years, from an accredited educational institution in a State or territory and received a health professions or medical degree (graduate, undergraduate, or associate) or certificate, which may include a degree (graduate, undergraduate, or associate) or certificate relating, but not limited, to public health laboratory sciences, or epidemiology;

''(2)(A) in the case of an individual described in paragraph (1)(A)—

''(i) maintain satisfactory academic progress, as determined by the Secretary; and

''(ii) have accepted employment with the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or a State, local, or tribal public health agency, in a priority service area, as recognized by the Secretary, to commence upon graduation; or

''(B) in the case of an individual described in paragraph (1)(B), be employed by, or have accepted employment with, the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or a State, local, or tribal public health agency, as recognized by the Secretary;

''(3) be a United States citizen;

''(4) submit an application to the Secretary to participate in the Program; and

''(5) sign and submit to the Secretary, at the time of the submittal of such application, a written contract (described in subsection (d)) to serve for the applicable period of obligated service in the full-

time employment of the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or a State, local, or tribal public health agency.

''(c) DISSEMINATION OF INFORMATION.—

''(1) APPLICATION AND CONTRACT FORMS.—The Secretary shall disseminate application forms and contract forms to individuals desiring to participate in the Program. The Secretary shall include with such forms—

''(A) a summary of the rights and obligations of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled to recover in the case of the individual's breach of the contract; and

''(B) information relating to the service obligation and such other information as may be necessary for the individual to understand the individual's prospective participation in the Program.

''(2) INFORMATION FOR SCHOOLS.—The Secretary shall distribute to health professions and medical schools and the National Institutes of

Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, and relevant State, local, and tribal public health agencies, materials providing information on the Program and shall encourage such schools, and agencies to disseminate such materials to potentially eligible students.

''(d) CONTRACT.—The written contract (referred to in this section) between the Secretary and an individual shall contain—

''(1) an agreement on the part of the Secretary that the Secretary will repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant public health preparedness workforce educational degree or certificate in accordance with the terms of the contract;

''(2) an agreement on the part of the individual that the individual will serve, immediately upon graduation in the case of an individual described in subsection (b)(1)(A) service, or in the case of an individual described in subsection (b)(1)(B) continue to serve, in the full-time employment of the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or a State, local, or tribal public health agency

in a position related to the course of study or program for which the contract was awarded for a period of time (referred to in this section as the 'period of obligated service') equal to the greater of—

"(i) 3 years; or

"(ii) such longer period of time as determined appropriate by the Secretary and the individual;

"(3) in the case of an individual described in subsection (b)(1)(A) who is in the final year of study and who has accepted employment with the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or a State, local, or tribal public health agency upon graduation, an agreement on the part of the individual to complete the education or training, maintain a satisfactory acceptable level of academic standing (as determined by the Secretary), and agree to the period of obligated service;

"(4) a provision that any financial obligation of the United States arising out of a contract entered into under this section and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this section;

''(5) a statement of the damages to which the United States is entitled, under this section for the individual's breach of the contract; and

''(6) such other statements of the rights and obligations of the Secretary and of the individual, not inconsistent with this section.

''(e) PAYMENTS.—

''(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for—

''(A) tuition expenses; or

''(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual.

''(2) PAYMENTS FOR YEARS SERVED.—

''(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (d) the Secretary may pay up to $35,000 on behalf of the individual

for loans described in paragraph (1). With respect to participants under the Program whose total eligible loans are less than $105,000, the Secretary shall pay an amount that does not exceed ⅓ of the eligible loan balance for each year of obligated service of the individual.

''(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

''(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

''(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount not to exceed 39 percent of the total amount of loan repayments made for the taxable year involved; and

''(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

''(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Program to establish a schedule for the making of such payments.

''(f) POSTPONING OBLIGATED SERVICE.—With respect to an individual receiving a degree or certificate that may require an internship, residency, or other relevant public health preparedness advance training program, the date of the initiation of the period of obligated service may be postponed, upon the submission by the individual of a petition for such postponement and approval by the Secretary, to the date on which the individual completes an approved internship, residency, or other relevant public health preparedness advanced training program.

''(g) ADMINISTRATIVE PROVISIONS.—

''(1) HIRING PRIORITY.—Notwithstanding any other provision of law, Federal, State, local, and tribal public health agencies may give hiring priority to any individual who has qualified for and is willing to execute a contract to participate in the Program.

''(2) EMPLOYMENT CEILINGS.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, who are serving as full-

time employees of a State or local public health agency, or who are in the last year of public health workforce academic preparation, shall not be counted against any employment ceiling affecting the Department or any other Federal agency.

''(h) BREACH OF CONTRACT.—An individual who fails to comply with the contract entered into under subsection (d) shall be subject to the same financial penalties as provided for under section 338E for breaches of loan repayment contracts under section 338B.

''SEC. 781. AUTHORIZATION OF APPROPRIATIONS.

''For the purpose of carrying out section 780, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2006 through 2010.''.

CHAPTER 3—PREPAREDNESS UPDATES

SEC. 191. REPORT ON PREPAREDNESS.

(a) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Comptroller General of the United States shall provide for the conduct of a study to—

(1) review existing processes for determining and purchasing the appropriate drugs, vaccines and other biological products, medical devices, and other supplies of the strategic national stockpile, the maintenance of such drugs, vaccines and other biological

products, medical devices, and other supplies, and the ability to deploy such drugs, vaccines and other biological products, medical devices, and other supplies (including the distribution of the drugs, vaccines and other biological products, medical devices, and other supplies at the local level) in an emergency situation;

(2) review and assess the adequacy of existing State and local processes for disease monitoring and control (including activities related to monitoring diseases under BioWatch, BioSense, and other programs that have been initiated or expanded within the last 3 years);

(3) review the existing ability of the health care community and its response to a mass casualty incidents and other public health emergencies, including interactions between public health, health care, and law enforcement, knowledge and training, surge capacity, influence of the health care community in an urban versus rural setting, and other key components of readiness of the health care community;

(4) determine whether and to what extent activities undertaken within the 3-year period ending on the date of the study have enhanced supply chain management of drugs, vaccines and other biological

products, medical devices, and other supplies that are not included within the strategic national stockpile, including a specific review of supply chain management issues for the influenza vaccine as it relates to the 2004–2005 influenza season;

(5) evaluate Federal activities primarily related—

(A) to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population; and

(B) the coordination of the activities described in paragraph (1);

(6) assess the progress of States in preparing for the public health and medical consequences of a potential bioterrorist attack against the civilian population; and

(7) review the progress on the implementation of the National Preparedness Plan, as outlined in section 2801 of the Public Health Service Act, as well as the development of preparedness goals as outlined by such section.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to the appropriate

committees of Congress, a report concerning the results of the study conducted under subsection (a). Such report shall include recommendations—

(1) to improve the activities described in subsection (a)(1);

(2) to improve the effectiveness of the activities described in subsection (a)(2);

(3) to improve the capacity of the health care community to respond under the circumstances described in subsection (a)(3) to enhance the protection of the public health;

(4) to improve the ability of the Secretary of Health and Human Services to carry out the activities described in subsection (a)(4) in the future.

(5) to improve the effectiveness of the activities described in subsection (a)(5);

(6) to improve the effectiveness of the activities described in subsection (a)(6), including potentials for and barriers to interstate collaborations; and

(7) to improve the activities described in subsection (a)(7).

SEC. 192. ENHANCING GLOBAL RESPONSE CAPABILITIES.

It is the sense of the Senate that, in order to effectively combat bioterrorism and prevent against the spread of deadly infectious disease, the United States should en-

hance cooperation with global and regional organizations, as well as cooperation with other countries, and should establish, enhance, and intensify a wide range of global activities to help prevent, detect, and contain infectious disease outbreaks and bioterrorism attacks.

TITLE II—INCREASED BENEFITS FOR FAMILIES OF DECEASED MEMBERS OF THE ARMED FORCES.

SEC. 201. INCREASE IN DEATH GRATUITY PAYABLE WITH RESPECT TO DEATHS OF MEMBERS OF THE ARMED FORCES FROM COMBAT-RELATED CAUSES OR FROM SERVICE IN OPERATION ENDURING FREEDOM OR IRAQI FREEDOM.

(a) INCREASED AMOUNT.—Section 1478 of title 10, United States Code, is amended—

(1) in subsection (a), by inserting ‘‘, except as provided in subsection (c)’’ after ‘‘$12,000’’;

(2) by redesignating subsection (c) as subsection (d); and

(3) by inserting after subsection (b) the following new subsection (c):

‘‘(c) The death gratuity payable under sections 1475 through 1477 of this title is $100,000 (as adjusted under

subsection (d)) in the case of a death resulting from wounds, injuries, or illnesses that are incurred—

''(1) as described in section 1413a(e)(2) of this title; or

''(2) in the theater of operations for Operation Enduring Freedom or Operation Iraqi Freedom.''.

(b) INCREASES CONSISTENT WITH INCREASES IN RATES OF BASIC PAY.—Subsection (d) of such section, as redesignated by paragraph (1)(B), is amended by striking ''amount of the death gratuity in effect under subsection (a)'' and inserting ''amounts of the death gratuities in effect under subsections (a) and (c)''.

(c) CONFORMING AMENDMENT.—Subsection (a) of such section, as amended by subsection (a) of this section, is further amended by striking ''(as adjusted under subsection (c))'' and inserting ''(as adjusted under subsection (d))''.

(d) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect as of October 7, 2001, and shall apply with respect to deaths occurring on or after such date.

SEC. 202. INCREASE IN AUTOMATIC MAXIMUM COVERAGE UNDER SERVICEMEMBERS' GROUP LIFE INSURANCE AND VETERANS' GROUP LIFE INSURANCE.

(a) MAXIMUM UNDER SERVICEMEMBERS' GROUP LIFE INSURANCE.—Section 1967 of title 38, United States Code, is amended in subsections (a) and (d) by striking ''$250,000'' each place it appears and inserting ''$300,000''.

(b) MAXIMUM UNDER VETERANS' GROUP LIFE INSURANCE.—Section 1977(a) of title 38, United States Code, is amended by striking ''$250,000'' each place it appears and inserting ''$300,000''.

(c) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect on the first day of the first month that begins on or after the date of the enactment of this Act.

SEC. 203. INCREASED PERIOD OF CONTINUED TRICARE COVERAGE OF CHILDREN OF MEMBERS OF THE UNIFORMED SERVICES WHO DIE WHILE SERVING ON ACTIVE DUTY FOR A PERIOD OF MORE THAN 30 DAYS.

(a) PERIOD OF ELIGIBILITY.—Section 1079(g) of title 10, United States Code, is amended—

(1) by inserting ''(1)'' after ''(g)'';

(2) by striking the second sentence and inserting the following:

''(2) In addition to any continuation of eligibility for benefits under paragraph (1), when a member dies while on active duty for a period of more than 30 days, the member's dependents who are receiving benefits under a plan covered by subsection (a) shall continue to be eligible for health benefits under TRICARE Prime for the following period:

''(A) In the case of a dependent who is a child of the deceased described in subparagraph (D) of section 1072(2) of this title, for the period during which the dependent continues to qualify as a dependent under any of clauses (i), (ii), and (iii) of such subparagraph.

''(B) In the case of a person who, on the day before the date of the member's death, is a dependent of the member described in subparagraph (I) of section 1072(2) of this title, for the period during which that person continues to meet the conditions set forth in any of subclauses (I), (II), and (III) of clause (ii) of such subparagraph.

''(C) In the case of other dependents, for the three-year period beginning on the date of the member's death.

''(3) The terms and conditions under which health benefits are provided under this chapter to a dependent of a deceased member under paragraph (2)(A) shall be the same as those that would apply to the dependent under this chapter if the member were living and serving on active duty for a period of more than 30 days.

''(4) In this subsection, the term 'TRICARE Prime' means the managed care option of the TRICARE program.''.

(b) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect as of October 7, 2001, and shall apply with respect to deaths occurring on or after such date.

TITLE III—HOMELAND SECURITY TECHNOLOGY IMPROVEMENT

SEC. 301. SHORT TITLE.

This title may be cited as the ''Homeland Security Technology Improvement Act of 2005''.

SEC. 302. HOMELAND SECURITY TRANSFER PROGRAM.

(a) IN GENERAL.—Section 430 of the Homeland Security Act of 2002 (6 U.S.C. 238) is amended—

(1) by redesignating subsection (d) as subsection (e);

(2) in subsection (c)—

(A) in paragraph (7), by striking ''and'' at the end;

(B) in paragraph (8), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(9) overseeing and coordinating a multi-agency homeland security technology, equipment, and information transfer program to allow for the transfer of technology, equipment, and information to State and local law enforcement agencies.''; and

(3) by inserting after subsection (c) the following:

''(d) TECHNOLOGY, EQUIPMENT, AND INFORMATION TRANSFER PROGRAM.—

''(1) IN GENERAL.—The Director shall—

''(A) identify counterterrorism technologies, equipment, and information developed or proven to be effective by—

''(i) consulting with the Undersecretary for Science and Technology;

''(ii) establishing an advisory committee comprised of retired and active-duty law enforcement officials from geographically diverse regions;

''(iii) consulting with State and local law enforcement agencies; and

''(iv) entering into agreements and coordinating with other Federal agencies to maximize the effectiveness of the technologies, equipment, and information available to law enforcement agencies;

''(B) make these technologies, equipment, and information available to State and local law enforcement agencies on an annual basis;

''(C) accept applications from the head of State and local law enforcement agencies that wish to acquire such technologies, equipment, and information to improve the homeland security capabilities of those agencies, and review such applications in coordination with the advisory committee established under subparagraph (A)(ii); and

''(D) transfer the approved technology, equipment, and information, and provide the appropriate training to the State or local law enforcement agency pending the approval of the application of the State or local law enforcement agency under subparagraph (C).

''(2) LIMITATION ON ADMINISTRATION EXPENDITURE.—No more than 10 percent of the budget of the technology, equipment, and information transfer program under this subsection may be used for administrative expenses.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $50,000,000 for each of fiscal years 2006 through 2016 to carry out this subsection.''.

TITLE IV—ANTITERRORISM IMPROVEMENTS

Subtitle A—Denial of Federal Benefits to Convicted Terrorists

SEC. 401. DENIAL OF FEDERAL BENEFITS TO CONVICTED TERRORISTS.

(a) IN GENERAL.—Chapter 113B of title 18, United States Code, is amended by adding at the end the following:

''§ 2339E. Denial of Federal benefits to terrorists

''(a) IN GENERAL.—Any individual who is convicted of a Federal crime of terrorism (as defined in section 2332b(g)) shall, as provided by the court on motion of the Government, be ineligible for any or all Federal benefits for any term of years or for life.

''(b) FEDERAL BENEFIT DEFINED.—As used in this section, the term 'Federal benefit' has the meaning given the term in section 421(d) of the Controlled Substances Act (21 U.S.C. 862(d)).''.

(b) CHAPTER ANALYSIS.—The table of sections of chapter 113B of title 18, United States Code, is amended by inserting at the end the following:

''2339E. Denial of Federal benefits to terrorists.''.

Subtitle B—Streamlined Information Sharing

SEC. 411. UNIFORM STANDARDS FOR INFORMATION SHARING ACROSS FEDERAL AGENCIES.

(a) TELEPHONE RECORDS.—Section 2709(d) of title 18, United States Code, is amended by striking ''for foreign'' and all that follows through ''such agency''.

(b) CONSUMER INFORMATION UNDER 15 U.S.C. 1681u.—Section 625(f) of the Fair Credit Reporting Act (15 U.S.C. 1681u(f)) is amended to read as follows:

''(f) DISSEMINATION OF INFORMATION.—The Federal Bureau of Investigation may disseminate information obtained pursuant to this section only as provided in guidelines approved by the Attorney General.''.

(c) CONSUMER INFORMATION UNDER 15 U.S.C. 1681v.—Section 626 of the Fair Credit Reporting Act (15 U.S.C. 1681v) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) DISSEMINATION OF INFORMATION.—The Federal Bureau of Investigation may disseminate information obtained pursuant to this section only as provided in guidelines approved by the Attorney General.''.

(d) FINANCIAL RECORDS.—Section 1114(a)(5)(B) of the Right to Financial Privacy Act (12 U.S.C. 3414(a)(5)(B)) is amended by striking ''for foreign'' and all that follows through ''such agency''.

(e) RECORDS CONCERNING CERTAIN GOVERNMENT EMPLOYEES.—Section 802(e) of the National Security Act of 1947 (50 U.S.C. 436(e)) is amended—

(1) by striking ''An agency'' and inserting the following: ''The Federal Bureau of Investigation may disseminate records or information received pursuant to a request under this section only as provided in guidelines approved by the Attorney General. Any other agency''; and

(2) in paragraph (3), by striking ''clearly''.

SEC. 412. AUTHORIZATION TO SHARE NATIONAL-SECURITY INFORMATION WITH STATE AND LOCAL GOVERNMENTS.

(a) INFORMATION OBTAINED IN NATIONAL SECURITY INVESTIGATIONS.—Section 203(d) of the USA PATRIOT ACT (50 U.S.C. 403–5d) is amended—

(1) in paragraph (1), by striking ''criminal investigation'' each place it appears and inserting ''criminal or national security investigation''; and

(2) by amending paragraph (2) to read as follows:

''(2) DEFINITIONS.—As used in this subsection—

''(A) the term 'foreign intelligence information' means—

''(i) information, whether or not concerning a United States person, that relates to the ability of the United States to protect against—

''(I) actual or potential attack or other grave hostile acts of a foreign power or an agent of a foreign power;

''(II) sabotage or international terrorism by a foreign power or an agent of a foreign power; or

"(III) clandestine intelligence activities by an intelligence service or network of a foreign power or by an agent of a foreign power; or

"(ii) information, whether or not concerning a United States person, with respect to a foreign power or foreign territory that relates to—

"(I) the national defense or the security of the United States; or

"(II) the conduct of the foreign affairs of the United States; and

"(B) the term 'national security investigation'—

"(i) means any investigative activity to protect the national security; and

"(ii) includes—

"(I) counterintelligence and the collection of intelligence (as defined in section 3 of the National Security Act of 1947 (50 U.S.C. 401a)); and

"(II) the collection of foreign intelligence information.".

(b) CONFORMING AMENDMENT.—Section 203(c) of the USA PATRIOT ACT (18 U.S.C. 2517 note) is

amended by striking ''Rule 6(e)(3)(C)(i)(V) and (VI)'' and inserting ''Rule 6(e)(3)(D)''.

Subtitle C—Protecting Critical Infrastructure

SEC. 421. ATTACKS AGAINST RAILROAD CARRIERS, PASSENGER VESSELS, AND MASS TRANSPORTATION SYSTEMS.

(a) IN GENERAL.—Chapter 97 of title 18, United States Code, is amended by striking sections 1992 through 1993 and inserting the following:

''§ 1992. Terrorist attacks and other violence against railroad carriers, passenger vessels, and against mass transportation systems on land, on water, or through the air

''(a) GENERAL PROHIBITIONS.—Whoever, in a circumstance described in subsection (c), knowingly—

''(1) wrecks, derails, sets fire to, or disables railroad on-track equipment, a passenger vessel, or a mass transportation vehicle;

''(2) with intent to endanger the safety of any passenger or employee of a railroad carrier, passenger vessel, or mass transportation provider, or with a reckless disregard for the safety of human life, and without previously obtaining the permission

of the railroad carrier, mass transportation provider, or owner of the passenger vessel—

''(A) places any biological agent or toxin, destructive substance, or destructive device in, upon, or near railroad on-track equipment, a passenger vessel, or a mass transportation vehicle; or

''(B) releases a hazardous material or a biological agent or toxin on or near the property of a railroad carrier, owner of a passenger vessel, or mass transportation provider;

''(3) sets fire to, undermines, makes unworkable, unusable, or hazardous to work on or use, or places any biological agent or toxin, destructive substance, or destructive device in, upon, or near any—

''(A) tunnel, bridge, viaduct, trestle, track, electromagnetic guideway, signal, station, depot, warehouse, terminal, or any other way, structure, property, or appurtenance used in the operation of, or in support of the operation of, a railroad carrier, without previously obtaining the permission of the railroad carrier, and with intent to, or knowing or having reason to know such activity would likely, derail, disable, or wreck railroad on-track equipment;

''(B) garage, terminal, structure, track, electromagnetic guideway, supply, or facility used in the operation of, or in support of the operation of, a mass transportation vehicle, without previously obtaining the permission of the mass transportation provider, and with intent to, or knowing or having reason to know such activity would likely, derail, disable, or wreck a mass transportation vehicle used, operated, or employed by a mass transportation provider; or

''(C) structure, supply, or facility used in the operation of, or in the support of the operation of, a passenger vessel, without previously obtaining the permission of the owner of the passenger vessel, and with intent to, or knowing or having reason to know that such activity would likely disable or wreck a passenger vessel;

''(4) removes an appurtenance from, damages, or otherwise impairs the operation of a railroad signal system or mass transportation signal or dispatching system, including a train control system, centralized dispatching system, or highway-railroad grade crossing warning signal, without authorization

from the rail carrier or mass transportation provider;

''(5) with intent to endanger the safety of any passenger or employee of a railroad carrier, owner of a passenger vessel, or mass transportation provider or with a reckless disregard for the safety of human life, interferes with, disables, or incapacitates any dispatcher, driver, captain, locomotive engineer, railroad conductor, or other person while the person is employed in dispatching, operating, or maintaining railroad on-track equipment, a passenger vessel, or a mass transportation vehicle;

''(6) engages in conduct, including the use of a dangerous weapon, with the intent to cause death or serious bodily injury to any person who is on the property of a railroad carrier, owner of a passenger vessel, or mass transportation provider that is used for railroad or mass transportation purposes;

''(7) conveys false information, knowing the information to be false, concerning an attempt or alleged attempt that was made, is being made, or is to be made, to engage in a violation of this subsection; or

''(8) attempts, threatens, or conspires to engage in any violation of any of paragraphs (1) through (7),

shall be fined under this title, imprisoned not more than 20 years, or both.

''(b) AGGRAVATED OFFENSE.—Whoever commits an offense under subsection (a) in a circumstance in which—

''(1) the railroad on-track equipment, passenger vessel, or mass transportation vehicle was carrying a passenger or employee at the time of the offense;

''(2) the railroad on-track equipment, passenger vessel, or mass transportation vehicle was carrying high-level radioactive waste or spent nuclear fuel at the time of the offense;

''(3) the railroad on-track equipment, passenger vessel, or mass transportation vehicle was carrying a hazardous material at the time of the offense that—

''(A) was required to be placarded under subpart F of part 172 of title 49, Code of Federal Regulations; and

''(B) is identified as class number 3, 4, 5, 6.1, or 8 and packing group I or packing group II, or class number 1, 2, or 7 under the hazardous materials table of section 172.101 of title 49, Code of Federal Regulations; or

''(4) the offense results in the death of any person,

shall be fined under this title, imprisoned for any term of years or life, or both. The term of imprisonment for a violation described in paragraph (2) shall be not less than 30 years. In the case of a violation described in paragraph (4), the offender shall be fined under this title and imprisoned for life and be subject to the death penalty.

''(c) CIRCUMSTANCES REQUIRED FOR OFFENSE.—A circumstance described in this subsection is any of the following:

''(1) Any of the conduct required for the offense is, or, in the case of an attempt, threat, or conspiracy to engage in conduct, the conduct required for the completed offense would be, engaged in, on, against, or affecting a mass transportation provider, owner of a passenger vessel, or railroad carrier engaged in or affecting interstate or foreign commerce.

''(2) Any person who travels or communicates across a State line in order to commit the offense, or transports materials across a State line in aid of the commission of the offense.

''(d) NONAPPLICABILITY.—Subsection (a) does not apply to the conduct with respect to a destructive substance or destructive device that is also classified under

chapter 51 of title 49 as a hazardous material in commerce if the conduct—

''(1) complies with chapter 51 of title 49 and regulations, exemptions, approvals, and orders issued under that chapter; or

''(2) constitutes a violation, other than a criminal violation, of chapter 51 of title 49 or a regulation or order issued under that chapter.

''(e) DEFINITIONS.—In this section—

''(1) the term 'biological agent' has the meaning given the term in section 178(1);

''(2) the term 'dangerous weapon' means a weapon, device, instrument, material, or substance, animate or inanimate, that is used for, or is readily capable of, causing death or serious bodily injury, including a pocket knife with a blade of less than 2½ inches in length and a box cutter;

''(3) the term 'destructive device' has the meaning given the term in section 921(a)(4);

''(4) the term 'destructive substance' means an explosive substance, flammable material, infernal machine, or other chemical, mechanical, or radioactive device or material, or matter of a combustible, contaminative, corrosive, or explosive nature, except that the term 'radioactive device' does not include

any radioactive device or material used solely for medical, industrial, research, or other peaceful purposes;

''(5) the term 'hazardous material' has the meaning given the term in section 5102(2) of title 49;

''(6) the term 'high-level radioactive waste' has the meaning given the term in section 2(12) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10101(12));

''(7) the term 'mass transportation' has the meaning given the term in section 5302(a)(7) of title 49, except that the term includes school bus, charter, and sightseeing transportation;

''(8) the term 'on-track equipment' means a carriage or other contrivance that runs on rails or electromagnetic guideways;

''(9) the term 'railroad on-track equipment' means a train, locomotive, tender, motor unit, freight or passenger car, or other on-track equipment used, operated, or employed by a railroad carrier;

''(10) the term 'railroad' has the meaning given the term in section 20102(1) of title 49;

''(11) the term 'railroad carrier' has the meaning given the term in section 20102(2) of title 49;

''(12) the term 'serious bodily injury' has the meaning given the term in section 1365(h)(3);

''(13) the term 'spent nuclear fuel' has the meaning given the term in section 2(23) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10101(23));

''(14) the term 'State' has the meaning given the term in section 2266(8);

''(15) the term 'toxin' has the meaning given the term in section 178(2);

''(16) the term 'vehicle' means any carriage or other contrivance used, or capable of being used, as a means of transportation on land, on water, or through the air; and

''(17) the term 'passenger vessel' has the meaning given the term in section 2101(22) of title 46, United States Code, and includes a small passenger vessel (as defined under section 2101(35) of that title).''.

(b) CONFORMING AMENDMENTS.—

(1) TABLE OF SECTIONS.—The table of sections at the beginning of chapter 97 of title 18, United States Code, is amended—

(A) by striking "**RAILROADS**" in the chapter heading and inserting "**RAILROAD CARRIERS AND MASS TRANSPORTATION SYSTEMS ON LAND, ON WATER, OR THROUGH THE AIR**";

(B) by striking the items relating to sections 1992 and 1993; and

(C) by inserting after the item relating to section 1991 the following:

"1992. Terrorist attacks and other violence against railroad carriers, passenger vessels, and against mass transportation systems on land, on water, or through the air.".

(2) TABLE OF CHAPTERS.—The table of chapters at the beginning of part I of title 18, United States Code, is amended by striking the item relating to chapter 97 and inserting the following:

"97. Railroad carriers and mass transportation systems on land, on water, or through the air ..... 1991".

(3) CONFORMING AMENDMENTS.—Title 18, United States Code, is amended—

(A) in section 2332b(g)(5)(B)(i), by striking "1992 (relating to wrecking trains), 1993 (relating to terrorist attacks and other acts of violence against mass transportation systems)," and inserting "1992 (relating to terrorist attacks and other acts of violence against railroad

carriers and against mass transportation systems on land, on water, or through the air),'';

(B) in section 2339A, by striking ''1993,'';

and

(C) in section 2516(1)(c) by striking ''1992 (relating to wrecking trains),'' and inserting ''1992 (relating to terrorist attacks and other acts of violence against railroad carriers and against mass transportation systems on land, on water, or through the air),''.

SEC. 422. ENTRY BY FALSE PRETENSES TO ANY SEAPORT.

(a) IN GENERAL.—Section 1036 of title 18, United States Code, is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''or'' at the end;

(B) by redesignating paragraph (3) as paragraph (4); and

(C) by inserting after paragraph (2) the following:

''(3) any secure or restricted area (as that term is defined under section 2285(c)) of any seaport; or'';

(2) in subsection (b)(1), by striking ''5'' and inserting ''10'';

(3) in subsection (c)(1), by inserting ", captain of the seaport," after "airport authority"; and

(4) in the section heading, by inserting "or seaport" after "airport".

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 47 of title 18 is amended by striking the matter relating to section 1036 and inserting the following:

"1036. Entry by false pretenses to any real property, vessel, or aircraft of the United States or secure area of any airport or seaport.".

(c) DEFINITION OF SEAPORT.—Chapter 1 of title 18, United States Code, is amended by adding at the end the following:

"§ 26. Definition of seaport

"As used in this title, the term 'seaport' means all piers, wharves, docks, and similar structures to which a vessel may be secured, areas of land, water, or land and water under and in immediate proximity to such structures, and buildings on or contiguous to such structures, and the equipment and materials on such structures or in such buildings.".

(d) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 1 of title 18 is amended by inserting after the matter relating to section 25 the following:

"26. Definition of seaport.".

SEC. 423. CRIMINAL SANCTIONS FOR FAILURE TO HEAVE TO, OBSTRUCTION OF BOARDING, OR PROVIDING FALSE INFORMATION.

(a) OFFENSE.—Chapter 109 of title 18, United States Code, is amended by adding at the end the following:

"§ 2237. Criminal sanctions for failure to heave to, obstruction of boarding, or providing false information

''(a)(1) It shall be unlawful for the master, operator, or person in charge of a vessel of the United States, or a vessel subject to the jurisdiction of the United States, to knowingly fail to obey an order by an authorized Federal law enforcement officer to heave to that vessel.

''(2) It shall be unlawful for any person on board a vessel of the United States, or a vessel subject to the jurisdiction of the United States, to—

''(A) forcibly resist, oppose, prevent, impede, intimidate, or interfere with a boarding or other law enforcement action authorized by any Federal law, or to resist a lawful arrest; or

''(B) provide information to a Federal law enforcement officer during a boarding of a vessel regarding the vessel's destination, origin, ownership, registration, nationality, cargo, or crew, which that person knows is false.

''(b) This section does not limit the authority of a customs officer under section 581 of the Tariff Act of 1930 (19 U.S.C. 1581), or any other provision of law enforced or administered by the Secretary of the Treasury or the Undersecretary for Border and Transportation Security of the Department of Homeland Security, or the authority of any Federal law enforcement officer under any law of the United States, to order a vessel to stop or heave to.

''(c) A foreign nation may consent or waive objection to the enforcement of United States law by the United States under this section by radio, telephone, or similar oral or electronic means. Consent or waiver may be proven by certification of the Secretary of State or the designee of the Secretary of State.

''(d) In this section—

''(1) the term 'Federal law enforcement officer' has the meaning given the term in section 115(c);

''(2) the term 'heave to' means to cause a vessel to slow, come to a stop, or adjust its course or speed to account for the weather conditions and sea state to facilitate a law enforcement boarding;

''(3) the term 'vessel subject to the jurisdiction of the United States' has the meaning given the

term in section 2(c) of the Maritime Drug Law Enforcement Act (46 App. U.S.C. 1903(b)); and

''(4) the term 'vessel of the United States' has the meaning given the term in section 2(c) of the Maritime Drug Law Enforcement Act (46 App. U.S.C. 1903(b)).

''(e) Any person who intentionally violates the provisions of this section shall be fined under this title, imprisoned for not more than 5 years, or both.''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 109, title 18, United States Code, is amended by inserting after the item for section 2236 the following:

''2237. Criminal sanctions for failure to heave to, obstruction of boarding, or providing false information.''.

SEC. 424. CRIMINAL SANCTIONS FOR VIOLENCE AGAINST MARITIME NAVIGATION, PLACEMENT OF DESTRUCTIVE DEVICES, AND MALICIOUS DUMPING.

(a) VIOLENCE AGAINST MARITIME NAVIGATION.—Section 2280(a) of title 18, United States Code, is amended—

(1) in paragraph (1)—

(A) in subparagraph (H), by striking ''(G)'' and inserting ''(H)'';

(B) by redesignating subparagraphs (F), (G), and (H) as subparagraphs (G), (H), and (I), respectively; and

(C) by inserting after subparagraph (E) the following:

''(F) destroys, seriously damages, alters, moves, or tampers with any aid to maritime navigation maintained by the Saint Lawrence Seaway Development Corporation under the authority of section 4 of the Act of May 13, 1954 (33 U.S.C. 984), by the Coast Guard pursuant to section 81 of title 14, United States Code, or lawfully maintained under authority granted by the Coast Guard pursuant to section 83 of title 14, United States Code, if such act endangers or is likely to endanger the safe navigation of a ship;''; and

(2) in paragraph (2), by striking ''(C) or (E)'' and inserting ''(C), (E), or (F)''.

(b) PLACEMENT OF DESTRUCTIVE DEVICES.—

(1) IN GENERAL.—Chapter 111 of title 18, United States Code, is amended by adding after section 2280 the following:

"§ 2280A. Devices or substances in waters of the United States likely to destroy or damage ships or to interfere with maritime commerce

''(a) A person who knowingly places, or causes to be placed, in navigable waters of the United States, by any means, a device or substance which is likely to destroy or cause damage to a vessel or its cargo, or cause interference with the safe navigation of vessels, or interference with maritime commerce, such as by damaging or destroying marine terminals, facilities, and any other marine structure or entity used in maritime commerce, with the intent of causing such destruction or damage, or interference with the safe navigation of vessels or with maritime commerce, shall be fined under this title, imprisoned for any term of years or for life, or both; and if the death of any person results from conduct prohibited under this subsection, may be punished by death.

''(b) Nothing in this section shall be construed to apply to otherwise lawfully authorized and conducted activities of the United States Government.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 111 of title 18, United States Code, is amended by adding after the item related to section 2280 the following:

''2280A. Devices or substances in waters of the United States likely to destroy or damage ships or to interfere with maritime commerce.''.

(c) MALICIOUS DUMPING.—

(1) IN GENERAL.—Chapter 111 of title 18, United States Code, is amended by adding at the end the following:

''§ 2282. Knowing discharge or release

''(a) ENDANGERMENT OF HUMAN LIFE.—Any person who knowingly discharges or releases oil, a hazardous material, a noxious liquid substance, or any other dangerous substance into the navigable waters of the United States or the adjoining shoreline with the intent to endanger human life, health, or welfare shall be fined under this title and imprisoned for any term of years or for life.

''(b) ENDANGERMENT OF MARINE ENVIRONMENT.—Any person who knowingly discharges or releases oil, a hazardous material, a noxious liquid substance, or any other dangerous substance into the navigable waters of the United States or the adjacent shoreline with the intent to endanger the marine environment shall be fined under this title, imprisoned not more than 30 years, or both.

''(c) DEFINITIONS.—In this section:

''(1) DISCHARGE.—The term 'discharge' means any spilling, leaking, pumping, pouring, emitting, emptying, or dumping.

''(2) HAZARDOUS MATERIAL.—The term 'hazardous material' has the meaning given the term in section 2101(14) of title 46, United States Code.

''(3) MARINE ENVIRONMENT.—The term 'marine environment' has the meaning given the term in section 2101(15) of title 46, United States Code.

''(4) NAVIGABLE WATERS.—The term 'navigable waters' has the meaning given the term in section 1362(7) of title 33, and also includes the territorial sea of the United States as described in Presidential Proclamation 5928 of December 27, 1988.

''(5) NOXIOUS LIQUID SUBSTANCE.—The term 'noxious liquid substance' has the meaning given the term in the MARPOL Protocol defined in section 2(1) of the Act to Prevent Pollution from Ships (33 U.S.C. 1901(a)(3)).''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 111 of title 18, United States Code, is amended by adding at the end the following:

''2282. Knowing discharge or release.''.

SEC. 425. TRANSPORTATION OF DANGEROUS MATERIALS AND TERRORISTS.

(a) TRANSPORTATION OF DANGEROUS MATERIALS AND TERRORISTS.—Chapter 111 of title 18, as amended by this Act, is amended by adding at the end the following:

"§ 2283. Transportation of explosive, biological, chemical, or radioactive or nuclear materials

''(a) IN GENERAL.—Any person who knowingly and willfully transports aboard any vessel within the United States, on the high seas, or having United States nationality, an explosive or incendiary device, biological agent, chemical weapon, or radioactive or nuclear material, knowing that any such item is intended to be used to commit an offense listed under section 2332b(g)(5)(B), shall be fined under this title, imprisoned for any term of years or for life, or both; and if the death of any person results from conduct prohibited by this subsection, may be punished by death.

''(b) DEFINITIONS.—In this section:

''(1) BIOLOGICAL AGENT.—The term 'biological agent' means any biological agent, toxin, or vector (as those terms are defined in section 178).

''(2) BY-PRODUCT MATERIAL.—The term 'by-product material' has the meaning given that term in section 11(e) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)).

''(3) CHEMICAL WEAPON.—The term 'chemical weapon' has the meaning given that term in section 229F.

''(4) EXPLOSIVE OR INCENDIARY DEVICE.—The term 'explosive or incendiary device' has the meaning given the term in section 232(5).

''(5) NUCLEAR MATERIAL.—The term 'nuclear material' has the meaning given that term in section 831(f)(1).

''(6) RADIOACTIVE MATERIAL.—The term 'radioactive material' means—

''(A) source material and special nuclear material, but does not include natural or depleted uranium;

''(B) nuclear by-product material;

''(C) material made radioactive by bombardment in an accelerator; or

''(D) all refined isotopes of radium.

''(7) SOURCE MATERIAL.—The term 'source material' has the meaning given that term in section 11(z) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(z)).

''(8) SPECIAL NUCLEAR MATERIAL.—The term 'special nuclear material' has the meaning given that term in section 11(aa) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(aa)).

"§ 2284. Transportation of terrorists

''(a) IN GENERAL.—Any person who knowingly and willfully transports any terrorist aboard any vessel within the United States, on the high seas, or having United States nationality, knowing that the transported person is a terrorist, shall be fined under this title, imprisoned for any term of years or for life, or both.

''(b) DEFINED TERM.—In this section, the term 'terrorist' means any person who intends to commit, or is avoiding apprehension after having committed, an offense listed under section 2332b(g)(5)(B).''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 111 of title 18, United States Code, as amended by this Act, is amended by adding at the end the following:

''2283. Transportation of explosive, biological, chemical, or radioactive or nuclear materials.
''2284. Transportation of terrorists.''.

SEC. 426. DESTRUCTION OR INTERFERENCE WITH VESSELS OR MARITIME FACILITIES.

(a) IN GENERAL.—Part 1 of title 18, United States Code, is amended by inserting after chapter 111 the following:

"CHAPTER 111A—DESTRUCTION OF, OR INTERFERENCE WITH, VESSELS OR MARITIME FACILITIES

"§ 2291. Jurisdiction and scope

''(a) JURISDICTION.—There is jurisdiction over an offense under this chapter if the prohibited activity takes place—

''(1) within the United States or within waters subject to the jurisdiction of the United States; or

''(2) outside United States and—

''(A) an offender or a victim is a national of the United States (as that term is defined under section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(22));

''(B) the activity involves a vessel in which a national of the United States was on board; or

''(C) the activity involves a vessel of the United States (as that term is defined under section 2(c) of the Maritime Drug Law Enforcement Act (42 App. U.S.C. 1903(c)).

''(b) SCOPE.—Nothing in this chapter shall apply to otherwise lawful activities carried out by or at the direction of the United States Government.

"§ 2292. Destruction of vessel or maritime facility

''(a) OFFENSE.—Whoever willfully—

''(1) sets fire to, damages, destroys, disables, or wrecks any vessel;

''(2) places or causes to be placed a destructive device (as defined in section 921(a)(4)) or destructive substance (as defined in section 13) in, upon, or in proximity to, or otherwise makes or causes to be made unworkable or unusable or hazardous to work or use, any vessel, or any part or other materials used or intended to be used in connection with the operation of a vessel;

''(3) sets fire to, damages, destroys, or disables or places a destructive device or substance in, upon, or in proximity to, any maritime facility, including but not limited to, any aid to navigation, lock, canal, or vessel traffic service facility or equipment, or interferes by force or violence with the operation of such facility, if such action is likely to endanger the safety of any vessel in navigation;

''(4) sets fire to, damages, destroys, or disables or places a destructive device or substance in, upon,

or in proximity to any appliance, structure, property, machine, or apparatus, or any facility or other material used, or intended to be used, in connection with the operation, maintenance, loading, unloading, or storage of any vessel or any passenger or cargo carried or intended to be carried on any vessel;

''(5) performs an act of violence against or incapacitates any individual on any vessel, if such act of violence or incapacitation is likely to endanger the safety of the vessel or those on board;

''(6) performs an act of violence against a person that causes or is likely to cause serious bodily injury (as defined in section 1365) in, upon, or in proximity to any appliance, structure, property, machine, or apparatus, or any facility or other material used, or intended to be used, in connection with the operation, maintenance, loading, unloading, or storage of any vessel or any passenger or cargo carried or intended to be carried on any vessel;

''(7) communicates information, knowing the information to be false and under circumstances in which such information may reasonably be believed, thereby endangering the safety of any vessel in navigation; or

''(8) attempts or conspires to do anything prohibited under paragraphs (1) through (7),

shall be fined under this title, imprisoned not more than 20 years, or both.

''(b) LIMITATION.—Subsection (a) shall not apply to any person that is engaging in otherwise lawful activity, such as normal repair and salvage activities, and the lawful transportation of hazardous materials.

''(c) PENALTY.—Whoever is fined or imprisoned under subsection (a) as a result of an act involving a vessel that, at the time of the violation, carried high-level radioactive waste (as that term is defined in section 2(12) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10101(12)) or spent nuclear fuel (as that term is defined in section 2(23) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10101(23)), shall be fined under title 18, imprisoned for a term up to life, or both.

''(d) PENALTY WHEN DEATH RESULTS.—Whoever is convicted of any crime prohibited by subsection (a), which has resulted in the death of any person, shall be subject also to the death penalty or to imprisonment for life.

''(e) THREATS.—Whoever willfully imparts or conveys any threat to do an act which would violate this chapter, with an apparent determination and will to carry the threat into execution, shall be fined under this title, im-

prisoned not more than 5 years, or both, and is liable for all costs incurred as a result of such threat.

"§ 2293. Imparting or conveying false information

''(a) IN GENERAL.—Whoever imparts or conveys or causes to be imparted or conveyed false information, knowing the information to be false, concerning an attempt or alleged attempt being made or to be made, to do any act which would be a crime prohibited by this chapter or by chapter 111, shall be subject to a civil penalty of not more than $5,000, which shall be recoverable in a civil action brought in the name of the United States.

''(b) MALICIOUS CONDUCT.—Whoever willfully and maliciously, or with reckless disregard for the safety of human life, imparts or conveys or causes to be imparted or conveyed false information, knowing the information to be false, concerning an attempt or alleged attempt to do any act which would be a crime prohibited by this chapter or by chapter 111 of this title, shall be fined under this title, imprisoned not more than 5 years, or both.

''(c) JURISDICTION.—

''(1) IN GENERAL.—Except as provided under paragraph (2), section 2291(a) shall not apply to any offense under this section.

''(2) JURISDICTION.—Jurisdiction over an offense under this section shall be determined in ac-

cordance with the provisions applicable to the crime prohibited by this chapter, or by chapter 2, 97, or 111 of this title, to which the imparted or conveyed false information relates, as applicable.

"§ 2294. Bar to prosecution

''(a) IN GENERAL.—It is a bar to prosecution under this chapter if—

''(1) the conduct in question occurred within the United States in relation to a labor dispute, and such conduct is prohibited as a felony under the law of the State in which it was committed; or

''(2) such conduct is prohibited as a misdemeanor under the law of the State in which it was committed.

''(b) DEFINITIONS.—In this section:

''(1) LABOR DISPUTE.—The term 'labor dispute' has the same meaning given that term in section 113(c) of the Norris-LaGuardia Act (29 U.S.C. 113(c)).

''(2) STATE.—The term 'State' means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of chapters at the beginning of title 18, United

States Code, is amended by inserting after the item for chapter 111 the following:

"111A. Destruction of, or interference with, vessels or maritime facilities ..... 2290".

SEC. 427. THEFT OF INTERSTATE OR FOREIGN SHIPMENTS OR VESSELS.

(a) THEFT OF INTERSTATE OR FOREIGN SHIPMENTS.—Section 659 of title 18, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by inserting "trailer," after "motortruck,";

(B) by inserting "air cargo container," after "aircraft,"; and

(C) by inserting ", or from any intermodal container, trailer, container freight station, warehouse, or freight consolidation facility," after "air navigation facility";

(2) in the fifth undesignated paragraph, by striking "one year" and inserting "3 years"; and

(3) by inserting after the first sentence in the eighth undesignated paragraph the following: "For purposes of this section, goods and chattel shall be construed to be moving as an interstate or foreign shipment at all points between the point of origin and the final destination (as evidenced by the waybill

or other shipping document of the shipment), regardless of any temporary stop while awaiting transshipment or otherwise.''.

(b) STOLEN VESSELS.—

(1) IN GENERAL.—Section 2311 of title 18, United States Code, is amended by adding at the end the following:

'' 'Vessel' means any watercraft or other contrivance used or designed for transportation or navigation on, under, or immediately above, water.''.

(2) TRANSPORTATION AND SALE OF STOLEN VESSELS.—Sections 2312 and 2313 of title 18, United States Code, are each amended by striking ''motor vehicle or aircraft'' and inserting ''motor vehicle, vessel, or aircraft''.

(c) REVIEW OF SENTENCING GUIDELINES.—Pursuant to section 994 of title 28, United States Code, the United States Sentencing Commission shall review the Federal Sentencing Guidelines to determine whether sentencing enhancement is appropriate for any offense under section 659 or 2311 of title 18, United States Code.

(d) ANNUAL REPORT OF LAW ENFORCEMENT ACTIVITIES.—The Attorney General shall annually submit to Congress a report, which shall include an evaluation of law enforcement activities relating to the investigation and

prosecution of offenses under section 659 of title 18, United States Code.

(e) REPORTING OF CARGO THEFT.—The Attorney General shall take the steps necessary to ensure that reports of cargo theft collected by Federal, State, and local officials are reflected as a separate category in the Uniform Crime Reporting System, or any successor system, by not later than December 31, 2005.

SEC. 428. INCREASED PENALTIES FOR NONCOMPLIANCE WITH MANIFEST REQUIREMENTS.

(a) REPORTING, ENTRY, CLEARANCE REQUIREMENTS.—Section 436(b) of the Tariff Act of 1930 (19 U.S.C. 1436(b)) is amended by—

(1) striking ''or aircraft pilot'' and inserting '', aircraft pilot, operator, owner of such vessel, vehicle or aircraft or any other responsible party (including non-vessel operating common carriers)'';

(2) striking ''$5,000'' and inserting ''$10,000''; and

(3) striking ''$10,000'' and inserting ''$25,000''.

(b) CRIMINAL PENALTY.—Section 436(c) of the Tariff Act of 1930 (19 U.S.C. 1436(c)) is amended by striking ''$2,000'' and inserting ''$10,000''.

(c) FALSITY OR LACK OF MANIFEST.—Section 584(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1584(a)(1)) is amended by striking ''$1,000'' each place it occurs and inserting ''$10,000''.

SEC. 429. STOWAWAYS ON VESSELS OR AIRCRAFT.

Section 2199 of title 18, United States Code, is amended by striking ''Shall be fined under this title or imprisoned not more than one year, or both.'' and inserting the following:

''(1) shall be fined under this title, imprisoned not more than 5 years, or both;

''(2) if the person commits an act proscribed by this section, with the intent to commit serious bodily injury, and serious bodily injury occurs (as defined in section 1365, including any conduct that, if the conduct occurred in the special maritime and territorial jurisdiction of the United States, would violate section 2241 or 2242) to any person other than a participant as a result of a violation of this section, shall be fined under this title, imprisoned not more than 20 years, or both; and

''(3) if an individual commits an act proscribed by this section, with the intent to cause death, and if the death of any person other than a participant occurs as a result of a violation of this section, shall

be fined under this title, imprisoned for any number of years or for life, or both.''.

SEC. 430. BRIBERY AFFECTING PORT SECURITY.

(a) IN GENERAL.—Chapter 11 of title 18, United States Code, is amended by adding at the end the following:

''§ 226. Bribery affecting port security

''(a) IN GENERAL.—Any person who knowingly—

''(1) directly or indirectly, corruptly gives, offers, or promises anything of value to any public or private person, with intent—

''(A) to commit international or domestic terrorism (as that term is defined under section 2331);

''(B) to influence any action or any person to commit or aid in committing, or collude in, or allow, any fraud, or make opportunity for the commission of any fraud affecting any secure or restricted area or seaport; or

''(C) to induce any official or person to do or omit to do any act in violation of the fiduciary duty of such official or person which affects any secure or restricted area or seaport; or

"(2) directly or indirectly, corruptly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally or for any other person or entity in return for—

"(A) being influenced in the performance of any official act affecting any secure or restricted area or seaport; and

"(B) knowing that such influence will be used to commit, or plan to commit, international or domestic terrorism,

shall be fined under this title, imprisoned not more than 15 years, or both.

"(b) DEFINITION.—In this section, the term 'secure or restricted area' has the meaning given that term in section 2285(c).".

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 11 of title 18, United States Code, is amended by adding at the end the following:

"226. Bribery affecting port security.".

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