109TH CONGRESS
2D SESSION

# S. _____

To reduce the Federal budget deficit, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

Mr. DORGAN introduced the following bill; which was read twice and referred to the Committee on _____

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# A BILL

To reduce the Federal budget deficit, and for other purposes.

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

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ''Act For Our Kids''.

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

Sec. 1. Short title; table of contents.

TITLE I—REDUCTIONS IN FEDERAL SPENDING

Subtitle A—Specific Reductions

Sec. 101. Prohibition on television broadcasting to Cuba.
Sec. 102. Termination of United States Court of Federal Claims.
Sec. 103. Reduction of administrative expenses of agencies.

Sec. 104. Elimination of Medicare Advantage regional plan stabilization (slush) fund.

Subtitle B—Reform of Federal Contracting

Part I—Elimination of Fraud and Abuse

Sec. 111. Prohibition of war profiteering and fraud.
Sec. 112. Suspension and debarment of unethical contractors.
Sec. 113. Disclosure of audit reports.

Part II—Contract Matters

subpart a—competition in contracting

Sec. 114. Prohibition on award of monopoly contracts.
Sec. 115. Competition in multiple award contracts.

subpart b—contract personnel matters

Sec. 116. Contractor conflicts of interest.
Sec. 117. Elimination of revolving door between Federal personnel and contractors.

Part III—Other Personnel Matters

Sec. 118. Minimum requirements for political appointees holding public contracting and safety positions.
Sec. 119. Protection of certain disclosures of information by Federal employees.

Subtitle C—Importation of Prescription Drugs

Sec. 121. Short title.
Sec. 122. Findings.
Sec. 123. Repeal of certain section regarding importation of prescription drugs.
Sec. 124. Importation of prescription drugs; waiver of certain import restrictions.
Sec. 125. Disposition of certain drugs denied admission into United States.
Sec. 126. Wholesale distribution of drugs; statements regarding prior sale, purchase, or trade.
Sec. 127. Internet sales of prescription drugs.
Sec. 128. Prohibiting payments to unregistered foreign pharmacies.
Sec. 129. Importation exemption under Controlled Substances Import and Export Act.
Sec. 130. Severability.

Subtitle D—Royalties Under Offshore Oil and Gas Leases

Sec. 141. Price thresholds for royalty suspension provisions.
Sec. 142. Clarification of authority to impose price thresholds for certain lease sales.
Sec. 143. Eligibility for new leases and the transfer of leases; conservation of resources fees.

TITLE II—REVENUE ENHANCEMENTS

Sec. 200. Amendment of 1986 Code.

Subtitle A—Rescission of Various Tax Cuts for Millionaire Taxpayers

Sec. 201. Repeal of top income tax rate reduction for taxpayers with $1,000,000 or more of taxable income.
Sec. 202. Elimination of the scheduled phaseout of the limitations on personal exemptions and itemized deductions for taxpayers earning in excess of $1,000,000.
Sec. 203. Modification of tax rates on capital gains and dividends for taxpayers with $1,000,000 or more of taxable income.

Subtitle B—Provisions to Discourage Offshore Shelters and Expatriation

Sec. 211. Taxation of income of controlled foreign corporations attributable to imported property.
Sec. 212. Tax treatment of controlled foreign corporations established in tax havens.
Sec. 213. Revision of tax rules on expatriation of individuals.
Sec. 214. Modification of effective date of leasing provisions of the American Jobs Creation Act of 2004.
Sec. 215. Application of rules treating inverted corporations as domestic corporations to certain transactions occurring after March 20, 2002.

Subtitle C—Economic Substance Doctrine

Sec. 221. Clarification of economic substance doctrine.
Sec. 222. Penalty for understatements attributable to transactions lacking economic substance, etc.
Sec. 223. Denial of deduction for interest on underpayments attributable to noneconomic substance transactions.

Subtitle D—Penalties and Fines

Sec. 231. Denial of deduction for certain fines, penalties, and other amounts.
Sec. 232. Denial of deduction for punitive damages.

Subtitle E—Duty Surcharge

Sec. 241. Temporary emergency duty surcharge.

Subtitle F—Other Provisions

Sec. 251. Offshore oil and gas leasing in 181 Area of Gulf of Mexico.
Sec. 252. Transfer of surplus funds of Federal Reserve Banks to Treasury.
Sec. 253. Permanent extension of FCC authority to auction licenses to use radio spectrum.
Sec. 254. Travel between the United States and Cuba.

# TITLE I—REDUCTIONS IN FEDERAL SPENDING

## Subtitle A—Specific Reductions

**SEC. 101. PROHIBITION ON TELEVISION BROADCASTING TO CUBA.**

(a) REPEAL OF THE TELEVISION BROADCASTING TO CUBA ACT.—

(1) IN GENERAL.—The Television Broadcasting to Cuba Act (22 U.S.C. 1465aa et seq.) is repealed.

(2) CONFORMING AMENDMENT.—Section 107 of the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (22 U.S.C. 6037) is amended to read as follows:

**"SEC. 107. TERMINATION OF RADIO BROADCASTING AUTHORITY.**

''Upon transmittal of a determination under section 203(c)(3), the Radio Broadcasting to Cuba Act (22 U.S.C. 1465 et seq.) is repealed.''.

(b) PROHIBITION ON FUNDING OF TELEVISION BROADCASTING TO CUBA.—Notwithstanding any other provision of law, no funds may appropriated or otherwise made available to carry out any program of the United States Government to provide television broadcasting to Cuba.

**SEC. 102. TERMINATION OF UNITED STATES COURT OF FEDERAL CLAIMS.**

(a) FILING OF CLAIMS.—Notwithstanding any other provision of law, no claim may be filed in the United States Court of Federal Claims on or after the date of enactment of this Act.

(b) PENDING CLAIMS.—Not later than 60 days after the date of enactment of this Act, the Chief Justice of the United States shall promulgate regulations to carry out an orderly transfer of all claims pending before the United States Court of Federal Claims to appropriate courts of the United States. Such transfers shall be completed during the 1-year period beginning on the date of enactment of this Act. Regulations under this subsection may provide for some claims to proceed in the United States Court of Federal Claims during that 1-year period. A congressional reference case for which a report is not transmitted to the appropriate House of Congress before the end of that 1-year period shall not be transferred and shall terminate.

(c) TERMINATION.—Notwithstanding any other provision of law, the United States Court of Federal Claims is terminated effective on and after the date occurring 1 year after the date of enactment of this Act.

**SEC. 103. REDUCTION OF ADMINISTRATIVE EXPENSES OF AGENCIES.**

(a) REQUIREMENT TO REDUCE EXPENSES.—An agency (as defined under section 101 of title 31, United States Code) shall not make, or obligate to make, expenditures for administrative expenses—

(1) in the case of each of the fiscal years 2008 through 2012, in an aggregate amount greater than 95 percent of the amount of such expenses for the preceding fiscal year (determined after application of this section); and

(2) in the case of fiscal year 2013 and each fiscal year thereafter, in an aggregate amount greater than the aggregate amount of such expenses for fiscal year 2012 (determined after application of this section).

(b) EXCEPTION FOR PROGRAM EXPENSES.—Nothing in this section shall be treated as requiring any reduction in program expenses.

(c) IDENTIFICATION OF AFFECTED EXPENSES.—The Director of the Office of Management and Budget shall, not later than September 1, 2007, establish guidelines for the determination of what expenses constitute administrative expenses or program expenses for purposes of this section. The guidelines shall identify specific expenses, and

classes of expenses, that are to be treated as administrative expenses or program expenses.

**SEC. 104. ELIMINATION OF MEDICARE ADVANTAGE REGIONAL PLAN STABILIZATION (SLUSH) FUND.**

(a) ELIMINATION.—

(1) IN GENERAL.—Subsection (e) of section 1858 of the Social Security Act (42 U.S.C. 1395w–27a) is repealed.

(2) CONFORMING AMENDMENT.—Section 1858(f)(1) of the Social Security Act (42 U.S.C. 1395w–27a(f)(1)) is amended by striking ''subject to subsection (e),''.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act.

# Subtitle B—Reform of Federal Contracting

## PART I—ELIMINATION OF FRAUD AND ABUSE

**SEC. 111. PROHIBITION OF WAR PROFITEERING AND FRAUD.**

(a) PROHIBITION.—

(1) IN GENERAL.—Chapter 47 of title 18, United States Code, is amended by adding at the end the following:

**"§ 1039. War profiteering and fraud**

''(a) PROHIBITION.—

''(1) IN GENERAL.—Whoever, in any matter involving a contract or the provision of goods or services, directly or indirectly, in connection with a war or military action knowingly and willfully—

''(A) executes or attempts to execute a scheme or artifice to defraud the United States or the entity having jurisdiction over the area in which such activities occur;

''(B) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

''(C) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; or

''(D) materially overvalues any good or service with the specific intent to excessively profit from the war or military action;

shall be fined under paragraph (2), imprisoned not more than 20 years, or both.

''(2) FINE.—A person convicted of an offense under paragraph (1) may be fined the greater of—

''(A) $1,000,000; or

''(B) if such person derives profits or other proceeds from the offense, not more than twice the gross profits or other proceeds.

''(b) EXTRATERRITORIAL JURISDICTION.—There is extraterritorial Federal jurisdiction over an offense under this section.

''(c) VENUE.—A prosecution for an offense under this section may be brought—

''(1) as authorized by chapter 211 of this title;

''(2) in any district where any act in furtherance of the offense took place; or

''(3) in any district where any party to the contract or provider of goods or services is located.''.

(2) CLERICAL AMENDMENT.—The table of sections for chapter 47 of title 18, United States Code, is amended by adding at the end the following:

''1039. War profiteering and fraud.''.

(b) CIVIL FORFEITURE.—Section 981(a)(1)(C) of title 18, United States Code, is amended by inserting ''1039,'' after ''1032,''.

(c) CRIMINAL FORFEITURE.—Section 982(a)(2)(B) of title 18, United States Code, is amended by striking ''or 1030'' and inserting ''1030, or 1039''.

(d) TREATMENT UNDER MONEY LAUNDERING OFFENSE.—Section 1956(c)(7)(D) of title 18, United States Code, is amended by inserting the following: '', section

1039 (relating to war profiteering and fraud)'' after ''liquidating agent of financial institution),''.

**SEC. 112. SUSPENSION AND DEBARMENT OF UNETHICAL CONTRACTORS.**

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Federal Acquisition Regulation issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421) shall be revised to provide that no prospective contractor shall be considered to have a satisfactory record of integrity and business ethics if it—

(1) has exhibited a pattern of overcharging the Government under Federal contracts; or

(2) has exhibited a pattern of failing to comply with the law, including tax, labor and employment, environmental, antitrust, and consumer protection laws.

(b) EFFECTIVE DATE.—The revised regulation required by this section shall apply with respect to all contracts for which solicitations are issued after the date that is 90 days after the date of the enactment of this Act.

**SEC. 113. DISCLOSURE OF AUDIT REPORTS.**

(a) DISCLOSURE OF INFORMATION TO CONGRESS.—

(1) IN GENERAL.—The head of each executive agency shall maintain a list of audit reports issued

by the agency during the current and previous calendar years that—

(A) describe significant contractor costs that have been identified as unjustified, unsupported, questioned, or unreasonable under any contract, task or delivery order, or subcontract; or

(B) identify significant or substantial deficiencies in any business system of any contractor under any contract, task or delivery order, or subcontract.

(2) SUBMISSION OF INDIVIDUAL AUDITS.—The head of each executive agency shall provide, within 14 days of a request in writing by the chairman or ranking member of a committee of jurisdiction, a full and unredacted copy of—

(A) the current version of the list maintained pursuant to paragraph (1); or

(B) any audit or other report identified on such list.

(b) PUBLICATION OF INFORMATION ON FEDERAL CONTRACTOR PENALTIES AND VIOLATIONS.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Fed-

eral Procurement Data System shall be modified to include—

(A) information on instances in which any major contractor has been fined, paid penalties or restitution, settled, plead guilty to, or had judgments entered against it in connection with allegations of improper conduct; and

(B) information on all sole source contract awards in excess of $2,000,000 entered into by an executive agency.

(2) PUBLICLY AVAILABLE WEBSITE.—The information required by paragraph (1) shall be made available through the publicly available website of the Federal Procurement Data System.

## PART II—CONTRACT MATTERS

### Subpart A—Competition in Contracting

#### SEC. 114. PROHIBITION ON AWARD OF MONOPOLY CONTRACTS.

(a) CIVILIAN AGENCY CONTRACTS.—Section 303H(d) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253h(d)) is amended by adding at the end the following new paragraph:

''(4)(A) No task or delivery order contract in an amount estimated to exceed $100,000,000 (including all

options) may be awarded to a single contractor unless the head of the agency determines in writing that—

''(i) because of the size, scope, or method of performance of the requirement, it would not be practical to award multiple task or delivery order contracts;

''(ii) the task orders expected under the contract are so integrally related that only a single contractor can reasonably perform the work; or

''(iii) for any other reason, it is necessary in the public interest to award the contract to a single contractor.

''(B) The head of the agency shall notify Congress within 30 days of any determination under subparagraph (A)(iii).''.

(b) DEFENSE CONTRACTS.—Section 2304a(d) of title 10, United States Code, is amended by adding at the end the following new paragraph:

''(4)(A) No task or delivery order contract in an amount estimated to exceed $100,000,000 (including all options) may be awarded to a single contractor unless the head of the agency determines in writing that—

''(i) because of the size, scope, or method of performance of the requirement, it would not be

practical to award multiple task or delivery order contracts;

''(ii) the task orders expected under the contract are so integrally related that only a single contractor can reasonably perform the work; or

''(iii) for any other reason, it is necessary in the public interest to award the contract to a single contractor.

''(B) The head of the agency shall notify Congress within 30 days of any determination under subparagraph (A)(iii).''.

**SEC. 115. COMPETITION IN MULTIPLE AWARD CONTRACTS.**

(a) REGULATIONS REQUIRED.—Not later than 180 days after the date of the enactment of this section, the Federal Acquisition Regulation shall be revised to require competition in the purchase of goods and services by each executive agency pursuant to multiple award contracts.

(b) CONTENT OF REGULATIONS.—(1) The regulations required by subsection (a) shall provide, at a minimum, that each individual purchase of goods or services in excess of $1,000,000 that is made under a multiple award contract shall be made on a competitive basis unless a contracting officer of the executive agency—

(A) waives the requirement on the basis of a determination that—

(i) one of the circumstances described in paragraphs (1) through (4) of section 303J(b) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253j(b)) applies to such individual purchase; or

(ii) a statute expressly authorizes or requires that the purchase be made from a specified source; and

(B) justifies the determination in writing.

(2) For purposes of this subsection, an individual purchase of goods or services is made on a competitive basis only if it is made pursuant to procedures that—

(A) require fair notice of the intent to make that purchase (including a description of the work to be performed and the basis on which the selection will be made) to be provided to all contractors offering such goods or services under the multiple award contract; and

(B) afford all contractors responding to the notice a fair opportunity to make an offer and have that offer fairly considered by the official making the purchase.

(3) Notwithstanding paragraph (2), notice may be provided to fewer than all contractors offering such goods or services under a multiple award contract described in

subsection (c)(2)(A) if notice is provided to as many contractors as practicable.

(4) A purchase may not be made pursuant to a notice that is provided to fewer than all contractors under paragraph (3) unless—

(A) offers were received from at least three qualified contractors; or

(B) a contracting officer of the executive agency determines in writing that no additional qualified contractors were able to be identified despite reasonable efforts to do so.

(c) DEFINITIONS.—In this section:

(1) The term ''individual purchase'' means a task order, delivery order, or other purchase.

(2) The term ''multiple award contract'' means—

(A) a contract that is entered into by the Administrator of General Services under the multiple award schedule program referred to in section 309(b)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 259(b)(3));

(B) a multiple award task order contract that is entered into under the authority of sections 2304a through 2304d of title 10, United

States Code, or sections 303H through 303K of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253h through 253k); and

(C) any other indefinite delivery, indefinite quantity contract that is entered into by the head of an executive agency with two or more sources pursuant to the same solicitation.

(d) APPLICABILITY.—The revisions to the Federal Acquisition Regulation pursuant to subsection (a) shall take effect not later than 180 days after the date of the enactment of this Act, and shall apply to all individual purchases of goods or services that are made under multiple award contracts on or after the effective date, without regard to whether the multiple award contracts were entered into before, on, or after such effective date.

(e) CONFORMING AMENDMENTS TO DEFENSE CONTRACT PROVISION.—Section 803 of the National Defense Authorization Act for Fiscal Year 2002 (Public Law 107–107; 10 U.S.C. 2304 note) is amended as follows:

(1) GOODS COVERED.—(A) The section heading is amended by inserting ''**GOODS OR**'' before ''**SERVICES**''.

(B) Subsection (a) is amended by inserting ''goods and'' before ''services''.

(C) The following provisions are amended by inserting ''goods or'' before ''services'' each place it appears:

(i) Paragraphs (1), (2), and (3) of subsection (b).

(ii) Subsection (d).

(D) Such section is amended by adding at the end the following new subsection:

''(e) APPLICABILITY TO GOODS.—The Secretary shall revise the regulations promulgated pursuant to subsection (a) to cover purchases of goods by the Department of Defense pursuant to multiple award contracts. The revised regulations shall take effect in final form not later than 180 days after the date of the enactment of this subsection and shall apply to all individual purchases of goods that are made under multiple award contracts on or after the effective date, without regard to whether the multiple award contracts were entered into before, on, or after such effective date.''.

(f) PROTEST RIGHTS FOR CERTAIN AWARDS.—

(1) CIVILIAN AGENCY CONTRACTS.—Section 303J(d) of the Federal Property and Administrative Services Act (41 U.S.C. 253j(d)) is amended by inserting ''with a value of less than $500,000'' after ''task or delivery order''.

(2) DEFENSE CONTRACTS.—Section 2304c(d) of title 10, United States Code, is amended by inserting ''with a value of less than $500,000'' after ''task or delivery order''.

## Subpart B—Contract Personnel Matters

### SEC. 116. CONTRACTOR CONFLICTS OF INTEREST.

(a) PROHIBITION ON CONTRACTS RELATING TO INHERENTLY GOVERNMENTAL FUNCTIONS.—The head of an agency may not enter into a contract for the performance of any inherently governmental function.

(b) PROHIBITION ON CONTRACTS FOR CONTRACT OVERSIGHT.—

(1) PROHIBITION.—The head of an agency may not enter into a contract for the performance of acquisition functions closely associated with inherently governmental functions with any entity unless the head of the agency determines in writing that—

(A) neither that entity nor any related entity will be responsible for performing any of the work under a contract which the entity will help plan, evaluate, select a source, manage or oversee; and

(B) the agency has taken appropriate steps to prevent or mitigate any organizational con-

flict of interest that may arise because the entity—

(i) has a separate ongoing business relationship, such as a joint venture or contract, with any of the contractors to be overseen;

(ii) would be placed in a position to affect the value or performance of work it or any related entity is doing under any other Government contract;

(iii) has a reverse role with the contractor to be overseen under one or more separate Government contracts; or

(iv) has some other relationship with the contractor to be overseen that could reasonably appear to bias the contractor's judgment.

(2) RELATED ENTITY DEFINED.—In this subsection, the term ''related entity'', with respect to a contractor, means any subsidiary, parent, affiliate, joint venture, or other entity related to the contractor.

(c) DEFINITIONS.—In this section:

(1) The term ''inherently governmental functions'' has the meaning given to such term in part 7.5 of the Federal Acquisition Regulation.

(2) The term ''functions closely associated with governmental functions'' means the functions described in section 7.503(d) of the Federal Acquisition Regulation.

(3) The term ''organizational conflict of interest'' has the meaning given such term in part 9.5 of the Federal Acquisition Regulation.

(d) EFFECTIVE DATE AND APPLICABILITY.—This section shall take effect on the date of the enactment of this Act and shall apply to—

(1) contracts entered into on or after such date;

(2) any task or delivery order issued on or after such date under a contract entered into before, on, or after such date; and

(3) any decision on or after such date to exercise an option or otherwise extend a contract for the performance of a function relating to contract oversight regardless of whether such contract was entered into before, on, or after such date.

**SEC. 117. ELIMINATION OF REVOLVING DOOR BETWEEN FEDERAL PERSONNEL AND CONTRACTORS.**

(a) ELIMINATION OF LOOPHOLES ALLOWING FORMER FEDERAL OFFICIALS TO ACCEPT COMPENSATION FROM CONTRACTORS OR RELATED ENTITIES.—

(1) IN GENERAL.—Paragraph (1) of subsection (d) of section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) is amended—

(A) by striking ''or consultant'' and inserting ''consultant, lawyer, or lobbyist'';

(B) by striking ''one year'' and inserting ''two years''; and

(C) in subparagraph (C), by striking ''personally made for the Federal agency—'' and inserting ''participated personally and substantially in—''.

(2) DEFINITION.—Paragraph (2) of such subsection is amended to read as follows:

''(2) For purposes of paragraph (1), the term 'contractor' includes any division, affiliate, subsidiary, parent, joint venture, or other related entity of a contractor.''.

(b) PROHIBITION ON AWARD OF GOVERNMENT CONTRACTS TO FORMER EMPLOYERS.—Such section is further amended by adding at the end the following new subsection:

''(i) PROHIBITION ON INVOLVEMENT BY CERTAIN FORMER CONTRACTOR EMPLOYEES IN PROCUREMENTS.—A former employee of a contractor who becomes an employee of the Federal Government shall not be personally and substantially involved with any Federal agency procurement involving the employee's former employer, including any division, affiliate, subsidiary, parent, joint venture, or other related entity of the former employer, for a period of two years beginning on the date on which the employee leaves the employment of the contractor unless the designated agency ethics officer for the agency determines in writing that the government's interest in the former employee's participation in a particular procurement outweighs any appearance of impropriety.''.

(c) REQUIREMENT FOR FEDERAL PROCUREMENT OFFICERS TO DISCLOSE JOB OFFERS MADE TO RELATIVES.—Subsection (c)(1) of such section is amended by inserting after ''that official'' the following: '', or for a relative of that official (as defined in section 3110 of title 5, United States Code),''.

(d) ADDITIONAL CRIMINAL PENALTIES.—Paragraph (1) of subsection (e) of such section is amended to read as follows:

''(1) CRIMINAL PENALTIES.—Whoever engages in conduct constituting a violation of—

''(A) subsection (a) or (b) for the purpose of either—

''(i) exchanging the information covered by such subsection for anything of value, or

''(ii) obtaining or giving anyone a competitive advantage in the award of a Federal agency procurement contract; or

''(B) subsection (c) or (d);

shall be imprisoned for not more than 5 years, fined as provided under title 18, Untied States Code, or both.''.

(e) REGULATIONS.—Such section is further amended by adding at the end the following new subsection:

''(j) REGULATIONS.—The Director of the Office of Government Ethics, in consultation with the Administrator, shall—

''(1) promulgate regulations to carry out and ensure the enforcement of this section; and

''(2) monitor and investigate individual and agency compliance with this section.''.

## PART III—OTHER PERSONNEL MATTERS

### SEC. 118. MINIMUM REQUIREMENTS FOR POLITICAL APPOINTEES HOLDING PUBLIC CONTRACTING AND SAFETY POSITIONS.

(a) IN GENERAL.—A position specified in subsection (b) may not be held by any political appointee who does not meet the requirements of subsection (c).

(b) SPECIFIED POSITIONS.—A position specified in this subsection is any position as follows:

(1) A public contracting position.

(2) A public safety position.

(c) MINIMUM REQUIREMENTS.—An individual shall not, with respect to any position, be considered to meet the requirements of this subsection unless such individual—

(1) has academic, management, and leadership credentials in one or more areas relevant to such position;

(2) has a superior record of achievement in one or more areas relevant to such position;

(3) has training and expertise in one or more areas relevant to such position; and

(4) has not, within the 2-year period ending on the date of such individual's nomination for or appointment to such position, been a lobbyist for any entity or other client that is subject to the authority

of the agency within which, if appointed, such individual would serve.

(d) POLITICAL APPOINTEE.—For purposes of this section, the term ''political appointee'' means any individual who—

(1) is employed in a position listed in sections 5312 through 5316 of title 5, United States Code (relating to the Executive Schedule);

(2) is a limited term appointee, limited emergency appointee, or noncareer appointee in the Senior Executive Service; or

(3) is employed in the executive branch of the Government in a position which has been excepted from the competitive service by reason of its policy-determining, policy-making, or policy-advocating character.

(e) PUBLIC CONTRACTING POSITION.—For purposes of this section, the term ''public contracting position'' means the following:

(1) The Administrator for Federal Procurement Policy.

(2) The Administrator of the General Services Administration.

(3) The Chief Acquisition Officer of any executive agency, as appointed or designated pursuant to

section 16 of the Office of Federal Procurement Policy Act (41 U.S.C. 414).

(4) The Under Secretary of Defense for Acquisition, Technology, and Logistics.

(5) Any position (not otherwise identified under any of the preceding provisions of this subsection) a primary function of which involves government procurement and procurement policy, as identified by the head of each employing agency in consultation with the Office of Personnel Management.

(f) PUBLIC SAFETY POSITION.—For purposes of this section, the term ''public safety position'' means the following:

(1) The Under Secretary for Emergency Preparedness and Response, Department of Homeland Security.

(2) The Director of the Federal Emergency Management Agency, Department of Homeland Security.

(3) Each regional director of the Federal Emergency Management Agency, Department of Homeland Security.

(4) The Recovery Division Director of the Federal Emergency Management Agency, Department of Homeland Security.

(5) The Assistant Secretary for Immigration and Customs Enforcement, Department of Homeland Security.

(6) The Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services.

(7) The Assistant Administrator for Solid Waste and Emergency Response, Environmental Protection Agency.

(8) Any position (not otherwise identified under any of the preceding provisions of this subsection) a primary function of which involves responding to a direct threat to life or property or a hazard to health, as identified by the head of each employing agency in consultation with the Office of Personnel Management.

(g) PUBLICATION OF POSITIONS.—Beginning not later than 30 days after the date of the enactment of this Act, the head of each agency shall maintain on such agency's public website a current list of all public contracting positions and public safety positions within such agency.

(h) COORDINATION WITH OTHER REQUIREMENTS.—The requirements set forth in subsection (c) shall be in addition to, and not in lieu of, any requirements that

might otherwise apply with respect to any particular position.

(i) DEFINITIONS.—In this section:

(1) The term ''agency'' means an Executive agency (as defined by section 105 of title 5, United States Code).

(2) The terms ''limited term appointee'', ''limited emergency appointee'', and ''noncareer appointee'' have the meanings given such terms in section 3132 of title 5, United States Code.

(3) The term ''Senior Executive Service'' has the meaning given such term by section 2101a of title 5, United States Code.

(4) The term ''competitive service'' has the meaning given such term by section 2102 of title 5, United States Code.

(5) The terms ''lobbyist'' and ''client'' have the respective meanings given them by section 3 of the Lobbying Disclosure Act of 1995 (2 U.S.C. 1602).

(j) CONFORMING AMENDMENT.—Section 16(a) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(a)) is amended by striking ''non-career employee as''.

**SEC. 119. PROTECTION OF CERTAIN DISCLOSURES OF INFORMATION BY FEDERAL EMPLOYEES.**

(a) CLARIFICATION OF DISCLOSURES COVERED.—Section 2302(b)(8) of title 5, United States Code, is amended—

(1) in subparagraph (A)—

(A) by striking ''which the employee or applicant reasonably believes evidences'' and inserting '', without restriction to time, place, form, motive, context, or prior disclosure made to any person by an employee or applicant, including a disclosure made in the ordinary course of an employee's duties, that the employee or applicant reasonably believes is evidence of''; and

(B) in clause (i), by striking ''a violation'' and inserting ''any violation'';

(2) in subparagraph (B)—

(A) by striking ''which the employee or applicant reasonably believes evidences'' and inserting '', without restriction to time, place, form, motive, context, or prior disclosure made to any person by an employee or applicant, including a disclosure made in the ordinary course of an employee's duties, of information

that the employee or applicant reasonably believes is evidence of''; and

(B) in clause (i), by striking ''a violation'' and inserting ''any violation (other than a violation of this section)''; and

(3) by adding at the end the following:

''(C) any disclosure that—

''(i) is made by an employee or applicant of information required by law or Executive order to be kept secret in the interest of national defense or the conduct of foreign affairs that the employee or applicant reasonably believes is direct and specific evidence of—

''(I) any violation of any law, rule, or regulation;

''(II) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety; or

''(III) a false statement to Congress on an issue of material fact; and

''(ii) is made to—

''(I) a member of a committee of Congress;

''(II) any other Member of Congress; or

''(III) an employee of Congress who has the appropriate security clearance and is authorized to receive information of the type disclosed.''.

(b) COVERED DISCLOSURES.—Section 2302(a)(2) of title 5, United States Code, is amended—

(1) in subparagraph (B)(ii), by striking ''and'' at the end;

(2) in subparagraph (C)(iii), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(D) 'disclosure' means a formal or informal communication or transmission, but does not include a communication concerning policy decisions that lawfully exercise discretionary authority unless the employee providing the disclosure reasonably believes that the disclosure evidences—

''(i) any violation of any law, rule, or regulation; or

''(ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.''.

(c) REBUTTABLE PRESUMPTION.—Section 2302(b) of title 5, United States Code, is amended by amending the matter following paragraph (12) to read as follows: ''This subsection shall not be construed to authorize the withholding of information from Congress or the taking of any personnel action against an employee who discloses information to Congress. For purposes of paragraph (8), any presumption relating to the performance of a duty by an employee who has authority to take, direct others to take, recommend, or approve any personnel action may be rebutted by substantial evidence. For purposes of paragraph (8), a determination as to whether an employee or applicant reasonably believes that they have disclosed information that evidences any violation of law, rule, regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety shall be made by determining whether a disinterested observer with knowledge of the essential facts known to and readily ascertainable by the employee would reasonably conclude that the actions of the Government evidence such violations, mismanagement, waste, abuse, or danger.''.

(d) NONDISCLOSURE POLICIES, FORMS, AND AGREEMENTS; SECURITY CLEARANCES; AND RETALIATORY INVESTIGATIONS.—

(1) PERSONNEL ACTION.—Section 2302(a)(2)(A) of title 5, United States Code, is amended—

(A) in clause (x), by striking ''and'' after the semicolon; and

(B) by redesignating clause (xi) as clause (xiv) and inserting after clause (x) the following:

''(xi) the implementation or enforcement of any nondisclosure policy, form, or agreement;

''(xii) a suspension, revocation, or other determination relating to a security clearance or any other access determination by a covered agency;

''(xiii) an investigation, other than any ministerial or nondiscretionary fact finding activities necessary for the agency to perform its mission, of an employee or applicant for employment because of any activity protected under this section; and''.

(2) PROHIBITED PERSONNEL PRACTICE.—Section 2302(b) of title 5, United States Code, is amended—

(A) in paragraph (11), by striking ''or'' at the end;

(B) in paragraph (12), by striking the period and inserting a semicolon; and

(C) by inserting after paragraph (12) the following:

''(13) implement or enforce any nondisclosure policy, form, or agreement, if such policy, form, or agreement does not contain the following statement: 'These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by Executive Order No. 12958; section 7211 (governing disclosures to Congress); section 1034 of title 10 (governing disclosure to Congress by members of the military); section 2302(b)(8) (governing disclosures of illegality, waste, fraud, abuse, or public health or safety threats); the Intelligence Identities Protection Act of 1982 (50 U.S.C. 421 et seq.) (governing disclosures that could expose confidential Government agents); and the statutes which protect against disclosures that could compromise national security, including sections 641, 793, 794, 798, and 952 of title 18 and section 4(b) of the Subversive Activities Control Act of 1950 (50 U.S.C. 783(b)). The defini-

tions, requirements, obligations, rights, sanctions, and liabilities created by such Executive order and such statutory provisions are incorporated into this agreement and are controlling'; or

''(14) conduct, or cause to be conducted, an investigation, other than any ministerial or nondiscretionary fact finding activities necessary for the agency to perform its mission, of an employee or applicant for employment because of any activity protected under this section.''.

(3) BOARD AND COURT REVIEW OF ACTIONS RELATING TO SECURITY CLEARANCES.—

(A) IN GENERAL.—Chapter 77 of title 5, United States Code, is amended by inserting after section 7702 the following:

**''§ 7702a. Actions relating to security clearances**

''(a) In any appeal relating to the suspension, revocation, or other determination relating to a security clearance or access determination, the Merit Systems Protection Board or any reviewing court—

''(1) shall determine whether paragraph (8) or (9) of section 2302(b) was violated;

''(2) may not order the President or the designee of the President to restore a security clearance

or otherwise reverse a determination of clearance status or reverse an access determination; and

''(3) subject to paragraph (2), may issue declaratory relief and any other appropriate relief.

''(b)(1) If, in any final judgment, the Board or court declares that any suspension, revocation, or other determination with regards to a security clearance or access determination was made in violation of paragraph (8) or (9) of section 2302(b), the affected agency shall conduct a review of that suspension, revocation, access determination, or other determination, giving great weight to the Board or court judgment.

''(2) Not later than 30 days after any Board or court judgment declaring that a security clearance suspension, revocation, access determination, or other determination was made in violation of paragraph (8) or (9) of section 2302(b), the affected agency shall issue an unclassified report to the congressional committees of jurisdiction (with a classified annex if necessary), detailing the circumstances of the agency's security clearance suspension, revocation, other determination, or access determination. A report under this paragraph shall include any proposed agency action with regards to the security clearance or access determination.

''(c) An allegation that a security clearance or access determination was revoked or suspended in retaliation for a protected disclosure shall receive expedited review by the Office of Special Counsel, the Merit Systems Protection Board, and any reviewing court.

''(d) For purposes of this section, corrective action may not be ordered if the agency demonstrates by a preponderance of the evidence that it would have taken the same personnel action in the absence of such disclosure.''.

(B) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 77 of title 5, United States Code, is amended by inserting after the item relating to section 7702 the following:

''7702a. Actions relating to security clearances.''.

(e) EXCLUSION OF AGENCIES BY THE PRESIDENT.—Section 2302(a)(2)(C) of title 5, United States Code, is amended by striking clause (ii) and inserting the following:

''(ii)(I) the Federal Bureau of Investigation, the Office of the Director of National Intelligence, the Central Intelligence Agency, the Defense Intelligence Agency, the National Geospatial-Intelligence Agency, and the National Security Agency; and

''(II) as determined by the President, any executive agency or unit thereof the principal

function of which is the conduct of foreign intelligence or counterintelligence activities, if the determination (as that determination relates to a personnel action) is made before that personnel action; or''.

(f) ATTORNEY FEES.—Section 1204(m)(1) of title 5, United States Code, is amended by striking ''agency involved'' and inserting ''agency where the prevailing party is employed or has applied for employment''.

(g) DISCIPLINARY ACTION.—Section 1215(a)(3) of title 5, United States Code, is amended to read as follows:

''(3)(A) A final order of the Board may impose—

''(i) disciplinary action consisting of removal, reduction in grade, debarment from Federal employment for a period not to exceed 5 years, suspension, or reprimand;

''(ii) an assessment of a civil penalty not to exceed $1,000; or

''(iii) any combination of disciplinary actions described under clause (i) and an assessment described under clause (ii).

''(B) In any case in which the Board finds that an employee has committed a prohibited personnel practice under paragraph (8) or (9) of section

2302(b), the Board shall impose disciplinary action if the Board finds that the activity protected under paragraph (8) or (9) of section 2302(b) was a significant motivating factor, even if other factors also motivated the decision, for the employee's decision to take, fail to take, or threaten to take or fail to take a personnel action, unless that employee demonstrates, by preponderance of evidence, that the employee would have taken, failed to take, or threatened to take or fail to take the same personnel action, in the absence of such protected activity.''.

(h) SPECIAL COUNSEL AMICUS CURIAE APPEARANCE.—Section 1212 of title 5, United States Code, is amended by adding at the end the following:

''(h)(1) The Special Counsel is authorized to appear as amicus curiae in any action brought in a court of the United States related to any civil action brought in connection with section 2302(b) (8) or (9), or subchapter III of chapter 73, or as otherwise authorized by law. In any such action, the Special Counsel is authorized to present the views of the Special Counsel with respect to compliance with section 2302(b) (8) or (9) or subchapter III of chapter 77 and the impact court decisions would have on the enforcement of such provisions of law.

''(2) A court of the United States shall grant the application of the Special Counsel to appear in any such action for the purposes described in subsection (a).''.

(i) JUDICIAL REVIEW.—

(1) IN GENERAL.—Section 7703(b)(1) of title 5, United States Code, is amended to read as follows:

''(b)(1)(A) Except as provided in subparagraph (B) and paragraph (2), a petition to review a final order or final decision of the Board shall be filed in the United States Court of Appeals for the Federal Circuit. Notwithstanding any other provision of law, any petition for review must be filed within 60 days after the date the petitioner received notice of the final order or decision of the Board.

''(B) During the 5-year period beginning on the effective date of this subsection, a petition to review a final order or final decision of the Board in a case alleging a violation of paragraph (8) or (9) of section 2302(b) shall be filed in the United States Court of Appeals for the Federal Circuit or any court of appeals of competent jurisdiction as provided under subsection (b)(2).''.

(2) REVIEW OBTAINED BY OFFICE OF PERSONNEL MANAGEMENT.—Section 7703(d) of title 5, United States Code, is amended to read as follows:

''(d)(1) Except as provided under paragraph (2), this paragraph shall apply to any review obtained by the Director of the Office of Personnel Management. The Director of the Office of Personnel Management may obtain review of any final order or decision of the Board by filing, within 60 days after the date the Director received notice of the final order or decision of the Board, a petition for judicial review in the United States Court of Appeals for the Federal Circuit if the Director determines, in his discretion, that the Board erred in interpreting a civil service law, rule, or regulation affecting personnel management and that the Board's decision will have a substantial impact on a civil service law, rule, regulation, or policy directive. If the Director did not intervene in a matter before the Board, the Director may not petition for review of a Board decision under this section unless the Director first petitions the Board for a reconsideration of its decision, and such petition is denied. In addition to the named respondent, the Board and all other parties to the proceedings before the Board shall have the right to appear in the proceeding before the Court of Appeals. The granting of the petition for judicial review shall be at the discretion of the Court of Appeals.

''(2) During the 5-year period beginning on the effective date of this subsection, this paragraph shall apply to

any review relating to paragraph (8) or (9) of section 2302(b) obtained by the Director of the Office of Personnel Management. The Director of the Office of Personnel Management may obtain review of any final order or decision of the Board by filing, within 60 days after the date the Director received notice of the final order or decision of the Board, a petition for judicial review in the United States Court of Appeals for the Federal Circuit or any court of appeals of competent jurisdiction as provided under subsection (b)(2) if the Director determines, in his discretion, that the Board erred in interpreting paragraph (8) or (9) of section 2302(b). If the Director did not intervene in a matter before the Board, the Director may not petition for review of a Board decision under this section unless the Director first petitions the Board for a reconsideration of its decision, and such petition is denied. In addition to the named respondent, the Board and all other parties to the proceedings before the Board shall have the right to appear in the proceeding before the court of appeals. The granting of the petition for judicial review shall be at the discretion of the Court of Appeals.''.

(j) NONDISCLOSURE POLICIES, FORMS, AND AGREEMENTS.—

(1) IN GENERAL.—

(A) REQUIREMENT.—Each agreement in Standard Forms 312 and 4414 of the Government and any other nondisclosure policy, form, or agreement of the Government shall contain the following statement: ''These restrictions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by Executive Order No. 12958; section 7211 of title 5, United States Code (governing disclosures to Congress); section 1034 of title 10, United States Code (governing disclosure to Congress by members of the military); section 2302(b)(8) of title 5, United States Code (governing disclosures of illegality, waste, fraud, abuse or public health or safety threats); the Intelligence Identities Protection Act of 1982 (50 U.S.C. 421 et seq.) (governing disclosures that could expose confidential Government agents); and the statutes which protect against disclosure that may compromise the national security, including sections 641, 793, 794, 798, and 952 of title 18, United States Code, and section 4(b) of the Subversive Activities Act of 1950 (50 U.S.C. 783(b)). The definitions, requirements, obliga-

tions, rights, sanctions, and liabilities created by such Executive order and such statutory provisions are incorporated into this agreement and are controlling.''.

(B) ENFORCEABILITY.—Any nondisclosure policy, form, or agreement described under subparagraph (A) that does not contain the statement required under subparagraph (A) may not be implemented or enforced to the extent such policy, form, or agreement is inconsistent with that statement.

(2) PERSONS OTHER THAN GOVERNMENT EMPLOYEES.—Notwithstanding paragraph (1), a nondisclosure policy, form, or agreement that is to be executed by a person connected with the conduct of an intelligence or intelligence-related activity, other than an employee or officer of the United States Government, may contain provisions appropriate to the particular activity for which such document is to be used. Such form or agreement shall, at a minimum, require that the person will not disclose any classified information received in the course of such activity unless specifically authorized to do so by the United States Government. Such nondisclosure forms shall also make it clear that such forms do

not bar disclosures to Congress or to an authorized official of an executive agency or the Department of Justice that are essential to reporting a substantial violation of law.

(k) CLARIFICATION OF WHISTLEBLOWER RIGHTS FOR CRITICAL INFRASTRUCTURE INFORMATION.—Section 214(c) of the Homeland Security Act of 2002 (6 U.S.C. 133(c)) is amended by adding at the end the following: ''For purposes of this section a permissible use of independently obtained information includes the disclosure of such information under section 2302(b)(8) of title 5, United States Code.''.

(l) ADVISING EMPLOYEES OF RIGHTS.—Section 2302(c) of title 5, United States Code, is amended by inserting '', including how to make a lawful disclosure of information that is specifically required by law or Executive order to be kept secret in the interest of national defense or the conduct of foreign affairs to the Special Counsel, the Inspector General of an agency, Congress, or other agency employee designated to receive such disclosures'' after ''chapter 12 of this title''.

(m) SCOPE OF DUE PROCESS.—

(1) SPECIAL COUNSEL.—Section 1214(b)(4)(B)(ii) of title 5, United States Code, is amended by inserting '', after a finding that a pro-

tected disclosure was a contributing factor,'' after ''ordered if''.

(2) INDIVIDUAL ACTION.—Section 1221(e)(2) of title 5, United States Code, is amended by inserting '', after a finding that a protected disclosure was a contributing factor,'' after ''ordered if''.

# Subtitle C—Importation of Prescription Drugs

**SEC. 121. SHORT TITLE.**

This subtitle may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2007''.

**SEC. 122. FINDINGS.**

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Ad-

ministration will provide a level of safety to American consumers that they do not currently enjoy;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

**SEC. 123. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.**

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

**SEC. 124. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 123, is further amended by inserting after section 803 the following:

**"SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.**

"(a) IMPORTATION OF PRESCRIPTION DRUGS.—

"(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

"(A) the limitation on importation that is established in section 801(d)(1) is waived; and

"(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

"(2) IMPORTERS.—A qualifying drug may not be imported under paragraph (1) unless—

"(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or

"(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

"(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is im-

ported or offered for import into the United States—

"(A) by a registered importer; or

"(B) from a registered exporter to an individual.

"(4) DEFINITIONS.—

"(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

"(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

"(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

"(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

"(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a

drug for which there is a corresponding U.S. label drug.

''(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

''(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

''(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

''(iii) is approved under section 505(c); and

''(iv) is not—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(aa) a therapeutic DNA plasmid product;

"(bb) a therapeutic synthetic peptide product;

"(cc) a monoclonal antibody product for in vivo use; and

"(dd) a therapeutic recombinant DNA-derived product;

"(III) an infused drug, including a peritoneal dialysis solution;

"(IV) an injected drug;

"(V) a drug that is inhaled during surgery;

"(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

"(VII) a sterile opthlamic drug intended for topical use on or in the eye.

"(D) OTHER DEFINITIONS.—For purposes of this section:

"(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country

designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from

the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

''(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

''(II) does not include a person authorized to import drugs under section 801(d)(1).

''(E) PERMITTED COUNTRY.—The term 'permitted country' means—

''(i) Australia;

''(ii) Canada;

''(iii) a member country of the European Union, but does not include a member country with respect to which—

''(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

''(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the reg-

ulation of human pharmaceutical products expires;

"(iv) Japan;

"(v) New Zealand;

"(vi) Switzerland; and

"(vii) a country in which the Secretary determines the following requirements are met:

"(I) The country has statutory or regulatory requirements—

"(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

"(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations,

conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

''(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

''(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

"(III) The importation of drugs to the United States from the country will not adversely affect public health.

"(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

"(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

"(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

"(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

"(B) Such information as the Secretary determines to be necessary to demonstrate that

the registrant is in compliance with registration conditions under—

"(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

"(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

"(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B)

against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter—

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000;

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to

the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a quali-

fying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary

has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(5) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; and

''(B)(i) inspected by the Secretary; or

''(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufac-

tured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards

under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting

the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

"(A) the exporter agrees to permit the Secretary—

"(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

"(ii) to have access, including on a day-to-day basis, to—

"(I) records of the exporter that relate to the export of such drugs, including financial records; and

"(II) samples of such drugs;

"(iii) to carry out the duties described in paragraph (3); and

"(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

"(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the

functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

"(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

"(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

"(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a sta-

tistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

"(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

"(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

"(E) the country from which the drug is shipped;

"(F) the name and complete contact information for the shipper of the drug;

"(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

"(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

"(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

"(J) such other information as the Secretary may require by regulation.

"(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved

agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business

of the importer at which a qualifying drug is initially received after importation.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

''(C) Reviewing notices under paragraph (4).

''(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

''(E) Determining whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in

the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

''(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

"(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

"(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Sec-

retary by each registered importer under subsection (b)(1)(J).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under

paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in

the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in

subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses

of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection

(a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

"(aa) the variations provided for in the application; and

"(bb) any difference in labeling (except ingredient labeling); or

"(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

"(aa) the variations provided for in the application; and

"(bb) any difference in labeling (except ingredient labeling).

"(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to

which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate,

with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Subject to appropriations Acts, fees collected by the Secretary under the preceding sentence are available only to

the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(v) TIMING OF SUBMISSION OF NOTICES.—

''(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

"(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary shall—

"(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

"(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the

U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a

mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

"(cc) the importation of the drug is permitted under subsection (a).

"(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

"(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

"(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

"(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by

the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the qualifying drug

for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the qualifying drug involved continues in effect.

''(ii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

"(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

"(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

"(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

"(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

"(ii) may not order that the importation of the qualifying drug involved cease; and

"(iii) shall promptly notify registered exporters and registered importers.

"(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

"(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

"(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

"(II) each active ingredient of the other drug is related to an active

ingredient of the drug approved under section 505(b), as defined in clause (v).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

"(IV) include such additional information as the Secretary may require.

"(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

"(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

"(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

"(I) the same; or

"(II) different salts, esters, or complexes of the same moiety.

"(3) SECTION 502; LABELING.—

"(A) IMPORTATION BY REGISTERED IMPORTER.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

"(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

"(II) the name of the manufacturer and location of the manufacturer;

"(III) the lot number assigned by the manufacturer;

"(IV) the name, location, and registration number of the importer; and

"(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

"(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

"(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

"(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

"(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

"(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

"(IV) if the inactive ingredients of the qualifying drug are different

from the inactive ingredients for the U.S. label drug, include—

"(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

"(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e).

"(B) IMPORTATION BY INDIVIDUAL.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regula-

tions promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

"(I) directions for use by the consumer;

"(II) the lot number assigned by the manufacturer;

"(III) the name and registration number of the exporter;

"(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

"(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

"(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the

ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under paragraph (2) (C) or (D).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(F) The Secretary becomes aware that—

''(i) the drug may be counterfeit;

"(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

"(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

"(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

"(H) The Secretary has under section 505(e) withdrawn approval of the drug.

"(I) The manufacturer of the drug has instituted a recall of the drug.

"(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

"(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

"(i) The shipping container for such drug does not bear the markings required under subsection (d)(2).

"(ii) The markings on the shipping container appear to be counterfeit.

"(iii) The shipping container or markings appear to have been tampered with.

"(h) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

"(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

"(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

"(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

"(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

''(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

"(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

"(E) The quantity of the drug does not exceed a 90-day supply.

"(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

"(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the

exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not more than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a phar-

macist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

"(A) The lot number assigned by the manufacturer.

"(B) The name and registration number of the importer.

"(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

"(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

"(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

"(ii) a list of the ingredients of the drug as would be required under section 502(e).

"(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

"(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

"(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

"(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the

United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug

under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under subsection (e) (3), (4), and (5) of section 4 of the Pharmaceutical Market Access and Drug Safety Act of 2007, knowingly

submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(ii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will

be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

"(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

"(3) AFFIRMATIVE DEFENSE.—

"(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

"(i) the person exporting or importing a qualifying drug into the United States under this section; or

"(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

"(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference de-

scribed in subparagraph (G) of paragraph (1) that—

"(i) the difference was required by the country in which the drug is distributed;

"(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

"(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

"(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

"(4) EFFECT OF SUBSECTION.—

"(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribu-

tion of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan,

or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and

with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

"(I) enjoin that practice;

"(II) enforce compliance with this subsection;

"(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

"(IV) obtain such other relief as the court may consider to be appropriate.

"(ii) NOTICE.—

"(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

"(aa) written notice of that action; and

"(bb) a copy of the complaint for that action.

"(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph,

if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph

(A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

"(i) conduct investigations;

"(ii) administer oaths or affirmations; or

"(iii) compel the attendance of witnesses or the production of documentary and other evidence.

"(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

"(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

"(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may

be served in any district in which the defendant—

"(i) is an inhabitant; or

"(ii) may be found.

"(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

"(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

''(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section,

or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i) (2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(2) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this Act.

(d) EXHAUSTION.—

(1) IN GENERAL.—Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

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

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this Act; and

(B) from permitted countries, as defined in such section 804, by importers registered under

such section 804 on the date that is 1 year after the date of enactment of this Act.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this Act will have priority during the 90 day period that begins on such date of enactment.

(B) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this Act shall not serve as a basis, in whole or in part, for disapproving a

registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) SECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning

on a date that is 2 or more years after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers

with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES FOR DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this Act that is required

under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) GUIDANCE ON SUBMISSION DATES.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this Act and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A)

are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this Act shall be submitted to and reviewed by the Secretary

as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this Act, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this Act takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of

days in such fiscal year during which this Act is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

(i) the first fiscal year in which this Act takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this Act is effective bears to 365; and

(ii) the second fiscal year in which this Act is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this Act is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during

the 4-month period from October 1 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this Act is in effect. Such reestimate shall be equal to—

(I) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this Act is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by reg-

istered importers during such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made

and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER CONTROL.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this Act (or an amendment made by this Act), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Govern-

ment of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) IMPLEMENTATION OF SECTION 804.—

(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall,

in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this Act;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this Act (and the amendments made by this Act), the practices and policies of the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this Act), including any pending investigations or civil actions under such section.

**SEC. 125. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 124, is further amended by adding at the end the following section:

**"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.**

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by

the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE OF PROCEDURES.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(f) RULE OF CONSTRUCTION.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this Act.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this Act.

**SEC. 126. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.**

(a) STRIKING OF EXEMPTIONS; APPLICABILITY TO REGISTERED EXPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

(C) by striking subparagraph (B) and inserting the following:

''(B) The fact that a drug subject to subsection (b) is exported from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which

the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2010.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 4.

(3) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this Act.

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2010.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this Act.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this Act, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(bb) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this

paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

**SEC. 127. INTERNET SALES OF PRESCRIPTION DRUGS.**

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

**"SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

''(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

''(C) such site, or any other Internet site used by such person for purposes of sales of a

prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

"(i) are not intended to be accessed by purchasers or prospective purchasers; or

"(ii) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

"(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

"(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

"(i) The name of such person.

"(ii) Each State in which the person is authorized by law to dispense prescription drugs.

"(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of

business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

''(i) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relation-

ship with the patient for purposes of this section if—

"(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

"(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

"(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

"(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner

without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(e) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern

or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in

this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State

to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

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

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to

such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

"(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

"(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

"(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

"(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.".

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (op-

erated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic

Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

**SEC. 128. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.**

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund

transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person en-

gaged in the operation of an unregistered foreign pharmacy, of—

"(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

"(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

"(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

"(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

"(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

"(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

"(6) OTHER DEFINITIONS.—

"(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

"(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

"(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

"(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

"(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

"(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

"(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

"(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

"(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

"(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

"(A) REGULATIONS.—The Board shall promulgate regulations requiring—

"(i) an operator of a credit card system;

"(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

"(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

"(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor trans-

actions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action

under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(I) The extent to which the payment system or person knowingly permits restricted transactions.

''(II) The history of the payment system or person in connection with permitting restricted transactions.

''(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents

and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (g)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as

added by subsection (a), not later than 90 days after the date of enactment of this Act.

**SEC. 129. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.**

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

**SEC. 130. SEVERABILITY.**

If any provision of this subtitle, an amendment by this subtitle, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this subtitle, the amendments made by this subtitle, and the application of the provisions of such to any person or circumstance shall not affected thereby.

# Subtitle D—Royalties Under Offshore Oil and Gas Leases

**SEC. 141. PRICE THRESHOLDS FOR ROYALTY SUSPENSION PROVISIONS.**

(a) IN GENERAL.—The Secretary of the Interior (referred to in this subtitle as the ''Secretary'') shall agree

to a request by any lessee to amend any lease issued for any Central and Western Gulf of Mexico tract during the period of January 1, 1998, through December 31, 1999, to incorporate price thresholds applicable to royalty suspension provisions, that are equal to or less than the price thresholds described in clauses (v) through (vii) of section 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)).

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Any lease amended under subsection (a) shall impose the new or revised price thresholds effective beginning October 1, 2006.

(2) EXISTING PROVISIONS.—Existing lease provisions in a lease amended under subsection (a) shall apply through September 30, 2006.

**SEC. 142. CLARIFICATION OF AUTHORITY TO IMPOSE PRICE THRESHOLDS FOR CERTAIN LEASE SALES.**

Congress reaffirms the authority of the Secretary under section 8(a)(1)(H) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(1)(H)) to vary, based on the price of production from a lease, the suspension of royalties under any lease subject to section 304 of the Outer Continental Shelf Deep Water Royalty Relief Act (43 U.S.C. 1337; Public Law 104–58).

**SEC. 143. ELIGIBILITY FOR NEW LEASES AND THE TRANSFER OF LEASES; CONSERVATION OF RESOURCES FEES.**

(a) DEFINITIONS.—In this section—

(1) COVERED LEASE.—The term ''covered lease'' means a lease for oil or gas production in the Gulf of Mexico that is—

(A) in existence on the date of enactment of this Act;

(B) issued by the Department of the Interior under section 304 of the Outer Continental Shelf Deep Water Royalty Relief Act (43 U.S.C. 1337 note; Public Law 104–58); and

(C) not subject to limitations on royalty relief based on market price that are equal to or less than the price thresholds described in clauses (v) through (vii) of section 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)).

(2) LESSEE.—The term ''lessee'' includes any person or other entity that controls, is controlled by, or is in or under common control with, a lessee.

(b) ISSUANCE OF NEW LEASES.—

(1) IN GENERAL.—The Secretary shall not issue any new lease that authorizes the production of oil or natural gas in the Gulf of Mexico under the

Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.) to a person described in paragraph (2) unless—

(A) the person has renegotiated each covered lease with respect to which the person is a lessee, to modify the payment responsibilities of the person to include price thresholds that are equal to or less than the price thresholds described in clauses (v) through (vii) of section 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)); or

(B) the person has—

(i) paid all fees established by the Secretary under subsection (c) that are due with respect to each covered lease for which the person is a lessee; or

(ii) entered into an agreement with the Secretary under which the person is obligated to pay the fees.

(2) PERSONS DESCRIBED.—A person referred to in paragraph (1) is—

(A) a lessee that—

(i) holds a covered lease on the date on which the Secretary considers the issuance of the new lease; or

(ii) was issued a covered lease before the date of enactment of this Act, but transferred the covered lease to another person or entity (including a subsidiary or affiliate of the lessee) after the date of enactment of this Act; or

(B) any other person or entity who has any direct or indirect interest in, or who derives any benefit from, a covered lease.

(3) MULTIPLE LESSEES.—

(A) IN GENERAL.—For purposes of paragraph (1), if there are multiple lessees that own a share of a covered lease, the Secretary may implement separate agreements with any lessee with a share of the covered lease that modifies the payment responsibilities with respect to the share of the lessee to include price thresholds that are equal to or less than the price thresholds described in clauses (v) through (vii) of section 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)).

(B) TREATMENT OF SHARE AS COVERED LEASE.—Beginning on the effective date of an agreement under subparagraph (A), any share subject to the agreement shall not constitute a

covered lease with respect to any lessees that entered into the agreement.

(c) CONSERVATION OF RESOURCES FEES.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary shall establish, by regulation, a conservation of resources fee for producing Federal oil and gas leases in the Gulf of Mexico.

(2) PRODUCING LEASE FEE TERMS.—The fee under paragraph (1)—

(A) subject to subparagraph (C), shall apply to covered leases that are producing leases;

(B) shall be set at $9 per barrel for oil and $1.25 per million Btu for gas, respectively, in 2005 dollars; and

(C) shall apply only to production of oil or gas occurring—

(i) in any calendar year in which the arithmetic average of the daily closing prices for light sweet crude oil on the New York Mercantile Exchange (NYMEX) exceeds $34.73 per barrel for oil and $4.34 per million Btu for gas in 2005 dollars; and

(ii) on or after October 1, 2006.

(3) TREATMENT OF RECEIPTS.—Amounts received by the United States as fees under this subsection shall be treated as offsetting receipts.

(d) TRANSFERS.—A lessee or any other person who has any direct or indirect interest in, or who derives a benefit from, a lease shall not be eligible to obtain by sale or other transfer (including through a swap, spinoff, servicing, or other agreement) any covered lease, the economic benefit of any covered lease, or any other lease for the production of oil or natural gas in the Gulf of Mexico under the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.), unless—

(1) the lessee or other person has—

(A) renegotiated all covered leases of the lessee or other person; and

(B) entered into an agreement with the Secretary to modify the terms of all covered leases of the lessee or other person to include limitations on royalty relief based on market prices that are equal to or less than the price thresholds described in clauses (v) through (vii) of section 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)); or

(2) the lessee or other person has—

(A) paid all fees established by the Secretary under subsection (c) that are due with respect to each covered lease for which the person is a lessee; or

(B) entered into an agreement with the Secretary under which the person is obligated to pay the fees.

# TITLE II—REVENUE ENHANCEMENTS

**SEC. 200. AMENDMENT OF 1986 CODE.**

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

## Subtitle A—Rescission of Various Tax Cuts for Millionaire Taxpayers

**SEC. 201. REPEAL OF TOP INCOME TAX RATE REDUCTION FOR TAXPAYERS WITH $1,000,000 OR MORE OF TAXABLE INCOME.**

(a) IN GENERAL.—Section 1(i) (relating to rate reductions) is amended by redesignating paragraph (3) as paragraph (4) and by inserting after paragraph (2) the following new paragraph:

''(3) EXCEPTION FOR TAXPAYERS WITH TAXABLE INCOME OF $1,000,000, OR MORE.—Notwithstanding paragraph (2), in the case of taxable years beginning in a calender year after 2007, the last item in the fourth column of the table under paragraph (2) shall be applied by substituting '39.6%' for '35.0%' with respect to taxable income in excess of $1,000,000 ($500,000 in the case of taxpayers to whom subsection (d) applies).''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2007.

(c) APPLICATION OF EGTRRA SUNSET.—The amendment made by this section shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 to the same extent and in the same manner as the provision of such Act to which such amendment relates.

**SEC. 202. ELIMINATION OF THE SCHEDULED PHASEOUT OF THE LIMITATIONS ON PERSONAL EXEMPTIONS AND ITEMIZED DEDUCTIONS FOR TAXPAYERS EARNING IN EXCESS OF $1,000,000.**

(a) PERSONAL EXEMPTIONS.—Section 151(d)(3)(E) is amended by adding at the end the following new clause:

''(iii) EXCEPTION.—This subparagraph shall not apply with respect to any taxpayer whose adjusted gross income for the taxable year exceeds $1,000,000 ($500,000 in the case of a married individual filing a separate return).''.

(b) ITEMIZED DEDUCTIONS.—Section 68(f) amended by adding at the end the following new paragraph:

''(3) EXCEPTION.—This subsection shall not apply with respect to any taxpayer whose adjusted gross income for the taxable year exceeds $1,000,000 ($500,000 in the case of a married individual filing a separate return).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2007.

(d) APPLICATION OF EGTRRA SUNSET.—The amendments made by this section shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 to the same extent and in the same manner as the provision of such Act to which such amendment relates.

**SEC. 203. MODIFICATION OF TAX RATES ON CAPITAL GAINS AND DIVIDENDS FOR TAXPAYERS WITH $1,000,000 OR MORE OF TAXABLE INCOME.**

(a) IN GENERAL.—Section 1(h) is amended by adding at the end the following new paragraph:

''(12) MODIFIED RATES FOR INDIVIDUALS WITH $1,000,000 OR MORE OF TAXABLE INCOME.—If a taxpayer has taxable income of $1,000,000 ($500,000 in the case of taxpayers to whom subsection (d) applies) or more for any taxable year—

''(A) paragraph (11) (relating to dividends taxed as capital gain) shall not apply to any qualified dividend income of the taxpayer for the taxable year, and

''(B) paragraph (1)(C) shall be applied by substituting '20 percent' for '15 percent' with respect to the adjusted net capital gain of the taxpayer for the taxable year, determined by only taking into account gain or loss properly allocable to the portion of the taxable year after December 31, 2007.''

(b) APPLICATION TO MINIMUM TAX.—Section 55(b)(3) is amended by adding at the end the following new sentence: ''In the case of a taxpayer with alternative minimum taxable income of $1,000,000 ($500,000 in the case of taxpayers to whom section 1(d) applies) or more

for any taxable year, the rules of section 1(h)(12) shall apply for purposes of this paragraph.''

(c) EFFECTIVE DATES.—

(1) CAPITAL GAINS.—Section 1(h)(12)(B) of the Internal Revenue Code of 1986 (as added by paragraph (1)) shall apply to taxable years beginning after December 31, 2007.

(2) DIVIDEND RATES.—Section 1(h)(12)(A) of such Code (as added by paragraph (1)) shall apply to dividends received after December 31, 2007.

(d) APPLICATION OF JGTRRA SUNSET.—The amendments made by this section shall be subject to section 303 of the Jobs and Growth Tax Relief Reconciliation Act of 2003 to the same extent and in the same manner as the provision of such Act to which such amendment relates.

# Subtitle B—Provisions to Discourage Offshore Shelters and Expatriation

### SEC. 211. TAXATION OF INCOME OF CONTROLLED FOREIGN CORPORATIONS ATTRIBUTABLE TO IMPORTED PROPERTY.

(a) GENERAL RULE.—Subsection (a) of section 954 (defining foreign base company income) is amended by striking ''and'' at the end of paragraph (4), by striking the period at the end of paragraph (5) and inserting '',

and'', and by adding at the end the following new paragraph:

''(6) imported property income for the taxable year (determined under subsection (j) and reduced as provided in subsection (b)(5)).''.

(b) DEFINITION OF IMPORTED PROPERTY INCOME.—Section 954 is amended by adding at the end the following new subsection:

''(j) IMPORTED PROPERTY INCOME.—

''(1) IN GENERAL.—For purposes of subsection (a)(6), the term 'imported property income' means income (whether in the form of profits, commissions, fees, or otherwise) derived in connection with—

''(A) manufacturing, producing, growing, or extracting imported property;

''(B) the sale, exchange, or other disposition of imported property; or

''(C) the lease, rental, or licensing of imported property.

Such term shall not include any foreign oil and gas extraction income (within the meaning of section 907(c)) or any foreign oil related income (within the meaning of section 907(c)).

''(2) IMPORTED PROPERTY.—For purposes of this subsection—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'imported property' means property which is imported into the United States by the controlled foreign corporation or a related person.

"(B) IMPORTED PROPERTY INCLUDES CERTAIN PROPERTY IMPORTED BY UNRELATED PERSONS.—The term 'imported property' includes any property imported into the United States by an unrelated person if, when such property was sold to the unrelated person by the controlled foreign corporation (or a related person), it was reasonable to expect that—

"(i) such property would be imported into the United States; or

"(ii) such property would be used as a component in other property which would be imported into the United States.

"(C) EXCEPTION FOR PROPERTY SUBSEQUENTLY EXPORTED.—The term 'imported property' does not include any property which is imported into the United States and which—

"(i) before substantial use in the United States, is sold, leased, or rented by the controlled foreign corporation or a re-

lated person for direct use, consumption, or disposition outside the United States; or

"(ii) is used by the controlled foreign corporation or a related person as a component in other property which is so sold, leased, or rented.

"(D) EXCEPTION FOR CERTAIN AGRICULTURAL COMMODITIES.—The term 'imported property' does not include any agricultural commodity which is not grown in the United States in commercially marketable quantities.

"(3) DEFINITIONS AND SPECIAL RULES.—

"(A) IMPORT.—For purposes of this subsection, the term 'import' means entering, or withdrawal from warehouse, for consumption or use. Such term includes any grant of the right to use intangible property (as defined in section 936(h)(3)(B)) in the United States.

"(B) UNITED STATES.—For purposes of this subsection, the term 'United States' includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

''(C) UNRELATED PERSON.—For purposes of this subsection, the term 'unrelated person' means any person who is not a related person with respect to the controlled foreign corporation.

''(D) COORDINATION WITH FOREIGN BASE COMPANY SALES INCOME.—For purposes of this section, the term 'foreign base company sales income' shall not include any imported property income.''.

(c) SEPARATE APPLICATION OF LIMITATIONS ON FOREIGN TAX CREDIT FOR IMPORTED PROPERTY INCOME.—

(1) IN GENERAL.—Paragraph (1) of section 904(d) (relating to separate application of section with respect to certain categories of income) is amended by striking ''and'' at the end of subparagraph (A), by redesignating subparagraph (B) as subparagraph (C), and by inserting after subparagraph (A) the following new subparagraph:

''(B) imported property income, and''.

(2) IMPORTED PROPERTY INCOME DEFINED.—Paragraph (2) of section 904(d) is amended by redesignating subparagraphs (I) and (J) as subparagraphs (J) and (K), respectively, and by inserting

after subparagraph (H) the following new subparagraph:

''(I) IMPORTED PROPERTY INCOME.—The term 'imported property income' means any income received or accrued by any person which is of a kind which would be imported property income (as defined in section 954(j)).''.

(3) CONFORMING AMENDMENT.—Clause (ii) of section 904(d)(2)(A) is amended by inserting ''or imported property income'' after ''passive category income''.

(d) TECHNICAL AMENDMENTS.—

(1) Clause (iii) of section 952(c)(1)(B) (relating to certain prior year deficits may be taken into account) is amended—

(A) by redesignating subclauses (II), (III), (IV), and (V) as subclauses (III), (IV), (V), and (VI), and

(B) by inserting after subclause (I) the following new subclause:

''(II) imported property income,''.

(2) Paragraph (5) of section 954(b) (relating to deductions to be taken into account) is amended by striking ''and the foreign base company oil related

income'' and inserting ''the foreign base company oil related income, and the imported property income''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years of foreign corporations beginning after the date of the enactment of this Act, and to taxable years of United States shareholders within which or with which such taxable years of such foreign corporations end.

**SEC. 212. TAX TREATMENT OF CONTROLLED FOREIGN CORPORATIONS ESTABLISHED IN TAX HAVENS.**

(a) IN GENERAL.—Subchapter C of chapter 80 (relating to provisions affecting more than one subtitle) is amended by adding at the end the following new section:

**''SEC. 7875. CONTROLLED FOREIGN CORPORATIONS IN TAX HAVENS TREATED AS DOMESTIC CORPORATIONS.**

''(a) GENERAL RULE.—If a controlled foreign corporation is a tax-haven CFC, then, notwithstanding section 7701(a)(4), such corporation shall be treated for purposes of this title as a domestic corporation.

''(b) TAX-HAVEN CFC.—For purposes of this section—

''(1) IN GENERAL.—The term 'tax-haven CFC' means, with respect to any taxable year, a foreign corporation which—

"(A) was created or organized under the laws of a tax-haven country, and

"(B) is a controlled foreign corporation (determined without regard to this section) for an uninterrupted period of 30 days or more during the taxable year.

"(2) EXCEPTION.—The term 'tax-haven CFC' does not include a foreign corporation for any taxable year if substantially all of its income for the taxable year is derived from the active conduct of trades or businesses within the country under the laws of which the corporation was created or organized.

"(c) TAX-HAVEN COUNTRY.—For purposes of this section—

"(1) IN GENERAL.—The term 'tax-haven country' means any of the following:

| | | |
|---|---|---|
| Andorra | Guernsey | Panama |
| Anguilla | Isle of Man | Samoa |
| Antigua and Barbuda | Jersey | San Marino |
| Aruba | Liberia | Federation of Saint Christopher and Nevis |
| Commonwealth of the Bahamas | Principality of Liechtenstein | Saint Lucia |
| Bahrain | Republic of the Maldives | Saint Vincent and the Grenadines |
| Barbados | Malta | Republic of the Seychelles |
| Belize | Republic of the Marshall Islands | Tonga |
| Bermuda | Mauritius | |
| British Virgin Islands | Principality of Monaco | |
| Cayman Islands | Montserrat | |
| Cook Islands | | |
| Cyprus | | |

| | | |
|---|---|---|
| Commonwealth of the Dominica | Republic of Nauru | Turks and Caicos |
| Gibraltar | Netherlands Antilles | Republic of Vanuatu |
| Grenada | Niue | |

''(2) SECRETARIAL AUTHORITY.—The Secretary may remove or add a foreign jurisdiction from the list of tax-haven countries under paragraph (1) if the Secretary determines such removal or addition is consistent with the purposes of this section.''.

(b) CONFORMING AMENDMENT.—The table of sections for subchapter C of chapter 80 is amended by adding at the end the following new item:

''Sec. 7875. Controlled foreign corporations in tax havens treated as domestic corporations.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

**SEC. 213. REVISION OF TAX RULES ON EXPATRIATION OF INDIVIDUALS.**

(a) IN GENERAL.—Subpart A of part II of subchapter N of chapter 1 is amended by inserting after section 877 the following new section:

**''SEC. 877A. TAX RESPONSIBILITIES OF EXPATRIATION.**

''(a) GENERAL RULES.—For purposes of this subtitle—

''(1) MARK TO MARKET.—Except as provided in subsections (d) and (f), all property of a covered expatriate to whom this section applies shall be treated as sold on the day before the expatriation date for its fair market value.

''(2) RECOGNITION OF GAIN OR LOSS.—In the case of any sale under paragraph (1)—

''(A) notwithstanding any other provision of this title, any gain arising from such sale shall be taken into account for the taxable year of the sale, and

''(B) any loss arising from such sale shall be taken into account for the taxable year of the sale to the extent otherwise provided by this title, except that section 1091 shall not apply to any such loss.

Proper adjustment shall be made in the amount of any gain or loss subsequently realized for gain or loss taken into account under the preceding sentence.

''(3) EXCLUSION FOR CERTAIN GAIN.—

''(A) IN GENERAL.—The amount which, but for this paragraph, would be includible in the gross income of any individual by reason of this section shall be reduced (but not below

zero) by $600,000. For purposes of this paragraph, allocable expatriation gain taken into account under subsection (f)(2) shall be treated in the same manner as an amount required to be includible in gross income.

''(B) COST-OF-LIVING ADJUSTMENT.—

''(i) IN GENERAL.—In the case of an expatriation date occurring in any calendar year after 2008, the $600,000 amount under subparagraph (A) shall be increased by an amount equal to—

''(I) such dollar amount, multiplied by

''(II) the cost-of-living adjustment determined under section 1(f)(3) for such calendar year, determined by substituting 'calendar year 2007' for 'calendar year 1992' in subparagraph (B) thereof.

''(ii) ROUNDING RULES.—If any amount after adjustment under clause (i) is not a multiple of $1,000, such amount shall be rounded to the next lower multiple of $1,000.

''(4) ELECTION TO CONTINUE TO BE TAXED AS UNITED STATES CITIZEN.—

''(A) IN GENERAL.—If a covered expatriate elects the application of this paragraph—

''(i) this section (other than this paragraph and subsection (i)) shall not apply to the expatriate, but

''(ii) in the case of property to which this section would apply but for such election, the expatriate shall be subject to tax under this title in the same manner as if the individual were a United States citizen.

''(B) REQUIREMENTS.—Subparagraph (A) shall not apply to an individual unless the individual—

''(i) provides security for payment of tax in such form and manner, and in such amount, as the Secretary may require,

''(ii) consents to the waiver of any right of the individual under any treaty of the United States which would preclude assessment or collection of any tax which may be imposed by reason of this paragraph, and

"(iii) complies with such other requirements as the Secretary may prescribe.

"(C) ELECTION.—An election under subparagraph (A) shall apply to all property to which this section would apply but for the election and, once made, shall be irrevocable. Such election shall also apply to property the basis of which is determined in whole or in part by reference to the property with respect to which the election was made.

"(b) ELECTION TO DEFER TAX.—

"(1) IN GENERAL.—If the taxpayer elects the application of this subsection with respect to any property treated as sold by reason of subsection (a), the payment of the additional tax attributable to such property shall be postponed until the due date of the return for the taxable year in which such property is disposed of (or, in the case of property disposed of in a transaction in which gain is not recognized in whole or in part, until such other date as the Secretary may prescribe).

"(2) DETERMINATION OF TAX WITH RESPECT TO PROPERTY.—For purposes of paragraph (1), the additional tax attributable to any property is an amount which bears the same ratio to the additional

tax imposed by this chapter for the taxable year solely by reason of subsection (a) as the gain taken into account under subsection (a) with respect to such property bears to the total gain taken into account under subsection (a) with respect to all property to which subsection (a) applies.

''(3) TERMINATION OF POSTPONEMENT.—No tax may be postponed under this subsection later than the due date for the return of tax imposed by this chapter for the taxable year which includes the date of death of the expatriate (or, if earlier, the time that the security provided with respect to the property fails to meet the requirements of paragraph (4), unless the taxpayer corrects such failure within the time specified by the Secretary).

''(4) SECURITY.—

''(A) IN GENERAL.—No election may be made under paragraph (1) with respect to any property unless adequate security is provided to the Secretary with respect to such property.

''(B) ADEQUATE SECURITY.—For purposes of subparagraph (A), security with respect to any property shall be treated as adequate security if—

''(i) it is a bond in an amount equal to the deferred tax amount under paragraph (2) for the property, or

''(ii) the taxpayer otherwise establishes to the satisfaction of the Secretary that the security is adequate.

''(5) WAIVER OF CERTAIN RIGHTS.—No election may be made under paragraph (1) unless the taxpayer consents to the waiver of any right under any treaty of the United States which would preclude assessment or collection of any tax imposed by reason of this section.

''(6) ELECTIONS.—An election under paragraph (1) shall only apply to property described in the election and, once made, is irrevocable. An election may be made under paragraph (1) with respect to an interest in a trust with respect to which gain is required to be recognized under subsection (f)(1).

''(7) INTEREST.—For purposes of section 6601—

''(A) the last date for the payment of tax shall be determined without regard to the election under this subsection, and

"(B) section 6621(a)(2) shall be applied by substituting '5 percentage points' for '3 percentage points' in subparagraph (B) thereof.

"(c) COVERED EXPATRIATE.—For purposes of this section—

"(1) IN GENERAL.—Except as provided in paragraph (2), the term 'covered expatriate' means an expatriate.

"(2) EXCEPTIONS.—An individual shall not be treated as a covered expatriate if—

"(A) the individual—

"(i) became at birth a citizen of the United States and a citizen of another country and, as of the expatriation date, continues to be a citizen of, and is taxed as a resident of, such other country, and

"(ii) has not been a resident of the United States (as defined in section 7701(b)(1)(A)(ii)) during the 5 taxable years ending with the taxable year during which the expatriation date occurs, or

"(B)(i) the individual's relinquishment of United States citizenship occurs before such individual attains age 18½, and

"(ii) the individual has been a resident of the United States (as so defined) for not more than 5 taxable years before the date of relinquishment.

"(d) EXEMPT PROPERTY; SPECIAL RULES FOR PENSION PLANS.—

"(1) EXEMPT PROPERTY.—This section shall not apply to the following:

"(A) UNITED STATES REAL PROPERTY INTERESTS.—Any United States real property interest (as defined in section 897(c)(1)), other than stock of a United States real property holding corporation which does not, on the day before the expatriation date, meet the requirements of section 897(c)(2).

"(B) SPECIFIED PROPERTY.—Any property or interest in property not described in subparagraph (A) which the Secretary specifies in regulations.

"(2) SPECIAL RULES FOR CERTAIN RETIREMENT PLANS.—

"(A) IN GENERAL.—If a covered expatriate holds on the day before the expatriation date any interest in a retirement plan to which this paragraph applies—

"(i) such interest shall not be treated as sold for purposes of subsection (a)(1), but

"(ii) an amount equal to the present value of the expatriate's nonforfeitable accrued benefit shall be treated as having been received by such individual on such date as a distribution under the plan.

"(B) TREATMENT OF SUBSEQUENT DISTRIBUTIONS.—In the case of any distribution on or after the expatriation date to or on behalf of the covered expatriate from a plan from which the expatriate was treated as receiving a distribution under subparagraph (A), the amount otherwise includible in gross income by reason of the subsequent distribution shall be reduced by the excess of the amount includible in gross income under subparagraph (A) over any portion of such amount to which this subparagraph previously applied.

"(C) TREATMENT OF SUBSEQUENT DISTRIBUTIONS BY PLAN.—For purposes of this title, a retirement plan to which this paragraph applies, and any person acting on the plan's behalf, shall treat any subsequent distribution de-

scribed in subparagraph (B) in the same manner as such distribution would be treated without regard to this paragraph.

''(D) APPLICABLE PLANS.—This paragraph shall apply to—

''(i) any qualified retirement plan (as defined in section 4974(c)),

''(ii) an eligible deferred compensation plan (as defined in section 457(b)) of an eligible employer described in section 457(e)(1)(A), and

''(iii) to the extent provided in regulations, any foreign pension plan or similar retirement arrangements or programs.

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

''(1) EXPATRIATE.—The term 'expatriate' means—

''(A) any United States citizen who relinquishes citizenship, and

''(B) any long-term resident of the United States who—

''(i) ceases to be a lawful permanent resident of the United States (within the meaning of section 7701(b)(6)), or

"(ii) commences to be treated as a resident of a foreign country under the provisions of a tax treaty between the United States and the foreign country and who does not waive the benefits of such treaty applicable to residents of the foreign country.

"(2) EXPATRIATION DATE.—The term 'expatriation date' means—

"(A) the date an individual relinquishes United States citizenship, or

"(B) in the case of a long-term resident of the United States, the date of the event described in clause (i) or (ii) of paragraph (1)(B).

"(3) RELINQUISHMENT OF CITIZENSHIP.—A citizen shall be treated as relinquishing United States citizenship on the earliest of—

"(A) the date the individual renounces such individual's United States nationality before a diplomatic or consular officer of the United States pursuant to paragraph (5) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(5)),

"(B) the date the individual furnishes to the United States Department of State a signed

statement of voluntary relinquishment of United States nationality confirming the performance of an act of expatriation specified in paragraph (1), (2), (3), or (4) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(1)–(4)),

''(C) the date the United States Department of State issues to the individual a certificate of loss of nationality, or

''(D) the date a court of the United States cancels a naturalized citizen's certificate of naturalization.

Subparagraph (A) or (B) shall not apply to any individual unless the renunciation or voluntary relinquishment is subsequently approved by the issuance to the individual of a certificate of loss of nationality by the United States Department of State.

''(4) LONG-TERM RESIDENT.—The term 'long-term resident' has the meaning given to such term by section 877(e)(2).

''(f) SPECIAL RULES APPLICABLE TO BENEFICIARIES' INTERESTS IN TRUST.—

''(1) IN GENERAL.—Except as provided in paragraph (2), if an individual is determined under para-

graph (3) to hold an interest in a trust on the day before the expatriation date—

"(A) the individual shall not be treated as having sold such interest,

"(B) such interest shall be treated as a separate share in the trust, and

"(C)(i) such separate share shall be treated as a separate trust consisting of the assets allocable to such share,

"(ii) the separate trust shall be treated as having sold its assets on the day before the expatriation date for their fair market value and as having distributed all of its assets to the individual as of such time, and

"(iii) the individual shall be treated as having recontributed the assets to the separate trust.

Subsection (a)(2) shall apply to any income, gain, or loss of the individual arising from a distribution described in subparagraph (C)(ii). In determining the amount of such distribution, proper adjustments shall be made for liabilities of the trust allocable to an individual's share in the trust.

"(2) SPECIAL RULES FOR INTERESTS IN QUALIFIED TRUSTS.—

"(A) IN GENERAL.—If the trust interest described in paragraph (1) is an interest in a qualified trust—

"(i) paragraph (1) and subsection (a) shall not apply, and

"(ii) in addition to any other tax imposed by this title, there is hereby imposed on each distribution with respect to such interest a tax in the amount determined under subparagraph (B).

"(B) AMOUNT OF TAX.—The amount of tax under subparagraph (A)(ii) shall be equal to the lesser of—

"(i) the highest rate of tax imposed by section 1(e) for the taxable year which includes the day before the expatriation date, multiplied by the amount of the distribution, or

"(ii) the balance in the deferred tax account immediately before the distribution determined without regard to any increases under subparagraph (C)(ii) after the 30th day preceding the distribution.

"(C) DEFERRED TAX ACCOUNT.—For purposes of subparagraph (B)(ii)—

''(i) OPENING BALANCE.—The opening balance in a deferred tax account with respect to any trust interest is an amount equal to the tax which would have been imposed on the allocable expatriation gain with respect to the trust interest if such gain had been included in gross income under subsection (a).

''(ii) INCREASE FOR INTEREST.—The balance in the deferred tax account shall be increased by the amount of interest determined (on the balance in the account at the time the interest accrues), for periods after the 90th day after the expatriation date, by using the rates and method applicable under section 6621 for underpayments of tax for such periods, except that section 6621(a)(2) shall be applied by substituting '5 percentage points' for '3 percentage points' in subparagraph (B) thereof.

''(iii) DECREASE FOR TAXES PREVIOUSLY PAID.—The balance in the tax deferred account shall be reduced—

"(I) by the amount of taxes imposed by subparagraph (A) on any distribution to the person holding the trust interest, and

"(II) in the case of a person holding a nonvested interest, to the extent provided in regulations, by the amount of taxes imposed by subparagraph (A) on distributions from the trust with respect to nonvested interests not held by such person.

"(D) ALLOCABLE EXPATRIATION GAIN.—For purposes of this paragraph, the allocable expatriation gain with respect to any beneficiary's interest in a trust is the amount of gain which would be allocable to such beneficiary's vested and nonvested interests in the trust if the beneficiary held directly all assets allocable to such interests.

"(E) TAX DEDUCTED AND WITHHELD.—

"(i) IN GENERAL.—The tax imposed by subparagraph (A)(ii) shall be deducted and withheld by the trustees from the distribution to which it relates.

''(ii) EXCEPTION WHERE FAILURE TO WAIVE TREATY RIGHTS.—If an amount may not be deducted and withheld under clause (i) by reason of the distributee failing to waive any treaty right with respect to such distribution—

''(I) the tax imposed by subparagraph (A)(ii) shall be imposed on the trust and each trustee shall be personally liable for the amount of such tax, and

''(II) any other beneficiary of the trust shall be entitled to recover from the distributee the amount of such tax imposed on the other beneficiary.

''(F) DISPOSITION.—If a trust ceases to be a qualified trust at any time, a covered expatriate disposes of an interest in a qualified trust, or a covered expatriate holding an interest in a qualified trust dies, then, in lieu of the tax imposed by subparagraph (A)(ii), there is hereby imposed a tax equal to the lesser of—

''(i) the tax determined under paragraph (1) as if the day before the expatriation date were the date of such cessation,

disposition, or death, whichever is applicable, or

''(ii) the balance in the tax deferred account immediately before such date.

Such tax shall be imposed on the trust and each trustee shall be personally liable for the amount of such tax and any other beneficiary of the trust shall be entitled to recover from the covered expatriate or the estate the amount of such tax imposed on the other beneficiary.

''(G) DEFINITIONS AND SPECIAL RULES.—For purposes of this paragraph—

''(i) QUALIFIED TRUST.—The term 'qualified trust' means a trust which is described in section 7701(a)(30)(E).

''(ii) VESTED INTEREST.—The term 'vested interest' means any interest which, as of the day before the expatriation date, is vested in the beneficiary.

''(iii) NONVESTED INTEREST.—The term 'nonvested interest' means, with respect to any beneficiary, any interest in a trust which is not a vested interest. Such interest shall be determined by assuming the maximum exercise of discretion in

favor of the beneficiary and the occurrence of all contingencies in favor of the beneficiary.

''(iv) ADJUSTMENTS.—The Secretary may provide for such adjustments to the bases of assets in a trust or a deferred tax account, and the timing of such adjustments, in order to ensure that gain is taxed only once.

''(v) COORDINATION WITH RETIREMENT PLAN RULES.—This subsection shall not apply to an interest in a trust which is part of a retirement plan to which subsection (d)(2) applies.

''(3) DETERMINATION OF BENEFICIARIES' INTEREST IN TRUST.—

''(A) DETERMINATIONS UNDER PARAGRAPH (1).—For purposes of paragraph (1), a beneficiary's interest in a trust shall be based upon all relevant facts and circumstances, including the terms of the trust instrument and any letter of wishes or similar document, historical patterns of trust distributions, and the existence of and functions performed by a trust protector or any similar adviser.

"(B) OTHER DETERMINATIONS.—For purposes of this section—

"(i) CONSTRUCTIVE OWNERSHIP.—If a beneficiary of a trust is a corporation, partnership, trust, or estate, the shareholders, partners, or beneficiaries shall be deemed to be the trust beneficiaries for purposes of this section.

"(ii) TAXPAYER RETURN POSITION.—A taxpayer shall clearly indicate on its income tax return—

"(I) the methodology used to determine that taxpayer's trust interest under this section, and

"(II) if the taxpayer knows (or has reason to know) that any other beneficiary of such trust is using a different methodology to determine such beneficiary's trust interest under this section.

"(g) TERMINATION OF DEFERRALS, ETC.—In the case of any covered expatriate, notwithstanding any other provision of this title—

''(1) any period during which recognition of income or gain is deferred shall terminate on the day before the expatriation date, and

''(2) any extension of time for payment of tax shall cease to apply on the day before the expatriation date and the unpaid portion of such tax shall be due and payable at the time and in the manner prescribed by the Secretary.

''(h) IMPOSITION OF TENTATIVE TAX.—

''(1) IN GENERAL.—If an individual is required to include any amount in gross income under subsection (a) for any taxable year, there is hereby imposed, immediately before the expatriation date, a tax in an amount equal to the amount of tax which would be imposed if the taxable year were a short taxable year ending on the expatriation date.

''(2) DUE DATE.—The due date for any tax imposed by paragraph (1) shall be the 90th day after the expatriation date.

''(3) TREATMENT OF TAX.—Any tax paid under paragraph (1) shall be treated as a payment of the tax imposed by this chapter for the taxable year to which subsection (a) applies.

''(4) DEFERRAL OF TAX.—The provisions of subsection (b) shall apply to the tax imposed by this

subsection to the extent attributable to gain includible in gross income by reason of this section.

''(i) SPECIAL LIENS FOR DEFERRED TAX AMOUNTS.—

''(1) IMPOSITION OF LIEN.—

''(A) IN GENERAL.—If a covered expatriate makes an election under subsection (a)(4) or (b) which results in the deferral of any tax imposed by reason of subsection (a), the deferred amount (including any interest, additional amount, addition to tax, assessable penalty, and costs attributable to the deferred amount) shall be a lien in favor of the United States on all property of the expatriate located in the United States (without regard to whether this section applies to the property).

''(B) DEFERRED AMOUNT.—For purposes of this subsection, the deferred amount is the amount of the increase in the covered expatriate's income tax which, but for the election under subsection (a)(4) or (b), would have occurred by reason of this section for the taxable year including the expatriation date.

''(2) PERIOD OF LIEN.—The lien imposed by this subsection shall arise on the expatriation date and continue until—

''(A) the liability for tax by reason of this section is satisfied or has become unenforceable by reason of lapse of time, or

''(B) it is established to the satisfaction of the Secretary that no further tax liability may arise by reason of this section.

''(3) CERTAIN RULES APPLY.—The rules set forth in paragraphs (1), (3), and (4) of section 6324A(d) shall apply with respect to the lien imposed by this subsection as if it were a lien imposed by section 6324A.

''(j) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this section.''.

(b) INCLUSION IN INCOME OF GIFTS AND BEQUESTS RECEIVED BY UNITED STATES CITIZENS AND RESIDENTS FROM EXPATRIATES.—Section 102 (relating to gifts, etc. not included in gross income) is amended by adding at the end the following new subsection:

''(d) GIFTS AND INHERITANCES FROM COVERED EXPATRIATES.—

''(1) IN GENERAL.—Subsection (a) shall not exclude from gross income the value of any property acquired by gift, bequest, devise, or inheritance from a covered expatriate after the expatriation date. For purposes of this subsection, any term used in this subsection which is also used in section 877A shall have the same meaning as when used in section 877A.

''(2) EXCEPTIONS FOR TRANSFERS OTHERWISE SUBJECT TO ESTATE OR GIFT TAX.—Paragraph (1) shall not apply to any property if either—

''(A) the gift, bequest, devise, or inheritance is—

''(i) shown on a timely filed return of tax imposed by chapter 12 as a taxable gift by the covered expatriate, or

''(ii) included in the gross estate of the covered expatriate for purposes of chapter 11 and shown on a timely filed return of tax imposed by chapter 11 of the estate of the covered expatriate, or

''(B) no such return was timely filed but no such return would have been required to be filed even if the covered expatriate were a cit-

izen or long-term resident of the United States.''.

(c) DEFINITION OF TERMINATION OF UNITED STATES CITIZENSHIP.—Section 7701(a) is amended by adding at the end the following new paragraph:

''(49) TERMINATION OF UNITED STATES CITIZENSHIP.—

''(A) IN GENERAL.—An individual shall not cease to be treated as a United States citizen before the date on which the individual's citizenship is treated as relinquished under section 877A(e)(3).

''(B) DUAL CITIZENS.—Under regulations prescribed by the Secretary, subparagraph (A) shall not apply to an individual who became at birth a citizen of the United States and a citizen of another country.''.

(d) INELIGIBILITY FOR VISA OR ADMISSION TO UNITED STATES.—

(1) IN GENERAL.—Section 212(a)(10)(E) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(10)(E)) is amended to read as follows:

''(E) FORMER CITIZENS NOT IN COMPLIANCE WITH EXPATRIATION REVENUE PROVISIONS.—Any alien who is a former citizen of

the United States who relinquishes United States citizenship (within the meaning of section 877A(e)(3) of the Internal Revenue Code of 1986) and who is not in compliance with section 877A of such Code (relating to expatriation) is inadmissible.''.

(2) AVAILABILITY OF INFORMATION.—

(A) IN GENERAL.—Section 6103(l) (relating to disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:

''(21) DISCLOSURE TO DENY VISA OR ADMISSION TO CERTAIN EXPATRIATES.—Upon written request of the Attorney General or the Attorney General's delegate, the Secretary shall disclose whether an individual is in compliance with section 877A (and if not in compliance, any items of noncompliance) to officers and employees of the Federal agency responsible for administering section 212(a)(10)(E) of the Immigration and Nationality Act solely for the purpose of, and to the extent necessary in, administering such section 212(a)(10)(E).''.

(B) SAFEGUARDS.—Section 6103(p)(4) (relating to safeguards) is amended by striking ''or (20)'' each place it appears and inserting ''(20), or (21)''.

(3) EFFECTIVE DATES.—The amendments made by this subsection shall apply to individuals who relinquish United States citizenship on or after the date of the enactment of this Act.

(e) CONFORMING AMENDMENTS.—

(1) Section 877 is amended by adding at the end the following new subsection:

''(h) APPLICATION.—This section shall not apply to an expatriate (as defined in section 877A(e)) whose expatriation date (as so defined) occurs on or after the date of the enactment of this subsection.''.

(2) Section 2107 is amended by adding at the end the following new subsection:

''(f) APPLICATION.—This section shall not apply to any expatriate subject to section 877A.''.

(3) Section 2501(a)(3) is amended by adding at the end the following new subparagraph:

''(C) APPLICATION.—This paragraph shall not apply to any expatriate subject to section 877A.''.

(4) Section 6039G(a) is amended by inserting ''or 877A'' after ''section 877(b)''.

(5) The second sentence of section 6039G(d) is amended by inserting ''or who relinquishes United States citizenship (within the meaning of section 877A(e)(3))'' after ''section 877(a))''.

(f) CLERICAL AMENDMENT.—The table of sections for subpart A of part II of subchapter N of chapter 1 is amended by inserting after the item relating to section 877 the following new item:

''Sec. 877A. Tax responsibilities of expatriation.''.

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendments made by this section shall apply to expatriates (within the meaning of section 877A(e) of the Internal Revenue Code of 1986, as added by this section) whose expatriation date (as so defined) occurs on or after the date of the enactment of this Act.

(2) GIFTS AND BEQUESTS.—Section 102(d) of the Internal Revenue Code of 1986 (as added by subsection (b)) shall apply to gifts and bequests received on or after the date of the enactment of this Act, from an individual or the estate of an individual whose expatriation date (as so defined) occurs after such date.

(3) DUE DATE FOR TENTATIVE TAX.—The due date under section 877A(h)(2) of the Internal Revenue Code of 1986, as added by this section, shall in no event occur before the 90th day after the date of the enactment of this Act.

**SEC. 214. MODIFICATION OF EFFECTIVE DATE OF LEASING PROVISIONS OF THE AMERICAN JOBS CREATION ACT OF 2004.**

(a) LEASES TO FOREIGN ENTITIES.—Section 849(b) of the American Jobs Creation Act of 2004 is amended by adding at the end the following new paragraph:

''(5) LEASES TO FOREIGN ENTITIES.—In the case of tax-exempt use property leased to a tax-exempt entity which is a foreign person or entity, the amendments made by this part shall apply to taxable years beginning after December 31, 2006, with respect to leases entered into on or before March 12, 2004.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect as if included in the enactment of the American Jobs Creation Act of 2004.

**SEC. 215. APPLICATION OF RULES TREATING INVERTED CORPORATIONS AS DOMESTIC CORPORATIONS TO CERTAIN TRANSACTIONS OCCURRING AFTER MARCH 20, 2002.**

(a) IN GENERAL.—Section 7874(b) (relating to inverted corporations treated as domestic corporations) is amended to read as follows:

''(b) INVERTED CORPORATIONS TREATED AS DOMESTIC CORPORATIONS.—

''(1) IN GENERAL.—Notwithstanding section 7701(a)(4), a foreign corporation shall be treated for purposes of this title as a domestic corporation if such corporation would be a surrogate foreign corporation if subsection (a)(2) were applied by substituting '80 percent' for '60 percent'.

''(2) SPECIAL RULE FOR CERTAIN TRANSACTIONS OCCURRING AFTER MARCH 20, 2002.—

''(A) IN GENERAL.—If—

''(i) paragraph (1) does not apply to a foreign corporation, but

''(ii) paragraph (1) would apply to such corporation if, in addition to the substitution under paragraph (1), subsection (a)(2) were applied by substituting 'March 20, 2002' for 'March 4, 2003' each place it appears,

then paragraph (1) shall apply to such corporation but only with respect to taxable years of such corporation beginning after December 31, 2006.

''(B) SPECIAL RULES.—Subject to such rules as the Secretary may prescribe, in the case of a corporation to which paragraph (1) applies by reason of this paragraph—

''(i) the corporation shall be treated, as of the close of its last taxable year beginning before January 1, 2007, as having transferred all of its assets, liabilities, and earnings and profits to a domestic corporation in a transaction with respect to which no tax is imposed under this title,

''(ii) the bases of the assets transferred in the transaction to the domestic corporation shall be the same as the bases of the assets in the hands of the foreign corporation, subject to any adjustments under this title for built-in losses,

''(iii) the basis of the stock of any shareholder in the domestic corporation shall be the same as the basis of the stock of the shareholder in the foreign corpora-

tion for which it is treated as exchanged, and

''(iv) the transfer of any earnings and profits by reason of clause (i) shall be disregarded in determining any deemed dividend or foreign tax creditable to the domestic corporation with respect to such transfer.

''(C) REGULATIONS.—The Secretary may prescribe such regulations as may be necessary or appropriate to carry out this paragraph, including regulations to prevent the avoidance of the purposes of this paragraph.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2006.

# Subtitle C—Economic Substance Doctrine

**SEC. 221. CLARIFICATION OF ECONOMIC SUBSTANCE DOCTRINE.**

(a) IN GENERAL.—Section 7701 is amended by redesignating subsection (o) as subsection (p) and by inserting after subsection (n) the following new subsection:

''(o) CLARIFICATION OF ECONOMIC SUBSTANCE DOCTRINE; ETC.—

''(1) GENERAL RULES.—

''(A) IN GENERAL.—In any case in which a court determines that the economic substance doctrine is relevant for purposes of this title to a transaction (or series of transactions), such transaction (or series of transactions) shall have economic substance only if the requirements of this paragraph are met.

''(B) DEFINITION OF ECONOMIC SUBSTANCE.—For purposes of subparagraph (A)—

''(i) IN GENERAL.—A transaction has economic substance only if—

''(I) the transaction changes in a meaningful way (apart from Federal tax effects) the taxpayer's economic position, and

''(II) the taxpayer has a substantial nontax purpose for entering into such transaction and the transaction is a reasonable means of accomplishing such purpose.

In applying subclause (II), a purpose of achieving a financial accounting benefit shall not be taken into account in determining whether a transaction has a sub-

stantial nontax purpose if the origin of such financial accounting benefit is a reduction of income tax.

''(ii) SPECIAL RULE WHERE TAXPAYER RELIES ON PROFIT POTENTIAL.—A transaction shall not be treated as having economic substance by reason of having a potential for profit unless—

''(I) the present value of the reasonably expected pre-tax profit from the transaction is substantial in relation to the present value of the expected net tax benefits that would be allowed if the transaction were respected, and

''(II) the reasonably expected pre-tax profit from the transaction exceeds a risk-free rate of return.

''(C) TREATMENT OF FEES AND FOREIGN TAXES.—Fees and other transaction expenses and foreign taxes shall be taken into account as expenses in determining pre-tax profit under subparagraph (B)(ii).

''(2) SPECIAL RULES FOR TRANSACTIONS WITH TAX-INDIFFERENT PARTIES.—

''(A) SPECIAL RULES FOR FINANCING TRANSACTIONS.—The form of a transaction which is in substance the borrowing of money or the acquisition of financial capital directly or indirectly from a tax-indifferent party shall not be respected if the present value of the deductions to be claimed with respect to the transaction is substantially in excess of the present value of the anticipated economic returns of the person lending the money or providing the financial capital. A public offering shall be treated as a borrowing, or an acquisition of financial capital, from a tax-indifferent party if it is reasonably expected that at least 50 percent of the offering will be placed with tax-indifferent parties.

''(B) ARTIFICIAL INCOME SHIFTING AND BASIS ADJUSTMENTS.—The form of a transaction with a tax-indifferent party shall not be respected if—

''(i) it results in an allocation of income or gain to the tax-indifferent party in excess of such party's economic income or gain, or

"(ii) it results in a basis adjustment or shifting of basis on account of overstating the income or gain of the tax-indifferent party.

"(3) DEFINITIONS AND SPECIAL RULES.—For purposes of this subsection—

"(A) ECONOMIC SUBSTANCE DOCTRINE.—The term 'economic substance doctrine' means the common law doctrine under which tax benefits under subtitle A with respect to a transaction are not allowable if the transaction does not have economic substance or lacks a business purpose.

"(B) TAX-INDIFFERENT PARTY.—The term 'tax-indifferent party' means any person or entity not subject to tax imposed by subtitle A. A person shall be treated as a tax-indifferent party with respect to a transaction if the items taken into account with respect to the transaction have no substantial impact on such person's liability under subtitle A.

"(C) EXCEPTION FOR PERSONAL TRANSACTIONS OF INDIVIDUALS.—In the case of an individual, this subsection shall apply only to transactions entered into in connection with a

trade or business or an activity engaged in for the production of income.

''(D) TREATMENT OF LESSORS.—In applying paragraph (1)(B)(ii) to the lessor of tangible property subject to a lease—

''(i) the expected net tax benefits with respect to the leased property shall not include the benefits of—

''(I) depreciation,

''(II) any tax credit, or

''(III) any other deduction as provided in guidance by the Secretary, and

''(ii) subclause (II) of paragraph (1)(B)(ii) shall be disregarded in determining whether any of such benefits are allowable.

''(4) OTHER COMMON LAW DOCTRINES NOT AFFECTED.—Except as specifically provided in this subsection, the provisions of this subsection shall not be construed as altering or supplanting any other rule of law, and the requirements of this subsection shall be construed as being in addition to any such other rule of law.

''(5) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this subsection. Such regulations may include exemptions from the application of this subsection.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to transactions entered into after the date of the enactment of this Act.

**SEC. 222. PENALTY FOR UNDERSTATEMENTS ATTRIBUTABLE TO TRANSACTIONS LACKING ECONOMIC SUBSTANCE, ETC.**

(a) IN GENERAL.—Subchapter A of chapter 68 is amended by inserting after section 6662A the following new section:

**''SEC. 6662B. PENALTY FOR UNDERSTATEMENTS ATTRIBUTABLE TO TRANSACTIONS LACKING ECONOMIC SUBSTANCE, ETC.**

''(a) IMPOSITION OF PENALTY.—If a taxpayer has an noneconomic substance transaction understatement for any taxable year, there shall be added to the tax an amount equal to 40 percent of the amount of such understatement.

''(b) REDUCTION OF PENALTY FOR DISCLOSED TRANSACTIONS.—Subsection (a) shall be applied by substituting '20 percent' for '40 percent' with respect to the

portion of any noneconomic substance transaction understatement with respect to which the relevant facts affecting the tax treatment of the item are adequately disclosed in the return or a statement attached to the return.

''(c) NONECONOMIC SUBSTANCE TRANSACTION UNDERSTATEMENT.—For purposes of this section—

''(1) IN GENERAL.—The term 'noneconomic substance transaction understatement' means any amount which would be an understatement under section 6662A(b)(1) if section 6662A were applied by taking into account items attributable to noneconomic substance transactions rather than items to which section 6662A would apply without regard to this paragraph.

''(2) NONECONOMIC SUBSTANCE TRANSACTION.—The term 'noneconomic substance transaction' means any transaction if—

''(A) there is a lack of economic substance (within the meaning of section 7701(o)(1)) for the transaction giving rise to the claimed benefit or the transaction was not respected under section 7701(o)(2), or

''(B) the transaction fails to meet the requirements of any similar rule of law.

''(d) RULES APPLICABLE TO COMPROMISE OF PENALTY.—

''(1) IN GENERAL.—If the 1st letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals has been sent with respect to a penalty to which this section applies, only the Commissioner of Internal Revenue may compromise all or any portion of such penalty.

''(2) APPLICABLE RULES.—The rules of paragraphs (2) and (3) of section 6707A(d) shall apply for purposes of paragraph (1).

''(e) COORDINATION WITH OTHER PENALTIES.—Except as otherwise provided in this part, the penalty imposed by this section shall be in addition to any other penalty imposed by this title.

''(f) CROSS REFERENCES.—

''(1) For coordination of penalty with understatements under section 6662 and other special rules, see section 6662A(e).

''(2) For reporting of penalty imposed under this section to the Securities and Exchange Commission, see section 6707A(e).''.

(b) COORDINATION WITH OTHER UNDERSTATEMENTS AND PENALTIES.—

(1) The second sentence of section 6662(d)(2)(A) is amended by inserting ''and without regard to items with respect to which a penalty is

imposed by section 6662B'' before the period at the end.

(2) Subsection (e) of section 6662A is amended—

(A) in paragraph (1), by inserting ''and noneconomic substance transaction understatements'' after ''reportable transaction understatements'' both places it appears,

(B) in paragraph (2)(A), by inserting ''and a noneconomic substance transaction understatement'' after ''reportable transaction understatement'',

(C) in paragraph (2)(B), by inserting ''6662B or'' before ''6663'',

(D) in paragraph (2)(C)(i), by inserting ''or section 6662B'' before the period at the end,

(E) in paragraph (2)(C)(ii), by inserting ''and section 6662B'' after ''This section'',

(F) in paragraph (3), by inserting ''or noneconomic substance transaction understatement'' after ''reportable transaction understatement'', and

(G) by adding at the end the following new paragraph:

''(4) NONECONOMIC SUBSTANCE TRANSACTION UNDERSTATEMENT.—For purposes of this subsection, the term 'noneconomic substance transaction understatement' has the meaning given such term by section 6662B(c).''.

(3) Subsection (e) of section 6707A is amended—

(A) by striking ''or'' at the end of subparagraph (B), and

(B) by striking subparagraph (C) and inserting the following new subparagraphs:

''(C) is required to pay a penalty under section 6662B with respect to any noneconomic substance transaction, or

''(D) is required to pay a penalty under section 6662(h) with respect to any transaction and would (but for section 6662A(e)(2)(C)) have been subject to penalty under section 6662A at a rate prescribed under section 6662A(c) or under section 6662B,''.

(c) CLERICAL AMENDMENT.—The table of sections for part II of subchapter A of chapter 68 is amended by inserting after the item relating to section 6662A the following new item:

''Sec. 6662B. Penalty for understatements attributable to transactions lacking economic substance, etc.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to transactions entered into after the date of the enactment of this Act.

**SEC. 223. DENIAL OF DEDUCTION FOR INTEREST ON UNDERPAYMENTS ATTRIBUTABLE TO NONECONOMIC SUBSTANCE TRANSACTIONS.**

(a) IN GENERAL.—Section 163(m) (relating to interest on unpaid taxes attributable to nondisclosed reportable transactions) is amended—

(1) by striking ''attributable'' and all that follows and inserting the following: ''attributable to—

''(1) the portion of any reportable transaction understatement (as defined in section 6662A(b)) with respect to which the requirement of section 6664(d)(2)(A) is not met, or

''(2) any noneconomic substance transaction understatement (as defined in section 6662B(c)).'', and

(2) by inserting ''And Noneconomic Substance Transactions'' in the heading thereof after ''Transactions''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to transactions after the date of the enactment of this Act in taxable years ending after such date.

# Subtitle D—Penalties and Fines

**SEC. 231. DENIAL OF DEDUCTION FOR CERTAIN FINES, PENALTIES, AND OTHER AMOUNTS.**

(a) IN GENERAL.—Subsection (f) of section 162 (relating to trade or business expenses) is amended to read as follows:

''(f) FINES, PENALTIES, AND OTHER AMOUNTS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), no deduction otherwise allowable shall be allowed under this chapter for any amount paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or entity described in paragraph (4) in relation to the violation of any law or the investigation or inquiry by such government or entity into the potential violation of any law.

''(2) EXCEPTION FOR AMOUNTS CONSTITUTING RESTITUTION OR PAID TO COME INTO COMPLIANCE WITH LAW.—Paragraph (1) shall not apply to any amount which—

''(A) the taxpayer establishes—

''(i) constitutes restitution (including remediation of property) for damage or harm caused by or which may be caused by

the violation of any law or the potential violation of any law, or

''(ii) is paid to come into compliance with any law which was violated or involved in the investigation or inquiry, and

''(B) is identified as restitution or as an amount paid to come into compliance with the law, as the case may be, in the court order or settlement agreement.

Identification pursuant to subparagraph (B) alone shall not satisfy the requirement under subparagraph (A). This paragraph shall not apply to any amount paid or incurred as reimbursement to the government or entity for the costs of any investigation or litigation.

''(3) EXCEPTION FOR AMOUNTS PAID OR INCURRED AS THE RESULT OF CERTAIN COURT ORDERS.—Paragraph (1) shall not apply to any amount paid or incurred by order of a court in a suit in which no government or entity described in paragraph (4) is a party.

''(4) CERTAIN NONGOVERNMENTAL REGULATORY ENTITIES.—An entity is described in this paragraph if it is—

''(A) a nongovernmental entity which exercises self-regulatory powers (including imposing sanctions) in connection with a qualified board or exchange (as defined in section 1256(g)(7)), or

''(B) to the extent provided in regulations, a nongovernmental entity which exercises self-regulatory powers (including imposing sanctions) as part of performing an essential governmental function.

''(5) EXCEPTION FOR TAXES DUE.—Paragraph (1) shall not apply to any amount paid or incurred as taxes due.''.

(b) REPORTING OF DEDUCTIBLE AMOUNTS.—

(1) IN GENERAL.—Subpart B of part III of subchapter A of chapter 61, as amended by this Act, is amended by adding at the end the following new section:

**''SEC. 6050V. INFORMATION WITH RESPECT TO CERTAIN FINES, PENALTIES, AND OTHER AMOUNTS.**

''(a) REQUIREMENT OF REPORTING.—

''(1) IN GENERAL.—The appropriate official of any government or entity which is described in section 162(f)(4) which is involved in a suit or agreement described in paragraph (2) shall make a return

in such form as determined by the Secretary setting forth—

''(A) the amount required to be paid as a result of the suit or agreement to which paragraph (1) of section 162(f) applies,

''(B) any amount required to be paid as a result of the suit or agreement which constitutes restitution or remediation of property, and

''(C) any amount required to be paid as a result of the suit or agreement for the purpose of coming into compliance with any law which was violated or involved in the investigation or inquiry.

''(2) SUIT OR AGREEMENT DESCRIBED.—

''(A) IN GENERAL.—A suit or agreement is described in this paragraph if—

''(i) it is—

''(I) a suit with respect to a violation of any law over which the government or entity has authority and with respect to which there has been a court order, or

''(II) an agreement which is entered into with respect to a violation

of any law over which the government or entity has authority, or with respect to an investigation or inquiry by the government or entity into the potential violation of any law over which such government or entity has authority, and

''(ii) the aggregate amount involved in all court orders and agreements with respect to the violation, investigation, or inquiry is $600 or more.

''(B) ADJUSTMENT OF REPORTING THRESHOLD.—The Secretary may adjust the $600 amount in subparagraph (A)(ii) as necessary in order to ensure the efficient administration of the internal revenue laws.

''(3) TIME OF FILING.—The return required under this subsection shall be filed not later than—

''(A) 30 days after the date on which a court order is issued with respect to the suit or the date the agreement is entered into, as the case may be, or

''(B) the date specified Secretary.

''(b) STATEMENTS TO BE FURNISHED TO INDIVIDUALS INVOLVED IN THE SETTLEMENT.—Every person re-

quired to make a return under subsection (a) shall furnish to each person who is a party to the suit or agreement a written statement showing—

''(1) the name of the government or entity, and

''(2) the information supplied to the Secretary under subsection (a)(1).

The written statement required under the preceding sentence shall be furnished to the person at the same time the government or entity provides the Secretary with the information required under subsection (a).

''(c) APPROPRIATE OFFICIAL DEFINED.—For purposes of this section, the term 'appropriate official' means the officer or employee having control of the suit, investigation, or inquiry or the person appropriately designated for purposes of this section.''.

(2) CONFORMING AMENDMENT.—The table of sections for subpart B of part III of subchapter A of chapter 61, as amended by this Act, is amended by adding at the end the following new item:

''Sec. 6050V. Information with respect to certain fines, penalties, and other amounts.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred on or after the date of the enactment of this Act, except that such amendments shall not apply to amounts paid or incurred under any binding order or agreement entered into

before such date. Such exception shall not apply to an order or agreement requiring court approval unless the approval was obtained before such date.

**SEC. 232. DENIAL OF DEDUCTION FOR PUNITIVE DAMAGES.**

(a) DISALLOWANCE OF DEDUCTION.—

(1) IN GENERAL.—Section 162(g) (relating to treble damage payments under the antitrust laws) is amended—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively,

(B) by striking ''If'' and inserting:

''(1) TREBLE DAMAGES.—If'', and

(C) by adding at the end the following new paragraph:

''(2) PUNITIVE DAMAGES.—No deduction shall be allowed under this chapter for any amount paid or incurred for punitive damages in connection with any judgment in, or settlement of, any action. This paragraph shall not apply to punitive damages described in section 104(c).''.

(2) CONFORMING AMENDMENT.—The heading for section 162(g) is amended by inserting ''Or Punitive Damages'' after ''Laws''.

(b) INCLUSION IN INCOME OF PUNITIVE DAMAGES PAID BY INSURER OR OTHERWISE.—

(1) IN GENERAL.—Part II of subchapter B of chapter 1 (relating to items specifically included in gross income) is amended by adding at the end the following new section:

**"SEC. 91. PUNITIVE DAMAGES COMPENSATED BY INSURANCE OR OTHERWISE.**

''Gross income shall include any amount paid to or on behalf of a taxpayer as insurance or otherwise by reason of the taxpayer's liability (or agreement) to pay punitive damages.''.

(2) REPORTING REQUIREMENTS.—Section 6041 (relating to information at source) is amended by adding at the end the following new subsection:

''(f) SECTION TO APPLY TO PUNITIVE DAMAGES COMPENSATION.—This section shall apply to payments by a person to or on behalf of another person as insurance or otherwise by reason of the other person's liability (or agreement) to pay punitive damages.''.

(3) CONFORMING AMENDMENT.—The table of sections for part II of subchapter B of chapter 1 is amended by adding at the end the following new item:

''Sec. 91. Punitive damages compensated by insurance or otherwise.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to damages paid or incurred on or after the date of the enactment of this Act.

# Subtitle E—Duty Surcharge

**SEC. 241. TEMPORARY EMERGENCY DUTY SURCHARGE.**

(a) IN GENERAL.—Notwithstanding any other provision of law, in addition to any other duty, there is hereby imposed a duty on the entry of any good during the 2-year period beginning on the day that is 15 days after the date of the enactment of this Act.

(b) RATE OF DUTY.—The rate of duty imposed by subsection (a) is 2 percent ad valorem.

(c) ENTRY.—For purposes of this section, the term ''entry'' means entry, or withdrawal from warehouse, for consumption in the customs territory of the United States.

# Subtitle F—Other Provisions

**SEC. 251. OFFSHORE OIL AND GAS LEASING IN 181 AREA OF GULF OF MEXICO.**

(a) DEFINITIONS.—In this section:

(1) 181 AREA.—The term ''181 Area'' means the area identified in map 15, page 58, of the Proposed Final Outer Continental Shelf Oil and Gas Leasing Program for 1997–2002 of the Minerals Management Service.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of the Interior, acting through the Minerals Management Service.

(b) LEASE SALE.—Except as otherwise provided in this section, the Secretary shall offer the 181 Area for oil and gas leasing pursuant to the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.) as soon as practicable, but not later than 1 year, after the date of enactment of this Act.

(c) LEASING PROGRAM.—The 181 Area shall be offered for lease under this section notwithstanding the omission of the 181 Area from any outer Continental Shelf leasing program under section 18 of the Outer Continental Shelf Lands Act (43 U.S.C. 1344).

**SEC. 252. TRANSFER OF SURPLUS FUNDS OF FEDERAL RESERVE BANKS TO TREASURY.**

Section 7 of the Federal Reserve Act (12 U.S.C. 789 et seq.) is amended by adding at the end the following:

''(d) ADDITIONAL TRANSFERS FOR FISCAL YEAR 2008.—

''(1) IN GENERAL.—The Federal reserve banks shall transfer from the surplus funds of such banks to the Board for transfer to the Secretary of the Treasury for deposit in the General Fund of the Treasury, a total amount of $13,000,000,000 for fiscal year 2008.

''(2) ALLOCATION BY FED.—Of the total amount required to be paid by the Federal reserve

banks under paragraph (1) for fiscal year 2008, the Board shall determine the amount that each such bank shall pay in such fiscal year.

''(3) REPLENISHMENT OF SURPLUS FUND PROHIBITED.—No Federal reserve bank may replenish the surplus fund of such bank by the amount of any transfer by such bank under paragraph (1) during fiscal year 2008.''.

**SEC. 253. PERMANENT EXTENSION OF FCC AUTHORITY TO AUCTION LICENSES TO USE RADIO SPECTRUM.**

Section 309(j)(11) of the Communications Act of 1934 (47 U.S.C. 309(j)(11)) is repealed.

**SEC. 254. TRAVEL BETWEEN THE UNITED STATES AND CUBA.**

(a) SHORT TITLE.—This section may be cited as the ''Freedom to Travel to Cuba Act of 2007''.

(b) TRAVEL TO CUBA.—

(1) FREEDOM OF TRAVEL FOR UNITED STATES CITIZENS AND LEGAL RESIDENTS.—Notwithstanding any other provision of law, subject to subsection (c), the President shall not regulate or prohibit, directly or indirectly, travel to or from Cuba by a United States citizen or legal resident, or any of the trans-

actions incident to such travel that are set forth in paragraph (2).

(2) TRANSACTIONS INCIDENT TO TRAVEL.—The transactions referred to in paragraph (1) are—

(A) any transactions ordinarily incident to travel to or from Cuba, including the importation into Cuba or the United States of accompanied baggage for personal use only;

(B) any transactions ordinarily incident to travel to or from Cuba, or maintenance within Cuba, including the payment of living expenses and the acquisition of goods or services for personal use;

(C) any transactions ordinarily incident to the arrangement, promotion, or facilitation of travel to, from, or within Cuba;

(D) any transactions incident to nonscheduled air, sea, or land voyages, except that this paragraph does not authorize the carriage of articles into Cuba or the United States other than accompanied baggage; and

(E) normal banking transactions incident to the activities described in the preceding provisions of this subsection, including the issuance, clearing, processing, or payment of

checks, drafts, traveler's checks, credit or debit card instruments, or similar instruments.

(c) EXCEPTIONS.—

(1) SPECIAL CIRCUMSTANCES.—The restrictions on authority contained in subsection (b) do not apply in a case in which the United States is at war with Cuba, armed hostilities between the two countries are in progress, or there is imminent danger to the public health or the physical safety of United States citizens or legal residents traveling to or from Cuba.

(2) IMPORTATION OF GOODS FOR PERSONAL CONSUMPTION.—Subsection (b) does not authorize the importation into the United States of any goods for personal consumption acquired in Cuba.

(d) APPLICABILITY.—This section applies to actions taken by the President before the date of the enactment of this Act that are in effect on such date of enactment, and to actions taken on or after such date.

(e) INAPPLICABILITY OF OTHER PROVISIONS.—This section applies notwithstanding section 102(h) of the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (22 U.S.C. 6032(h)) and section 910(b) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7209(b)).