

110TH CONGRESS
1ST SESSION

S. 554

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2007

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Act For Our Kids”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 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.

1 **TITLE I—REDUCTIONS IN**
 2 **FEDERAL SPENDING**
 3 **Subtitle A—Specific Reductions**

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

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

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 is repealed.

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

14 **“SEC. 107. TERMINATION OF RADIO BROADCASTING AU-**
 15 **THORITY.**

16 “Upon transmittal of a determination under section
 17 203(c)(3), the Radio Broadcasting to Cuba Act (22 U.S.C.
 18 1465 et seq.) is repealed.”.

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

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

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

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

21 (c) TERMINATION.—Notwithstanding any other pro-
22 vision of law, the United States Court of Federal Claims
23 is terminated effective on and after the date occurring 1
24 year after the date of enactment of this Act.

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

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

7 (1) in the case of each of the fiscal years 2008
8 through 2012, in an aggregate amount greater than
9 95 percent of the amount of such expenses for the
10 preceding fiscal year (determined after application of
11 this section); and

12 (2) in the case of fiscal year 2013 and each fis-
13 cal year thereafter, in an aggregate amount greater
14 than the aggregate amount of such expenses for fis-
15 cal year 2012 (determined after application of this
16 section).

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

20 (c) IDENTIFICATION OF AFFECTED EXPENSES.—The
21 Director of the Office of Management and Budget shall,
22 not later than September 1, 2007, establish guidelines for
23 the determination of what expenses constitute administra-
24 tive expenses or program expenses for purposes of this sec-
25 tion. The guidelines shall identify specific expenses, and

1 classes of expenses, that are to be treated as administra-
 2 tive expenses or program expenses.

3 **SEC. 104. ELIMINATION OF MEDICARE ADVANTAGE RE-**
 4 **GIONAL PLAN STABILIZATION (SLUSH) FUND.**

5 (a) ELIMINATION.—

6 (1) IN GENERAL.—Subsection (e) of section
 7 1858 of the Social Security Act (42 U.S.C. 1395w–
 8 27a) is repealed.

9 (2) CONFORMING AMENDMENT.—Section
 10 1858(f)(1) of the Social Security Act (42 U.S.C.
 11 1395w–27a(f)(1)) is amended by striking “subject to
 12 subsection (e),”.

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

16 **Subtitle B—Reform of Federal**
 17 **Contracting**

18 **PART I—ELIMINATION OF FRAUD AND ABUSE**

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

21 (a) PROHIBITION.—

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

1 **“§ 1039. War profiteering and fraud**

2 “(a) PROHIBITION.—

3 “(1) IN GENERAL.—Whoever, in any matter in-
4 volving a contract or the provision of goods or serv-
5 ices, directly or indirectly, in connection with a war
6 or military action knowingly and willfully—

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

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

13 “(C) makes any materially false, fictitious,
14 or fraudulent statements or representations, or
15 makes or uses any materially false writing or
16 document knowing the same to contain any ma-
17 terially false, fictitious, or fraudulent statement
18 or entry; or

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

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

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

26 “(A) \$1,000,000; or

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

4 “(b) EXTRATERRITORIAL JURISDICTION.—There is
 5 extraterritorial Federal jurisdiction over an offense under
 6 this section.

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

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

10 “(2) in any district where any act in further-
 11 ance of the offense took place; or

12 “(3) in any district where any party to the con-
 13 tract or provider of goods or services is located.”.

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

“1039. War profiteering and fraud.”.

17 (b) CIVIL FORFEITURE.—Section 981(a)(1)(C) of
 18 title 18, United States Code, is amended by inserting
 19 “1039,” after “1032,”.

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

23 (d) TREATMENT UNDER MONEY LAUNDERING OF-
 24 FENSE.—Section 1956(c)(7)(D) of title 18, United States
 25 Code, is amended by inserting the following: “, section

1 1039 (relating to war profiteering and fraud)” after “liq-
 2 uidating agent of financial institution),”.

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

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

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

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

18 (b) EFFECTIVE DATE.—The revised regulation re-
 19 quired by this section shall apply with respect to all con-
 20 tracts for which solicitations are issued after the date that
 21 is 90 days after the date of the enactment of this Act.

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

23 (a) DISCLOSURE OF INFORMATION TO CONGRESS.—

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

1 by the agency during the current and previous cal-
2 endar years that—

3 (A) describe significant contractor costs
4 that have been identified as unjustified, unsup-
5 ported, questioned, or unreasonable under any
6 contract, task or delivery order, or subcontract;
7 or

8 (B) identify significant or substantial defi-
9 ciencies in any business system of any con-
10 tractor under any contract, task or delivery
11 order, or subcontract.

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

17 (A) the current version of the list main-
18 tained pursuant to paragraph (1); or

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

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

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

1 eral Procurement Data System shall be modified to
2 include—

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

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

11 (2) PUBLICLY AVAILABLE WEBSITE.—The in-
12 formation required by paragraph (1) shall be made
13 available through the publicly available website of
14 the Federal Procurement Data System.

15 **PART II—CONTRACT MATTERS**

16 **Subpart A—Competition in Contracting**

17 **SEC. 114. PROHIBITION ON AWARD OF MONOPOLY CON-** 18 **TRACTS.**

19 (a) CIVILIAN AGENCY CONTRACTS.—Section
20 303H(d) of the Federal Property and Administrative
21 Services Act of 1949 (41 U.S.C. 253h(d)) is amended by
22 adding at the end the following new paragraph:

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

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

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

7 “(ii) the task orders expected under the con-
8 tract are so integrally related that only a single con-
9 tractor can reasonably perform the work; or

10 “(iii) for any other reason, it is necessary in the
11 public interest to award the contract to a single con-
12 tractor.

13 “(B) The head of the agency shall notify Congress
14 within 30 days of any determination under subparagraph
15 (A)(iii).”.

16 (b) DEFENSE CONTRACTS.—Section 2304a(d) of title
17 10, United States Code, is amended by adding at the end
18 the following new paragraph:

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

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

1 practical to award multiple task or delivery order
2 contracts;

3 “(ii) the task orders expected under the con-
4 tract are so integrally related that only a single con-
5 tractor can reasonably perform the work; or

6 “(iii) for any other reason, it is necessary in the
7 public interest to award the contract to a single con-
8 tractor.

9 “(B) The head of the agency shall notify Congress
10 within 30 days of any determination under subparagraph
11 (A)(iii).”.

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

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

18 (b) CONTENT OF REGULATIONS.—(1) The regula-
19 tions required by subsection (a) shall provide, at a min-
20 imum, that each individual purchase of goods or services
21 in excess of \$1,000,000 that is made under a multiple
22 award contract shall be made on a competitive basis unless
23 a contracting officer of the executive agency—

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

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

6 (ii) a statute expressly authorizes or re-
7 quires that the purchase be made from a speci-
8 fied source; and

9 (B) justifies the determination in writing.

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

13 (A) require fair notice of the intent to make
14 that purchase (including a description of the work to
15 be performed and the basis on which the selection
16 will be made) to be provided to all contractors offer-
17 ing such goods or services under the multiple award
18 contract; and

19 (B) afford all contractors responding to the no-
20 tice a fair opportunity to make an offer and have
21 that offer fairly considered by the official making
22 the purchase.

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

1 subsection (c)(2)(A) if notice is provided to as many con-
 2 tractors as practicable.

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

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

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

12 (c) DEFINITIONS.—In this section:

13 (1) The term “individual purchase” means a
 14 task order, delivery order, or other purchase.

15 (2) The term “multiple award contract”
 16 means—

17 (A) a contract that is entered into by the
 18 Administrator of General Services under the
 19 multiple award schedule program referred to in
 20 section 309(b)(3) of the Federal Property and
 21 Administrative Services Act of 1949 (41 U.S.C.
 22 259(b)(3));

23 (B) a multiple award task order contract
 24 that is entered into under the authority of sec-
 25 tions 2304a through 2304d of title 10, United

1 States Code, or sections 303H through 303K of
 2 the Federal Property and Administrative Serv-
 3 ices Act of 1949 (41 U.S.C. 253h through
 4 253k); and

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

9 (d) APPLICABILITY.—The revisions to the Federal
 10 Acquisition Regulation pursuant to subsection (a) shall
 11 take effect not later than 180 days after the date of the
 12 enactment of this Act, and shall apply to all individual
 13 purchases of goods or services that are made under mul-
 14 tiple award contracts on or after the effective date, with-
 15 out regard to whether the multiple award contracts were
 16 entered into before, on, or after such effective date.

17 (e) CONFORMING AMENDMENTS TO DEFENSE CON-
 18 TRACT PROVISION.—Section 803 of the National Defense
 19 Authorization Act for Fiscal Year 2002 (Public Law 107–
 20 107; 10 U.S.C. 2304 note) is amended as follows:

21 (1) GOODS COVERED.—(A) The section heading
 22 is amended by inserting “**GOODS OR**” before
 23 “**SERVICES**”.

24 (B) Subsection (a) is amended by inserting
 25 “goods and” before “services”.

1 (C) The following provisions are amended by in-
 2 serting “goods or” before “services” each place it
 3 appears:

4 (i) Paragraphs (1), (2), and (3) of sub-
 5 section (b).

6 (ii) Subsection (d).

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

9 “(e) APPLICABILITY TO GOODS.—The Secretary shall
 10 revise the regulations promulgated pursuant to subsection
 11 (a) to cover purchases of goods by the Department of De-
 12 fense pursuant to multiple award contracts. The revised
 13 regulations shall take effect in final form not later than
 14 180 days after the date of the enactment of this subsection
 15 and shall apply to all individual purchases of goods that
 16 are made under multiple award contracts on or after the
 17 effective date, without regard to whether the multiple
 18 award contracts were entered into before, on, or after such
 19 effective date.”.

20 (f) PROTEST RIGHTS FOR CERTAIN AWARDS.—

21 (1) CIVILIAN AGENCY CONTRACTS.—Section
 22 303J(d) of the Federal Property and Administrative
 23 Services Act (41 U.S.C. 253j(d)) is amended by in-
 24 serting “with a value of less than \$500,000” after
 25 “task or delivery order”.

1 (2) DEFENSE CONTRACTS.—Section 2304c(d)
 2 of title 10, United States Code, is amended by in-
 3 serting “with a value of less than \$500,000” after
 4 “task or delivery order”.

5 **Subpart B—Contract Personnel Matters**

6 **SEC. 116. CONTRACTOR CONFLICTS OF INTEREST.**

7 (a) PROHIBITION ON CONTRACTS RELATING TO IN-
 8 HERENTLY GOVERNMENTAL FUNCTIONS.—The head of
 9 an agency may not enter into a contract for the perform-
 10 ance of any inherently governmental function.

11 (b) PROHIBITION ON CONTRACTS FOR CONTRACT
 12 OVERSIGHT.—

13 (1) PROHIBITION.—The head of an agency may
 14 not enter into a contract for the performance of ac-
 15 quisition functions closely associated with inherently
 16 governmental functions with any entity unless the
 17 head of the agency determines in writing that—

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

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

1 flict of interest that may arise because the enti-
2 ty—

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

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

11 (iii) has a reverse role with the con-
12 tractor to be overseen under one or more
13 separate Government contracts; or

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

18 (2) RELATED ENTITY DEFINED.—In this sub-
19 section, the term “related entity”, with respect to a
20 contractor, means any subsidiary, parent, affiliate,
21 joint venture, or other entity related to the con-
22 tractor.

23 (c) DEFINITIONS.—In this section:

1 (1) The term “inherently governmental func-
2 tions” has the meaning given to such term in part
3 7.5 of the Federal Acquisition Regulation.

4 (2) The term “functions closely associated with
5 governmental functions” means the functions de-
6 scribed in section 7.503(d) of the Federal Acquisi-
7 tion Regulation.

8 (3) The term “organizational conflict of inter-
9 est” has the meaning given such term in part 9.5 of
10 the Federal Acquisition Regulation.

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

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

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

18 (3) any decision on or after such date to exer-
19 cise an option or otherwise extend a contract for the
20 performance of a function relating to contract over-
21 sight regardless of whether such contract was en-
22 tered into before, on, or after such date.

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

3 (a) ELIMINATION OF LOOPHOLES ALLOWING
4 FORMER FEDERAL OFFICIALS TO ACCEPT COMPENSA-
5 TION FROM CONTRACTORS OR RELATED ENTITIES.—

6 (1) IN GENERAL.—Paragraph (1) of subsection
7 (d) of section 27 of the Office of Federal Procure-
8 ment Policy Act (41 U.S.C. 423) is amended—

9 (A) by striking “or consultant” and insert-
10 ing “consultant, lawyer, or lobbyist”;

11 (B) by striking “one year” and inserting
12 “two years”; and

13 (C) in subparagraph (C), by striking “per-
14 sonally made for the Federal agency—” and in-
15 serting “participated personally and substan-
16 tially in—”.

17 (2) DEFINITION.—Paragraph (2) of such sub-
18 section is amended to read as follows:

19 “(2) For purposes of paragraph (1), the term ‘con-
20 tractor’ includes any division, affiliate, subsidiary, parent,
21 joint venture, or other related entity of a contractor.”.

22 (b) PROHIBITION ON AWARD OF GOVERNMENT CON-
23 TRACTS TO FORMER EMPLOYERS.—Such section is fur-
24 ther amended by adding at the end the following new sub-
25 section:

1 “(i) PROHIBITION ON INVOLVEMENT BY CERTAIN
 2 FORMER CONTRACTOR EMPLOYEES IN PROCURE-
 3 MENTS.—A former employee of a contractor who becomes
 4 an employee of the Federal Government shall not be per-
 5 sonally and substantially involved with any Federal agency
 6 procurement involving the employee’s former employer, in-
 7 cluding any division, affiliate, subsidiary, parent, joint
 8 venture, or other related entity of the former employer,
 9 for a period of two years beginning on the date on which
 10 the employee leaves the employment of the contractor un-
 11 less the designated agency ethics officer for the agency
 12 determines in writing that the government’s interest in the
 13 former employee’s participation in a particular procure-
 14 ment outweighs any appearance of impropriety.”.

15 (c) REQUIREMENT FOR FEDERAL PROCUREMENT
 16 OFFICERS TO DISCLOSE JOB OFFERS MADE TO REL-
 17 ATIVES.—Subsection (c)(1) of such section is amended by
 18 inserting after “that official” the following: “, or for a rel-
 19 ative of that official (as defined in section 3110 of title
 20 5, United States Code),”.

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

24 “(1) CRIMINAL PENALTIES.—Whoever engages
 25 in conduct constituting a violation of—

1 “(A) subsection (a) or (b) for the purpose
2 of either—

3 “(i) exchanging the information cov-
4 ered by such subsection for anything of
5 value, or

6 “(ii) obtaining or giving anyone a
7 competitive advantage in the award of a
8 Federal agency procurement contract; or

9 “(B) subsection (c) or (d);
10 shall be imprisoned for not more than 5 years, fined
11 as provided under title 18, United States Code, or
12 both.”.

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

15 “(j) REGULATIONS.—The Director of the Office of
16 Government Ethics, in consultation with the Adminis-
17 trator, shall—

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

20 “(2) monitor and investigate individual and
21 agency compliance with this section.”.

1 **PART III—OTHER PERSONNEL MATTERS**

2 **SEC. 118. MINIMUM REQUIREMENTS FOR POLITICAL AP-**
3 **POINTEES HOLDING PUBLIC CONTRACTING**
4 **AND SAFETY POSITIONS.**

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

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

10 (1) A public contracting position.

11 (2) A public safety position.

12 (c) MINIMUM REQUIREMENTS.—An individual shall
13 not, with respect to any position, be considered to meet
14 the requirements of this subsection unless such indi-
15 vidual—

16 (1) has academic, management, and leadership
17 credentials in one or more areas relevant to such po-
18 sition;

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

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

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

1 of the agency within which, if appointed, such indi-
2 vidual would serve.

3 (d) POLITICAL APPOINTEE.—For purposes of this
4 section, the term “political appointee” means any indi-
5 vidual who—

6 (1) is employed in a position listed in sections
7 5312 through 5316 of title 5, United States Code
8 (relating to the Executive Schedule);

9 (2) is a limited term appointee, limited emer-
10 gency appointee, or noncareer appointee in the Sen-
11 ior Executive Service; or

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

17 (e) PUBLIC CONTRACTING POSITION.—For purposes
18 of this section, the term “public contracting position”
19 means the following:

20 (1) The Administrator for Federal Procurement
21 Policy.

22 (2) The Administrator of the General Services
23 Administration.

24 (3) The Chief Acquisition Officer of any execu-
25 tive agency, as appointed or designated pursuant to

1 section 16 of the Office of Federal Procurement Pol-
2 icy Act (41 U.S.C. 414).

3 (4) The Under Secretary of Defense for Acqui-
4 sition, Technology, and Logistics.

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

11 (f) PUBLIC SAFETY POSITION.—For purposes of this
12 section, the term “public safety position” means the fol-
13 lowing:

14 (1) The Under Secretary for Emergency Pre-
15 paredness and Response, Department of Homeland
16 Security.

17 (2) The Director of the Federal Emergency
18 Management Agency, Department of Homeland Se-
19 curity.

20 (3) Each regional director of the Federal Emer-
21 gency Management Agency, Department of Home-
22 land Security.

23 (4) The Recovery Division Director of the Fed-
24 eral Emergency Management Agency, Department
25 of Homeland Security.

1 (5) The Assistant Secretary for Immigration
2 and Customs Enforcement, Department of Home-
3 land Security.

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

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

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

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

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

1 might otherwise apply with respect to any particular posi-
 2 tion.

3 (i) DEFINITIONS.—In this section:

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

7 (2) The terms “limited term appointee”, “lim-
 8 ited emergency appointee”, and “noncareer ap-
 9 pointee” have the meanings given such terms in sec-
 10 tion 3132 of title 5, United States Code.

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

14 (4) The term “competitive service” has the
 15 meaning given such term by section 2102 of title 5,
 16 United States Code.

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

20 (j) CONFORMING AMENDMENT.—Section 16(a) of the
 21 Office of Federal Procurement Policy Act (41 U.S.C.
 22 414(a)) is amended by striking “non-career employee as”.

1 **SEC. 119. PROTECTION OF CERTAIN DISCLOSURES OF IN-**
2 **FORMATION BY FEDERAL EMPLOYEES.**

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

6 (1) in subparagraph (A)—

7 (A) by striking “which the employee or ap-
8 plicant reasonably believes evidences” and in-
9 serting “, without restriction to time, place,
10 form, motive, context, or prior disclosure made
11 to any person by an employee or applicant, in-
12 cluding a disclosure made in the ordinary
13 course of an employee’s duties, that the em-
14 ployee or applicant reasonably believes is evi-
15 dence of”; and

16 (B) in clause (i), by striking “a violation”
17 and inserting “any violation”;

18 (2) in subparagraph (B)—

19 (A) by striking “which the employee or ap-
20 plicant reasonably believes evidences” and in-
21 serting “, without restriction to time, place,
22 form, motive, context, or prior disclosure made
23 to any person by an employee or applicant, in-
24 cluding a disclosure made in the ordinary
25 course of an employee’s duties, of information

1 that the employee or applicant reasonably be-
2 lieves is evidence of”; and

3 (B) in clause (i), by striking “a violation”
4 and inserting “any violation (other than a viola-
5 tion of this section)”; and

6 (3) by adding at the end the following:

7 “(C) any disclosure that—

8 “(i) is made by an employee or appli-
9 cant of information required by law or Ex-
10 ecutive order to be kept secret in the inter-
11 est of national defense or the conduct of
12 foreign affairs that the employee or appli-
13 cant reasonably believes is direct and spe-
14 cific evidence of—

15 “(I) any violation of any law,
16 rule, or regulation;

17 “(II) gross mismanagement, a
18 gross waste of funds, an abuse of au-
19 thority, or a substantial and specific
20 danger to public health or safety; or

21 “(III) a false statement to Con-
22 gress on an issue of material fact; and

23 “(ii) is made to—

24 “(I) a member of a committee of
25 Congress;

1 “(II) any other Member of Con-
2 gress; or

3 “(III) an employee of Congress
4 who has the appropriate security
5 clearance and is authorized to receive
6 information of the type disclosed.”.

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

9 (1) in subparagraph (B)(ii), by striking “and”
10 at the end;

11 (2) in subparagraph (C)(iii), by striking the pe-
12 riod at the end and inserting “; and”; and

13 (3) by adding at the end the following:

14 “(D) ‘disclosure’ means a formal or informal
15 communication or transmission, but does not include
16 a communication concerning policy decisions that
17 lawfully exercise discretionary authority unless the
18 employee providing the disclosure reasonably believes
19 that the disclosure evidences—

20 “(i) any violation of any law, rule, or regu-
21 lation; or

22 “(ii) gross mismanagement, a gross waste
23 of funds, an abuse of authority, or a substantial
24 and specific danger to public health or safety.”.

1 (c) REBUTTABLE PRESUMPTION.—Section 2302(b)
2 of title 5, United States Code, is amended by amending
3 the matter following paragraph (12) to read as follows:
4 “This subsection shall not be construed to authorize the
5 withholding of information from Congress or the taking
6 of any personnel action against an employee who discloses
7 information to Congress. For purposes of paragraph (8),
8 any presumption relating to the performance of a duty by
9 an employee who has authority to take, direct others to
10 take, recommend, or approve any personnel action may be
11 rebutted by substantial evidence. For purposes of para-
12 graph (8), a determination as to whether an employee or
13 applicant reasonably believes that they have disclosed in-
14 formation that evidences any violation of law, rule, regula-
15 tion, gross mismanagement, a gross waste of funds, an
16 abuse of authority, or a substantial and specific danger
17 to public health or safety shall be made by determining
18 whether a disinterested observer with knowledge of the es-
19 sential facts known to and readily ascertainable by the em-
20 ployee would reasonably conclude that the actions of the
21 Government evidence such violations, mismanagement,
22 waste, abuse, or danger.”.

23 (d) NONDISCLOSURE POLICIES, FORMS, AND AGREE-
24 MENTS; SECURITY CLEARANCES; AND RETALIATORY IN-
25 VESTIGATIONS.—

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

4 (A) in clause (x), by striking “and” after
5 the semicolon; and

6 (B) by redesignating clause (xi) as clause
7 (xiv) and inserting after clause (x) the fol-
8 lowing:

9 “(xi) the implementation or enforce-
10 ment of any nondisclosure policy, form, or
11 agreement;

12 “(xii) a suspension, revocation, or
13 other determination relating to a security
14 clearance or any other access determina-
15 tion by a covered agency;

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

22 (2) PROHIBITED PERSONNEL PRACTICE.—Sec-
23 tion 2302(b) of title 5, United States Code, is
24 amended—

1 (A) in paragraph (11), by striking “or” at
2 the end;

3 (B) in paragraph (12), by striking the pe-
4 riod and inserting a semicolon; and

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

7 “(13) implement or enforce any nondisclosure
8 policy, form, or agreement, if such policy, form, or
9 agreement does not contain the following statement:
10 ‘These provisions are consistent with and do not su-
11 persede, conflict with, or otherwise alter the em-
12 ployee obligations, rights, or liabilities created by
13 Executive Order No. 12958; section 7211 (governing
14 disclosures to Congress); section 1034 of title 10
15 (governing disclosure to Congress by members of the
16 military); section 2302(b)(8) (governing disclosures
17 of illegality, waste, fraud, abuse, or public health or
18 safety threats); the Intelligence Identities Protection
19 Act of 1982 (50 U.S.C. 421 et seq.) (governing dis-
20 closures that could expose confidential Government
21 agents); and the statutes which protect against dis-
22 closures that could compromise national security, in-
23 cluding sections 641, 793, 794, 798, and 952 of title
24 18 and section 4(b) of the Subversive Activities Con-
25 trol 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

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

3 “(3) subject to paragraph (2), may issue declar-
4 atory relief and any other appropriate relief.

5 “(b)(1) If, in any final judgment, the Board or court
6 declares that any suspension, revocation, or other deter-
7 mination with regards to a security clearance or access
8 determination was made in violation of paragraph (8) or
9 (9) of section 2302(b), the affected agency shall conduct
10 a review of that suspension, revocation, access determina-
11 tion, or other determination, giving great weight to the
12 Board or court judgment.

13 “(2) Not later than 30 days after any Board or court
14 judgment declaring that a security clearance suspension,
15 revocation, access determination, or other determination
16 was made in violation of paragraph (8) or (9) of section
17 2302(b), the affected agency shall issue an unclassified re-
18 port to the congressional committees of jurisdiction (with
19 a classified annex if necessary), detailing the cir-
20 cumstances of the agency’s security clearance suspension,
21 revocation, other determination, or access determination.
22 A report under this paragraph shall include any proposed
23 agency action with regards to the security clearance or ac-
24 cess determination.

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

6 “(d) For purposes of this section, corrective action
 7 may not be ordered if the agency demonstrates by a pre-
 8 ponderance of the evidence that it would have taken the
 9 same personnel action in the absence of such disclosure.”.

10 (B) TECHNICAL AND CONFORMING AMEND-
 11 MENT.—The table of sections for chapter 77 of
 12 title 5, United States Code, is amended by in-
 13 serting after the item relating to section 7702
 14 the following:

“7702a. Actions relating to security clearances.”.

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

18 “(ii)(I) the Federal Bureau of Investiga-
 19 tion, the Office of the Director of National In-
 20 telligence, the Central Intelligence Agency, the
 21 Defense Intelligence Agency, the National
 22 Geospatial-Intelligence Agency, and the Na-
 23 tional Security Agency; and

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

1 function of which is the conduct of foreign in-
 2 telligence or counterintelligence activities, if the
 3 determination (as that determination relates to
 4 a personnel action) is made before that per-
 5 sonnel action; or”.

6 (f) ATTORNEY FEES.—Section 1204(m)(1) of title 5,
 7 United States Code, is amended by striking “agency in-
 8 volved” and inserting “agency where the prevailing party
 9 is employed or has applied for employment”.

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

12 “(3)(A) A final order of the Board may im-
 13 pose—

14 “(i) disciplinary action consisting of re-
 15 moval, reduction in grade, debarment from
 16 Federal employment for a period not to exceed
 17 5 years, suspension, or reprimand;

18 “(ii) an assessment of a civil penalty not to
 19 exceed \$1,000; or

20 “(iii) any combination of disciplinary ac-
 21 tions described under clause (i) and an assess-
 22 ment described under clause (ii).

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

1 2302(b), the Board shall impose disciplinary action
 2 if the Board finds that the activity protected under
 3 paragraph (8) or (9) of section 2302(b) was a sig-
 4 nificant motivating factor, even if other factors also
 5 motivated the decision, for the employee’s decision to
 6 take, fail to take, or threaten to take or fail to take
 7 a personnel action, unless that employee dem-
 8 onstrates, by preponderance of evidence, that the
 9 employee would have taken, failed to take, or threat-
 10 ened to take or fail to take the same personnel ac-
 11 tion, in the absence of such protected activity.”.

12 (h) SPECIAL COUNSEL AMICUS CURIAE APPEAR-
 13 ANCE.—Section 1212 of title 5, United States Code, is
 14 amended by adding at the end the following:

15 “(h)(1) The Special Counsel is authorized to appear
 16 as amicus curiae in any action brought in a court of the
 17 United States related to any civil action brought in con-
 18 nection with section 2302(b) (8) or (9), or subchapter III
 19 of chapter 73, or as otherwise authorized by law. In any
 20 such action, the Special Counsel is authorized to present
 21 the views of the Special Counsel with respect to compli-
 22 ance with section 2302(b) (8) or (9) or subchapter III of
 23 chapter 77 and the impact court decisions would have on
 24 the enforcement of such provisions of law.

1 “(2) A court of the United States shall grant the ap-
 2 plication of the Special Counsel to appear in any such ac-
 3 tion for the purposes described in subsection (a).”.

4 (i) JUDICIAL REVIEW.—

5 (1) IN GENERAL.—Section 7703(b)(1) of title
 6 5, United States Code, is amended to read as fol-
 7 lows:

8 “(b)(1)(A) Except as provided in subparagraph (B)
 9 and paragraph (2), a petition to review a final order or
 10 final decision of the Board shall be filed in the United
 11 States Court of Appeals for the Federal Circuit. Notwith-
 12 standing any other provision of law, any petition for re-
 13 view must be filed within 60 days after the date the peti-
 14 tioner received notice of the final order or decision of the
 15 Board.

16 “(B) During the 5-year period beginning on the effec-
 17 tive date of this subsection, a petition to review a final
 18 order or final decision of the Board in a case alleging a
 19 violation of paragraph (8) or (9) of section 2302(b) shall
 20 be filed in the United States Court of Appeals for the Fed-
 21 eral Circuit or any court of appeals of competent jurisdic-
 22 tion as provided under subsection (b)(2).”.

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

1 “(d)(1) Except as provided under paragraph (2), this
2 paragraph shall apply to any review obtained by the Direc-
3 tor of the Office of Personnel Management. The Director
4 of the Office of Personnel Management may obtain review
5 of any final order or decision of the Board by filing, within
6 60 days after the date the Director received notice of the
7 final order or decision of the Board, a petition for judicial
8 review in the United States Court of Appeals for the Fed-
9 eral Circuit if the Director determines, in his discretion,
10 that the Board erred in interpreting a civil service law,
11 rule, or regulation affecting personnel management and
12 that the Board’s decision will have a substantial impact
13 on a civil service law, rule, regulation, or policy directive.
14 If the Director did not intervene in a matter before the
15 Board, the Director may not petition for review of a Board
16 decision under this section unless the Director first peti-
17 tions the Board for a reconsideration of its decision, and
18 such petition is denied. In addition to the named respond-
19 ent, the Board and all other parties to the proceedings
20 before the Board shall have the right to appear in the pro-
21 ceeding before the Court of Appeals. The granting of the
22 petition for judicial review shall be at the discretion of the
23 Court of Appeals.

24 “(2) During the 5-year period beginning on the effec-
25 tive date of this subsection, this paragraph shall apply to

1 any review relating to paragraph (8) or (9) of section
 2 2302(b) obtained by the Director of the Office of Per-
 3 sonnel Management. The Director of the Office of Per-
 4 sonnel Management may obtain review of any final order
 5 or decision of the Board by filing, within 60 days after
 6 the date the Director received notice of the final order or
 7 decision of the Board, a petition for judicial review in the
 8 United States Court of Appeals for the Federal Circuit
 9 or any court of appeals of competent jurisdiction as pro-
 10 vided under subsection (b)(2) if the Director determines,
 11 in his discretion, that the Board erred in interpreting
 12 paragraph (8) or (9) of section 2302(b). If the Director
 13 did not intervene in a matter before the Board, the Direc-
 14 tor may not petition for review of a Board decision under
 15 this section unless the Director first petitions the Board
 16 for a reconsideration of its decision, and such petition is
 17 denied. In addition to the named respondent, the Board
 18 and all other parties to the proceedings before the Board
 19 shall have the right to appear in the proceeding before
 20 the court of appeals. The granting of the petition for judi-
 21 cial review shall be at the discretion of the Court of Ap-
 22 peals.”.

23 (j) NONDISCLOSURE POLICIES, FORMS, AND AGREE-
 24 MENTS.—

25 (1) IN GENERAL.—

1 (A) REQUIREMENT.—Each agreement in
2 Standard Forms 312 and 4414 of the Govern-
3 ment and any other nondisclosure policy, form,
4 or agreement of the Government shall contain
5 the following statement: “These restrictions are
6 consistent with and do not supersede, conflict
7 with, or otherwise alter the employee obliga-
8 tions, rights, or liabilities created by Executive
9 Order No. 12958; section 7211 of title 5,
10 United States Code (governing disclosures to
11 Congress); section 1034 of title 10, United
12 States Code (governing disclosure to Congress
13 by members of the military); section 2302(b)(8)
14 of title 5, United States Code (governing disclo-
15 sures of illegality, waste, fraud, abuse or public
16 health or safety threats); the Intelligence Iden-
17 tities Protection Act of 1982 (50 U.S.C. 421 et
18 seq.) (governing disclosures that could expose
19 confidential Government agents); and the stat-
20 utes which protect against disclosure that may
21 compromise the national security, including sec-
22 tions 641, 793, 794, 798, and 952 of title 18,
23 United States Code, and section 4(b) of the
24 Subversive Activities Act of 1950 (50 U.S.C.
25 783(b)). The definitions, requirements, obliga-

1 tions, rights, sanctions, and liabilities created
2 by such Executive order and such statutory
3 provisions are incorporated into this agreement
4 and are controlling.”.

5 (B) ENFORCEABILITY.—Any nondisclosure
6 policy, form, or agreement described under sub-
7 paragraph (A) that does not contain the state-
8 ment required under subparagraph (A) may not
9 be implemented or enforced to the extent such
10 policy, form, or agreement is inconsistent with
11 that statement.

12 (2) PERSONS OTHER THAN GOVERNMENT EM-
13 PLOYEES.—Notwithstanding paragraph (1), a non-
14 disclosure policy, form, or agreement that is to be
15 executed by a person connected with the conduct of
16 an intelligence or intelligence-related activity, other
17 than an employee or officer of the United States
18 Government, may contain provisions appropriate to
19 the particular activity for which such document is to
20 be used. Such form or agreement shall, at a min-
21 imum, require that the person will not disclose any
22 classified information received in the course of such
23 activity unless specifically authorized to do so by the
24 United States Government. Such nondisclosure
25 forms shall also make it clear that such forms do

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

5 (k) CLARIFICATION OF WHISTLEBLOWER RIGHTS
 6 FOR CRITICAL INFRASTRUCTURE INFORMATION.—Section
 7 214(c) of the Homeland Security Act of 2002 (6 U.S.C.
 8 133(c)) is amended by adding at the end the following:
 9 “For purposes of this section a permissible use of inde-
 10 pendently obtained information includes the disclosure of
 11 such information under section 2302(b)(8) of title 5,
 12 United States Code.”.

13 (l) ADVISING EMPLOYEES OF RIGHTS.—Section
 14 2302(c) of title 5, United States Code, is amended by in-
 15 serting “, including how to make a lawful disclosure of
 16 information that is specifically required by law or Execu-
 17 tive order to be kept secret in the interest of national de-
 18 fense or the conduct of foreign affairs to the Special Coun-
 19 sel, the Inspector General of an agency, Congress, or other
 20 agency employee designated to receive such disclosures”
 21 after “chapter 12 of this title”.

22 (m) SCOPE OF DUE PROCESS.—

23 (1) SPECIAL COUNSEL.—Section
 24 1214(b)(4)(B)(ii) of title 5, United States Code, is
 25 amended by inserting “, after a finding that a pro-

1 tected disclosure was a contributing factor,” after
 2 “ordered if”.

3 (2) INDIVIDUAL ACTION.—Section 1221(e)(2)
 4 of title 5, United States Code, is amended by insert-
 5 ing “, after a finding that a protected disclosure was
 6 a contributing factor,” after “ordered if”.

7 **Subtitle C—Importation of** 8 **Prescription Drugs**

9 **SEC. 121. SHORT TITLE.**

10 This subtitle may be cited as the “Pharmaceutical
 11 Market Access and Drug Safety Act of 2007”.

12 **SEC. 122. FINDINGS.**

13 Congress finds that—

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

17 (2) the United States is the largest market for
 18 pharmaceuticals in the world, yet American con-
 19 sumers pay the highest prices for brand pharma-
 20 ceuticals in the world;

21 (3) a prescription drug is neither safe nor effec-
 22 tive to an individual who cannot afford it;

23 (4) allowing and structuring the importation of
 24 prescription drugs to ensure access to safe and af-
 25 fordable drugs approved by the Food and Drug Ad-

1 ministration will provide a level of safety to Amer-
 2 ican consumers that they do not currently enjoy;

3 (5) American spend more than
 4 \$200,000,000,000 on prescription drugs every year;

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

9 (7) promoting competitive market pricing would
 10 both contribute to health care savings and allow
 11 greater access to therapy, improving health and sav-
 12 ing lives.

13 **SEC. 123. REPEAL OF CERTAIN SECTION REGARDING IM-**
 14 **PORTATION OF PRESCRIPTION DRUGS.**

15 Chapter VIII of the Federal Food, Drug, and Cos-
 16 metic Act (21 U.S.C. 381 et seq.) is amended by striking
 17 section 804.

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

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

1 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
 2 **PRESCRIPTION DRUGS.**

3 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

4 “(1) IN GENERAL.—In the case of qualifying
 5 drugs imported or offered for import into the United
 6 States from registered exporters or by registered im-
 7 porters—

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

10 “(B) the standards referred to in section
 11 801(a) regarding admission of the drugs are
 12 subject to subsection (g) of this section (includ-
 13 ing with respect to qualifying drugs to which
 14 section 801(d)(1) does not apply).

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

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

20 “(B) the drug is imported by an individual
 21 for personal use or for the use of a family mem-
 22 ber of the individual (not for resale) from a reg-
 23 istered exporter.

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

1 ported or offered for import into the United
2 States—

3 “(A) by a registered importer; or

4 “(B) from a registered exporter to an indi-
5 vidual.

6 “(4) DEFINITIONS.—

7 “(A) REGISTERED EXPORTER; REG-
8 ISTERED IMPORTER.—For purposes of this sec-
9 tion:

10 “(i) The term ‘registered exporter’
11 means an exporter for which a registration
12 under subsection (b) has been approved
13 and is in effect.

14 “(ii) The term ‘registered importer’
15 means a pharmacy, group of pharmacies,
16 or a wholesaler for which a registration
17 under subsection (b) has been approved
18 and is in effect.

19 “(iii) The term ‘registration condition’
20 means a condition that must exist for a
21 registration under subsection (b) to be ap-
22 proved.

23 “(B) QUALIFYING DRUG.—For purposes of
24 this section, the term ‘qualifying drug’ means a

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

3 “(C) U.S. LABEL DRUG.—For purposes of
4 this section, the term ‘U.S. label drug’ means
5 a prescription drug that—

6 “(i) with respect to a qualifying drug,
7 has the same active ingredient or ingredi-
8 ents, route of administration, dosage form,
9 and strength as the qualifying drug;

10 “(ii) with respect to the qualifying
11 drug, is manufactured by or for the person
12 that manufactures the qualifying drug;

13 “(iii) is approved under section
14 505(c); and

15 “(iv) is not—

16 “(I) a controlled substance, as
17 defined in section 102 of the Con-
18 trolled Substances Act (21 U.S.C.
19 802);

20 “(II) a biological product, as de-
21 fined in section 351 of the Public
22 Health Service Act (42 U.S.C. 262),
23 including—

24 “(aa) a therapeutic DNA
25 plasmid product;

1 “(bb) a therapeutic synthetic
2 peptide product;

3 “(cc) a monoclonal antibody
4 product for in vivo use; and

5 “(dd) a therapeutic recom-
6 binant DNA-derived product;

7 “(III) an infused drug, including
8 a peritoneal dialysis solution;

9 “(IV) an injected drug;

10 “(V) a drug that is inhaled dur-
11 ing surgery;

12 “(VI) a drug that is the listed
13 drug referred to in 2 or more abbrevi-
14 ated new drug applications under
15 which the drug is commercially mar-
16 keted; or

17 “(VII) a sterile ophthalmic drug
18 intended for topical use on or in the
19 eye.

20 “(D) OTHER DEFINITIONS.—For purposes
21 of this section:

22 “(i)(I) The term ‘exporter’ means a
23 person that is in the business of exporting
24 a drug to individuals in the United States
25 from Canada or from a permitted country

1 designated by the Secretary under sub-
2 clause (II), or that, pursuant to submitting
3 a registration under subsection (b), seeks
4 to be in such business.

5 “(II) The Secretary shall designate a
6 permitted country under subparagraph (E)
7 (other than Canada) as a country from
8 which an exporter may export a drug to in-
9 dividuals in the United States if the Sec-
10 retary determines that—

11 “(aa) the country has statutory
12 or regulatory standards that are
13 equivalent to the standards in the
14 United States and Canada with re-
15 spect to—

16 “(AA) the training of phar-
17 macists;

18 “(BB) the practice of phar-
19 macy; and

20 “(CC) the protection of the
21 privacy of personal medical infor-
22 mation; and

23 “(bb) the importation of drugs to
24 individuals in the United States from

1 the country will not adversely affect
2 public health.

3 “(ii) The term ‘importer’ means a
4 pharmacy, a group of pharmacies, or a
5 wholesaler that is in the business of im-
6 porting a drug into the United States or
7 that, pursuant to submitting a registration
8 under subsection (b), seeks to be in such
9 business.

10 “(iii) The term ‘pharmacist’ means a
11 person licensed by a State to practice
12 pharmacy, including the dispensing and
13 selling of prescription drugs.

14 “(iv) The term ‘pharmacy’ means a
15 person that—

16 “(I) is licensed by a State to en-
17 gage in the business of selling pre-
18 scription drugs at retail; and

19 “(II) employs 1 or more phar-
20 macists.

21 “(v) The term ‘prescription drug’
22 means a drug that is described in section
23 503(b)(1).

24 “(vi) The term ‘wholesaler’—

1 “(I) means a person licensed as a
2 wholesaler or distributor of prescrip-
3 tion drugs in the United States under
4 section 503(e)(2)(A); and

5 “(II) does not include a person
6 authorized to import drugs under sec-
7 tion 801(d)(1).

8 “(E) PERMITTED COUNTRY.—The term
9 ‘permitted country’ means—

10 “(i) Australia;

11 “(ii) Canada;

12 “(iii) a member country of the Euro-
13 pean Union, but does not include a mem-
14 ber country with respect to which—

15 “(I) the country’s Annex to the
16 Treaty of Accession to the European
17 Union 2003 includes a transitional
18 measure for the regulation of human
19 pharmaceutical products that has not
20 expired; or

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

1 ulation of human pharmaceutical
2 products expires;

3 “(iv) Japan;

4 “(v) New Zealand;

5 “(vi) Switzerland; and

6 “(vii) a country in which the Sec-
7 retary determines the following require-
8 ments are met:

9 “(I) The country has statutory or
10 regulatory requirements—

11 “(aa) that require the review
12 of drugs for safety and effective-
13 ness by an entity of the govern-
14 ment of the country;

15 “(bb) that authorize the ap-
16 proval of only those drugs that
17 have been determined to be safe
18 and effective by experts employed
19 by or acting on behalf of such en-
20 tity and qualified by scientific
21 training and experience to evalu-
22 ate the safety and effectiveness of
23 drugs on the basis of adequate
24 and well-controlled investigations,
25 including clinical investigations,

1 conducted by experts qualified by
2 scientific training and experience
3 to evaluate the safety and effec-
4 tiveness of drugs;

5 “(cc) that require the meth-
6 ods used in, and the facilities and
7 controls used for the manufac-
8 ture, processing, and packing of
9 drugs in the country to be ade-
10 quate to preserve their identity,
11 quality, purity, and strength;

12 “(dd) for the reporting of
13 adverse reactions to drugs and
14 procedures to withdraw approval
15 and remove drugs found not to
16 be safe or effective; and

17 “(ee) that require the label-
18 ing and promotion of drugs to be
19 in accordance with the approval
20 of the drug.

21 “(II) The valid marketing au-
22 thorization system in the country is
23 equivalent to the systems in the coun-
24 tries described in clauses (i) through
25 (vi).

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

4 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
 5 ERS.—

6 “(1) REGISTRATION OF IMPORTERS AND EX-
 7 PORTERS.—A registration condition is that the im-
 8 porter or exporter involved (referred to in this sub-
 9 section as a ‘registrant’) submits to the Secretary a
 10 registration containing the following:

11 “(A)(i) In the case of an exporter, the
 12 name of the exporter and an identification of all
 13 places of business of the exporter that relate to
 14 qualifying drugs, including each warehouse or
 15 other facility owned or controlled by, or oper-
 16 ated for, the exporter.

17 “(ii) In the case of an importer, the name
 18 of the importer and an identification of the
 19 places of business of the importer at which the
 20 importer initially receives a qualifying drug
 21 after importation (which shall not exceed 3
 22 places of business except by permission of the
 23 Secretary).

24 “(B) Such information as the Secretary
 25 determines to be necessary to demonstrate that

1 the registrant is in compliance with registration
2 conditions under—

3 “(i) in the case of an importer, sub-
4 sections (c), (d), (e), (g), and (j) (relating
5 to the sources of imported qualifying
6 drugs; the inspection of facilities of the im-
7 porter; the payment of fees; compliance
8 with the standards referred to in section
9 801(a); and maintenance of records and
10 samples); or

11 “(ii) in the case of an exporter, sub-
12 sections (c), (d), (f), (g), (h), (i), and (j)
13 (relating to the sources of exported quali-
14 fying drugs; the inspection of facilities of
15 the exporter and the marking of compliant
16 shipments; the payment of fees; and com-
17 pliance with the standards referred to in
18 section 801(a); being licensed as a phar-
19 macist; conditions for individual importa-
20 tion; and maintenance of records and sam-
21 ples).

22 “(C) An agreement by the registrant that
23 the registrant will not under subsection (a) im-
24 port or export any drug that is not a qualifying
25 drug.

1 “(D) An agreement by the registrant to—

2 “(i) notify the Secretary of a recall or
3 withdrawal of a qualifying drug distributed
4 in a permitted country that the registrant
5 has exported or imported, or intends to ex-
6 port or import, to the United States under
7 subsection (a);

8 “(ii) provide for the return to the reg-
9 istrant of such drug; and

10 “(iii) cease, or not begin, the expor-
11 tation or importation of such drug unless
12 the Secretary has notified the registrant
13 that exportation or importation of such
14 drug may proceed.

15 “(E) An agreement by the registrant to
16 ensure and monitor compliance with each reg-
17 istration condition, to promptly correct any
18 noncompliance with such a condition, and to
19 promptly report to the Secretary any such non-
20 compliance.

21 “(F) A plan describing the manner in
22 which the registrant will comply with the agree-
23 ment under subparagraph (E).

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

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

5 “(H) An agreement by the registrant to
6 notify the Secretary not more than 30 days be-
7 fore the registrant intends to make the change,
8 of—

9 “(i) any change that the registrant in-
10 tends to make regarding information pro-
11 vided under subparagraph (A) or (B); and

12 “(ii) any change that the registrant
13 intends to make in the compliance plan
14 under subparagraph (F).

15 “(I) In the case of an exporter—

16 “(i) An agreement by the exporter
17 that a qualifying drug will not under sub-
18 section (a) be exported to any individual
19 not authorized pursuant to subsection
20 (a)(2)(B) to be an importer of such drug.

21 “(ii) An agreement to post a bond,
22 payable to the Treasury of the United
23 States that is equal in value to the lesser
24 of—

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

5 “(II) \$1,000,000;

6 “(iii) An agreement by the exporter to
7 comply with applicable provisions of Cana-
8 dian law, or the law of the permitted coun-
9 try designated under subsection
10 (a)(4)(D)(i)(II) in which the exporter is lo-
11 cated, that protect the privacy of personal
12 information with respect to each individual
13 importing a prescription drug from the ex-
14 porter under subsection (a)(2)(B).

15 “(iv) An agreement by the exporter to
16 report to the Secretary—

17 “(I) not later than August 1 of
18 each fiscal year, the total price and
19 the total volume of drugs exported to
20 the United States by the exporter dur-
21 ing the 6-month period from January
22 1 through June 30 of that year; and

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

1 the United States by the exporter dur-
2 ing the previous fiscal year.

3 “(J) In the case of an importer, an agree-
4 ment by the importer to report to the Sec-
5 retary—

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

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

17 “(K) Such other provisions as the Sec-
18 retary may require by regulation to protect the
19 public health while permitting—

20 “(i) the importation by pharmacies,
21 groups of pharmacies, and wholesalers as
22 registered importers of qualifying drugs
23 under subsection (a); and

24 “(ii) importation by individuals of
25 qualifying drugs under subsection (a).

1 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
2 TION.—

3 “(A) IN GENERAL.—Not later than 90
4 days after the date on which a registrant sub-
5 mits to the Secretary a registration under para-
6 graph (1), the Secretary shall notify the reg-
7 istrant whether the registration is approved or
8 is disapproved. The Secretary shall disapprove
9 a registration if there is reason to believe that
10 the registrant is not in compliance with one or
11 more registration conditions, and shall notify
12 the registrant of such reason. In the case of a
13 disapproved registration, the Secretary shall
14 subsequently notify the registrant that the reg-
15 istration is approved if the Secretary deter-
16 mines that the registrant is in compliance with
17 such conditions.

18 “(B) CHANGES IN REGISTRATION INFOR-
19 MATION.—Not later than 30 days after receiv-
20 ing a notice under paragraph (1)(H) from a
21 registrant, the Secretary shall determine wheth-
22 er the change involved affects the approval of
23 the registration of the registrant under para-
24 graph (1), and shall inform the registrant of
25 the determination.

1 “(3) PUBLICATION OF CONTACT INFORMATION
2 FOR REGISTERED EXPORTERS.—Through the Inter-
3 net website of the Food and Drug Administration
4 and a toll-free telephone number, the Secretary shall
5 make readily available to the public a list of reg-
6 istered exporters, including contact information for
7 the exporters. Promptly after the approval of a reg-
8 istration submitted under paragraph (1), the Sec-
9 retary shall update the Internet website and the in-
10 formation provided through the toll-free telephone
11 number accordingly.

12 “(4) SUSPENSION AND TERMINATION.—

13 “(A) SUSPENSION.—With respect to the
14 effectiveness of a registration submitted under
15 paragraph (1):

16 “(i) Subject to clause (ii), the Sec-
17 retary may suspend the registration if the
18 Secretary determines, after notice and op-
19 portunity for a hearing, that the registrant
20 has failed to maintain substantial compli-
21 ance with a registration condition.

22 “(ii) If the Secretary determines that,
23 under color of the registration, the ex-
24 porter has exported a drug or the importer
25 has imported a drug that is not a quali-

1 fying drug, or a drug that does not comply
2 with subsection (g)(2)(A) or (g)(4), or has
3 exported a qualifying drug to an individual
4 in violation of subsection (i)(2)(F), the
5 Secretary shall immediately suspend the
6 registration. A suspension under the pre-
7 ceding sentence is not subject to the provi-
8 sion by the Secretary of prior notice, and
9 the Secretary shall provide to the reg-
10 istrant an opportunity for a hearing not
11 later than 10 days after the date on which
12 the registration is suspended.

13 “(iii) The Secretary may reinstate the
14 registration, whether suspended under
15 clause (i) or (ii), if the Secretary deter-
16 mines that the registrant has demonstrated
17 that further violations of registration con-
18 ditions will not occur.

19 “(B) TERMINATION.—The Secretary, after
20 notice and opportunity for a hearing, may ter-
21 minate the registration under paragraph (1) of
22 a registrant if the Secretary determines that
23 the registrant has engaged in a pattern or prac-
24 tice of violating 1 or more registration condi-
25 tions, or if on 1 or more occasions the Secretary

1 has under subparagraph (A)(ii) suspended the
2 registration of the registrant. The Secretary
3 may make the termination permanent, or for a
4 fixed period of not less than 1 year. During the
5 period in which the registration is terminated,
6 any registration submitted under paragraph (1)
7 by the registrant, or a person that is a partner
8 in the export or import enterprise, or a prin-
9 cipal officer in such enterprise, and any reg-
10 istration prepared with the assistance of the
11 registrant or such a person, has no legal effect
12 under this section.

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

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

23 “(B) failed to permit the Secretary to con-
24 duct an inspection described under subsection
25 (d).

1 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
2 tion condition is that the exporter or importer involved
3 agrees that a qualifying drug will under subsection (a) be
4 exported or imported into the United States only if there
5 is compliance with the following:

6 “(1) The drug was manufactured in an estab-
7 lishment—

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

10 “(B)(i) inspected by the Secretary; or

11 “(ii) for which the Secretary has elected to
12 rely on a satisfactory report of a good manufac-
13 turing practice inspection of the establishment
14 from a permitted country whose regulatory sys-
15 tem the Secretary recognizes as equivalent
16 under a mutual recognition agreement, as pro-
17 vided for under section 510(i)(3), section 803,
18 or part 26 of title 21, Code of Federal Regula-
19 tions (or any corresponding successor rule or
20 regulation).

21 “(2) The establishment is located in any coun-
22 try, and the establishment manufactured the drug
23 for distribution in the United States or for distribu-
24 tion in 1 or more of the permitted countries (without
25 regard to whether in addition the drug is manufac-

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

3 “(3) The exporter or importer obtained the
4 drug—

5 “(A) directly from the establishment; or

6 “(B) directly from an entity that, by con-
7 tract with the exporter or importer—

8 “(i) provides to the exporter or im-
9 porter a statement (in such form and con-
10 taining such information as the Secretary
11 may require) that, for the chain of custody
12 from the establishment, identifies each
13 prior sale, purchase, or trade of the drug
14 (including the date of the transaction and
15 the names and addresses of all parties to
16 the transaction);

17 “(ii) agrees to permit the Secretary to
18 inspect such statements and related
19 records to determine their accuracy;

20 “(iii) agrees, with respect to the quali-
21 fying drugs involved, to permit the Sec-
22 retary to inspect warehouses and other fa-
23 cilities, including records, of the entity for
24 purposes of determining whether the facili-
25 ties are in compliance with any standards

1 under this Act that are applicable to facili-
2 ties of that type in the United States; and

3 “(iv) has ensured, through such con-
4 tractual relationships as may be necessary,
5 that the Secretary has the same authority
6 regarding other parties in the chain of cus-
7 tody from the establishment that the Sec-
8 retary has under clauses (ii) and (iii) re-
9 garding such entity.

10 “(4)(A) The foreign country from which the im-
11 porter will import the drug is a permitted country;
12 or

13 “(B) The foreign country from which the ex-
14 porter will export the drug is the permitted country
15 in which the exporter is located.

16 “(5) During any period in which the drug was
17 not in the control of the manufacturer of the drug,
18 the drug did not enter any country that is not a per-
19 mitted country.

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

22 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
23 MENTS.—

24 “(1) INSPECTION OF FACILITIES.—A registra-
25 tion condition is that, for the purpose of assisting

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

4 “(A) the exporter agrees to permit the Sec-
5 retary—

6 “(i) to conduct onsite inspections, in-
7 cluding monitoring on a day-to-day basis,
8 of places of business of the exporter that
9 relate to qualifying drugs, including each
10 warehouse or other facility owned or con-
11 trolled by, or operated for, the exporter;

12 “(ii) to have access, including on a
13 day-to-day basis, to—

14 “(I) records of the exporter that
15 relate to the export of such drugs, in-
16 cluding financial records; and

17 “(II) samples of such drugs;

18 “(iii) to carry out the duties described
19 in paragraph (3); and

20 “(iv) to carry out any other functions
21 determined by the Secretary to be nec-
22 essary regarding the compliance of the ex-
23 porter; and

24 “(B) the Secretary has assigned 1 or more
25 employees of the Secretary to carry out the

1 functions described in this subsection for the
2 Secretary randomly, but not less than 12 times
3 annually, on the premises of places of busi-
4 nesses referred to in subparagraph (A)(i), and
5 such an assignment remains in effect on a con-
6 tinuous basis.

7 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
8 registration condition is that the exporter involved
9 agrees to affix to each shipping container of quali-
10 fying drugs exported under subsection (a) such
11 markings as the Secretary determines to be nec-
12 essary to identify the shipment as being in compli-
13 ance with all registration conditions. Markings under
14 the preceding sentence shall—

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

18 “(B) include anticounterfeiting or track-
19 and-trace technologies, taking into account the
20 economic and technical feasibility of those tech-
21 nologies.

22 “(3) CERTAIN DUTIES RELATING TO EXPORT-
23 ERS.—Duties of the Secretary with respect to an ex-
24 porter include the following:

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

6 “(B) During the inspections under sub-
7 paragraph (A), verifying the chain of custody of
8 a statistically significant sample of qualifying
9 drugs from the establishment in which the drug
10 was manufactured to the exporter, which shall
11 be accomplished or supplemented by the use of
12 anticounterfeiting or track-and-trace tech-
13 nologies, taking into account the economic and
14 technical feasibility of those technologies, except
15 that a drug that lacks such technologies from
16 the point of manufacture shall not for that rea-
17 son be excluded from importation by an ex-
18 porter.

19 “(C) Randomly reviewing records of ex-
20 ports to individuals for the purpose of deter-
21 mining whether the drugs are being imported
22 by the individuals in accordance with the condi-
23 tions under subsection (i). Such reviews shall be
24 conducted in a manner that will result in a sta-

1 tistically significant determination of compli-
2 ance with all such conditions.

3 “(D) Monitoring the affixing of markings
4 under paragraph (2).

5 “(E) Inspecting as the Secretary deter-
6 mines is necessary the warehouses and other fa-
7 cilities, including records, of other parties in the
8 chain of custody of qualifying drugs.

9 “(F) Determining whether the exporter is
10 in compliance with all other registration condi-
11 tions.

12 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-
13 istration condition is that, not less than 8 hours and
14 not more than 5 days in advance of the time of the
15 importation of a shipment of qualifying drugs, the
16 importer involved agrees to submit to the Secretary
17 a notice with respect to the shipment of drugs to be
18 imported or offered for import into the United
19 States under subsection (a). A notice under the pre-
20 ceding sentence shall include—

21 “(A) the name and complete contact infor-
22 mation of the person submitting the notice;

23 “(B) the name and complete contact infor-
24 mation of the importer involved;

1 “(C) the identity of the drug, including the
2 established name of the drug, the quantity of
3 the drug, and the lot number assigned by the
4 manufacturer;

5 “(D) the identity of the manufacturer of
6 the drug, including the identity of the establish-
7 ment at which the drug was manufactured;

8 “(E) the country from which the drug is
9 shipped;

10 “(F) the name and complete contact infor-
11 mation for the shipper of the drug;

12 “(G) anticipated arrival information, in-
13 cluding the port of arrival and crossing location
14 within that port, and the date and time;

15 “(H) a summary of the chain of custody of
16 the drug from the establishment in which the
17 drug was manufactured to the importer;

18 “(I) a declaration as to whether the Sec-
19 retary has ordered that importation of the drug
20 from the permitted country cease under sub-
21 section (g)(2)(C) or (D); and

22 “(J) such other information as the Sec-
23 retary may require by regulation.

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

1 agrees, before wholesale distribution (as defined in
2 section 503(e)) of a qualifying drug that has been
3 imported under subsection (a), to affix to each con-
4 tainer of such drug such markings or other tech-
5 nology as the Secretary determines necessary to
6 identify the shipment as being in compliance with all
7 registration conditions, except that the markings or
8 other technology shall not be required on a drug
9 that bears comparable, compatible markings or tech-
10 nology from the manufacturer of the drug. Markings
11 or other technology under the preceding sentence
12 shall—

13 “(A) be designed to prevent affixation of
14 the markings or other technology to any con-
15 tainer that is not authorized to bear the mark-
16 ings; and

17 “(B) shall include anticounterfeiting or
18 track-and-trace technologies, taking into ac-
19 count the economic and technical feasibility of
20 such technologies.

21 “(6) CERTAIN DUTIES RELATING TO IMPORT-
22 ERS.—Duties of the Secretary with respect to an im-
23 porter include the following:

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

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

3 “(B) During the inspections under sub-
4 paragraph (A), verifying the chain of custody of
5 a statistically significant sample of qualifying
6 drugs from the establishment in which the drug
7 was manufactured to the importer, which shall
8 be accomplished or supplemented by the use of
9 anticounterfeiting or track-and-trace tech-
10 nologies, taking into account the economic and
11 technical feasibility of those technologies, except
12 that a drug that lacks such technologies from
13 the point of manufacture shall not for that rea-
14 son be excluded from importation by an im-
15 porter.

16 “(C) Reviewing notices under paragraph
17 (4).

18 “(D) Inspecting as the Secretary deter-
19 mines is necessary the warehouses and other fa-
20 cilities, including records of other parties in the
21 chain of custody of qualifying drugs.

22 “(E) Determining whether the importer is
23 in compliance with all other registration condi-
24 tions.

25 “(e) IMPORTER FEES.—

1 “(1) REGISTRATION FEE.—A registration con-
2 dition is that the importer involved pays to the Sec-
3 retary a fee of \$10,000 due on the date on which
4 the importer first submits the registration to the
5 Secretary under subsection (b).

6 “(2) INSPECTION FEE.—A registration condi-
7 tion is that the importer involved pays a fee to the
8 Secretary in accordance with this subsection. Such
9 fee shall be paid not later than October 1 and April
10 1 of each fiscal year in the amount provided for
11 under paragraph (3).

12 “(3) AMOUNT OF INSPECTION FEE.—

13 “(A) AGGREGATE TOTAL OF FEES.—Not
14 later than 30 days before the start of each fis-
15 cal year, the Secretary, in consultation with the
16 Secretary of Homeland Security and the Sec-
17 retary of the Treasury, shall establish an aggre-
18 gate total of fees to be collected under para-
19 graph (2) for importers for that fiscal year that
20 is sufficient, and not more than necessary, to
21 pay the costs for that fiscal year of admin-
22 istering this section with respect to registered
23 importers, including the costs associated with—

24 “(i) inspecting the facilities of reg-
25 istered importers, and of other entities in

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

3 “(ii) developing, implementing, and
4 operating under such subsection an elec-
5 tronic system for submission and review of
6 the notices required under subsection
7 (d)(4) with respect to shipments of quali-
8 fying drugs under subsection (a) to assess
9 compliance with all registration conditions
10 when such shipments are offered for im-
11 port into the United States; and

12 “(iii) inspecting such shipments as
13 necessary, when offered for import into the
14 United States to determine if such a ship-
15 ment should be refused admission under
16 subsection (g)(5).

17 “(B) LIMITATION.—Subject to subpara-
18 graph (C), the aggregate total of fees collected
19 under paragraph (2) for a fiscal year shall not
20 exceed 2.5 percent of the total price of quali-
21 fying drugs imported during that fiscal year
22 into the United States by registered importers
23 under subsection (a).

24 “(C) TOTAL PRICE OF DRUGS.—

1 “(i) ESTIMATE.—For the purposes of
2 complying with the limitation described in
3 subparagraph (B) when establishing under
4 subparagraph (A) the aggregate total of
5 fees to be collected under paragraph (2)
6 for a fiscal year, the Secretary shall esti-
7 mate the total price of qualifying drugs im-
8 ported into the United States by registered
9 importers during that fiscal year by adding
10 the total price of qualifying drugs imported
11 by each registered importer during the 6-
12 month period from January 1 through
13 June 30 of the previous fiscal year, as re-
14 ported to the Secretary by each registered
15 importer under subsection (b)(1)(J).

16 “(ii) CALCULATION.—Not later than
17 March 1 of the fiscal year that follows the
18 fiscal year for which the estimate under
19 clause (i) is made, the Secretary shall cal-
20 culate the total price of qualifying drugs
21 imported into the United States by reg-
22 istered importers during that fiscal year by
23 adding the total price of qualifying drugs
24 imported by each registered importer dur-
25 ing 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 “(1) REGISTRATION FEE.—A registration con-
 2 dition is that the exporter involved pays to the Sec-
 3 retary a fee of \$10,000 due on the date on which
 4 the exporter first submits that registration to the
 5 Secretary under subsection (b).

6 “(2) INSPECTION FEE.—A registration condi-
 7 tion is that the exporter involved pays a fee to the
 8 Secretary in accordance with this subsection. Such
 9 fee shall be paid not later than October 1 and April
 10 1 of each fiscal year in the amount provided for
 11 under paragraph (3).

12 “(3) AMOUNT OF INSPECTION FEE.—

13 “(A) AGGREGATE TOTAL OF FEES.—Not
 14 later than 30 days before the start of each fis-
 15 cal year, the Secretary, in consultation with the
 16 Secretary of Homeland Security and the Sec-
 17 retary of the Treasury, shall establish an aggre-
 18 gate total of fees to be collected under para-
 19 graph (2) for exporters for that fiscal year that
 20 is sufficient, and not more than necessary, to
 21 pay the costs for that fiscal year of admin-
 22 istering this section with respect to registered
 23 exporters, including the costs associated with—

24 “(i) inspecting the facilities of reg-
 25 istered exporters, and of other entities in

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

3 “(ii) developing, implementing, and
4 operating under such subsection a system
5 to screen marks on shipments of qualifying
6 drugs under subsection (a) that indicate
7 compliance with all registration conditions,
8 when such shipments are offered for im-
9 port into the United States; and

10 “(iii) screening such markings, and
11 inspecting such shipments as necessary,
12 when offered for import into the United
13 States to determine if such a shipment
14 should be refused admission under sub-
15 section (g)(5).

16 “(B) LIMITATION.—Subject to subpara-
17 graph (C), the aggregate total of fees collected
18 under paragraph (2) for a fiscal year shall not
19 exceed 2.5 percent of the total price of quali-
20 fying drugs imported during that fiscal year
21 into the United States by registered exporters
22 under subsection (a).

23 “(C) TOTAL PRICE OF DRUGS.—

24 “(i) ESTIMATE.—For the purposes of
25 complying with the limitation described in

1 subparagraph (B) when establishing under
2 subparagraph (A) the aggregate total of
3 fees to be collected under paragraph (2)
4 for a fiscal year, the Secretary shall esti-
5 mate the total price of qualifying drugs im-
6 ported into the United States by registered
7 exporters during that fiscal year by adding
8 the total price of qualifying drugs exported
9 by each registered exporter during the 6-
10 month period from January 1 through
11 June 30 of the previous fiscal year, as re-
12 ported to the Secretary by each registered
13 exporter under subsection (b)(1)(I)(iv).

14 “(ii) CALCULATION.—Not later than
15 March 1 of the fiscal year that follows the
16 fiscal year for which the estimate under
17 clause (i) is made, the Secretary shall cal-
18 culate the total price of qualifying drugs
19 imported into the United States by reg-
20 istered exporters during that fiscal year by
21 adding the total price of qualifying drugs
22 exported by each registered exporter dur-
23 ing that fiscal year, as reported to the Sec-
24 retary by each registered exporter under
25 subsection (b)(1)(I)(iv).

1 “(iii) ADJUSTMENT.—If the total
2 price of qualifying drugs imported into the
3 United States by registered exporters dur-
4 ing a fiscal year as calculated under clause
5 (ii) is less than the aggregate total of fees
6 collected under paragraph (2) for that fis-
7 cal year, the Secretary shall provide for a
8 pro-rata reduction in the fee due from each
9 registered exporter on April 1 of the subse-
10 quent fiscal year so that the limitation de-
11 scribed in subparagraph (B) is observed.

12 “(D) INDIVIDUAL EXPORTER FEE.—Sub-
13 ject to the limitation described in subparagraph
14 (B), the fee under paragraph (2) to be paid on
15 October 1 and April 1 by an exporter shall be
16 an amount that is proportional to a reasonable
17 estimate by the Secretary of the semiannual
18 share of the exporter of the volume of quali-
19 fying drugs exported by exporters under sub-
20 section (a).

21 “(4) USE OF FEES.—

22 “(A) IN GENERAL.—Subject to appropria-
23 tions Acts, fees collected by the Secretary under
24 paragraphs (1) and (2) shall be credited to the
25 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

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

7 “(2) SECTION 505; APPROVAL STATUS.—

8 “(A) IN GENERAL.—A qualifying drug that
9 is imported or offered for import under sub-
10 section (a) shall comply with the conditions es-
11 tablished in the approved application under sec-
12 tion 505(b) for the U.S. label drug as described
13 under this subsection.

14 “(B) NOTICE BY MANUFACTURER; GEN-
15 ERAL PROVISIONS.—

16 “(i) IN GENERAL.—The person that
17 manufactures a qualifying drug that is, or
18 will be, introduced for commercial distribu-
19 tion in a permitted country shall in accord-
20 ance with this paragraph submit to the
21 Secretary a notice that—

22 “(I) includes each difference in
23 the qualifying drug from a condition
24 established in the approved applica-
25 tion for the U.S. label drug beyond—

1 “(aa) the variations provided
2 for in the application; and

3 “(bb) any difference in label-
4 ing (except ingredient labeling);
5 or

6 “(II) states that there is no dif-
7 ference in the qualifying drug from a
8 condition established in the approved
9 application for the U.S. label drug be-
10 yond—

11 “(aa) the variations provided
12 for in the application; and

13 “(bb) any difference in label-
14 ing (except ingredient labeling).

15 “(ii) INFORMATION IN NOTICE.—A
16 notice under clause (i)(I) shall include the
17 information that the Secretary may require
18 under section 506A, any additional infor-
19 mation the Secretary may require (which
20 may include data on bioequivalence if such
21 data are not required under section 506A),
22 and, with respect to the permitted country
23 that approved the qualifying drug for com-
24 mercial distribution, or with respect to

1 which such approval is sought, include the
2 following:

3 “(I) The date on which the quali-
4 fying drug with such difference was,
5 or will be, introduced for commercial
6 distribution in the permitted country.

7 “(II) Information demonstrating
8 that the person submitting the notice
9 has also notified the government of
10 the permitted country in writing that
11 the person is submitting to the Sec-
12 retary a notice under clause (i)(I),
13 which notice describes the difference
14 in the qualifying drug from a condi-
15 tion established in the approved appli-
16 cation for the U.S. label drug.

17 “(III) The information that the
18 person submitted or will submit to the
19 government of the permitted country
20 for purposes of obtaining approval for
21 commercial distribution of the drug in
22 the country which, if in a language
23 other than English, shall be accom-
24 panied by an English translation
25 verified to be complete and accurate,

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

4 “(iii) CERTIFICATIONS.—The chief ex-
5 ecutive officer and the chief medical officer
6 of the manufacturer involved shall each
7 certify in the notice under clause (i) that—

8 “(I) the information provided in
9 the notice is complete and true; and

10 “(II) a copy of the notice has
11 been provided to the Federal Trade
12 Commission and to the State attor-
13 neys general.

14 “(iv) FEE.—If a notice submitted
15 under clause (i) includes a difference that
16 would, under section 506A, require the
17 submission of a supplemental application if
18 made as a change to the U.S. label drug,
19 the person that submits the notice shall
20 pay to the Secretary a fee in the same
21 amount as would apply if the person were
22 paying a fee pursuant to section
23 736(a)(1)(A)(ii). Subject to appropriations
24 Acts, fees collected by the Secretary under
25 the preceding sentence are available only to

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

4 “(v) TIMING OF SUBMISSION OF NO-
 5 TICES.—

6 “(I) PRIOR APPROVAL NO-
 7 TICES.—A notice under clause (i) to
 8 which subparagraph (C) applies shall
 9 be submitted to the Secretary not
 10 later than 120 days before the quali-
 11 fying drug with the difference is intro-
 12 duced for commercial distribution in a
 13 permitted country, unless the country
 14 requires that distribution of the quali-
 15 fying drug with the difference begin
 16 less than 120 days after the country
 17 requires the difference.

18 “(II) OTHER APPROVAL NO-
 19 TICES.—A notice under clause (i) to
 20 which subparagraph (D) applies shall
 21 be submitted to the Secretary not
 22 later than the day on which the quali-
 23 fying drug with the difference is intro-
 24 duced for commercial distribution in a
 25 permitted country.

1 “(III) OTHER NOTICES.—A no-
2 tice under clause (i) to which subpara-
3 graph (E) applies shall be submitted
4 to the Secretary on the date that the
5 qualifying drug is first introduced for
6 commercial distribution in a permitted
7 country and annually thereafter.

8 “(vi) REVIEW BY SECRETARY.—

9 “(I) IN GENERAL.—In this para-
10 graph, the difference in a qualifying
11 drug that is submitted in a notice
12 under clause (i) from the U.S. label
13 drug shall be treated by the Secretary
14 as if it were a manufacturing change
15 to the U.S. label drug under section
16 506A.

17 “(II) STANDARD OF REVIEW.—
18 Except as provided in subclause (III),
19 the Secretary shall review and approve
20 or disapprove the difference in a no-
21 tice submitted under clause (i), if re-
22 quired under section 506A, using the
23 safe and effective standard for ap-
24 proving or disapproving a manufac-
25 turing change under section 506A.

1 “(III) BIOEQUIVALENCE.—If the
2 Secretary would approve the dif-
3 ference in a notice submitted under
4 clause (i) using the safe and effective
5 standard under section 506A and if
6 the Secretary determines that the
7 qualifying drug is not bioequivalent to
8 the U.S. label drug, the Secretary
9 shall—

10 “(aa) include in the labeling
11 provided under paragraph (3) a
12 prominent advisory that the
13 qualifying drug is safe and effec-
14 tive but is not bioequivalent to
15 the U.S. label drug if the Sec-
16 retary determines that such an
17 advisory is necessary for health
18 care practitioners and patients to
19 use the qualifying drug safely
20 and effectively; or

21 “(bb) decline to approve the
22 difference if the Secretary deter-
23 mines that the availability of
24 both the qualifying drug and the

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

3 “(IV) REVIEW BY THE SEC-
4 RETARY.—The Secretary shall review
5 and approve or disapprove the dif-
6 ference in a notice submitted under
7 clause (i), if required under section
8 506A, not later than 120 days after
9 the date on which the notice is sub-
10 mitted.

11 “(V) ESTABLISHMENT INSPEC-
12 TION.—If review of such difference
13 would require an inspection of the es-
14 tablishment in which the qualifying
15 drug is manufactured—

16 “(aa) such inspection by the
17 Secretary shall be authorized;
18 and

19 “(bb) the Secretary may rely
20 on a satisfactory report of a good
21 manufacturing practice inspec-
22 tion of the establishment from a
23 permitted country whose regu-
24 latory system the Secretary rec-
25 ognizes as equivalent under a

1 mutual recognition agreement, as
2 provided under section 510(i)(3),
3 section 803, or part 26 of title
4 21, Code of Federal Regulations
5 (or any corresponding successor
6 rule or regulation).

7 “(vii) PUBLICATION OF INFORMATION
8 ON NOTICES.—

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

16 “(II) CONTENTS.—The list under
17 subclause (I) shall include the date on
18 which a notice is submitted and
19 whether—

20 “(aa) a notice is under re-
21 view;

22 “(bb) the Secretary has or-
23 dered that importation of the
24 qualifying drug from a permitted
25 country cease; or

1 “(cc) the importation of the
2 drug is permitted under sub-
3 section (a).

4 “(III) UPDATE.—The Secretary
5 shall promptly update the Internet
6 website with any changes to the list.

7 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
8 ING PRIOR APPROVAL.—In the case of a notice
9 under subparagraph (B)(i) that includes a dif-
10 ference that would, under section 506A(c) or
11 (d)(3)(B)(i), require the approval of a supple-
12 mental application before the difference could
13 be made to the U.S. label drug the following
14 shall occur:

15 “(i) Promptly after the notice is sub-
16 mitted, the Secretary shall notify reg-
17 istered exporters, registered importers, the
18 Federal Trade Commission, and the State
19 attorneys general that the notice has been
20 submitted with respect to the qualifying
21 drug involved.

22 “(ii) If the Secretary has not made a
23 determination whether such a supple-
24 mental application regarding the U.S. label
25 drug would be approved or disapproved by

1 the date on which the qualifying drug in-
2 volved is to be introduced for commercial
3 distribution in a permitted country, the
4 Secretary shall—

5 “(I) order that the importation of
6 the qualifying drug involved from the
7 permitted country not begin until the
8 Secretary completes review of the no-
9 tice; and

10 “(II) promptly notify registered
11 exporters, registered importers, the
12 Federal Trade Commission, and the
13 State attorneys general of the order.

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

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

23 “(II) notify the permitted coun-
24 try that approved the qualifying drug

1 for commercial distribution of the de-
2 termination; and

3 “(III) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 State attorneys general of the deter-
7 mination.

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

12 “(I) vacate the order under
13 clause (ii), if any;

14 “(II) consider the difference to
15 be a variation provided for in the ap-
16 proved application for the U.S. label
17 drug;

18 “(III) permit importation of the
19 qualifying drug under subsection (a);
20 and

21 “(IV) promptly notify registered
22 exporters, registered importers, the
23 Federal Trade Commission, and the
24 State attorneys general of the deter-
25 mination.

1 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
2 QUIRING PRIOR APPROVAL.—In the case of a
3 notice under subparagraph (B)(i) that includes
4 a difference that would, under section
5 506A(d)(3)(B)(ii), not require the approval of a
6 supplemental application before the difference
7 could be made to the U.S. label drug the fol-
8 lowing shall occur:

9 “(i) During the period in which the
10 notice is being reviewed by the Secretary,
11 the authority under this subsection to im-
12 port the qualifying drug involved continues
13 in effect.

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

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country cease;

21 “(II) notify the permitted coun-
22 try that approved the qualifying drug
23 for commercial distribution of the de-
24 termination; and

1 “(III) promptly notify registered
2 exporters, registered importers, the
3 Federal Trade Commission, and the
4 State attorneys general of the deter-
5 mination.

6 “(iii) If the Secretary determines that
7 such a supplemental application regarding
8 the U.S. label drug would be approved, the
9 difference shall be considered to be a vari-
10 ation provided for in the approved applica-
11 tion for the U.S. label drug.

12 “(E) NOTICE; DRUG DIFFERENCE NOT RE-
13 QUIRING APPROVAL; NO DIFFERENCE.—In the
14 case of a notice under subparagraph (B)(i) that
15 includes a difference for which, under section
16 506A(d)(1)(A), a supplemental application
17 would not be required for the difference to be
18 made to the U.S. label drug, or that states that
19 there is no difference, the Secretary—

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

23 “(ii) may not order that the importa-
24 tion of the qualifying drug involved cease;
25 and

1 “(iii) shall promptly notify registered
2 exporters and registered importers.

3 “(F) DIFFERENCES IN ACTIVE INGRE-
4 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
5 FORM, OR STRENGTH.—

6 “(i) IN GENERAL.—A person who
7 manufactures a drug approved under sec-
8 tion 505(b) shall submit an application
9 under section 505(b) for approval of an-
10 other drug that is manufactured for dis-
11 tribution in a permitted country by or for
12 the person that manufactures the drug ap-
13 proved under section 505(b) if—

14 “(I) there is no qualifying drug
15 in commercial distribution in per-
16 mitted countries whose combined pop-
17 ulation represents at least 50 percent
18 of the total population of all permitted
19 countries with the same active ingre-
20 dient or ingredients, route of adminis-
21 tration, dosage form, and strength as
22 the drug approved under section
23 505(b); and

24 “(II) each active ingredient of
25 the other drug is related to an active

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

4 “(ii) APPLICATION UNDER SECTION
5 505(b).—The application under section
6 505(b) required under clause (i) shall—

7 “(I) request approval of the other
8 drug for the indication or indications
9 for which the drug approved under
10 section 505(b) is labeled;

11 “(II) include the information that
12 the person submitted to the govern-
13 ment of the permitted country for
14 purposes of obtaining approval for
15 commercial distribution of the other
16 drug in that country, which if in a
17 language other than English, shall be
18 accompanied by an English trans-
19 lation verified to be complete and ac-
20 curate, with the name, address, and a
21 brief statement of the qualifications of
22 the person that made the translation;

23 “(III) include a right of reference
24 to the application for the drug ap-
25 proved under section 505(b); and

1 “(IV) include such additional in-
 2 formation as the Secretary may re-
 3 quire.

4 “(iii) TIMING OF SUBMISSION OF AP-
 5 PPLICATION.—An application under section
 6 505(b) required under clause (i) shall be
 7 submitted to the Secretary not later than
 8 the day on which the information referred
 9 to in clause (ii)(II) is submitted to the gov-
 10 ernment of the permitted country.

11 “(iv) NOTICE OF DECISION ON APPLI-
 12 CATION.—The Secretary shall promptly no-
 13 tify registered exporters, registered import-
 14 ers, the Federal Trade Commission, and
 15 the State attorneys general of a determina-
 16 tion to approve or to disapprove an appli-
 17 cation under section 505(b) required under
 18 clause (i).

19 “(v) RELATED ACTIVE INGREDI-
 20 ENTS.—For purposes of clause (i)(II), 2
 21 active ingredients are related if they are—

22 “(I) the same; or

23 “(II) different salts, esters, or
 24 complexes of the same moiety.

25 “(3) SECTION 502; LABELING.—

1 “(A) IMPORTATION BY REGISTERED IM-
2 PORTER.—

3 “(i) IN GENERAL.—In the case of a
4 qualifying drug that is imported or offered
5 for import by a registered importer, such
6 drug shall be considered to be in compli-
7 ance with section 502 and the labeling re-
8 quirements under the approved application
9 for the U.S. label drug if the qualifying
10 drug bears—

11 “(I) a copy of the labeling ap-
12 proved for the U.S. label drug under
13 section 505, without regard to wheth-
14 er the copy bears any trademark in-
15 volved;

16 “(II) the name of the manufac-
17 turer and location of the manufac-
18 turer;

19 “(III) the lot number assigned by
20 the manufacturer;

21 “(IV) the name, location, and
22 registration number of the importer;
23 and

1 “(V) the National Drug Code
2 number assigned to the qualifying
3 drug by the Secretary.

4 “(ii) REQUEST FOR COPY OF THE LA-
5 BELING.—The Secretary shall provide such
6 copy to the registered importer involved,
7 upon request of the importer.

8 “(iii) REQUESTED LABELING.—The
9 labeling provided by the Secretary under
10 clause (ii) shall—

11 “(I) include the established
12 name, as defined in section 502(e)(3),
13 for each active ingredient in the quali-
14 fying drug;

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

18 “(III) if required under para-
19 graph (2)(B)(vi)(III), a prominent ad-
20 visory that the qualifying drug is safe
21 and effective but not bioequivalent to
22 the U.S. label drug; and

23 “(IV) if the inactive ingredients
24 of the qualifying drug are different

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

3 “(aa) a prominent notice
4 that the ingredients of the quali-
5 fying drug differ from the ingre-
6 dients of the U.S. label drug and
7 that the qualifying drug must be
8 dispensed with an advisory to
9 people with allergies about this
10 difference and a list of ingredi-
11 ents; and

12 “(bb) a list of the ingredi-
13 ents of the qualifying drug as
14 would be required under section
15 502(e).

16 “(B) IMPORTATION BY INDIVIDUAL.—

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

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

5 “(I) directions for use by the
6 consumer;

7 “(II) the lot number assigned by
8 the manufacturer;

9 “(III) the name and registration
10 number of the exporter;

11 “(IV) if required under para-
12 graph (2)(B)(vi)(III), a prominent ad-
13 visory that the drug is safe and effec-
14 tive but not bioequivalent to the U.S.
15 label drug;

16 “(V) if the inactive ingredients of
17 the drug are different from the inac-
18 tive ingredients for the U.S. label
19 drug—

20 “(aa) a prominent advisory
21 that persons with an allergy
22 should check the ingredient list
23 of the drug because the ingredi-
24 ents of the drug differ from the

1 ingredients of the U.S. label
2 drug; and

3 “(bb) a list of the ingredi-
4 ents of the drug as would be re-
5 quired under section 502(e); and

6 “(VI) a copy of any special label-
7 ing that would be required by the Sec-
8 retary had the U.S. label drug been
9 dispensed by a pharmacist in the
10 United States, without regard to
11 whether the special labeling bears any
12 trademark involved.

13 “(ii) PACKAGING.—A qualifying drug
14 offered for import to an individual by an
15 exporter under this section that is pack-
16 aged in a unit-of-use container (as those
17 items are defined in the United States
18 Pharmacopeia and National Formulary)
19 shall not be repackaged, provided that—

20 “(I) the packaging complies with
21 all applicable regulations under sec-
22 tions 3 and 4 of the Poison Preven-
23 tion Packaging Act of 1970 (15
24 U.S.C. 1471 et seq.); or

1 “(II) the consumer consents to
2 waive the requirements of such Act,
3 after being informed that the pack-
4 aging does not comply with such Act
5 and that the exporter will provide the
6 drug in packaging that is compliant at
7 no additional cost.

8 “(iii) REQUEST FOR COPY OF SPECIAL
9 LABELING AND INGREDIENT LIST.—The
10 Secretary shall provide to the registered
11 exporter involved a copy of the special la-
12 beling, the advisory, and the ingredient list
13 described under clause (i), upon request of
14 the exporter.

15 “(iv) REQUESTED LABELING AND IN-
16 GREDIENT LIST.—The labeling and ingre-
17 dient list provided by the Secretary under
18 clause (iii) shall—

19 “(I) include the established
20 name, as defined in section 502(e)(3),
21 for each active ingredient in the drug;
22 and

23 “(II) not include the proprietary
24 name of the U.S. label drug or any
25 active ingredient thereof.

1 “(4) SECTION 501; ADULTERATION.—A quali-
2 fying drug that is imported or offered for import
3 under subsection (a) shall be considered to be in
4 compliance with section 501 if the drug is in compli-
5 ance with subsection (c).

6 “(5) STANDARDS FOR REFUSING ADMISSION.—
7 A drug exported under subsection (a) from a reg-
8 istered exporter or imported by a registered importer
9 may be refused admission into the United States if
10 1 or more of the following applies:

11 “(A) The drug is not a qualifying drug.

12 “(B) A notice for the drug required under
13 paragraph (2)(B) has not been submitted to the
14 Secretary.

15 “(C) The Secretary has ordered that im-
16 portation of the drug from the permitted coun-
17 try cease under paragraph (2) (C) or (D).

18 “(D) The drug does not comply with para-
19 graph (3) or (4).

20 “(E) The shipping container appears dam-
21 aged in a way that may affect the strength,
22 quality, or purity of the drug.

23 “(F) The Secretary becomes aware that—

24 “(i) the drug may be counterfeit;

1 “(ii) the drug may have been pre-
2 pared, packed, or held under insanitary
3 conditions; or

4 “(iii) the methods used in, or the fa-
5 cilities or controls used for, the manufac-
6 turing, processing, packing, or holding of
7 the drug do not conform to good manufac-
8 turing practice.

9 “(G) The Secretary has obtained an in-
10 junction under section 302 that prohibits the
11 distribution of the drug in interstate commerce.

12 “(H) The Secretary has under section
13 505(e) withdrawn approval of the drug.

14 “(I) The manufacturer of the drug has in-
15 stituted a recall of the drug.

16 “(J) If the drug is imported or offered for
17 import by a registered importer without submis-
18 sion of a notice in accordance with subsection
19 (d)(4).

20 “(K) If the drug is imported or offered for
21 import from a registered exporter to an indi-
22 vidual and 1 or more of the following applies:

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

1 “(ii) The markings on the shipping
2 container appear to be counterfeit.

3 “(iii) The shipping container or mark-
4 ings appear to have been tampered with.

5 “(h) EXPORTER LICENSURE IN PERMITTED COUN-
6 TRY.—A registration condition is that the exporter in-
7 volved agrees that a qualifying drug will be exported to
8 an individual only if the Secretary has verified that—

9 “(1) the exporter is authorized under the law of
10 the permitted country in which the exporter is lo-
11 cated to dispense prescription drugs; and

12 “(2) the exporter employs persons that are li-
13 censed under the law of the permitted country in
14 which the exporter is located to dispense prescription
15 drugs in sufficient number to dispense safely the
16 drugs exported by the exporter to individuals, and
17 the exporter assigns to those persons responsibility
18 for dispensing such drugs to individuals.

19 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
20 TION.—

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

1 “(A) The drug is accompanied by a copy of
2 a prescription for the drug, which prescrip-
3 tion—

4 “(i) is valid under applicable Federal
5 and State laws; and

6 “(ii) was issued by a practitioner who,
7 under the law of a State of which the indi-
8 vidual is a resident, or in which the indi-
9 vidual receives care from the practitioner
10 who issues the prescription, is authorized
11 to administer prescription drugs.

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

17 “(C) The copies referred to in subpara-
18 graphs (A)(i) and (B) are marked in a manner
19 sufficient—

20 “(i) to indicate that the prescription,
21 and the equivalent document in the per-
22 mitted country in which the exporter is lo-
23 cated, have been filled; and

24 “(ii) to prevent a duplicative filling by
25 another pharmacist.

1 “(D) The individual has provided to the
2 registered exporter a complete list of all drugs
3 used by the individual for review by the individ-
4 uals who dispense the drug.

5 “(E) The quantity of the drug does not ex-
6 ceed a 90-day supply.

7 “(F) The drug is not an ineligible subpart
8 H drug. For purposes of this section, a pre-
9 scription drug is an ‘ineligible subpart H drug’
10 if the drug was approved by the Secretary
11 under subpart H of part 314 of title 21, Code
12 of Federal Regulations (relating to accelerated
13 approval), with restrictions under section 520 of
14 such part to assure safe use, and the Secretary
15 has published in the Federal Register a notice
16 that the Secretary has determined that good
17 cause exists to prohibit the drug from being im-
18 ported pursuant to this subsection.

19 “(2) NOTICE REGARDING DRUG REFUSED AD-
20 MISSION.—If a registered exporter ships a drug to
21 an individual pursuant to subsection (a)(2)(B) and
22 the drug is refused admission to the United States,
23 a written notice shall be sent to the individual and
24 to the exporter that informs the individual and the

1 exporter of such refusal and the reason for the re-
2 fusar.

3 “(j) MAINTENANCE OF RECORDS AND SAMPLES.—

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

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

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

11 “(2) PLACE OF RECORD MAINTENANCE.—The
12 records described under paragraph (1) shall be
13 maintained—

14 “(A) in the case of an importer, at the
15 place of business of the importer at which the
16 importer initially receives the qualifying drug
17 after importation; or

18 “(B) in the case of an exporter, at the fa-
19 cility from which the exporter ships the quali-
20 fying drug to the United States.

21 “(k) DRUG RECALLS.—

22 “(1) MANUFACTURERS.—A person that manu-
23 factures a qualifying drug imported from a per-
24 mitted country under this section shall promptly in-
25 form the Secretary—

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

3 “(B) how the drug may be identified, in-
4 cluding lot number; and

5 “(C) the reason for the recall or with-
6 drawal.

7 “(2) SECRETARY.—With respect to each per-
8 mitted country, the Secretary shall—

9 “(A) enter into an agreement with the gov-
10 ernment of the country to receive information
11 about recalls and withdrawals of qualifying
12 drugs in the country; or

13 “(B) monitor recalls and withdrawals of
14 qualifying drugs in the country using any infor-
15 mation that is available to the public in any
16 media.

17 “(3) NOTICE.—The Secretary may notify, as
18 appropriate, registered exporters, registered import-
19 ers, wholesalers, pharmacies, or the public of a recall
20 or withdrawal of a qualifying drug in a permitted
21 country.

22 “(1) DRUG LABELING AND PACKAGING.—

23 “(1) IN GENERAL.—When a qualifying drug
24 that is imported into the United States by an im-
25 porter under subsection (a) is dispensed by a phar-

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

8 “(A) The lot number assigned by the man-
9 ufacturer.

10 “(B) The name and registration number of
11 the importer.

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

16 “(D) If the inactive ingredients of the drug
17 are different from the inactive ingredients for
18 the U.S. label drug—

19 “(i) a prominent advisory that persons
20 with allergies should check the ingredient
21 list of the drug because the ingredients of
22 the drug differ from the ingredients of the
23 U.S. label drug; and

1 “(ii) a list of the ingredients of the
2 drug as would be required under section
3 502(e).

4 “(2) PACKAGING.—A qualifying drug that is
5 packaged in a unit-of-use container (as those terms
6 are defined in the United States Pharmacopeia and
7 National Formulary) shall not be repackaged, pro-
8 vided that—

9 “(A) the packaging complies with all appli-
10 cable regulations under sections 3 and 4 of the
11 Poison Prevention Packaging Act of 1970 (15
12 U.S.C. 1471 et seq.); or

13 “(B) the consumer consents to waive the
14 requirements of such Act, after being informed
15 that the packaging does not comply with such
16 Act and that the pharmacist will provide the
17 drug in packaging that is compliant at no addi-
18 tional cost.

19 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-
20 standing any other provision of this section, this section
21 does not authorize the importation into the United States
22 of a qualifying drug donated or otherwise supplied for free
23 or at nominal cost by the manufacturer of the drug to
24 a charitable or humanitarian organization, including the

1 United Nations and affiliates, or to a government of a for-
 2 eign country.

3 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
 4 TICES.—

5 “(1) IN GENERAL.—It is unlawful for a manu-
 6 facturer, directly or indirectly (including by being a
 7 party to a licensing agreement or other agreement),
 8 to—

9 “(A) discriminate by charging a higher
 10 price for a prescription drug sold to a registered
 11 exporter or other person in a permitted country
 12 that exports a qualifying drug to the United
 13 States under this section than the price that is
 14 charged, inclusive of rebates or other incentives
 15 to the permitted country or other person, to an-
 16 other person that is in the same country and
 17 that does not export a qualifying drug into the
 18 United States under this section;

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

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

3 “(C) discriminate by denying, restricting,
4 or delaying supplies of a prescription drug to a
5 registered exporter or other person in a per-
6 mitted country that exports a qualifying drug to
7 the United States under this section or to a
8 registered importer or other person that distrib-
9 utes, sells, or uses a qualifying drug imported
10 into the United States under this section;

11 “(D) discriminate by publicly, privately, or
12 otherwise refusing to do business with a reg-
13 istered exporter or other person in a permitted
14 country that exports a qualifying drug to the
15 United States under this section or with a reg-
16 istered importer or other person that distrib-
17 utes, sells, or uses a qualifying drug imported
18 into the United States under this section;

19 “(E) knowingly fail to submit a notice
20 under subsection (g)(2)(B)(i), knowingly fail to
21 submit such a notice on or before the date spec-
22 ified in subsection (g)(2)(B)(v) or as otherwise
23 required under subsection (e) (3), (4), and (5)
24 of section 4 of the Pharmaceutical Market Ac-
25 cess and Drug Safety Act of 2007, knowingly

1 submit such a notice that makes a materially
2 false, fictitious, or fraudulent statement, or
3 knowingly fail to provide promptly any informa-
4 tion requested by the Secretary to review such
5 a notice;

6 “(F) knowingly fail to submit an applica-
7 tion required under subsection (g)(2)(F), know-
8 ingly fail to submit such an application on or
9 before the date specified in subsection
10 (g)(2)(F)(ii), knowingly submit such an applica-
11 tion that makes a materially false, fictitious, or
12 fraudulent statement, or knowingly fail to pro-
13 vide promptly any information requested by the
14 Secretary to review such an application;

15 “(G) cause there to be a difference (includ-
16 ing a difference in active ingredient, route of
17 administration, dosage form, strength, formula-
18 tion, manufacturing establishment, manufac-
19 turing process, or person that manufactures the
20 drug) between a prescription drug for distribu-
21 tion in the United States and the drug for dis-
22 tribution in a permitted country;

23 “(H) refuse to allow an inspection author-
24 ized under this section of an establishment that
25 manufactures a qualifying drug that is, or will

1 be, introduced for commercial distribution in a
2 permitted country;

3 “(I) fail to conform to the methods used
4 in, or the facilities used for, the manufacturing,
5 processing, packing, or holding of a qualifying
6 drug that is, or will be, introduced for commer-
7 cial distribution in a permitted country to good
8 manufacturing practice under this Act;

9 “(J) become a party to a licensing agree-
10 ment or other agreement related to a qualifying
11 drug that fails to provide for compliance with
12 all requirements of this section with respect to
13 such drug;

14 “(K) enter into a contract that restricts,
15 prohibits, or delays the importation of a quali-
16 fying drug under this section;

17 “(L) engage in any other action to restrict,
18 prohibit, or delay the importation of a quali-
19 fying drug under this section; or

20 “(M) engage in any other action that the
21 Federal Trade Commission determines to dis-
22 criminate against a person that engages or at-
23 tempts to engage in the importation of a quali-
24 fying drug under this section.

1 “(2) REFERRAL OF POTENTIAL VIOLATIONS.—

2 The Secretary shall promptly refer to the Federal
3 Trade Commission each potential violation of sub-
4 paragraph (E), (F), (G), (H), or (I) of paragraph
5 (1) that becomes known to the Secretary.

6 “(3) AFFIRMATIVE DEFENSE.—

7 “(A) DISCRIMINATION.—It shall be an af-
8 firmative defense to a charge that a manufac-
9 turer has discriminated under subparagraph
10 (A), (B), (C), (D), or (M) of paragraph (1) that
11 the higher price charged for a prescription drug
12 sold to a person, the denial, restriction, or delay
13 of supplies of a prescription drug to a person,
14 the refusal to do business with a person, or
15 other discriminatory activity against a person,
16 is not based, in whole or in part, on—

17 “(i) the person exporting or importing
18 a qualifying drug into the United States
19 under this section; or

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

23 “(B) DRUG DIFFERENCES.—It shall be an
24 affirmative defense to a charge that a manufac-
25 turer 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 im-
prove 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 dif-
ferent from a drug for distribution in per-
mitted countries whose combined popu-
lation 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 re-
stricting 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,

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

3 “(C) CHARITABLE CONTRIBUTIONS.—

4 Nothing in this subsection shall be construed
 5 to—

6 “(i) prevent a manufacturer from do-
 7 nating a prescription drug, or supplying a
 8 prescription drug at nominal cost, to a
 9 charitable or humanitarian organization,
 10 including the United Nations and affili-
 11 ates, or to a government of a foreign coun-
 12 try; or

13 “(ii) apply to such donations or sup-
 14 plying of a prescription drug.

15 “(5) ENFORCEMENT.—

16 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-
 17 TICE.—A violation of this subsection shall be
 18 treated as a violation of a rule defining an un-
 19 fair or deceptive act or practice prescribed
 20 under section 18(a)(1)(B) of the Federal Trade
 21 Commission Act (15 U.S.C. 57a(a)(1)(B)).

22 “(B) ACTIONS BY THE COMMISSION.—The
 23 Federal Trade Commission—

24 “(i) shall enforce this subsection in
 25 the same manner, by the same means, and

1 with the same jurisdiction, powers, and du-
 2 ties as though all applicable terms and pro-
 3 visions of the Federal Trade Commission
 4 Act (15 U.S.C. 41 et seq.) were incor-
 5 porated into and made a part of this sec-
 6 tion; and

7 “(ii) may seek monetary relief three-
 8 fold the damages sustained, in addition to
 9 any other remedy available to the Federal
 10 Trade Commission under the Federal
 11 Trade Commission Act (15 U.S.C. 41 et
 12 seq.).

13 “(6) ACTIONS BY STATES.—

14 “(A) IN GENERAL.—

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

1 “(I) enjoin that practice;

2 “(II) enforce compliance with
3 this subsection;

4 “(III) obtain damages, restitu-
5 tion, or other compensation on behalf
6 of residents of the State and persons
7 doing business in the State, including
8 threefold the damages; or

9 “(IV) obtain such other relief as
10 the court may consider to be appro-
11 priate.

12 “(ii) NOTICE.—

13 “(I) IN GENERAL.—Before filing
14 an action under clause (i), the attor-
15 ney general of the State involved shall
16 provide to the Federal Trade Commis-
17 sion—

18 “(aa) written notice of that
19 action; and

20 “(bb) a copy of the com-
21 plaint for that action.

22 “(II) EXEMPTION.—Subclause
23 (I) shall not apply with respect to the
24 filing of an action by an attorney gen-
25 eral of a State under this paragraph,

1 if the attorney general determines
 2 that it is not feasible to provide the
 3 notice described in that subclause be-
 4 fore filing of the action. In such case,
 5 the attorney general of a State shall
 6 provide notice and a copy of the com-
 7 plaint to the Federal Trade Commis-
 8 sion at the same time as the attorney
 9 general files the action.

10 “(B) INTERVENTION.—

11 “(i) IN GENERAL.—On receiving no-
 12 tice under subparagraph (A)(ii), the Fed-
 13 eral Trade Commission shall have the right
 14 to intervene in the action that is the sub-
 15 ject of the notice.

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

20 “(I) to be heard with respect to
 21 any matter that arises in that action;
 22 and

23 “(II) to file a petition for appeal.

24 “(C) CONSTRUCTION.—For purposes of
 25 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

1 be served in any district in which the defend-
2 ant—

3 “(i) is an inhabitant; or

4 “(ii) may be found.

5 “(G) MEASUREMENT OF DAMAGES.—In
6 any action under this paragraph to enforce a
7 cause of action under this subsection in which
8 there has been a determination that a defend-
9 ant has violated a provision of this subsection,
10 damages may be proved and assessed in the ag-
11 gregate by statistical or sampling methods, by
12 the computation of illegal overcharges or by
13 such other reasonable system of estimating ag-
14 gregate damages as the court in its discretion
15 may permit without the necessity of separately
16 proving the individual claim of, or amount of
17 damage to, persons on whose behalf the suit
18 was brought.

19 “(H) EXCLUSION ON DUPLICATIVE RE-
20 LIEF.—The district court shall exclude from the
21 amount of monetary relief awarded in an action
22 under this paragraph brought by the attorney
23 general of a State any amount of monetary re-
24 lief which duplicates amounts which have been
25 awarded for the same injury.

1 “(7) EFFECT ON ANTITRUST LAWS.—Nothing
 2 in this subsection shall be construed to modify, im-
 3 pair, or supersede the operation of the antitrust
 4 laws. For the purpose of this subsection, the term
 5 ‘antitrust laws’ has the meaning given it in the first
 6 section of the Clayton Act, except that it includes
 7 section 5 of the Federal Trade Commission Act to
 8 the extent that such section 5 applies to unfair
 9 methods of competition.

10 “(8) MANUFACTURER.—In this subsection, the
 11 term ‘manufacturer’ means any entity, including any
 12 affiliate or licensee of that entity, that is engaged
 13 in—

14 “(A) the production, preparation, propaga-
 15 tion, compounding, conversion, or processing of
 16 a prescription drug, either directly or indirectly
 17 by extraction from substances of natural origin,
 18 or independently by means of chemical syn-
 19 thesis, or by a combination of extraction and
 20 chemical synthesis; or

21 “(B) the packaging, repackaging, labeling,
 22 relabeling, or distribution of a prescription
 23 drug.”.

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

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

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

7 “(A) a sale at retail made pursuant to dis-
8 pensing the drug to a customer of the pharmacist or
9 organization; or

10 “(B) a sale or trade of the drug to a pharmacy
11 or a wholesaler registered to import drugs under sec-
12 tion 804.

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

16 “(3) The making of a materially false, fictitious, or
17 fraudulent statement or representation, or a material
18 omission, in a notice under clause (i) of section
19 804(g)(2)(B) or in an application required under section
20 804(g)(2)(F), or the failure to submit such a notice or
21 application.

22 “(4) The importation of a drug in violation of a reg-
23 istration condition or other requirement under section
24 804, the falsification of any record required to be main-
25 tained, or provided to the Secretary, under such section,

1 or the violation of any registration condition or other re-
 2 quirement under such section.”; and

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

5 “(6) Notwithstanding subsection (a), any person that
 6 knowingly violates section 301(i) (2) or (3) or section
 7 301(aa)(4) shall be imprisoned not more than 10 years,
 8 or fined in accordance with title 18, United States Code,
 9 or both.”.

10 (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

15 “(g) With respect to a prescription drug that is im-
 16 ported or offered for import into the United States by an
 17 individual who is not in the business of such importation,
 18 that is not shipped by a registered exporter under section
 19 804, and that is refused admission under subsection (a),
 20 the Secretary shall notify the individual that—

21 “(1) the drug has been refused admission be-
 22 cause the drug was not a lawful import under sec-
 23 tion 804;

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

1 “(3) the individual may under section 804 law-
2 fully import certain prescription drugs from export-
3 ers registered with the Secretary under section 804;
4 and

5 “(4) the individual can find information about
6 such importation, including a list of registered ex-
7 porters, on the Internet website of the Food and
8 Drug Administration or through a toll-free telephone
9 number required under section 804.”.

10 (2) ESTABLISHMENT REGISTRATION.—Section
11 510(i) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 360(i)) is amended in paragraph (1) by
13 inserting after “import into the United States” the
14 following: “, including a drug that is, or may be, im-
15 ported or offered for import into the United States
16 under section 804,”.

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

20 (d) EXHAUSTION.—

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

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

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

3 “(h) It shall not be an act of infringement to use,
4 offer to sell, or sell within the United States or to import
5 into the United States any patented invention under sec-
6 tion 804 of the Federal Food, Drug, and Cosmetic Act
7 that was first sold abroad by or under authority of the
8 owner or licensee of such patent.”.

9 (2) RULE OF CONSTRUCTION.—Nothing in the
10 amendment made by paragraph (1) shall be con-
11 strued to affect the ability of a patent owner or li-
12 censee to enforce their patent, subject to such
13 amendment.

14 (e) EFFECT OF SECTION 804.—

15 (1) IN GENERAL.—Section 804 of the Federal
16 Food, Drug, and Cosmetic Act, as added by sub-
17 section (a), shall permit the importation of quali-
18 fying drugs (as defined in such section 804) into the
19 United States without regard to the status of the
20 issuance of implementing regulations—

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

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

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

3 (2) REVIEW OF REGISTRATION BY CERTAIN EX-
4 PORTERS.—

5 (A) REVIEW PRIORITY.—In the review of
6 registrations submitted under subsection (b) of
7 such section 804, registrations submitted by en-
8 tities in Canada that are significant exporters
9 of prescription drugs to individuals in the
10 United States as of the date of enactment of
11 this Act will have priority during the 90 day pe-
12 riod that begins on such date of enactment.

13 (B) PERIOD FOR REVIEW.—During such
14 90-day period, the reference in subsection
15 (b)(2)(A) of such section 804 to 90 days (relat-
16 ing to approval or disapproval of registrations)
17 is, as applied to such entities, deemed to be 30
18 days.

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

1 registration under such section 804 from the
2 exporter.

3 (D) FIRST YEAR LIMIT ON NUMBER OF
4 EXPORTERS.—During the 1-year period begin-
5 ning on the date of enactment of this Act, the
6 Secretary of Health and Human Services (re-
7 ferred to in this section as the “Secretary”)
8 may limit the number of registered exporters
9 under such section 804 to not less than 50, so
10 long as the Secretary gives priority to those ex-
11 porters with demonstrated ability to process a
12 high volume of shipments of drugs to individ-
13 uals in the United States.

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

24 (F) FURTHER LIMIT ON NUMBER OF EX-
25 PORTERS.—During any 1-year period beginning

1 on a date that is 2 or more years after the date
2 of enactment of this Act, the Secretary may
3 limit the number of registered exporters under
4 such section 804 to not less than 25 more than
5 the number of such exporters during the pre-
6 vious 1-year period, so long as the Secretary
7 gives priority to those exporters with dem-
8 onstrated ability to process a high volume of
9 shipments of drugs to individuals in the United
10 States.

11 (3) LIMITS ON NUMBER OF IMPORTERS.—

12 (A) FIRST YEAR LIMIT ON NUMBER OF IM-
13 PORTERS.—During the 1-year period beginning
14 on the date that is 1 year after the date of en-
15 actment of this Act, the Secretary may limit the
16 number of registered importers under such sec-
17 tion 804 to not less than 100 (of which at least
18 a significant number shall be groups of phar-
19 macies, to the extent feasible given the applica-
20 tions submitted by such groups), so long as the
21 Secretary gives priority to those importers with
22 demonstrated ability to process a high volume
23 of shipments of drugs imported into the United
24 States.

1 (B) SECOND YEAR LIMIT ON NUMBER OF
2 IMPORTERS.—During the 1-year period begin-
3 ning on the date that is 2 years after the date
4 of enactment of this Act, the Secretary may
5 limit the number of registered importers under
6 such section 804 to not less than 200 (of which
7 at least a significant number shall be groups of
8 pharmacies, to the extent feasible given the ap-
9 plications submitted by such groups), so long as
10 the Secretary gives priority to those importers
11 with demonstrated ability to process a high vol-
12 ume of shipments of drugs into the United
13 States.

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

1 with demonstrated ability to process a high vol-
2 ume of shipments of drugs to the United
3 States.

4 (4) NOTICES FOR DRUGS FOR IMPORT FROM
5 CANADA.—The notice with respect to a qualifying
6 drug introduced for commercial distribution in Can-
7 ada as of the date of enactment of this Act that is
8 required under subsection (g)(2)(B)(i) of such sec-
9 tion 804 shall be submitted to the Secretary not
10 later than 30 days after the date of enactment of
11 this Act if—

12 (A) the U.S. label drug (as defined in such
13 section 804) for the qualifying drug is 1 of the
14 100 prescription drugs with the highest dollar
15 volume of sales in the United States based on
16 the 12 calendar month period most recently
17 completed before the date of enactment of this
18 Act; or

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

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

1 under subsection (g)(2)(B)(i) of such section 804
2 shall be submitted to the Secretary not later than
3 180 days after the date of enactment of this Act
4 if—

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

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

13 (6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

14 (A) GUIDANCE ON SUBMISSION DATES.—

15 The Secretary shall by guidance establish a se-
16 ries of submission dates for the notices under
17 subsection (g)(2)(B)(i) of such section 804 with
18 respect to qualifying drugs introduced for com-
19 mercial distribution as of the date of enactment
20 of this Act and that are not required to be sub-
21 mitted under paragraph (4) or (5).

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

1 are submitted and reviewed at a rate that al-
2 lows consistent and efficient use of the re-
3 sources and staff available to the Secretary for
4 such reviews. The Secretary may condition the
5 requirement to submit such a notice, and the
6 review of such a notice, on the submission by a
7 registered exporter or a registered importer to
8 the Secretary of a notice that such exporter or
9 importer intends to import such qualifying drug
10 to the United States under such section 804.

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

19 (7) NOTICES FOR DRUGS APPROVED AFTER EF-
20 FECTIVE DATE.—The notice required under sub-
21 section (g)(2)(B)(i) of such section 804 for a quali-
22 fying drug first introduced for commercial distribu-
23 tion in a permitted country (as defined in such sec-
24 tion 804) after the date of enactment of this Act
25 shall be submitted to and reviewed by the Secretary

1 as provided under subsection (g)(2)(B) of such sec-
2 tion 804, without regard to paragraph (4), (5), or
3 (6).

4 (8) REPORT.—Beginning with the first full fis-
5 cal year after the date of enactment of this Act, not
6 later than 90 days after the end of each fiscal year
7 during which the Secretary reviews a notice referred
8 to in paragraph (4), (5), or (6), the Secretary shall
9 submit a report to Congress concerning the progress
10 of the Food and Drug Administration in reviewing
11 the notices referred to in paragraphs (4), (5), and
12 (6).

13 (9) USER FEES.—

14 (A) EXPORTERS.—When establishing an
15 aggregate total of fees to be collected from ex-
16 porters under subsection (f)(2) of such section
17 804, the Secretary shall, under subsection
18 (f)(3)(C)(i) of such section 804, estimate the
19 total price of drugs imported under subsection
20 (a) of such section 804 into the United States
21 by registered exporters during the first fiscal
22 year in which this Act takes effect to be an
23 amount equal to the amount which bears the
24 same ratio to \$1,000,000,000 as the number of

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

3 (B) IMPORTERS.—When establishing an
4 aggregate total of fees to be collected from im-
5 porters under subsection (e)(2) of such section
6 804, the Secretary shall, under subsection
7 (e)(3)(C)(i) of such section 804, estimate the
8 total price of drugs imported under subsection
9 (a) of such section 804 into the United States
10 by registered importers during—

11 (i) the first fiscal year in which this
12 Act takes effect to be an amount equal to
13 the amount which bears the same ratio to
14 \$1,000,000,000 as the number of days in
15 such fiscal year during which this Act is
16 effective bears to 365; and

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

19 (C) SECOND YEAR ADJUSTMENT.—

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

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

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

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

16 (II) 3.

17 (iii) ADJUSTMENT.—The Secretary
18 shall adjust the fee due on April 1 of the
19 second fiscal year in which this Act is in
20 effect, from each importer so that the ag-
21 gregate total of fees collected under sub-
22 section (e)(2) for such fiscal year does not
23 exceed the total price of qualifying drugs
24 imported under subsection (a) of such sec-
25 tion 804 into the United States by reg-

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

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

12 (E) ANNUAL REPORT.—

13 (i) FOOD AND DRUG ADMINISTRA-
14 TION.—Not later than 180 days after the
15 end of each fiscal year during which fees
16 are collected under subsection (e), (f), or
17 (g)(2)(B)(iv) of such section 804, the Sec-
18 retary shall prepare and submit to the
19 House of Representatives and the Senate a
20 report on the implementation of the au-
21 thority for such fees during such fiscal
22 year and the use, by the Food and Drug
23 Administration, of the fees collected for the
24 fiscal year for which the report is made

1 and credited to the Food and Drug Admin-
2 istration.

3 (ii) CUSTOMS AND BORDER CON-
4 TROL.—Not later than 180 days after the
5 end of each fiscal year during which fees
6 are collected under subsection (e) or (f) of
7 such section 804, the Secretary of Home-
8 land Security, in consultation with the Sec-
9 retary of the Treasury, shall prepare and
10 submit to the House of Representatives
11 and the Senate a report on the use, by the
12 Bureau of Customs and Border Protection,
13 of the fees, if any, transferred by the Sec-
14 retary to the Bureau of Customs and Bor-
15 der Protection for the fiscal year for which
16 the report is made.

17 (10) SPECIAL RULE REGARDING IMPORTATION
18 BY INDIVIDUALS.—

19 (A) IN GENERAL.—Notwithstanding any
20 provision of this Act (or an amendment made
21 by this Act), the Secretary shall expedite the
22 designation of any additional countries from
23 which an individual may import a qualifying
24 drug into the United States under such section
25 804 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,

1 in accordance with procedures under section 553 of
2 title 5, United States Code, promulgate a final rule
3 for implementing such section 804, which may incor-
4 porate by reference provisions of the interim rule
5 provided for under paragraph (1), to the extent that
6 such provisions are not modified.

7 (g) CONSUMER EDUCATION.—The Secretary shall
8 carry out activities that educate consumers—

9 (1) with regard to the availability of qualifying
10 drugs for import for personal use from an exporter
11 registered with and approved by the Food and Drug
12 Administration under section 804 of the Federal
13 Food, Drug, and Cosmetic Act, as added by this sec-
14 tion, including information on how to verify whether
15 an exporter is registered and approved by use of the
16 Internet website of the Food and Drug Administra-
17 tion and the toll-free telephone number required by
18 this Act;

19 (2) that drugs that consumers attempt to im-
20 port from an exporter that is not registered with and
21 approved by the Food and Drug Administration can
22 be seized by the United States Customs Service and
23 destroyed, and that such drugs may be counterfeit,
24 unapproved, unsafe, or ineffective;

1 (3) with regard to the suspension and termi-
2 nation of any registration of a registered importer or
3 exporter under such section 804; and

4 (4) with regard to the availability at domestic
5 retail pharmacies of qualifying drugs imported under
6 such section 804 by domestic wholesalers and phar-
7 macies registered with and approved by the Food
8 and Drug Administration.

9 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-
10 withstanding any provision of this Act (and the amend-
11 ments made by this Act), the practices and policies of the
12 Food and Drug Administration and Bureau of Customs
13 and Border Protection, in effect on January 1, 2004, with
14 respect to the importation of prescription drugs into the
15 United States by an individual, on the person of such indi-
16 vidual, for personal use, shall remain in effect.

17 (i) REPORT TO CONGRESS.—The Federal Trade
18 Commission shall, on an annual basis, submit to Congress
19 a report that describes any action taken during the period
20 for which the report is being prepared to enforce the provi-
21 sions of section 804(n) of the Federal Food, Drug, and
22 Cosmetic Act (as added by this Act), including any pend-
23 ing investigations or civil actions under such section.

1 **SEC. 125. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
2 **SION INTO UNITED STATES.**

3 (a) IN GENERAL.—Chapter VIII of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
5 as amended by section 124, is further amended by adding
6 at the end the following section:

7 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
8 **MISSION.**

9 “(a) IN GENERAL.—The Secretary of Homeland Se-
10 curity shall deliver to the Secretary a shipment of drugs
11 that is imported or offered for import into the United
12 States if—

13 “(1) the shipment has a declared value of less
14 than \$10,000; and

15 “(2)(A) the shipping container for such drugs
16 does not bear the markings required under section
17 804(d)(2); or

18 “(B) the Secretary has requested delivery of
19 such shipment of drugs.

20 “(b) NO BOND OR EXPORT.—Section 801(b) does
21 not authorize the delivery to the owner or consignee of
22 drugs delivered to the Secretary under subsection (a) pur-
23 suant to the execution of a bond, and such drugs may not
24 be exported.

25 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
26 Secretary shall destroy a shipment of drugs delivered by

1 the Secretary of Homeland Security to the Secretary
2 under subsection (a) if—

3 “(1) in the case of drugs that are imported or
4 offered for import from a registered exporter under
5 section 804, the drugs are in violation of any stand-
6 ard described in section 804(g)(5); or

7 “(2) in the case of drugs that are not imported
8 or offered for import from a registered exporter
9 under section 804, the drugs are in violation of a
10 standard referred to in section 801(a) or 801(d)(1).

11 “(d) CERTAIN PROCEDURES.—

12 “(1) IN GENERAL.—The delivery and destruc-
13 tion of drugs under this section may be carried out
14 without notice to the importer, owner, or consignee
15 of the drugs except as required by section 801(g) or
16 section 804(i)(2). The issuance of receipts for the
17 drugs, and recordkeeping activities regarding the
18 drugs, may be carried out on a summary basis.

19 “(2) OBJECTIVE OF PROCEDURES.—Procedures
20 promulgated under paragraph (1) shall be designed
21 toward the objective of ensuring that, with respect to
22 efficiently utilizing Federal resources available for
23 carrying out this section, a substantial majority of
24 shipments of drugs subject to described in sub-
25 section (c) are identified and destroyed.

1 “(e) EVIDENCE EXCEPTION.—Drugs may not be de-
 2 stroyed under subsection (c) to the extent that the Attor-
 3 ney General of the United States determines that the
 4 drugs should be preserved as evidence or potential evi-
 5 dence with respect to an offense against the United States.

6 “(f) RULE OF CONSTRUCTION.—This section may
 7 not be construed as having any legal effect on applicable
 8 law with respect to a shipment of drugs that is imported
 9 or offered for import into the United States and has a
 10 declared value equal to or greater than \$10,000.”.

11 (b) PROCEDURES.—Procedures for carrying out sec-
 12 tion 805 of the Federal Food, Drug, and Cosmetic Act,
 13 as added by subsection (a), shall be established not later
 14 than 90 days after the date of the enactment of this Act.

15 (c) EFFECTIVE DATE.—The amendments made by
 16 this section shall take effect on the date that is 90 days
 17 after the date of enactment of this Act.

18 **SEC. 126. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
 19 **MENTS REGARDING PRIOR SALE, PURCHASE,**
 20 **OR TRADE.**

21 (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO
 22 REGISTERED EXPORTERS.—Section 503(e) of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is
 24 amended—

25 (1) in paragraph (1)—

1 (A) by striking “and who is not the manu-
2 facturer or an authorized distributor of record
3 of such drug”;

4 (B) by striking “to an authorized dis-
5 tributor of record or”; and

6 (C) by striking subparagraph (B) and in-
7 serting the following:

8 “(B) The fact that a drug subject to subsection (b)
9 is exported from the United States does not with respect
10 to such drug exempt any person that is engaged in the
11 business of the wholesale distribution of the drug from
12 providing the statement described in subparagraph (A) to
13 the person that receives the drug pursuant to the export
14 of the drug.

15 “(C)(i) The Secretary shall by regulation establish re-
16 quirements that supersede subparagraph (A) (referred to
17 in this subparagraph as ‘alternative requirements’) to
18 identify the chain of custody of a drug subject to sub-
19 section (b) from the manufacturer of the drug throughout
20 the wholesale distribution of the drug to a pharmacist who
21 intends to sell the drug at retail if the Secretary deter-
22 mines that the alternative requirements, which may in-
23 clude standardized anti-counterfeiting or track-and-trace
24 technologies, will identify such chain of custody or the
25 identity of the discrete package of the drug from which

1 the drug is dispensed with equal or greater certainty to
 2 the requirements of subparagraph (A), and that the alter-
 3 native requirements are economically and technically fea-
 4 sible.

5 “(ii) When the Secretary promulgates a final rule to
 6 establish such alternative requirements, the final rule in
 7 addition shall, with respect to the registration condition
 8 established in clause (i) of section 804(c)(3)(B), establish
 9 a condition equivalent to the alternative requirements, and
 10 such equivalent condition may be met in lieu of the reg-
 11 istration condition established in such clause (i).”;

12 (2) in paragraph (2)(A), by adding at the end
 13 the following: “The preceding sentence may not be
 14 construed as having any applicability with respect to
 15 a registered exporter under section 804.”; and

16 (3) in paragraph (3), by striking “and sub-
 17 section (d)—” in the matter preceding subparagraph
 18 (A) and all that follows through “the term ‘whole-
 19 sale distribution’ means” in subparagraph (B) and
 20 inserting the following: “and subsection (d), the
 21 term ‘wholesale distribution’ means”.

22 (b) CONFORMING AMENDMENT.—Section 503(d) of
 23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 24 353(d)) is amended by adding at the end the following:

1 “(4) Each manufacturer of a drug subject to sub-
 2 section (b) shall maintain at its corporate offices a current
 3 list of the authorized distributors of record of such drug.

4 “(5) For purposes of this subsection, the term ‘au-
 5 thorized distributors of record’ means those distributors
 6 with whom a manufacturer has established an ongoing re-
 7 lationship to distribute such manufacturer’s products.”.

8 (c) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The amendments made by
 10 paragraphs (1) and (3) of subsection (a) and by sub-
 11 section (b) shall take effect on January 1, 2010.

12 (2) DRUGS IMPORTED BY REGISTERED IMPORT-
 13 ERS UNDER SECTION 804.—Notwithstanding para-
 14 graph (1), the amendments made by paragraphs (1)
 15 and (3) of subsection (a) and by subsection (b) shall
 16 take effect on the date that is 90 days after the date
 17 of enactment of this Act with respect to qualifying
 18 drugs imported under section 804 of the Federal
 19 Food, Drug, and Cosmetic Act, as added by section
 20 4.

21 (3) EFFECT WITH RESPECT TO REGISTERED
 22 EXPORTERS.—The amendment made by subsection
 23 (a)(2) shall take effect on the date that is 90 days
 24 after the date of enactment of this Act.

1 (4) ALTERNATIVE REQUIREMENTS.—The Sec-
2 retary shall issue regulations to establish the alter-
3 native requirements, referred to in the amendment
4 made by subsection (a)(1), that take effect not later
5 than January 1, 2010.

6 (5) INTERMEDIATE REQUIREMENTS.—The Sec-
7 retary shall by regulation require the use of stand-
8 ardized anti-counterfeiting or track-and-trace tech-
9 nologies on prescription drugs at the case and pallet
10 level effective not later than 1 year after the date of
11 enactment of this Act.

12 (6) ADDITIONAL REQUIREMENTS.—

13 (A) IN GENERAL.—Notwithstanding any
14 other provision of this section, the Secretary
15 shall, not later than 18 months after the date
16 of enactment of this Act, require that the pack-
17 aging of any prescription drug incorporates—

18 (i) a standardized numerical identifier
19 unique to each package of such drug, ap-
20 plied at the point of manufacturing and re-
21 packaging (in which case the numerical
22 identifier shall be linked to the numerical
23 identifier applied at the point of manufac-
24 turing); and

1 (ii)(I) overt optically variable counter-
2 feit-resistant technologies that—

3 (aa) are visible to the naked eye,
4 providing for visual identification of
5 product authenticity without the need
6 for readers, microscopes, lighting de-
7 vices, or scanners;

8 (bb) are similar to that used by
9 the Bureau of Engraving and Printing
10 to secure United States currency;

11 (cc) are manufactured and dis-
12 tributed in a highly secure, tightly
13 controlled environment; and

14 (dd) incorporate additional layers
15 of nonvisible covert security features
16 up to and including forensic capa-
17 bility, as described in subparagraph
18 (B); or

19 (II) technologies that have a function
20 of security comparable to that described in
21 subclause (I), as determined by the Sec-
22 retary.

23 (B) STANDARDS FOR PACKAGING.—For
24 the purpose of making it more difficult to coun-
25 terfeit the packaging of drugs subject to this

1 paragraph, the manufacturers of such drugs
 2 shall incorporate the technologies described in
 3 subparagraph (A) into at least 1 additional ele-
 4 ment of the physical packaging of the drugs, in-
 5 cluding blister packs, shrink wrap, package la-
 6 bels, package seals, bottles, and boxes.

7 **SEC. 127. INTERNET SALES OF PRESCRIPTION DRUGS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
 9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 10 ed by inserting after section 503A the following:

11 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

12 “(a) REQUIREMENTS REGARDING INFORMATION ON
 13 INTERNET SITE.—

14 “(1) IN GENERAL.—A person may not dispense
 15 a prescription drug pursuant to a sale of the drug
 16 by such person if—

17 “(A) the purchaser of the drug submitted
 18 the purchase order for the drug, or conducted
 19 any other part of the sales transaction for the
 20 drug, through an Internet site;

21 “(B) the person dispenses the drug to the
 22 purchaser by mailing or shipping the drug to
 23 the purchaser; and

24 “(C) such site, or any other Internet site
 25 used by such person for purposes of sales of a

1 prescription drug, fails to meet each of the re-
 2 quirements specified in paragraph (2), other
 3 than a site or pages on a site that—

4 “(i) are not intended to be accessed
 5 by purchasers or prospective purchasers; or

6 “(ii) provide an Internet information
 7 location tool within the meaning of section
 8 231(e)(5) of the Communications Act of
 9 1934 (47 U.S.C. 231(e)(5)).

10 “(2) REQUIREMENTS.—With respect to an
 11 Internet site, the requirements referred to in sub-
 12 paragraph (C) of paragraph (1) for a person to
 13 whom such paragraph applies are as follows:

14 “(A) Each page of the site shall include ei-
 15 ther the following information or a link to a
 16 page that provides the following information:

17 “(i) The name of such person.

18 “(ii) Each State in which the person
 19 is authorized by law to dispense prescrip-
 20 tion drugs.

21 “(iii) The address and telephone num-
 22 ber of each place of business of the person
 23 with respect to sales of prescription drugs
 24 through the Internet, other than a place of

1 business that does not mail or ship pre-
 2 scription drugs to purchasers.

3 “(iv) The name of each individual who
 4 serves as a pharmacist for prescription
 5 drugs that are mailed or shipped pursuant
 6 to the site, and each State in which the in-
 7 dividual is authorized by law to dispense
 8 prescription drugs.

9 “(v) If the person provides for medical
 10 consultations through the site for purposes
 11 of providing prescriptions, the name of
 12 each individual who provides such con-
 13 sultations; each State in which the indi-
 14 vidual is licensed or otherwise authorized
 15 by law to provide such consultations or
 16 practice medicine; and the type or types of
 17 health professions for which the individual
 18 holds such licenses or other authorizations.

19 “(B) A link to which paragraph (1) applies
 20 shall be displayed in a clear and prominent
 21 place and manner, and shall include in the cap-
 22 tion for the link the words ‘licensing and con-
 23 tact information’.

24 “(b) INTERNET SALES WITHOUT APPROPRIATE
 25 MEDICAL RELATIONSHIPS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), a person may not dispense a prescription
3 drug, or sell such a drug, if—

4 “(A) for purposes of such dispensing or
5 sale, the purchaser communicated with the per-
6 son through the Internet;

7 “(B) the patient for whom the drug was
8 dispensed or purchased did not, when such
9 communications began, have a prescription for
10 the drug that is valid in the United States;

11 “(C) pursuant to such communications, the
12 person provided for the involvement of a practi-
13 tioner, or an individual represented by the per-
14 son as a practitioner, and the practitioner or
15 such individual issued a prescription for the
16 drug that was purchased;

17 “(D) the person knew, or had reason to
18 know, that the practitioner or the individual re-
19 ferred to in subparagraph (C) did not, when
20 issuing the prescription, have a qualifying med-
21 ical relationship with the patient; and

22 “(E) the person received payment for the
23 dispensing or sale of the drug.

1 For purposes of subparagraph (E), payment is re-
2 ceived if money or other valuable consideration is re-
3 ceived.

4 “(2) EXCEPTIONS.—Paragraph (1) does not
5 apply to—

6 “(A) the dispensing or selling of a pre-
7 scription drug pursuant to telemedicine prac-
8 tices sponsored by—

9 “(i) a hospital that has in effect a
10 provider agreement under title XVIII of
11 the Social Security Act (relating to the
12 Medicare program); or

13 “(ii) a group practice that has not
14 fewer than 100 physicians who have in ef-
15 fect provider agreements under such title;
16 or

17 “(B) the dispensing or selling of a pre-
18 scription drug pursuant to practices that pro-
19 mote the public health, as determined by the
20 Secretary by regulation.

21 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

22 “(A) IN GENERAL.—With respect to
23 issuing a prescription for a drug for a patient,
24 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 re-

spect 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.

“(c) 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

1 or practice that violates section 301(l), the State
 2 may bring a civil action on behalf of its residents in
 3 an appropriate district court of the United States to
 4 enjoin such practice, to enforce compliance with such
 5 section (including a nationwide injunction), to obtain
 6 damages, restitution, or other compensation on be-
 7 half of residents of such State, to obtain reasonable
 8 attorneys fees and costs if the State prevails in the
 9 civil action, or to obtain such further and other relief
 10 as the court may deem appropriate.

11 “(2) NOTICE.—The State shall serve prior writ-
 12 ten notice of any civil action under paragraph (1) or
 13 (5)(B) upon the Secretary and provide the Secretary
 14 with a copy of its complaint, except that if it is not
 15 feasible for the State to provide such prior notice,
 16 the State shall serve such notice immediately upon
 17 instituting such action. Upon receiving a notice re-
 18 specting a civil action, the Secretary shall have the
 19 right—

20 “(A) to intervene in such action;

21 “(B) upon so intervening, to be heard on
 22 all matters arising therein; and

23 “(C) to file petitions for appeal.

24 “(3) CONSTRUCTION.—For purposes of bring-
 25 ing any civil action under paragraph (1), nothing in

1 this chapter shall prevent an attorney general of a
2 State from exercising the powers conferred on the
3 attorney general by the laws of such State to con-
4 duct investigations or to administer oaths or affir-
5 mations or to compel the attendance of witnesses or
6 the production of documentary and other evidence.

7 “(4) VENUE; SERVICE OF PROCESS.—Any civil
8 action brought under paragraph (1) in a district
9 court of the United States may be brought in the
10 district in which the defendant is found, is an inhab-
11 itant, or transacts business or wherever venue is
12 proper under section 1391 of title 28, United States
13 Code. Process in such an action may be served in
14 any district in which the defendant is an inhabitant
15 or in which the defendant may be found.

16 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

17 “(A) Nothing contained in this section
18 shall prohibit an authorized State official from
19 proceeding in State court on the basis of an al-
20 leged violation of any civil or criminal statute of
21 such State.

22 “(B) In addition to actions brought by an
23 attorney general of a State under paragraph
24 (1), such an action may be brought by officers
25 of such State who are authorized by the State

1 to bring actions in such State on behalf of its
2 residents.

3 “(d) EFFECT OF SECTION.—This section shall not
4 apply to a person that is a registered exporter under sec-
5 tion 804.

6 “(e) GENERAL DEFINITIONS.—For purposes of this
7 section:

8 “(1) The term ‘practitioner’ means a practi-
9 tioner referred to in section 503(b)(1) with respect
10 to issuing a written or oral prescription.

11 “(2) The term ‘prescription drug’ means a drug
12 that is described in section 503(b)(1).

13 “(3) The term ‘qualifying medical relationship’,
14 with respect to a practitioner and a patient, has the
15 meaning indicated for such term in subsection (b).

16 “(f) INTERNET-RELATED DEFINITIONS.—

17 “(1) IN GENERAL.—For purposes of this sec-
18 tion:

19 “(A) The term ‘Internet’ means collectively
20 the myriad of computer and telecommunications
21 facilities, including equipment and operating
22 software, which comprise the interconnected
23 world-wide network of networks that employ the
24 transmission control protocol/internet protocol,
25 or any predecessor or successor protocols to

1 such protocol, to communicate information of
2 all kinds by wire or radio.

3 “(B) The term ‘link’, with respect to the
4 Internet, means one or more letters, words,
5 numbers, symbols, or graphic items that appear
6 on a page of an Internet site for the purpose
7 of serving, when activated, as a method for exe-
8 cuting an electronic command—

9 “(i) to move from viewing one portion
10 of a page on such site to another portion
11 of the page;

12 “(ii) to move from viewing one page
13 on such site to another page on such site;
14 or

15 “(iii) to move from viewing a page on
16 one Internet site to a page on another
17 Internet site.

18 “(C) The term ‘page’, with respect to the
19 Internet, means a document or other file
20 accessed at an Internet site.

21 “(D)(i) The terms ‘site’ and ‘address’, with
22 respect to the Internet, mean a specific location
23 on the Internet that is determined by Internet
24 Protocol numbers. Such term includes the do-
25 main name, if any.

1 “(ii) The term ‘domain name’ means a
 2 method of representing an Internet address
 3 without direct reference to the Internet Protocol
 4 numbers for the address, including methods
 5 that use designations such as ‘.com’, ‘.edu’,
 6 ‘.gov’, ‘.net’, or ‘.org’.

7 “(iii) The term ‘Internet Protocol num-
 8 bers’ includes any successor protocol for deter-
 9 mining a specific location on the Internet.

10 “(2) AUTHORITY OF SECRETARY.—The Sec-
 11 retary may by regulation modify any definition
 12 under paragraph (1) to take into account changes in
 13 technology.

14 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
 15 TISING.—No provider of an interactive computer service,
 16 as defined in section 230(f)(2) of the Communications Act
 17 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
 18 shall be liable under this section for dispensing or selling
 19 prescription drugs in violation of this section on account
 20 of another person’s selling or dispensing such drugs, pro-
 21 vided that the provider of the interactive computer service
 22 or of advertising services does not own or exercise cor-
 23 porate control over such person.”.

24 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
 25 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 331) is amended by inserting after paragraph (k) the fol-
 2 lowing:

3 “(l) The dispensing or selling of a prescription drug
 4 in violation of section 503B.”.

5 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
 6 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
 7 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
 8 NESSES.—In carrying out section 503B of the Federal
 9 Food, Drug, and Cosmetic Act (as added by subsection
 10 (a) of this section), the Secretary of Health and Human
 11 Services shall take into consideration the practices and
 12 procedures of public or private entities that certify that
 13 businesses selling prescription drugs through Internet
 14 sites are legitimate businesses, including practices and
 15 procedures regarding disclosure formats and verification
 16 programs.

17 (d) REPORTS REGARDING INTERNET-RELATED VIO-
 18 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
 19 OF DRUGS.—

20 (1) IN GENERAL.—The Secretary of Health and
 21 Human Services (referred to in this subsection as
 22 the “Secretary”) shall, pursuant to the submission
 23 of an application meeting the criteria of the Sec-
 24 retary, make an award of a grant or contract to the
 25 National Clearinghouse on Internet Prescribing (op-

1 erated by the Federation of State Medical Boards)
2 for the purpose of—

3 (A) identifying Internet sites that appear
4 to be in violation of Federal or State laws con-
5 cerning the dispensing of drugs;

6 (B) reporting such sites to State medical
7 licensing boards and State pharmacy licensing
8 boards, and to the Attorney General and the
9 Secretary, for further investigation; and

10 (C) submitting, for each fiscal year for
11 which the award under this subsection is made,
12 a report to the Secretary describing investiga-
13 tions undertaken with respect to violations de-
14 scribed in subparagraph (A).

15 (2) AUTHORIZATION OF APPROPRIATIONS.—For
16 the purpose of carrying out paragraph (1), there is
17 authorized to be appropriated \$100,000 for each of
18 the first 3 fiscal years in which this section is in ef-
19 fect.

20 (e) EFFECTIVE DATE.—The amendments made by
21 subsections (a) and (b) take effect 90 days after the date
22 of enactment of this Act, without regard to whether a final
23 rule to implement such amendments has been promulgated
24 by the Secretary of Health and Human Services under
25 section 701(a) of the Federal Food, Drug, and Cosmetic

1 Act. The preceding sentence may not be construed as af-
 2 fecting the authority of such Secretary to promulgate such
 3 a final rule.

4 **SEC. 128. PROHIBITING PAYMENTS TO UNREGISTERED**
 5 **FOREIGN PHARMACIES.**

6 (a) IN GENERAL.—Section 303 of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
 8 adding at the end the following:

9 “(g) RESTRICTED TRANSACTIONS.—

10 “(1) IN GENERAL.—The introduction of re-
 11 stricted transactions into a payment system or the
 12 completion of restricted transactions using a pay-
 13 ment system is prohibited.

14 “(2) PAYMENT SYSTEM.—

15 “(A) IN GENERAL.—The term ‘payment
 16 system’ means a system used by a person de-
 17 scribed in subparagraph (B) to effect a credit
 18 transaction, electronic fund transfer, or money
 19 transmitting service that may be used in con-
 20 nection with, or to facilitate, a restricted trans-
 21 action, and includes—

22 “(i) a credit card system;

23 “(ii) an international, national, re-
 24 gional, or local network used to effect a
 25 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-

1 gaged in the operation of an unregistered foreign
2 pharmacy, of—

3 “(A) credit, or the proceeds of credit, ex-
4 tended to or on behalf of the individual for the
5 purpose of the unlawful drug importation re-
6 quest (including credit extended through the
7 use of a credit card);

8 “(B) an electronic fund transfer or funds
9 transmitted by or through a money transmit-
10 ting business, or the proceeds of an electronic
11 fund transfer or money transmitting service,
12 from or on behalf of the individual for the pur-
13 pose of the unlawful drug importation request;

14 “(C) a check, draft, or similar instrument
15 which is drawn by or on behalf of the individual
16 for the purpose of the unlawful drug importa-
17 tion request and is drawn on or payable at or
18 through any financial institution; or

19 “(D) the proceeds of any other form of fi-
20 nancial transaction (identified by the Board by
21 regulation) that involves a financial institution
22 as a payor or financial intermediary on behalf
23 of or for the benefit of the individual for the
24 purpose of the unlawful drug importation re-
25 quest.

1 “(4) UNLAWFUL DRUG IMPORTATION RE-
 2 QUEST.—The term ‘unlawful drug importation re-
 3 quest’ means the request, or transmittal of a re-
 4 quest, made to an unregistered foreign pharmacy for
 5 a prescription drug by mail (including a private car-
 6 rier), facsimile, phone, or electronic mail, or by a
 7 means that involves the use, in whole or in part, of
 8 the Internet.

9 “(5) UNREGISTERED FOREIGN PHARMACY.—
 10 The term ‘unregistered foreign pharmacy’ means a
 11 person in a country other than the United States
 12 that is not a registered exporter under section 804.

13 “(6) OTHER DEFINITIONS.—

14 “(A) CREDIT; CREDITOR; CREDIT CARD.—
 15 The terms ‘credit’, ‘creditor’, and ‘credit card’
 16 have the meanings given the terms in section
 17 103 of the Truth in Lending Act (15 U.S.C.
 18 1602).

19 “(B) ACCESS DEVICE; ELECTRONIC FUND
 20 TRANSFER.—The terms ‘access device’ and
 21 ‘electronic fund transfer’—

22 “(i) have the meaning given the term
 23 in section 903 of the Electronic Fund
 24 Transfer Act (15 U.S.C. 1693a); and

1 “(ii) the term ‘electronic fund trans-
 2 fer’ also includes any fund transfer covered
 3 under Article 4A of the Uniform Commer-
 4 cial Code, as in effect in any State.

5 “(C) FINANCIAL INSTITUTION.—The term
 6 ‘financial institution’—

7 “(i) has the meaning given the term
 8 in section 903 of the Electronic Transfer
 9 Fund Act (15 U.S.C. 1693a); and

10 “(ii) includes a financial institution
 11 (as defined in section 509 of the Gramm-
 12 Leach-Bliley Act (15 U.S.C. 6809)).

13 “(D) MONEY TRANSMITTING BUSINESS;
 14 MONEY TRANSMITTING SERVICE.—The terms
 15 ‘money transmitting business’ and ‘money
 16 transmitting service’ have the meaning given
 17 the terms in section 5330(d) of title 31, United
 18 States Code.

19 “(E) BOARD.—The term ‘Board’ means
 20 the Board of Governors of the Federal Reserve
 21 System.

22 “(7) POLICIES AND PROCEDURES REQUIRED TO
 23 PREVENT RESTRICTED TRANSACTIONS.—

24 “(A) REGULATIONS.—The Board shall
 25 promulgate regulations requiring—

1 “(i) an operator of a credit card sys-
2 tem;

3 “(ii) an operator of an international,
4 national, regional, or local network used to
5 effect a credit transaction, an electronic
6 fund transfer, or a money transmitting
7 service;

8 “(iii) an operator of any other pay-
9 ment system that is centrally managed and
10 is primarily engaged in the transmission
11 and settlement of credit transactions, elec-
12 tronic transfers or money transmitting
13 services where at least one party to the
14 transaction or transfer is an individual;
15 and

16 “(iv) any other person described in
17 paragraph (2)(B) and specified by the
18 Board in such regulations,
19 to establish policies and procedures that are
20 reasonably designed to prevent the introduction
21 of a restricted transaction into a payment sys-
22 tem or the completion of a restricted trans-
23 action using a payment system

1 “(B) REQUIREMENTS FOR POLICIES AND
2 PROCEDURES.—In promulgating regulations
3 under subparagraph (A), the Board shall—

4 “(i) identify types of policies and pro-
5 cedures, including nonexclusive examples,
6 that shall be considered to be reasonably
7 designed to prevent the introduction of re-
8 stricted transactions into a payment sys-
9 tem or the completion of restricted trans-
10 actions using a payment system; and

11 “(ii) to the extent practicable, permit
12 any payment system, or person described
13 in paragraph (2)(B), as applicable, to
14 choose among alternative means of pre-
15 venting the introduction or completion of
16 restricted transactions.

17 “(C) NO LIABILITY FOR BLOCKING OR RE-
18 FUSING TO HONOR RESTRICTED TRANS-
19 ACTION.—

20 “(i) IN GENERAL.—A payment sys-
21 tem, or a person described in paragraph
22 (2)(B) that is subject to a regulation
23 issued under this subsection, and any par-
24 ticipant in such payment system that pre-
25 vents or otherwise refuses to honor trans-

1 actions in an effort to implement the poli-
2 cies and procedures required under this
3 subsection or to otherwise comply with this
4 subsection shall not be liable to any party
5 for such action.

6 “(ii) COMPLIANCE.—A person de-
7 scribed in paragraph (2)(B) meets the re-
8 quirements of this subsection if the person
9 relies on and complies with the policies and
10 procedures of a payment system of which
11 the person is a member or in which the
12 person is a participant, and such policies
13 and procedures of the payment system
14 comply with the requirements of the regu-
15 lations promulgated under subparagraph
16 (A).

17 “(D) ENFORCEMENT.—

18 “(i) IN GENERAL.—This section shall
19 be enforced by the Federal functional regu-
20 lators and the Federal Trade Commission
21 under applicable law in the manner pro-
22 vided in section 505(a) of the Gramm-
23 Leach-Bliley Act (15 U.S.C. 6805(a)).

24 “(ii) FACTORS TO BE CONSIDERED.—
25 In considering any enforcement action

1 under this subsection against a payment
2 system or person described in paragraph
3 (2)(B), the Federal functional regulators
4 and the Federal Trade Commission shall
5 consider the following factors:

6 “(I) The extent to which the pay-
7 ment system or person knowingly per-
8 mits restricted transactions.

9 “(II) The history of the payment
10 system or person in connection with
11 permitting restricted transactions.

12 “(III) The extent to which the
13 payment system or person has estab-
14 lished and is maintaining policies and
15 procedures in compliance with regula-
16 tions prescribed under this subsection.

17 “(8) TRANSACTIONS PERMITTED.—A payment
18 system, or a person described in paragraph (2)(B)
19 that is subject to a regulation issued under this sub-
20 section, is authorized to engage in transactions with
21 foreign pharmacies in connection with investigating
22 violations or potential violations of any rule or re-
23 quirement adopted by the payment system or person
24 in connection with complying with paragraph (7). A
25 payment system, or such a person, and its agents

1 and employees shall not be found to be in violation
2 of, or liable under, any Federal, State or other law
3 by virtue of engaging in any such transaction.

4 “(9) RELATION TO STATE LAWS.—No require-
5 ment, prohibition, or liability may be imposed on a
6 payment system, or a person described in paragraph
7 (2)(B) that is subject to a regulation issued under
8 this subsection, under the laws of any state with re-
9 spect to any payment transaction by an individual
10 because the payment transaction involves a payment
11 to a foreign pharmacy.

12 “(10) TIMING OF REQUIREMENTS.—A payment
13 system, or a person described in paragraph (2)(B)
14 that is subject to a regulation issued under this sub-
15 section, must adopt policies and procedures reason-
16 ably designed to comply with any regulations re-
17 quired under paragraph (7) within 60 days after
18 such regulations are issued in final form.”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 this section shall take effect on the day that is 90 days
21 after the date of enactment of this Act.

22 (c) IMPLEMENTATION.—The Board of Governors of
23 the Federal Reserve System shall promulgate regulations
24 as required by subsection (g)(7) of section 303 of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333), as

1 added by subsection (a), not later than 90 days after the
 2 date of enactment of this Act.

3 **SEC. 129. IMPORTATION EXEMPTION UNDER CONTROLLED**
 4 **SUBSTANCES IMPORT AND EXPORT ACT.**

5 Section 1006(a)(2) of the Controlled Substances Im-
 6 port and Export Act (21 U.S.C. 956(a)(2)) is amended
 7 by striking “not import the controlled substance into the
 8 United States in an amount that exceeds 50 dosage units
 9 of the controlled substance.” and inserting “import into
 10 the United States not more than 10 dosage units com-
 11 bined of all such controlled substances.”.

12 **SEC. 130. SEVERABILITY.**

13 If any provision of this subtitle, an amendment by
 14 this subtitle, or the application of such provision or
 15 amendment to any person or circumstance is held to be
 16 unconstitutional, the remainder of this subtitle, the
 17 amendments made by this subtitle, and the application of
 18 the provisions of such to any person or circumstance shall
 19 not affected thereby.

20 **Subtitle D—Royalties Under**
 21 **Offshore Oil and Gas Leases**

22 **SEC. 141. PRICE THRESHOLDS FOR ROYALTY SUSPENSION**
 23 **PROVISIONS.**

24 (a) IN GENERAL.—The Secretary of the Interior (re-
 25 ferred to in this subtitle as the “Secretary”) shall agree

1 to a request by any lessee to amend any lease issued for
 2 any Central and Western Gulf of Mexico tract during the
 3 period of January 1, 1998, through December 31, 1999,
 4 to incorporate price thresholds applicable to royalty sus-
 5 pension provisions, that are equal to or less than the price
 6 thresholds described in clauses (v) through (vii) of section
 7 8(a)(3)(C) of the Outer Continental Shelf Lands Act (43
 8 U.S.C. 1337(a)(3)(C)).

9 (b) EFFECTIVE DATE.—

10 (1) IN GENERAL.—Any lease amended under
 11 subsection (a) shall impose the new or revised price
 12 thresholds effective beginning October 1, 2006.

13 (2) EXISTING PROVISIONS.—Existing lease pro-
 14 visions in a lease amended under subsection (a) shall
 15 apply through September 30, 2006.

16 **SEC. 142. CLARIFICATION OF AUTHORITY TO IMPOSE**
 17 **PRICE THRESHOLDS FOR CERTAIN LEASE**
 18 **SALES.**

19 Congress reaffirms the authority of the Secretary
 20 under section 8(a)(1)(H) of the Outer Continental Shelf
 21 Lands Act (43 U.S.C. 1337(a)(1)(H)) to vary, based on
 22 the price of production from a lease, the suspension of
 23 royalties under any lease subject to section 304 of the
 24 Outer Continental Shelf Deep Water Royalty Relief Act
 25 (43 U.S.C. 1337; Public Law 104–58).

1 **SEC. 143. ELIGIBILITY FOR NEW LEASES AND THE TRANS-**
 2 **FER OF LEASES; CONSERVATION OF RE-**
 3 **SOURCES FEES.**

4 (a) DEFINITIONS.—In this section—

5 (1) COVERED LEASE.—The term “covered
 6 lease” means a lease for oil or gas production in the
 7 Gulf of Mexico that is—

8 (A) in existence on the date of enactment
 9 of this Act;

10 (B) issued by the Department of the Inte-
 11 rior under section 304 of the Outer Continental
 12 Shelf Deep Water Royalty Relief Act (43
 13 U.S.C. 1337 note; Public Law 104–58); and

14 (C) not subject to limitations on royalty re-
 15 lief based on market price that are equal to or
 16 less than the price thresholds described in
 17 clauses (v) through (vii) of section 8(a)(3)(C) of
 18 the Outer Continental Shelf Lands Act (43
 19 U.S.C. 1337(a)(3)(C)).

20 (2) LESSEE.—The term “lessee” includes any
 21 person or other entity that controls, is controlled by,
 22 or is in or under common control with, a lessee.

23 (b) ISSUANCE OF NEW LEASES.—

24 (1) IN GENERAL.—The Secretary shall not
 25 issue any new lease that authorizes the production
 26 of oil or natural gas in the Gulf of Mexico under the

1 Outer Continental Shelf Lands Act (43 U.S.C. 1331
2 et seq.) to a person described in paragraph (2) un-
3 less—

4 (A) the person has renegotiated each cov-
5 ered lease with respect to which the person is
6 a lessee, to modify the payment responsibilities
7 of the person to include price thresholds that
8 are equal to or less than the price thresholds
9 described in clauses (v) through (vii) of section
10 8(a)(3)(C) of the Outer Continental Shelf
11 Lands Act (43 U.S.C. 1337(a)(3)(C)); or

12 (B) the person has—

13 (i) paid all fees established by the
14 Secretary under subsection (c) that are
15 due with respect to each covered lease for
16 which the person is a lessee; or

17 (ii) entered into an agreement with
18 the Secretary under which the person is
19 obligated to pay the fees.

20 (2) PERSONS DESCRIBED.—A person referred
21 to in paragraph (1) is—

22 (A) a lessee that—

23 (i) holds a covered lease on the date
24 on which the Secretary considers the
25 issuance of the new lease; or

1 (ii) was issued a covered lease before
 2 the date of enactment of this Act, but
 3 transferred the covered lease to another
 4 person or entity (including a subsidiary or
 5 affiliate of the lessee) after the date of en-
 6 actment of this Act; or

7 (B) any other person or entity who has
 8 any direct or indirect interest in, or who derives
 9 any benefit from, a covered lease.

10 (3) MULTIPLE LESSEES.—

11 (A) IN GENERAL.—For purposes of para-
 12 graph (1), if there are multiple lessees that own
 13 a share of a covered lease, the Secretary may
 14 implement separate agreements with any lessee
 15 with a share of the covered lease that modifies
 16 the payment responsibilities with respect to the
 17 share of the lessee to include price thresholds
 18 that are equal to or less than the price thresh-
 19 olds described in clauses (v) through (vii) of
 20 section 8(a)(3)(C) of the Outer Continental
 21 Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)).

22 (B) TREATMENT OF SHARE AS COVERED
 23 LEASE.—Beginning on the effective date of an
 24 agreement under subparagraph (A), any share
 25 subject to the agreement shall not constitute a

1 covered lease with respect to any lessees that
2 entered into the agreement.

3 (c) CONSERVATION OF RESOURCES FEES.—

4 (1) IN GENERAL.—Not later than 60 days after
5 the date of enactment of this Act, the Secretary
6 shall establish, by regulation, a conservation of re-
7 sources fee for producing Federal oil and gas leases
8 in the Gulf of Mexico.

9 (2) PRODUCING LEASE FEE TERMS.—The fee
10 under paragraph (1)—

11 (A) subject to subparagraph (C), shall
12 apply to covered leases that are producing
13 leases;

14 (B) shall be set at \$9 per barrel for oil and
15 \$1.25 per million Btu for gas, respectively, in
16 2005 dollars; and

17 (C) shall apply only to production of oil or
18 gas occurring—

19 (i) in any calendar year in which the
20 arithmetic average of the daily closing
21 prices for light sweet crude oil on the New
22 York Mercantile Exchange (NYMEX) ex-
23 ceeds \$34.73 per barrel for oil and \$4.34
24 per million Btu for gas in 2005 dollars;
25 and

1 (ii) on or after October 1, 2006.

2 (3) TREATMENT OF RECEIPTS.—Amounts re-
3 ceived by the United States as fees under this sub-
4 section shall be treated as offsetting receipts.

5 (d) TRANSFERS.—A lessee or any other person who
6 has any direct or indirect interest in, or who derives a
7 benefit from, a lease shall not be eligible to obtain by sale
8 or other transfer (including through a swap, spinoff, serv-
9 icing, or other agreement) any covered lease, the economic
10 benefit of any covered lease, or any other lease for the
11 production of oil or natural gas in the Gulf of Mexico
12 under the Outer Continental Shelf Lands Act (43 U.S.C.
13 1331 et seq.), unless—

14 (1) the lessee or other person has—

15 (A) renegotiated all covered leases of the
16 lessee or other person; and

17 (B) entered into an agreement with the
18 Secretary to modify the terms of all covered
19 leases of the lessee or other person to include
20 limitations on royalty relief based on market
21 prices that are equal to or less than the price
22 thresholds described in clauses (v) through (vii)
23 of section 8(a)(3)(C) of the Outer Continental
24 Shelf Lands Act (43 U.S.C. 1337(a)(3)(C)); or

25 (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:

1 “(3) EXCEPTION FOR TAXPAYERS WITH TAX-
 2 ABLE INCOME OF \$1,000,000, OR MORE.—Notwith-
 3 standing paragraph (2), in the case of taxable years
 4 beginning in a calender year after 2007, the last
 5 item in the fourth column of the table under para-
 6 graph (2) shall be applied by substituting ‘39.6%’
 7 for ‘35.0%’ with respect to taxable income in excess
 8 of \$1,000,000 (\$500,000 in the case of taxpayers to
 9 whom subsection (d) applies).”.

10 (b) EFFECTIVE DATE.—The amendment made by
 11 this section shall apply to taxable years beginning after
 12 December 31, 2007.

13 (c) APPLICATION OF EGTRRA SUNSET.—The amend-
 14 ment made by this section shall be subject to title IX of
 15 the Economic Growth and Tax Relief Reconciliation Act
 16 of 2001 to the same extent and in the same manner as
 17 the provision of such Act to which such amendment re-
 18 lates.

19 **SEC. 202. ELIMINATION OF THE SCHEDULED PHASEOUT OF**
 20 **THE LIMITATIONS ON PERSONAL EXEMP-**
 21 **TIONS AND ITEMIZED DEDUCTIONS FOR TAX-**
 22 **PAYERS EARNING IN EXCESS OF \$1,000,000.**

23 (a) PERSONAL EXEMPTIONS.—Section 151(d)(3)(E)
 24 is amended by adding at the end the following new clause:

1 “(iii) EXCEPTION.—This subpara-
2 graph shall not apply with respect to any
3 taxpayer whose adjusted gross income for
4 the taxable year exceeds \$1,000,000
5 (\$500,000 in the case of a married indi-
6 vidual filing a separate return).”.

7 (b) ITEMIZED DEDUCTIONS.—Section 68(f) amended
8 by adding at the end the following new paragraph:

9 “(3) EXCEPTION.—This subsection shall not
10 apply with respect to any taxpayer whose adjusted
11 gross income for the taxable year exceeds
12 \$1,000,000 (\$500,000 in the case of a married indi-
13 vidual filing a separate return).”.

14 (c) EFFECTIVE DATE.—The amendments made by
15 this section shall apply to taxable years beginning after
16 December 31, 2007.

17 (d) APPLICATION OF EGTRRA SUNSET.—The
18 amendments made by this section shall be subject to title
19 IX of the Economic Growth and Tax Relief Reconciliation
20 Act of 2001 to the same extent and in the same manner
21 as the provision of such Act to which such amendment
22 relates.

1 **SEC. 203. MODIFICATION OF TAX RATES ON CAPITAL GAINS**
 2 **AND DIVIDENDS FOR TAXPAYERS WITH**
 3 **\$1,000,000 OR MORE OF TAXABLE INCOME.**

4 (a) IN GENERAL.—Section 1(h) is amended by add-
 5 ing at the end the following new paragraph:

6 “(12) MODIFIED RATES FOR INDIVIDUALS
 7 WITH \$1,000,000 OR MORE OF TAXABLE INCOME.—If
 8 a taxpayer has taxable income of \$1,000,000
 9 (\$500,000 in the case of taxpayers to whom sub-
 10 section (d) applies) or more for any taxable year—

11 “(A) paragraph (11) (relating to dividends
 12 taxed as capital gain) shall not apply to any
 13 qualified dividend income of the taxpayer for
 14 the taxable year, and

15 “(B) paragraph (1)(C) shall be applied by
 16 substituting ‘20 percent’ for ‘15 percent’ with
 17 respect to the adjusted net capital gain of the
 18 taxpayer for the taxable year, determined by
 19 only taking into account gain or loss properly
 20 allocable to the portion of the taxable year after
 21 December 31, 2007.”

22 (b) APPLICATION TO MINIMUM TAX.—Section
 23 55(b)(3) is amended by adding at the end the following
 24 new sentence: “In the case of a taxpayer with alternative
 25 minimum taxable income of \$1,000,000 (\$500,000 in the
 26 case of taxpayers to whom section 1(d) applies) or more

1 for any taxable year, the rules of section 1(h)(12) shall
 2 apply for purposes of this paragraph.”

3 (c) EFFECTIVE DATES.—

4 (1) CAPITAL GAINS.—Section 1(h)(12)(B) of
 5 the Internal Revenue Code of 1986 (as added by
 6 paragraph (1)) shall apply to taxable years begin-
 7 ning after December 31, 2007.

8 (2) DIVIDEND RATES.—Section 1(h)(12)(A) of
 9 such Code (as added by paragraph (1)) shall apply
 10 to dividends received after December 31, 2007.

11 (d) APPLICATION OF JGTRRA SUNSET.—The amend-
 12 ments made by this section shall be subject to section 303
 13 of the Jobs and Growth Tax Relief Reconciliation Act of
 14 2003 to the same extent and in the same manner as the
 15 provision of such Act to which such amendment relates.

16 **Subtitle B—Provisions to Discour-**
 17 **age Offshore Shelters and Expa-**
 18 **triation**

19 **SEC. 211. TAXATION OF INCOME OF CONTROLLED FOREIGN**
 20 **CORPORATIONS ATTRIBUTABLE TO IM-**
 21 **PORTED PROPERTY.**

22 (a) GENERAL RULE.—Subsection (a) of section 954
 23 (defining foreign base company income) is amended by
 24 striking “and” at the end of paragraph (4), by striking
 25 the period at the end of paragraph (5) and inserting “,

1 and”, and by adding at the end the following new para-
 2 graph:

3 “(6) imported property income for the taxable
 4 year (determined under subsection (j) and reduced
 5 as provided in subsection (b)(5)).”.

6 (b) DEFINITION OF IMPORTED PROPERTY IN-
 7 COME.—Section 954 is amended by adding at the end the
 8 following new subsection:

9 “(j) IMPORTED PROPERTY INCOME.—

10 “(1) IN GENERAL.—For purposes of subsection
 11 (a)(6), the term ‘imported property income’ means
 12 income (whether in the form of profits, commissions,
 13 fees, or otherwise) derived in connection with—

14 “(A) manufacturing, producing, growing,
 15 or extracting imported property;

16 “(B) the sale, exchange, or other disposi-
 17 tion of imported property; or

18 “(C) the lease, rental, or licensing of im-
 19 ported property.

20 Such term shall not include any foreign oil and gas
 21 extraction income (within the meaning of section
 22 907(c)) or any foreign oil related income (within the
 23 meaning of section 907(c)).

24 “(2) IMPORTED PROPERTY.—For purposes of
 25 this subsection—

1 “(A) IN GENERAL.—Except as otherwise
2 provided in this paragraph, the term ‘imported
3 property’ means property which is imported
4 into the United States by the controlled foreign
5 corporation or a related person.

6 “(B) IMPORTED PROPERTY INCLUDES CER-
7 TAIN PROPERTY IMPORTED BY UNRELATED
8 PERSONS.—The term ‘imported property’ in-
9 cludes any property imported into the United
10 States by an unrelated person if, when such
11 property was sold to the unrelated person by
12 the controlled foreign corporation (or a related
13 person), it was reasonable to expect that—

14 “(i) such property would be imported
15 into the United States; or

16 “(ii) such property would be used as
17 a component in other property which would
18 be imported into the United States.

19 “(C) EXCEPTION FOR PROPERTY SUBSE-
20 QUENTLY EXPORTED.—The term ‘imported
21 property’ does not include any property which is
22 imported into the United States and which—

23 “(i) before substantial use in the
24 United States, is sold, leased, or rented by
25 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 com-
ponent in other property which is so sold,
leased, or rented.

“(D) EXCEPTION FOR CERTAIN AGRICUL-
TURAL COMMODITIES.—The term ‘imported
property’ does not include any agricultural com-
modity which is not grown in the United States
in commercially marketable quantities.

“(3) DEFINITIONS AND SPECIAL RULES.—

“(A) IMPORT.—For purposes of this sub-
section, 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’ in-
cludes the Commonwealth of Puerto Rico, the
Virgin Islands of the United States, Guam,
American Samoa, and the Commonwealth of
the Northern Mariana Islands.

1 “(C) UNRELATED PERSON.—For purposes
 2 of this subsection, the term ‘unrelated person’
 3 means any person who is not a related person
 4 with respect to the controlled foreign corpora-
 5 tion.

6 “(D) COORDINATION WITH FOREIGN BASE
 7 COMPANY SALES INCOME.—For purposes of this
 8 section, the term ‘foreign base company sales
 9 income’ shall not include any imported property
 10 income.”.

11 (c) SEPARATE APPLICATION OF LIMITATIONS ON
 12 FOREIGN TAX CREDIT FOR IMPORTED PROPERTY IN-
 13 COME.—

14 (1) IN GENERAL.—Paragraph (1) of section
 15 904(d) (relating to separate application of section
 16 with respect to certain categories of income) is
 17 amended by striking “and” at the end of subpara-
 18 graph (A), by redesignating subparagraph (B) as
 19 subparagraph (C), and by inserting after subpara-
 20 graph (A) the following new subparagraph:

21 “(B) imported property income, and”.

22 (2) IMPORTED PROPERTY INCOME DEFINED.—
 23 Paragraph (2) of section 904(d) is amended by re-
 24 designating subparagraphs (I) and (J) as subpara-
 25 graphs (J) and (K), respectively, and by inserting

1 after subparagraph (H) the following new subpara-
 2 graph:

3 “(I) IMPORTED PROPERTY INCOME.—The
 4 term ‘imported property income’ means any in-
 5 come received or accrued by any person which
 6 is of a kind which would be imported property
 7 income (as defined in section 954(j)).”.

8 (3) CONFORMING AMENDMENT.—Clause (ii) of
 9 section 904(d)(2)(A) is amended by inserting “or
 10 imported property income” after “passive category
 11 income”.

12 (d) TECHNICAL AMENDMENTS.—

13 (1) Clause (iii) of section 952(c)(1)(B) (relating
 14 to certain prior year deficits may be taken into ac-
 15 count) is amended—

16 (A) by redesignating subclauses (II), (III),
 17 (IV), and (V) as subclauses (III), (IV), (V), and
 18 (VI), and

19 (B) by inserting after subclause (I) the fol-
 20 lowing new subclause:

21 “(II) imported property in-
 22 come,”.

23 (2) Paragraph (5) of section 954(b) (relating to
 24 deductions to be taken into account) is amended by
 25 striking “and the foreign base company oil related

1 income” and inserting “the foreign base company oil
2 related income, and the imported property income”.

3 (e) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to taxable years of foreign corpora-
5 tions beginning after the date of the enactment of this
6 Act, and to taxable years of United States shareholders
7 within which or with which such taxable years of such for-
8 eign corporations end.

9 **SEC. 212. TAX TREATMENT OF CONTROLLED FOREIGN COR-**
10 **PORATIONS ESTABLISHED IN TAX HAVENS.**

11 (a) IN GENERAL.—Subchapter C of chapter 80 (re-
12 lating to provisions affecting more than one subtitle) is
13 amended by adding at the end the following new section:

14 **“SEC. 7875. CONTROLLED FOREIGN CORPORATIONS IN TAX**
15 **HAVENS TREATED AS DOMESTIC CORPORA-**
16 **TIONS.**

17 “(a) GENERAL RULE.—If a controlled foreign cor-
18 poration is a tax-haven CFC, then, notwithstanding sec-
19 tion 7701(a)(4), such corporation shall be treated for pur-
20 poses of this title as a domestic corporation.

21 “(b) TAX-HAVEN CFC.—For purposes of this sec-
22 tion—

23 “(1) IN GENERAL.—The term ‘tax-haven CFC’
24 means, with respect to any taxable year, a foreign
25 corporation which—

1 “(A) was created or organized under the
2 laws of a tax-haven country, and

3 “(B) is a controlled foreign corporation
4 (determined without regard to this section) for
5 an uninterrupted period of 30 days or more
6 during the taxable year.

7 “(2) EXCEPTION.—The term ‘tax-haven CFC’
8 does not include a foreign corporation for any tax-
9 able year if substantially all of its income for the
10 taxable year is derived from the active conduct of
11 trades or businesses within the country under the
12 laws of which the corporation was created or orga-
13 nized.

14 “(c) TAX-HAVEN COUNTRY.—For purposes of this
15 section—

16 “(1) IN GENERAL.—The term ‘tax-haven coun-
17 try’ means any of the following:

“Andorra	Guernsey	Panama
Anguilla	Isle of Man	Samoa
Antigua and Barbuda	Jersey	San Marino
Aruba	Liberia	Federation of
Commonwealth of the	Principality of	Saint
Bahamas	Liechtenstein	Christopher
Bahrain	Republic of the	and Nevis
Barbados	Maldives	Saint Lucia
Belize	Malta	Saint Vincent
Bermuda	Republic of the	and the
British Virgin Islands	Marshall Islands	Grenadines
Cayman Islands	Mauritius	Republic of the
Cook Islands	Principality of Monaco	Seychelles
Cyprus	Montserrat	Tonga
Commonwealth of the	Republic of Nauru	Turks and Caicos
Dominica	Netherlands	Republic of
Gibraltar	Antilles	Vanuatu
Grenada	Niue	

“Sec. 7875. Controlled foreign corporations in tax havens treated as domestic corporations.”.

12 SEC. 213. REVISION OF TAX RULES ON EXPATRIATION OF
13 INDIVIDUALS.

17 **“SEC. 877A. TAX RESPONSIBILITIES OF EXPATRIATION.**

“(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.

1 “(2) RECOGNITION OF GAIN OR LOSS.—In the
2 case of any sale under paragraph (1)—

3 “(A) notwithstanding any other provision
4 of this title, any gain arising from such sale
5 shall be taken into account for the taxable year
6 of the sale, and

7 “(B) any loss arising from such sale shall
8 be taken into account for the taxable year of
9 the sale to the extent otherwise provided by this
10 title, except that section 1091 shall not apply to
11 any such loss.

12 Proper adjustment shall be made in the amount of
13 any gain or loss subsequently realized for gain or
14 loss taken into account under the preceding sen-
15 tence.

16 “(3) EXCLUSION FOR CERTAIN GAIN.—

17 “(A) IN GENERAL.—The amount which,
18 but for this paragraph, would be includible in
19 the gross income of any individual by reason of
20 this section shall be reduced (but not below
21 zero) by \$600,000. For purposes of this para-
22 graph, allocable expatriation gain taken into ac-
23 count under subsection (f)(2) shall be treated in
24 the same manner as an amount required to be
25 includible in gross income.

1 “(B) COST-OF-LIVING ADJUSTMENT.—

2 “(i) IN GENERAL.—In the case of an
3 expatriation date occurring in any calendar
4 year after 2008, the \$600,000 amount
5 under subparagraph (A) shall be increased
6 by an amount equal to—

7 “(I) such dollar amount, multi-
8 plied by

9 “(II) the cost-of-living adjust-
10 ment determined under section 1(f)(3)
11 for such calendar year, determined by
12 substituting ‘calendar year 2007’ for
13 ‘calendar year 1992’ in subparagraph
14 (B) thereof.

15 “(ii) ROUNDING RULES.—If any
16 amount after adjustment under clause (i)
17 is not a multiple of \$1,000, such amount
18 shall be rounded to the next lower multiple
19 of \$1,000.

20 “(4) ELECTION TO CONTINUE TO BE TAXED AS
21 UNITED STATES CITIZEN.—

22 “(A) IN GENERAL.—If a covered expatriate
23 elects the application of this paragraph—

1 “(i) this section (other than this para-
2 graph and subsection (i)) shall not apply to
3 the expatriate, but

4 “(ii) in the case of property to which
5 this section would apply but for such elec-
6 tion, the expatriate shall be subject to tax
7 under this title in the same manner as if
8 the individual were a United States citizen.

9 “(B) REQUIREMENTS.—Subparagraph (A)
10 shall not apply to an individual unless the indi-
11 vidual—

12 “(i) provides security for payment of
13 tax in such form and manner, and in such
14 amount, as the Secretary may require,

15 “(ii) consents to the waiver of any
16 right of the individual under any treaty of
17 the United States which would preclude as-
18 sessment or collection of any tax which
19 may be imposed by reason of this para-
20 graph, and

21 “(iii) complies with such other re-
22 quirements as the Secretary may prescribe.

23 “(C) ELECTION.—An election under sub-
24 paragraph (A) shall apply to all property to
25 which this section would apply but for the elec-

1 tion and, once made, shall be irrevocable. Such
 2 election shall also apply to property the basis of
 3 which is determined in whole or in part by ref-
 4 erence to the property with respect to which the
 5 election was made.

6 “(b) ELECTION TO DEFER TAX.—

7 “(1) IN GENERAL.—If the taxpayer elects the
 8 application of this subsection with respect to any
 9 property treated as sold by reason of subsection (a),
 10 the payment of the additional tax attributable to
 11 such property shall be postponed until the due date
 12 of the return for the taxable year in which such
 13 property is disposed of (or, in the case of property
 14 disposed of in a transaction in which gain is not rec-
 15 ognized in whole or in part, until such other date as
 16 the Secretary may prescribe).

17 “(2) DETERMINATION OF TAX WITH RESPECT
 18 TO PROPERTY.—For purposes of paragraph (1), the
 19 additional tax attributable to any property is an
 20 amount which bears the same ratio to the additional
 21 tax imposed by this chapter for the taxable year
 22 solely by reason of subsection (a) as the gain taken
 23 into account under subsection (a) with respect to
 24 such property bears to the total gain taken into ac-

1 count under subsection (a) with respect to all prop-
2 erty to which subsection (a) applies.

3 “(3) TERMINATION OF POSTPONEMENT.—No
4 tax may be postponed under this subsection later
5 than the due date for the return of tax imposed by
6 this chapter for the taxable year which includes the
7 date of death of the expatriate (or, if earlier, the
8 time that the security provided with respect to the
9 property fails to meet the requirements of paragraph
10 (4), unless the taxpayer corrects such failure within
11 the time specified by the Secretary).

12 “(4) SECURITY.—

13 “(A) IN GENERAL.—No election may be
14 made under paragraph (1) with respect to any
15 property unless adequate security is provided to
16 the Secretary with respect to such property.

17 “(B) ADEQUATE SECURITY.—For purposes
18 of subparagraph (A), security with respect to
19 any property shall be treated as adequate secu-
20 rity if—

21 “(i) it is a bond in an amount equal
22 to the deferred tax amount under para-
23 graph (2) for the property, or

1 “(ii) the taxpayer otherwise estab-
2 lishes to the satisfaction of the Secretary
3 that the security is adequate.

4 “(5) WAIVER OF CERTAIN RIGHTS.—No elec-
5 tion may be made under paragraph (1) unless the
6 taxpayer consents to the waiver of any right under
7 any treaty of the United States which would pre-
8 clude assessment or collection of any tax imposed by
9 reason of this section.

10 “(6) ELECTIONS.—An election under paragraph
11 (1) shall only apply to property described in the elec-
12 tion and, once made, is irrevocable. An election may
13 be made under paragraph (1) with respect to an in-
14 terest in a trust with respect to which gain is re-
15 quired to be recognized under subsection (f)(1).

16 “(7) INTEREST.—For purposes of section
17 6601—

18 “(A) the last date for the payment of tax
19 shall be determined without regard to the elec-
20 tion under this subsection, and

21 “(B) section 6621(a)(2) shall be applied by
22 substituting ‘5 percentage points’ for ‘3 per-
23 centage points’ in subparagraph (B) thereof.

24 “(c) COVERED EXPATRIATE.—For purposes of this
25 section—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), the term ‘covered expatriate’ means an
3 expatriate.

4 “(2) EXCEPTIONS.—An individual shall not be
5 treated as a covered expatriate if—

6 “(A) the individual—

7 “(i) became at birth a citizen of the
8 United States and a citizen of another
9 country and, as of the expatriation date,
10 continues to be a citizen of, and is taxed
11 as a resident of, such other country, and

12 “(ii) has not been a resident of the
13 United States (as defined in section
14 7701(b)(1)(A)(ii)) during the 5 taxable
15 years ending with the taxable year during
16 which the expatriation date occurs, or

17 “(B)(i) the individual’s relinquishment of
18 United States citizenship occurs before such in-
19 dividual attains age 18½, and

20 “(ii) the individual has been a resident of
21 the United States (as so defined) for not more
22 than 5 taxable years before the date of relin-
23 quishment.

24 “(d) EXEMPT PROPERTY; SPECIAL RULES FOR PEN-
25 SION PLANS.—

1 “(1) EXEMPT PROPERTY.—This section shall
2 not apply to the following:

3 “(A) UNITED STATES REAL PROPERTY IN-
4 TERESTS.—Any United States real property in-
5 terest (as defined in section 897(c)(1)), other
6 than stock of a United States real property
7 holding corporation which does not, on the day
8 before the expatriation date, meet the require-
9 ments of section 897(c)(2).

10 “(B) SPECIFIED PROPERTY.—Any prop-
11 erty or interest in property not described in
12 subparagraph (A) which the Secretary specifies
13 in regulations.

14 “(2) SPECIAL RULES FOR CERTAIN RETIRE-
15 MENT PLANS.—

16 “(A) IN GENERAL.—If a covered expatriate
17 holds on the day before the expatriation date
18 any interest in a retirement plan to which this
19 paragraph applies—

20 “(i) such interest shall not be treated
21 as sold for purposes of subsection (a)(1),
22 but

23 “(ii) an amount equal to the present
24 value of the expatriate’s nonforfeitable ac-
25 crued benefit shall be treated as having

1 been received by such individual on such
2 date as a distribution under the plan.

3 “(B) TREATMENT OF SUBSEQUENT DIS-
4 TRIBUTIONS.—In the case of any distribution
5 on or after the expatriation date to or on behalf
6 of the covered expatriate from a plan from
7 which the expatriate was treated as receiving a
8 distribution under subparagraph (A), the
9 amount otherwise includible in gross income by
10 reason of the subsequent distribution shall be
11 reduced by the excess of the amount includible
12 in gross income under subparagraph (A) over
13 any portion of such amount to which this sub-
14 paragraph previously applied.

15 “(C) TREATMENT OF SUBSEQUENT DIS-
16 TRIBUTIONS BY PLAN.—For purposes of this
17 title, a retirement plan to which this paragraph
18 applies, and any person acting on the plan’s be-
19 half, shall treat any subsequent distribution de-
20 scribed in subparagraph (B) in the same man-
21 ner as such distribution would be treated with-
22 out regard to this paragraph.

23 “(D) APPLICABLE PLANS.—This para-
24 graph shall apply to—

1 “(i) any qualified retirement plan (as
2 defined in section 4974(c)),

3 “(ii) an eligible deferred compensation
4 plan (as defined in section 457(b)) of an
5 eligible employer described in section
6 457(e)(1)(A), and

7 “(iii) to the extent provided in regula-
8 tions, any foreign pension plan or similar
9 retirement arrangements or programs.

10 “(e) DEFINITIONS.—For purposes of this section—

11 “(1) EXPATRIATE.—The term ‘expatriate’
12 means—

13 “(A) any United States citizen who relin-
14 quishes citizenship, and

15 “(B) any long-term resident of the United
16 States who—

17 “(i) ceases to be a lawful permanent
18 resident of the United States (within the
19 meaning of section 7701(b)(6)), or

20 “(ii) commences to be treated as a
21 resident of a foreign country under the
22 provisions of a tax treaty between the
23 United States and the foreign country and
24 who does not waive the benefits of such

1 treaty applicable to residents of the foreign
2 country.

3 “(2) EXPATRIATION DATE.—The term ‘expa-
4 triation date’ means—

5 “(A) the date an individual relinquishes
6 United States citizenship, or

7 “(B) in the case of a long-term resident of
8 the United States, the date of the event de-
9 scribed in clause (i) or (ii) of paragraph (1)(B).

10 “(3) RELINQUISHMENT OF CITIZENSHIP.—A
11 citizen shall be treated as relinquishing United
12 States citizenship on the earliest of—

13 “(A) the date the individual renounces
14 such individual’s United States nationality be-
15 fore a diplomatic or consular officer of the
16 United States pursuant to paragraph (5) of sec-
17 tion 349(a) of the Immigration and Nationality
18 Act (8 U.S.C. 1481(a)(5)),

19 “(B) the date the individual furnishes to
20 the United States Department of State a signed
21 statement of voluntary relinquishment of
22 United States nationality confirming the per-
23 formance of an act of expatriation specified in
24 paragraph (1), (2), (3), or (4) of section 349(a)

1 of the Immigration and Nationality Act (8
2 U.S.C. 1481(a)(1)–(4)),

3 “(C) the date the United States Depart-
4 ment of State issues to the individual a certifi-
5 cate of loss of nationality, or

6 “(D) the date a court of the United States
7 cancels a naturalized citizen’s certificate of nat-
8 uralization.

9 Subparagraph (A) or (B) shall not apply to any indi-
10 vidual unless the renunciation or voluntary relin-
11 quishment is subsequently approved by the issuance
12 to the individual of a certificate of loss of nationality
13 by the United States Department of State.

14 “(4) LONG-TERM RESIDENT.—The term ‘long-
15 term resident’ has the meaning given to such term
16 by section 877(e)(2).

17 “(f) SPECIAL RULES APPLICABLE TO BENE-
18 FICIARIES’ INTERESTS IN TRUST.—

19 “(1) IN GENERAL.—Except as provided in para-
20 graph (2), if an individual is determined under para-
21 graph (3) to hold an interest in a trust on the day
22 before the expatriation date—

23 “(A) the individual shall not be treated as
24 having sold such interest,

1 “(B) such interest shall be treated as a
2 separate share in the trust, and

3 “(C)(i) such separate share shall be treat-
4 ed as a separate trust consisting of the assets
5 allocable to such share,

6 “(ii) the separate trust shall be treated as
7 having sold its assets on the day before the ex-
8 patriation date for their fair market value and
9 as having distributed all of its assets to the in-
10 dividual as of such time, and

11 “(iii) the individual shall be treated as hav-
12 ing recontributed the assets to the separate
13 trust.

14 Subsection (a)(2) shall apply to any income, gain, or
15 loss of the individual arising from a distribution de-
16 scribed in subparagraph (C)(ii). In determining the
17 amount of such distribution, proper adjustments
18 shall be made for liabilities of the trust allocable to
19 an individual’s share in the trust.

20 “(2) SPECIAL RULES FOR INTERESTS IN QUALI-
21 FIED TRUSTS.—

22 “(A) IN GENERAL.—If the trust interest
23 described in paragraph (1) is an interest in a
24 qualified trust—

1 “(i) paragraph (1) and subsection (a)
2 shall not apply, and

3 “(ii) in addition to any other tax im-
4 posed by this title, there is hereby imposed
5 on each distribution with respect to such
6 interest a tax in the amount determined
7 under subparagraph (B).

8 “(B) AMOUNT OF TAX.—The amount of
9 tax under subparagraph (A)(ii) shall be equal to
10 the lesser of—

11 “(i) the highest rate of tax imposed by
12 section 1(e) for the taxable year which in-
13 cludes the day before the expatriation date,
14 multiplied by the amount of the distribu-
15 tion, or

16 “(ii) the balance in the deferred tax
17 account immediately before the distribution
18 determined without regard to any increases
19 under subparagraph (C)(ii) after the 30th
20 day preceding the distribution.

21 “(C) DEFERRED TAX ACCOUNT.—For pur-
22 poses of subparagraph (B)(ii)—

23 “(i) OPENING BALANCE.—The open-
24 ing balance in a deferred tax account with
25 respect to any trust interest is an amount

1 equal to the tax which would have been im-
2 posed on the allocable expatriation gain
3 with respect to the trust interest if such
4 gain had been included in gross income
5 under subsection (a).

6 “(ii) INCREASE FOR INTEREST.—The
7 balance in the deferred tax account shall
8 be increased by the amount of interest de-
9 termined (on the balance in the account at
10 the time the interest accrues), for periods
11 after the 90th day after the expatriation
12 date, by using the rates and method appli-
13 cable under section 6621 for underpay-
14 ments of tax for such periods, except that
15 section 6621(a)(2) shall be applied by sub-
16 stituting ‘5 percentage points’ for ‘3 per-
17 centage points’ in subparagraph (B) there-
18 of.

19 “(iii) DECREASE FOR TAXES PRE-
20 VIOUSLY PAID.—The balance in the tax de-
21 ferred account shall be reduced—

22 “(I) by the amount of taxes im-
23 posed by subparagraph (A) on any
24 distribution to the person holding the
25 trust interest, and

1 “(II) in the case of a person
2 holding a nonvested interest, to the
3 extent provided in regulations, by the
4 amount of taxes imposed by subpara-
5 graph (A) on distributions from the
6 trust with respect to nonvested inter-
7 ests not held by such person.

8 “(D) ALLOCABLE EXPATRIATION GAIN.—
9 For purposes of this paragraph, the allocable
10 expatriation gain with respect to any bene-
11 ficiary’s interest in a trust is the amount of
12 gain which would be allocable to such bene-
13 ficiary’s vested and nonvested interests in the
14 trust if the beneficiary held directly all assets
15 allocable to such interests.

16 “(E) TAX DEDUCTED AND WITHHELD.—
17 “(i) IN GENERAL.—The tax imposed
18 by subparagraph (A)(ii) shall be deducted
19 and withheld by the trustees from the dis-
20 tribution to which it relates.

21 “(ii) EXCEPTION WHERE FAILURE TO
22 WAIVE TREATY RIGHTS.—If an amount
23 may not be deducted and withheld under
24 clause (i) by reason of the distributee fail-

1 ing to waive any treaty right with respect
2 to such distribution—

3 “(I) the tax imposed by subpara-
4 graph (A)(ii) shall be imposed on the
5 trust and each trustee shall be person-
6 ally liable for the amount of such tax,
7 and

8 “(II) any other beneficiary of the
9 trust shall be entitled to recover from
10 the distributee the amount of such tax
11 imposed on the other beneficiary.

12 “(F) DISPOSITION.—If a trust ceases to be
13 a qualified trust at any time, a covered expa-
14 triate disposes of an interest in a qualified
15 trust, or a covered expatriate holding an inter-
16 est in a qualified trust dies, then, in lieu of the
17 tax imposed by subparagraph (A)(ii), there is
18 hereby imposed a tax equal to the lesser of—

19 “(i) the tax determined under para-
20 graph (1) as if the day before the expatria-
21 tion date were the date of such cessation,
22 disposition, or death, whichever is applica-
23 ble, or

24 “(ii) the balance in the tax deferred
25 account immediately before such date.

1 Such tax shall be imposed on the trust and
2 each trustee shall be personally liable for the
3 amount of such tax and any other beneficiary
4 of the trust shall be entitled to recover from the
5 covered expatriate or the estate the amount of
6 such tax imposed on the other beneficiary.

7 “(G) DEFINITIONS AND SPECIAL RULES.—

8 For purposes of this paragraph—

9 “(i) QUALIFIED TRUST.—The term
10 ‘qualified trust’ means a trust which is de-
11 scribed in section 7701(a)(30)(E).

12 “(ii) VESTED INTEREST.—The term
13 ‘vested interest’ means any interest which,
14 as of the day before the expatriation date,
15 is vested in the beneficiary.

16 “(iii) NONVESTED INTEREST.—The
17 term ‘nonvested interest’ means, with re-
18 spect to any beneficiary, any interest in a
19 trust which is not a vested interest. Such
20 interest shall be determined by assuming
21 the maximum exercise of discretion in
22 favor of the beneficiary and the occurrence
23 of all contingencies in favor of the bene-
24 ficiary.

1 “(iv) ADJUSTMENTS.—The Secretary
 2 may provide for such adjustments to the
 3 bases of assets in a trust or a deferred tax
 4 account, and the timing of such adjust-
 5 ments, in order to ensure that gain is
 6 taxed only once.

7 “(v) COORDINATION WITH RETIRE-
 8 MENT PLAN RULES.—This subsection shall
 9 not apply to an interest in a trust which
 10 is part of a retirement plan to which sub-
 11 section (d)(2) applies.

12 “(3) DETERMINATION OF BENEFICIARIES’ IN-
 13 TEREST IN TRUST.—

14 “(A) DETERMINATIONS UNDER PARA-
 15 GRAPH (1).—For purposes of paragraph (1), a
 16 beneficiary’s interest in a trust shall be based
 17 upon all relevant facts and circumstances, in-
 18 cluding the terms of the trust instrument and
 19 any letter of wishes or similar document, histor-
 20 ical patterns of trust distributions, and the ex-
 21 istence of and functions performed by a trust
 22 protector or any similar adviser.

23 “(B) OTHER DETERMINATIONS.—For pur-
 24 poses of this section—

1 “(i) CONSTRUCTIVE OWNERSHIP.—If
2 a beneficiary of a trust is a corporation,
3 partnership, trust, or estate, the share-
4 holders, partners, or beneficiaries shall be
5 deemed to be the trust beneficiaries for
6 purposes of this section.

7 “(ii) TAXPAYER RETURN POSITION.—
8 A taxpayer shall clearly indicate on its in-
9 come tax return—

10 “(I) the methodology used to de-
11 termine that taxpayer’s trust interest
12 under this section, and

13 “(II) if the taxpayer knows (or
14 has reason to know) that any other
15 beneficiary of such trust is using a
16 different methodology to determine
17 such beneficiary’s trust interest under
18 this section.

19 “(g) TERMINATION OF DEFERRALS, ETC.—In the
20 case of any covered expatriate, notwithstanding any other
21 provision of this title—

22 “(1) any period during which recognition of in-
23 come or gain is deferred shall terminate on the day
24 before the expatriation date, and

1 “(2) any extension of time for payment of tax
2 shall cease to apply on the day before the expatria-
3 tion date and the unpaid portion of such tax shall
4 be due and payable at the time and in the manner
5 prescribed by the Secretary.

6 “(h) IMPOSITION OF TENTATIVE TAX.—

7 “(1) IN GENERAL.—If an individual is required
8 to include any amount in gross income under sub-
9 section (a) for any taxable year, there is hereby im-
10 posed, immediately before the expatriation date, a
11 tax in an amount equal to the amount of tax which
12 would be imposed if the taxable year were a short
13 taxable year ending on the expatriation date.

14 “(2) DUE DATE.—The due date for any tax im-
15 posed by paragraph (1) shall be the 90th day after
16 the expatriation date.

17 “(3) TREATMENT OF TAX.—Any tax paid under
18 paragraph (1) shall be treated as a payment of the
19 tax imposed by this chapter for the taxable year to
20 which subsection (a) applies.

21 “(4) DEFERRAL OF TAX.—The provisions of
22 subsection (b) shall apply to the tax imposed by this
23 subsection to the extent attributable to gain includ-
24 ible in gross income by reason of this section.

1 “(i) SPECIAL LIENS FOR DEFERRED TAX
2 AMOUNTS.—

3 “(1) IMPOSITION OF LIEN.—

4 “(A) IN GENERAL.—If a covered expatriate
5 makes an election under subsection (a)(4) or
6 (b) which results in the deferral of any tax im-
7 posed by reason of subsection (a), the deferred
8 amount (including any interest, additional
9 amount, addition to tax, assessable penalty, and
10 costs attributable to the deferred amount) shall
11 be a lien in favor of the United States on all
12 property of the expatriate located in the United
13 States (without regard to whether this section
14 applies to the property).

15 “(B) DEFERRED AMOUNT.—For purposes
16 of this subsection, the deferred amount is the
17 amount of the increase in the covered expatri-
18 ate’s income tax which, but for the election
19 under subsection (a)(4) or (b), would have oc-
20 curred by reason of this section for the taxable
21 year including the expatriation date.

22 “(2) PERIOD OF LIEN.—The lien imposed by
23 this subsection shall arise on the expatriation date
24 and continue until—

1 “(A) the liability for tax by reason of this
 2 section is satisfied or has become unenforceable
 3 by reason of lapse of time, or

4 “(B) it is established to the satisfaction of
 5 the Secretary that no further tax liability may
 6 arise by reason of this section.

7 “(3) CERTAIN RULES APPLY.—The rules set
 8 forth in paragraphs (1), (3), and (4) of section
 9 6324A(d) shall apply with respect to the lien im-
 10 posed by this subsection as if it were a lien imposed
 11 by section 6324A.

12 “(j) REGULATIONS.—The Secretary shall prescribe
 13 such regulations as may be necessary or appropriate to
 14 carry out the purposes of this section.”.

15 (b) INCLUSION IN INCOME OF GIFTS AND BEQUESTS
 16 RECEIVED BY UNITED STATES CITIZENS AND RESIDENTS
 17 FROM EXPATRIATES.—Section 102 (relating to gifts, etc.
 18 not included in gross income) is amended by adding at
 19 the end the following new subsection:

20 “(d) GIFTS AND INHERITANCES FROM COVERED EX-
 21 PATRIATES.—

22 “(1) IN GENERAL.—Subsection (a) shall not ex-
 23 clude from gross income the value of any property
 24 acquired by gift, bequest, devise, or inheritance from
 25 a covered expatriate after the expatriation date. For

1 purposes of this subsection, any term used in this
 2 subsection which is also used in section 877A shall
 3 have the same meaning as when used in section
 4 877A.

5 “(2) EXCEPTIONS FOR TRANSFERS OTHERWISE
 6 SUBJECT TO ESTATE OR GIFT TAX.—Paragraph (1)
 7 shall not apply to any property if either—

8 “(A) the gift, bequest, devise, or inherit-
 9 ance is—

10 “(i) shown on a timely filed return of
 11 tax imposed by chapter 12 as a taxable gift
 12 by the covered expatriate, or

13 “(ii) included in the gross estate of
 14 the covered expatriate for purposes of
 15 chapter 11 and shown on a timely filed re-
 16 turn of tax imposed by chapter 11 of the
 17 estate of the covered expatriate, or

18 “(B) no such return was timely filed but
 19 no such return would have been required to be
 20 filed even if the covered expatriate were a cit-
 21 izen or long-term resident of the United
 22 States.”.

23 (c) DEFINITION OF TERMINATION OF UNITED
 24 STATES CITIZENSHIP.—Section 7701(a) is amended by
 25 adding at the end the following new paragraph:

1 “(49) TERMINATION OF UNITED STATES CITI-
2 ZENSHIP.—

3 “(A) IN GENERAL.—An individual shall
4 not cease to be treated as a United States cit-
5 izen before the date on which the individual’s
6 citizenship is treated as relinquished under sec-
7 tion 877A(e)(3).

8 “(B) DUAL CITIZENS.—Under regulations
9 prescribed by the Secretary, subparagraph (A)
10 shall not apply to an individual who became at
11 birth a citizen of the United States and a cit-
12 izen of another country.”.

13 (d) INELIGIBILITY FOR VISA OR ADMISSION TO
14 UNITED STATES.—

15 (1) IN GENERAL.—Section 212(a)(10)(E) of the
16 Immigration and Nationality Act (8 U.S.C.
17 1182(a)(10)(E)) is amended to read as follows:

18 “(E) FORMER CITIZENS NOT IN COMPLI-
19 ANCE WITH EXPATRIATION REVENUE PROVI-
20 SIONS.—Any alien who is a former citizen of
21 the United States who relinquishes United
22 States citizenship (within the meaning of sec-
23 tion 877A(e)(3) of the Internal Revenue Code
24 of 1986) and who is not in compliance with sec-

1 tion 877A of such Code (relating to expatria-
2 tion) is inadmissible.”.

3 (2) AVAILABILITY OF INFORMATION.—

4 (A) IN GENERAL.—Section 6103(l) (relat-
5 ing to disclosure of returns and return informa-
6 tion for purposes other than tax administration)
7 is amended by adding at the end the following
8 new paragraph:

9 “(21) DISCLOSURE TO DENY VISA OR ADMIS-
10 SION TO CERTAIN EXPATRIATES.—Upon written re-
11 quest of the Attorney General or the Attorney Gen-
12 eral’s delegate, the Secretary shall disclose whether
13 an individual is in compliance with section 877A
14 (and if not in compliance, any items of noncompli-
15 ance) to officers and employees of the Federal agen-
16 cy responsible for administering section
17 212(a)(10)(E) of the Immigration and Nationality
18 Act solely for the purpose of, and to the extent nec-
19 essary in, administering such section
20 212(a)(10)(E).”.

21 (B) SAFEGUARDS.—Section 6103(p)(4)
22 (relating to safeguards) is amended by striking
23 “or (20)” each place it appears and inserting
24 “(20), or (21)”.

1 (3) EFFECTIVE DATES.—The amendments
2 made by this subsection shall apply to individuals
3 who relinquish United States citizenship on or after
4 the date of the enactment of this Act.

5 (e) CONFORMING AMENDMENTS.—

6 (1) Section 877 is amended by adding at the
7 end the following new subsection:

8 “(h) APPLICATION.—This section shall not apply to
9 an expatriate (as defined in section 877A(e)) whose expa-
10 triation date (as so defined) occurs on or after the date
11 of the enactment of this subsection.”.

12 (2) Section 2107 is amended by adding at the
13 end the following new subsection:

14 “(f) APPLICATION.—This section shall not apply to
15 any expatriate subject to section 877A.”.

16 (3) Section 2501(a)(3) is amended by adding at
17 the end the following new subparagraph:

18 “(C) APPLICATION.—This paragraph shall
19 not apply to any expatriate subject to section
20 877A.”.

21 (4) Section 6039G(a) is amended by inserting
22 “or 877A” after “section 877(b)”.

23 (5) The second sentence of section 6039G(d) is
24 amended by inserting “or who relinquishes United

1 States citizenship (within the meaning of section
2 877A(e)(3))” after “section 877(a))”.

3 (f) CLERICAL AMENDMENT.—The table of sections
4 for subpart A of part II of subchapter N of chapter 1
5 is amended by inserting after the item relating to section
6 877 the following new item:

“Sec. 877A. Tax responsibilities of expatriation.”.

7 (g) EFFECTIVE DATE.—

8 (1) IN GENERAL.—Except as provided in this
9 subsection, the amendments made by this section
10 shall apply to expatriates (within the meaning of
11 section 877A(e) of the Internal Revenue Code of
12 1986, as added by this section) whose expatriation
13 date (as so defined) occurs on or after the date of
14 the enactment of this Act.

15 (2) GIFTS AND BEQUESTS.—Section 102(d) of
16 the Internal Revenue Code of 1986 (as added by
17 subsection (b)) shall apply to gifts and bequests re-
18 ceived on or after the date of the enactment of this
19 Act, from an individual or the estate of an individual
20 whose expatriation date (as so defined) occurs after
21 such date.

22 (3) DUE DATE FOR TENTATIVE TAX.—The due
23 date under section 877A(h)(2) of the Internal Rev-
24 enue Code of 1986, as added by this section, shall

1 in no event occur before the 90th day after the date
2 of the enactment of this Act.

3 **SEC. 214. MODIFICATION OF EFFECTIVE DATE OF LEASING**
4 **PROVISIONS OF THE AMERICAN JOBS CRE-**
5 **ATION ACT OF 2004.**

6 (a) LEASES TO FOREIGN ENTITIES.—Section 849(b)
7 of the American Jobs Creation Act of 2004 is amended
8 by adding at the end the following new paragraph:

9 “(5) LEASES TO FOREIGN ENTITIES.—In the
10 case of tax-exempt use property leased to a tax-ex-
11 empt entity which is a foreign person or entity, the
12 amendments made by this part shall apply to taxable
13 years beginning after December 31, 2006, with re-
14 spect to leases entered into on or before March 12,
15 2004.”.

16 (b) EFFECTIVE DATE.—The amendment made by
17 this section shall take effect as if included in the enact-
18 ment of the American Jobs Creation Act of 2004.

19 **SEC. 215. APPLICATION OF RULES TREATING INVERTED**
20 **CORPORATIONS AS DOMESTIC CORPORA-**
21 **TIONS TO CERTAIN TRANSACTIONS OCCUR-**
22 **RING AFTER MARCH 20, 2002.**

23 (a) IN GENERAL.—Section 7874(b) (relating to in-
24 verted corporations treated as domestic corporations) is
25 amended to read as follows:

1 “(b) INVERTED CORPORATIONS TREATED AS DO-
2 MESTIC CORPORATIONS.—

3 “(1) IN GENERAL.—Notwithstanding section
4 7701(a)(4), a foreign corporation shall be treated for
5 purposes of this title as a domestic corporation if
6 such corporation would be a surrogate foreign cor-
7 poration if subsection (a)(2) were applied by sub-
8 stituting ‘80 percent’ for ‘60 percent’.

9 “(2) SPECIAL RULE FOR CERTAIN TRANS-
10 ACTIONS OCCURRING AFTER MARCH 20, 2002.—

11 “(A) IN GENERAL.—If—

12 “(i) paragraph (1) does not apply to
13 a foreign corporation, but

14 “(ii) paragraph (1) would apply to
15 such corporation if, in addition to the sub-
16 stitution under paragraph (1), subsection
17 (a)(2) were applied by substituting ‘March
18 20, 2002’ for ‘March 4, 2003’ each place
19 it appears,

20 then paragraph (1) shall apply to such corpora-
21 tion but only with respect to taxable years of
22 such corporation beginning after December 31,
23 2006.

24 “(B) SPECIAL RULES.—Subject to such
25 rules as the Secretary may prescribe, in the

1 case of a corporation to which paragraph (1)
2 applies by reason of this paragraph—

3 “(i) the corporation shall be treated,
4 as of the close of its last taxable year be-
5 ginning before January 1, 2007, as having
6 transferred all of its assets, liabilities, and
7 earnings and profits to a domestic corpora-
8 tion in a transaction with respect to which
9 no tax is imposed under this title,

10 “(ii) the bases of the assets trans-
11 ferred in the transaction to the domestic
12 corporation shall be the same as the bases
13 of the assets in the hands of the foreign
14 corporation, subject to any adjustments
15 under this title for built-in losses,

16 “(iii) the basis of the stock of any
17 shareholder in the domestic corporation
18 shall be the same as the basis of the stock
19 of the shareholder in the foreign corpora-
20 tion for which it is treated as exchanged,
21 and

22 “(iv) the transfer of any earnings and
23 profits by reason of clause (i) shall be dis-
24 regarded in determining any deemed divi-
25 dend or foreign tax creditable to the do-

1 mestic corporation with respect to such
2 transfer.

3 “(C) REGULATIONS.—The Secretary may
4 prescribe such regulations as may be necessary
5 or appropriate to carry out this paragraph, in-
6 cluding regulations to prevent the avoidance of
7 the purposes of this paragraph.”.

8 (b) EFFECTIVE DATE.—The amendment made by
9 this section shall apply to taxable years beginning after
10 December 31, 2006.

11 **Subtitle C—Economic Substance** 12 **Doctrine**

13 **SEC. 221. CLARIFICATION OF ECONOMIC SUBSTANCE DOC-** 14 **TRINE.**

15 (a) IN GENERAL.—Section 7701 is amended by re-
16 designating subsection (o) as subsection (p) and by insert-
17 ing after subsection (n) the following new subsection:

18 “(o) CLARIFICATION OF ECONOMIC SUBSTANCE
19 DOCTRINE; ETC.—

20 “(1) GENERAL RULES.—

21 “(A) IN GENERAL.—In any case in which
22 a court determines that the economic substance
23 doctrine is relevant for purposes of this title to
24 a transaction (or series of transactions), such
25 transaction (or series of transactions) shall have

1 economic substance only if the requirements of
 2 this paragraph are met.

3 “(B) DEFINITION OF ECONOMIC SUB-
 4 STANCE.—For purposes of subparagraph (A)—

5 “(i) IN GENERAL.—A transaction has
 6 economic substance only if—

7 “(I) the transaction changes in a
 8 meaningful way (apart from Federal
 9 tax effects) the taxpayer’s economic
 10 position, and

11 “(II) the taxpayer has a substan-
 12 tial nontax purpose for entering into
 13 such transaction and the transaction
 14 is a reasonable means of accom-
 15 plishing such purpose.

16 In applying subclause (II), a purpose of
 17 achieving a financial accounting benefit
 18 shall not be taken into account in deter-
 19 mining whether a transaction has a sub-
 20 stantial nontax purpose if the origin of
 21 such financial accounting benefit is a re-
 22 duction of income tax.

23 “(ii) SPECIAL RULE WHERE TAX-
 24 PAYER RELIES ON PROFIT POTENTIAL.—A
 25 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 deduc-

tions 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—

1 “(A) ECONOMIC SUBSTANCE DOCTRINE.—

2 The term ‘economic substance doctrine’ means
3 the common law doctrine under which tax bene-
4 fits under subtitle A with respect to a trans-
5 action are not allowable if the transaction does
6 not have economic substance or lacks a business
7 purpose.

8 “(B) TAX-INDIFFERENT PARTY.—The

9 term ‘tax-indifferent party’ means any person
10 or entity not subject to tax imposed by subtitle
11 A. A person shall be treated as a tax-indifferent
12 party with respect to a transaction if the items
13 taken into account with respect to the trans-
14 action have no substantial impact on such per-
15 son’s liability under subtitle A.

16 “(C) EXCEPTION FOR PERSONAL TRANS-

17 ACTIONS OF INDIVIDUALS.—In the case of an
18 individual, this subsection shall apply only to
19 transactions entered into in connection with a
20 trade or business or an activity engaged in for
21 the production of income.

22 “(D) TREATMENT OF LESSORS.—In apply-

23 ing paragraph (1)(B)(ii) to the lessor of tan-
24 gible property subject to a lease—

1 “(i) the expected net tax benefits with
2 respect to the leased property shall not in-
3 clude the benefits of—

4 “(I) depreciation,

5 “(II) any tax credit, or

6 “(III) any other deduction as
7 provided in guidance by the Secretary,
8 and

9 “(ii) subclause (II) of paragraph
10 (1)(B)(ii) shall be disregarded in deter-
11 mining whether any of such benefits are al-
12 lowable.

13 “(4) OTHER COMMON LAW DOCTRINES NOT AF-
14 FECTED.—Except as specifically provided in this
15 subsection, the provisions of this subsection shall not
16 be construed as altering or supplanting any other
17 rule of law, and the requirements of this subsection
18 shall be construed as being in addition to any such
19 other rule of law.

20 “(5) REGULATIONS.—The Secretary shall pre-
21 scribe such regulations as may be necessary or ap-
22 propriate to carry out the purposes of this sub-
23 section. Such regulations may include exemptions
24 from the application of this subsection.”.

1 (b) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to transactions entered into after
 3 the date of the enactment of this Act.

4 **SEC. 222. PENALTY FOR UNDERSTATEMENTS ATTRIB-**
 5 **UTABLE TO TRANSACTIONS LACKING ECO-**
 6 **NOMIC SUBSTANCE, ETC.**

7 (a) IN GENERAL.—Subchapter A of chapter 68 is
 8 amended by inserting after section 6662A the following
 9 new section:

10 **“SEC. 6662B. PENALTY FOR UNDERSTATEMENTS ATTRIB-**
 11 **UTABLE TO TRANSACTIONS LACKING ECO-**
 12 **NOMIC SUBSTANCE, ETC.**

13 “(a) IMPOSITION OF PENALTY.—If a taxpayer has an
 14 noneconomic substance transaction understatement for
 15 any taxable year, there shall be added to the tax an
 16 amount equal to 40 percent of the amount of such under-
 17 statement.

18 “(b) REDUCTION OF PENALTY FOR DISCLOSED
 19 TRANSACTIONS.—Subsection (a) shall be applied by sub-
 20 stituting ‘20 percent’ for ‘40 percent’ with respect to the
 21 portion of any noneconomic substance transaction under-
 22 statement with respect to which the relevant facts affect-
 23 ing the tax treatment of the item are adequately disclosed
 24 in the return or a statement attached to the return.

1 “(c) NONECONOMIC SUBSTANCE TRANSACTION UN-
2 DERSTATEMENT.—For purposes of this section—

3 “(1) IN GENERAL.—The term ‘noneconomic
4 substance transaction understatement’ means any
5 amount which would be an understatement under
6 section 6662A(b)(1) if section 6662A were applied
7 by taking into account items attributable to non-
8 economic substance transactions rather than items
9 to which section 6662A would apply without regard
10 to this paragraph.

11 “(2) NONECONOMIC SUBSTANCE TRANS-
12 ACTION.—The term ‘noneconomic substance trans-
13 action’ means any transaction if—

14 “(A) there is a lack of economic substance
15 (within the meaning of section 7701(o)(1)) for
16 the transaction giving rise to the claimed ben-
17 efit or the transaction was not respected under
18 section 7701(o)(2), or

19 “(B) the transaction fails to meet the re-
20 quirements of any similar rule of law.

21 “(d) RULES APPLICABLE TO COMPROMISE OF PEN-
22 ALTY.—

23 “(1) IN GENERAL.—If the 1st letter of pro-
24 posed deficiency which allows the taxpayer an oppor-
25 tunity for administrative review in the Internal Rev-

1 enue Service Office of Appeals has been sent with
 2 respect to a penalty to which this section applies,
 3 only the Commissioner of Internal Revenue may
 4 compromise all or any portion of such penalty.

5 “(2) APPLICABLE RULES.—The rules of para-
 6 graphs (2) and (3) of section 6707A(d) shall apply
 7 for purposes of paragraph (1).

8 “(e) COORDINATION WITH OTHER PENALTIES.—Ex-
 9 cept as otherwise provided in this part, the penalty im-
 10 posed by this section shall be in addition to any other pen-
 11 alty imposed by this title.

12 “(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).”.

13 (b) COORDINATION WITH OTHER UNDERSTATE-
 14 MENTS AND PENALTIES.—

15 (1) The second sentence of section
 16 6662(d)(2)(A) is amended by inserting “and without
 17 regard to items with respect to which a penalty is
 18 imposed by section 6662B” before the period at the
 19 end.

20 (2) Subsection (e) of section 6662A is amend-
 21 ed—

1 (A) in paragraph (1), by inserting “and
 2 noneconomic substance transaction understate-
 3 ments” after “reportable transaction under-
 4 statements” both places it appears,

5 (B) in paragraph (2)(A), by inserting “and
 6 a noneconomic substance transaction under-
 7 statement” after “reportable transaction under-
 8 statement”,

9 (C) in paragraph (2)(B), by inserting
 10 “6662B or” before “6663”,

11 (D) in paragraph (2)(C)(i), by inserting
 12 “or section 6662B” before the period at the
 13 end,

14 (E) in paragraph (2)(C)(ii), by inserting
 15 “and section 6662B” after “This section”,

16 (F) in paragraph (3), by inserting “or non-
 17 economic substance transaction understate-
 18 ment” after “reportable transaction understate-
 19 ment”, and

20 (G) by adding at the end the following new
 21 paragraph:

22 “(4) NONECONOMIC SUBSTANCE TRANSACTION
 23 UNDERSTATEMENT.—For purposes of this sub-
 24 section, the term ‘noneconomic substance trans-

1 action understatement’ has the meaning given such
2 term by section 6662B(c).”.

3 (3) Subsection (e) of section 6707A is amend-
4 ed—

5 (A) by striking “or” at the end of subpara-
6 graph (B), and

7 (B) by striking subparagraph (C) and in-
8 serting the following new subparagraphs:

9 “(C) is required to pay a penalty under
10 section 6662B with respect to any noneconomic
11 substance transaction, or

12 “(D) is required to pay a penalty under
13 section 6662(h) with respect to any transaction
14 and would (but for section 6662A(e)(2)(C))
15 have been subject to penalty under section
16 6662A at a rate prescribed under section
17 6662A(c) or under section 6662B,”.

18 (c) CLERICAL AMENDMENT.—The table of sections
19 for part II of subchapter A of chapter 68 is amended by
20 inserting after the item relating to section 6662A the fol-
21 lowing new item:

 “Sec. 6662B. Penalty for understatements attributable to transactions lacking
 economic substance, etc.”.

22 (d) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to transactions entered into after
24 the date of the enactment of this Act.

1 **SEC. 223. DENIAL OF DEDUCTION FOR INTEREST ON UN-**
2 **DERPAYMENTS ATTRIBUTABLE TO NON-**
3 **ECONOMIC SUBSTANCE TRANSACTIONS.**

4 (a) IN GENERAL.—Section 163(m) (relating to inter-
5 est on unpaid taxes attributable to nondisclosed reportable
6 transactions) is amended—

7 (1) by striking “attributable” and all that fol-
8 lows and inserting the following: “attributable to—

9 “(1) the portion of any reportable transaction
10 understatement (as defined in section 6662A(b))
11 with respect to which the requirement of section
12 6664(d)(2)(A) is not met, or

13 “(2) any noneconomic substance transaction
14 understatement (as defined in section 6662B(c)).”,
15 and

16 (2) by inserting “And Noneconomic Substance
17 Transactions” in the heading thereof after “Trans-
18 actions”.

19 (b) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to transactions after the date of
21 the enactment of this Act in taxable years ending after
22 such date.

1 Subtitle D—Penalties and Fines

2 SEC. 231. DENIAL OF DEDUCTION FOR CERTAIN FINES, 3 PENALTIES, AND OTHER AMOUNTS.

4 (a) IN GENERAL.—Subsection (f) of section 162 (re-
5 relating to trade or business expenses) is amended to read
6 as follows:

7 “(f) FINES, PENALTIES, AND OTHER AMOUNTS.—

8 “(1) IN GENERAL.—Except as provided in para-
9 graph (2), no deduction otherwise allowable shall be
10 allowed under this chapter for any amount paid or
11 incurred (whether by suit, agreement, or otherwise)
12 to, or at the direction of, a government or entity de-
13 scribed in paragraph (4) in relation to the violation
14 of any law or the investigation or inquiry by such
15 government or entity into the potential violation of
16 any law.

17 “(2) EXCEPTION FOR AMOUNTS CONSTITUTING
18 RESTITUTION OR PAID TO COME INTO COMPLIANCE
19 WITH LAW.—Paragraph (1) shall not apply to any
20 amount which—

21 “(A) the taxpayer establishes—

22 “(i) constitutes restitution (including
23 remediation of property) for damage or
24 harm caused by or which may be caused by

1 the violation of any law or the potential
2 violation of any law, or

3 “(ii) is paid to come into compliance
4 with any law which was violated or in-
5 volved in the investigation or inquiry, and

6 “(B) is identified as restitution or as an
7 amount paid to come into compliance with the
8 law, as the case may be, in the court order or
9 settlement agreement.

10 Identification pursuant to subparagraph (B) alone
11 shall not satisfy the requirement under subpara-
12 graph (A). This paragraph shall not apply to any
13 amount paid or incurred as reimbursement to the
14 government or entity for the costs of any investiga-
15 tion or litigation.

16 “(3) EXCEPTION FOR AMOUNTS PAID OR IN-
17 CURRED AS THE RESULT OF CERTAIN COURT OR-
18 DERS.—Paragraph (1) shall not apply to any
19 amount paid or incurred by order of a court in a
20 suit in which no government or entity described in
21 paragraph (4) is a party.

22 “(4) CERTAIN NONGOVERNMENTAL REGU-
23 LATORY ENTITIES.—An entity is described in this
24 paragraph if it is—

1 “(A) a nongovernmental entity which exer-
 2 cises self-regulatory powers (including imposing
 3 sanctions) in connection with a qualified board
 4 or exchange (as defined in section 1256(g)(7)),
 5 or

6 “(B) to the extent provided in regulations,
 7 a nongovernmental entity which exercises self-
 8 regulatory powers (including imposing sanc-
 9 tions) as part of performing an essential gov-
 10 ernmental function.

11 “(5) EXCEPTION FOR TAXES DUE.—Paragraph
 12 (1) shall not apply to any amount paid or incurred
 13 as taxes due.”.

14 (b) REPORTING OF DEDUCTIBLE AMOUNTS.—

15 (1) IN GENERAL.—Subpart B of part III of
 16 subchapter A of chapter 61, as amended by this Act,
 17 is amended by adding at the end the following new
 18 section:

19 **“SEC. 6050V. INFORMATION WITH RESPECT TO CERTAIN**
 20 **FINES, PENALTIES, AND OTHER AMOUNTS.**

21 “(a) REQUIREMENT OF REPORTING.—

22 “(1) IN GENERAL.—The appropriate official of
 23 any government or entity which is described in sec-
 24 tion 162(f)(4) which is involved in a suit or agree-
 25 ment described in paragraph (2) shall make a return

1 in such form as determined by the Secretary setting
2 forth—

3 “(A) the amount required to be paid as a
4 result of the suit or agreement to which para-
5 graph (1) of section 162(f) applies,

6 “(B) any amount required to be paid as a
7 result of the suit or agreement which con-
8 stitutes restitution or remediation of property,
9 and

10 “(C) any amount required to be paid as a
11 result of the suit or agreement for the purpose
12 of coming into compliance with any law which
13 was violated or involved in the investigation or
14 inquiry.

15 “(2) SUIT OR AGREEMENT DESCRIBED.—

16 “(A) IN GENERAL.—A suit or agreement is
17 described in this paragraph if—

18 “(i) it is—

19 “(I) a suit with respect to a vio-
20 lation of any law over which the gov-
21 ernment or entity has authority and
22 with respect to which there has been
23 a court order, or

24 “(II) an agreement which is en-
25 tered into with respect to a violation

1 of any law over which the government
 2 or entity has authority, or with re-
 3 spect to an investigation or inquiry by
 4 the government or entity into the po-
 5 tential violation of any law over which
 6 such government or entity has author-
 7 ity, and

8 “(ii) the aggregate amount involved in
 9 all court orders and agreements with re-
 10 spect to the violation, investigation, or in-
 11 quiry is \$600 or more.

12 “(B) ADJUSTMENT OF REPORTING
 13 THRESHOLD.—The Secretary may adjust the
 14 \$600 amount in subparagraph (A)(ii) as nec-
 15 essary in order to ensure the efficient adminis-
 16 tration of the internal revenue laws.

17 “(3) TIME OF FILING.—The return required
 18 under this subsection shall be filed not later than—

19 “(A) 30 days after the date on which a
 20 court order is issued with respect to the suit or
 21 the date the agreement is entered into, as the
 22 case may be, or

23 “(B) the date specified Secretary.

24 “(b) STATEMENTS TO BE FURNISHED TO INDIVID-
 25 UALS INVOLVED IN THE SETTLEMENT.—Every person re-

1 quired to make a return under subsection (a) shall furnish
 2 to each person who is a party to the suit or agreement
 3 a written statement showing—

4 “(1) the name of the government or entity, and
 5 “(2) the information supplied to the Secretary
 6 under subsection (a)(1).

7 The written statement required under the preceding sen-
 8 tence shall be furnished to the person at the same time
 9 the government or entity provides the Secretary with the
 10 information required under subsection (a).

11 “(c) APPROPRIATE OFFICIAL DEFINED.—For pur-
 12 poses of this section, the term ‘appropriate official’ means
 13 the officer or employee having control of the suit, inves-
 14 tigation, or inquiry or the person appropriately designated
 15 for purposes of this section.”.

16 (2) CONFORMING AMENDMENT.—The table of
 17 sections for subpart B of part III of subchapter A
 18 of chapter 61, as amended by this Act, is amended
 19 by adding at the end the following new item:

“Sec. 6050V. Information with respect to certain fines, penalties, and other
 amounts.”.

20 (c) EFFECTIVE DATE.—The amendments made by
 21 this section shall apply to amounts paid or incurred on
 22 or after the date of the enactment of this Act, except that
 23 such amendments shall not apply to amounts paid or in-
 24 curred under any binding order or agreement entered into

1 before such date. Such exception shall not apply to an
 2 order or agreement requiring court approval unless the ap-
 3 proval was obtained before such date.

4 **SEC. 232. DENIAL OF DEDUCTION FOR PUNITIVE DAMAGES.**

5 (a) DISALLOWANCE OF DEDUCTION.—

6 (1) IN GENERAL.—Section 162(g) (relating to
 7 treble damage payments under the antitrust laws) is
 8 amended—

9 (A) by redesignating paragraphs (1) and
 10 (2) as subparagraphs (A) and (B), respectively,

11 (B) by striking “If” and inserting:

12 “(1) TREBLE DAMAGES.—If”, and

13 (C) by adding at the end the following new
 14 paragraph:

15 “(2) PUNITIVE DAMAGES.—No deduction shall
 16 be allowed under this chapter for any amount paid
 17 or incurred for punitive damages in connection with
 18 any judgment in, or settlement of, any action. This
 19 paragraph shall not apply to punitive damages de-
 20 scribed in section 104(c).”.

21 (2) CONFORMING AMENDMENT.—The heading
 22 for section 162(g) is amended by inserting “Or Pu-
 23 nitive Damages” after “Laws”.

24 (b) INCLUSION IN INCOME OF PUNITIVE DAMAGES
 25 PAID BY INSURER OR OTHERWISE.—

1 (1) IN GENERAL.—Part II of subchapter B of
2 chapter 1 (relating to items specifically included in
3 gross income) is amended by adding at the end the
4 following new section:

5 **“SEC. 91. PUNITIVE DAMAGES COMPENSATED BY INSUR-**
6 **ANCE OR OTHERWISE.**

7 “Gross income shall include any amount paid to or
8 on behalf of a taxpayer as insurance or otherwise by rea-
9 son of the taxpayer’s liability (or agreement) to pay puni-
10 tive damages.”.

11 (2) REPORTING REQUIREMENTS.—Section 6041
12 (relating to information at source) is amended by
13 adding at the end the following new subsection:

14 “(f) SECTION TO APPLY TO PUNITIVE DAMAGES
15 COMPENSATION.—This section shall apply to payments by
16 a person to or on behalf of another person as insurance
17 or otherwise by reason of the other person’s liability (or
18 agreement) to pay punitive damages.”.

19 (3) CONFORMING AMENDMENT.—The table of
20 sections for part II of subchapter B of chapter 1 is
21 amended by adding at the end the following new
22 item:

“Sec. 91. Punitive damages compensated by insurance or otherwise.”.

23 (c) EFFECTIVE DATE.—The amendments made by
24 this section shall apply to damages paid or incurred on
25 or after the date of the enactment of this Act.

1 **Subtitle E—Duty Surcharge**

2 **SEC. 241. TEMPORARY EMERGENCY DUTY SURCHARGE.**

3 (a) IN GENERAL.—Notwithstanding any other provi-
 4 sion of law, in addition to any other duty, there is hereby
 5 imposed a duty on the entry of any good during the 2-
 6 year period beginning on the day that is 15 days after
 7 the date of the enactment of this Act.

8 (b) RATE OF DUTY.—The rate of duty imposed by
 9 subsection (a) is 2 percent ad valorem.

10 (c) ENTRY.—For purposes of this section, the term
 11 “entry” means entry, or withdrawal from warehouse, for
 12 consumption in the customs territory of the United States.

13 **Subtitle F—Other Provisions**

14 **SEC. 251. OFFSHORE OIL AND GAS LEASING IN 181 AREA OF** 15 **GULF OF MEXICO.**

16 (a) DEFINITIONS.—In this section:

17 (1) 181 AREA.—The term “181 Area” means
 18 the area identified in map 15, page 58, of the Pro-
 19 posed Final Outer Continental Shelf Oil and Gas
 20 Leasing Program for 1997–2002 of the Minerals
 21 Management Service.

22 (2) SECRETARY.—The term “Secretary” means
 23 the Secretary of the Interior, acting through the
 24 Minerals Management Service.

1 (b) LEASE SALE.—Except as otherwise provided in
 2 this section, the Secretary shall offer the 181 Area for oil
 3 and gas leasing pursuant to the Outer Continental Shelf
 4 Lands Act (43 U.S.C. 1331 et seq.) as soon as practicable,
 5 but not later than 1 year, after the date of enactment of
 6 this Act.

7 (c) LEASING PROGRAM.—The 181 Area shall be of-
 8 fered for lease under this section notwithstanding the
 9 omission of the 181 Area from any outer Continental Shelf
 10 leasing program under section 18 of the Outer Continental
 11 Shelf Lands Act (43 U.S.C. 1344).

12 **SEC. 252. TRANSFER OF SURPLUS FUNDS OF FEDERAL RE-**
 13 **SERVE BANKS TO TREASURY.**

14 Section 7 of the Federal Reserve Act (12 U.S.C. 789
 15 et seq.) is amended by adding at the end the following:

16 “(d) ADDITIONAL TRANSFERS FOR FISCAL YEAR
 17 2008.—

18 “(1) IN GENERAL.—The Federal reserve banks
 19 shall transfer from the surplus funds of such banks
 20 to the Board for transfer to the Secretary of the
 21 Treasury for deposit in the General Fund of the
 22 Treasury, a total amount of \$13,000,000,000 for fis-
 23 cal year 2008.

24 “(2) ALLOCATION BY FED.—Of the total
 25 amount required to be paid by the Federal reserve

1 banks under paragraph (1) for fiscal year 2008, the
 2 Board shall determine the amount that each such
 3 bank shall pay in such fiscal year.

4 “(3) REPLENISHMENT OF SURPLUS FUND PRO-
 5 HIBITED.—No Federal reserve bank may replenish
 6 the surplus fund of such bank by the amount of any
 7 transfer by such bank under paragraph (1) during
 8 fiscal year 2008.”.

9 **SEC. 253. PERMANENT EXTENSION OF FCC AUTHORITY TO**
 10 **AUCTION LICENSES TO USE RADIO SPEC-**
 11 **TRUM.**

12 Section 309(j)(11) of the Communications Act of
 13 1934 (47 U.S.C. 309(j)(11)) is repealed.

14 **SEC. 254. TRAVEL BETWEEN THE UNITED STATES AND**
 15 **CUBA.**

16 (a) SHORT TITLE.—This section may be cited as the
 17 “Freedom to Travel to Cuba Act of 2007”.

18 (b) TRAVEL TO CUBA.—

19 (1) FREEDOM OF TRAVEL FOR UNITED STATES
 20 CITIZENS AND LEGAL RESIDENTS.—Notwithstanding
 21 any other provision of law, subject to subsection (c),
 22 the President shall not regulate or prohibit, directly
 23 or indirectly, travel to or from Cuba by a United
 24 States citizen or legal resident, or any of the trans-

1 actions incident to such travel that are set forth in
2 paragraph (2).

3 (2) TRANSACTIONS INCIDENT TO TRAVEL.—

4 The transactions referred to in paragraph (1) are—

5 (A) any transactions ordinarily incident to
6 travel to or from Cuba, including the importa-
7 tion into Cuba or the United States of accom-
8 panied baggage for personal use only;

9 (B) any transactions ordinarily incident to
10 travel to or from Cuba, or maintenance within
11 Cuba, including the payment of living expenses
12 and the acquisition of goods or services for per-
13 sonal use;

14 (C) any transactions ordinarily incident to
15 the arrangement, promotion, or facilitation of
16 travel to, from, or within Cuba;

17 (D) any transactions incident to non-
18 scheduled air, sea, or land voyages, except that
19 this paragraph does not authorize the carriage
20 of articles into Cuba or the United States other
21 than accompanied baggage; and

22 (E) normal banking transactions incident
23 to the activities described in the preceding pro-
24 visions of this subsection, including the
25 issuance, clearing, processing, or payment of

1 checks, drafts, traveler's checks, credit or debit
2 card instruments, or similar instruments.

3 (c) EXCEPTIONS.—

4 (1) SPECIAL CIRCUMSTANCES.—The restrictions
5 on authority contained in subsection (b) do not
6 apply in a case in which the United States is at war
7 with Cuba, armed hostilities between the two coun-
8 tries are in progress, or there is imminent danger to
9 the public health or the physical safety of United
10 States citizens or legal residents traveling to or from
11 Cuba.

12 (2) IMPORTATION OF GOODS FOR PERSONAL
13 CONSUMPTION.—Subsection (b) does not authorize
14 the importation into the United States of any goods
15 for personal consumption acquired in Cuba.

16 (d) APPLICABILITY.—This section applies to actions
17 taken by the President before the date of the enactment
18 of this Act that are in effect on such date of enactment,
19 and to actions taken on or after such date.

20 (e) INAPPLICABILITY OF OTHER PROVISIONS.—This
21 section applies notwithstanding section 102(h) of the
22 Cuban Liberty and Democratic Solidarity (LIBERTAD)
23 Act of 1996 (22 U.S.C. 6032(h)) and section 910(b) of

- 1 the Trade Sanctions Reform and Export Enhancement
- 2 Act of 2000 (22 U.S.C. 7209(b)).

