comply with complex and confusing deprecation rules. Accordingly, this provision encourages stable investment in new equipment that will contribute to continued productivity and growth in the business community.

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

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

S. 2322

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

SECTION 1. SHORT TITLE; AMENDMENT OF 1986 CODE; TABLE OF CONTENTS. This Act may be cited as the “Small Business Expiring Permanency Act”.

SEC. 2. PERMANENT INCREASE IN LIMITATIONS ON EXPENSING OF CERTAIN DEPRECIABLE BUSINESS ASSETS.

(a) In General.—Subsection (b) of section 179 of the Internal Revenue Code of 1986 (relating to expensing) is amended—

(1) by striking “$25,000” and all that follows in paragraph (1) and inserting “$250,000”;

(2) by striking “$200,000” and all that follows in paragraph (2) and inserting “$800,000”;

(3) by striking “after 2007 and before 2011, the $250,000 and $500,000” in paragraph (5)(A) and inserting “after 2009, the $250,000 and the $800,000”;

(4) by striking “2006” in paragraph (5)(A)(ii) and by striking paragraph (7).

(b) Permanent Expensing of Computer Software.—Section 179(d)(1)(A)(ii) of the Internal Revenue Code of 1986 (defining section 179 property) is amended by striking “and before 2011”.

(c) Effective Date.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 365—RECOGNIZING THE 50TH ANNIVERSARY OF THE SIGNING OF THE ANTARCTIC TREATY

Mr. DURBIN submitted the following resolution; which was considered and agreed to:

S. Res. 365

Whereas the Antarctic Treaty was signed by 12 nations in Washington, DC, on December 1, 1959, “with the interests of science and the progress of all mankind”;

Whereas the Antarctic Treaty was established to develop international “cooperation on the basis of freedom of scientific investigation in Antarctica as applied during the International Geophysical Year”;

Whereas the Antarctic Treaty came into force on June 23, 1961, after its unanimous ratification by the seven countries (Argentina, Australia, Chile, France, New Zealand, Norway, and the United Kingdom) with territorial claims in the region and five other countries (Belgium, Japan, South Africa, the Soviet Union, and the United States), which had conducted Antarctic research activities during the International Geophysical Year from July 1, 1957, through December 31, 1958;

Whereas the Antarctic Treaty now has 47 nations as signatories that together represent nearly 90 percent of humanity;

Whereas Article IV of the Antarctic Treaty states that “no acts or activities taking place while the present Treaty is in force shall constitute a basis for asserting, supporting or denying a claim to territorial sovereignty in Antarctica”;

Whereas the 14 articles of the Antarctic Treaty have provided a lasting foundation for maintaining the region south of 60 degrees south latitude, nearly 10 percent of the Earth’s surface, “for peaceful purposes only”;

Whereas the Antarctic Treaty prohibits “any measure of a military nature”;

Whereas the Antarctic Treaty has promoted international nuclear cooperation by prohibiting any nuclear explosions in Antarctica and the disposal there of radioactive waste material”;

Whereas the Antarctic Treaty provides a framework for the signatories to continue to meet “for the purpose of exchanging information, consulting together on matters of common interest pertaining to Antarctica, and formulating and considering, and recommending to their Governments, measures in furtherance of the principles and objectives of the Treaty”;

Whereas common interests among the Antarctic Treaty nations facilitated the development and ratification of the Convention on the Conservation of Antarctic Marine Living Resources;

Whereas the international cooperation represented by the Antarctic Treaty offers humankind a precedent for the peaceful governance of international spaces;

Whereas in celebration of the 50th anniversary of the International Geophysical Year, the Antarctic Treaty Parties in their Edinburgh Declaration on the occasion of the International Polar Year for its contributions to science worldwide and to international cooperation; and

Whereas the International Polar Year program has endorsed the Antarctic Treaty Summit that will convene in Washington, DC, at the Smithsonian Institution on the 50th anniversary of the Antarctic Treaty; Now, therefore, be it

Resolved, That the Senate—

(1) recognizes that the Antarctic Treaty has greatly contributed to science and science cooperation worldwide and successfully ensured the “use of Antarctica for peaceful purposes only and the continuance of international harmony” on the past half century; and

(2) encourages international and interdisciplinary cooperation of the Antarctic Treaty Summit to identify lessons from 50 years of international cooperation under the Antarctic Treaty that have legacy value for humankind.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2792. Mr. KAUFMAN (for himself, Mr. LEAHY, Mr. SPECTER, Mr. KOHL, Mr. SCHUMER, and Ms. KLOBUCHAR) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 2794. Mr. LEAHY submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 2795. Mr. LEAHY (for himself, Mr. REID, Mr. KERRY, Mr. ROCKEFELLER, Mr. LIEBERMAN, Ms. FEINSTEIN, Mr. FRINGOLD, Mr. WYDEN, Mr. SCHUMER, Mr. LAUTENBERG, Ms. MCCASKILL, Mr. WHITEHOUSE, Mr. BURRIS, Mr. KAUFMAN, Mr. BENNET, and Mr. FRANKE) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 2796. Mr. DURBIN (for Mr. WYDEN) proposed an amendment to the resolution S. Res. 71, condemning the Government of Iran for its state-sponsored persecution of the Baha’i minority in Iran and its continued violation of the International Covenants on Human Rights.

SA 2797. Mr. DURBIN (for Mr. WYDEN) proposed an amendment to the resolution S. Res. 71, supra.

TEXT OF AMENDMENTS

SA 2792. Mr. KAUFMAN (for himself, Mr. LEAHY, Mr. SPECTER, Mr. KOHL, Mr. SCHUMER, and Ms. KLOBUCHAR) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

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SA 2794. Mr. LEAHY submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table. December 1, 2009
(bb) a 3-level increase in the offense level for any defendant convicted of a Federal health care offense relating to a Government health care program which involves a loss of not less than $7,000,000 and less than $20,000,000; and
(cc) a 4-level increase in the offense level for any defendant convicted of a Federal health care offense relating to a Government health care program which involves a loss of not less than $20,000,000; and
(dd) if appropriate, otherwise amend the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal health care offenses involving Government health care programs.

(iii) In carrying out this subparagraph, the United States Sentencing Commission shall—
(I) ensure that the Federal Sentencing Guidelines and policy statements—
(aa) reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud; and
(bb) provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances;
(II) take into account the unique characteristics of individuals or groups representing health care fraud victims, law enforcement officials, the health care industry, and the Federal judiciary as part of the review described in clause (I);
(III) ensure reasonable consistency with other relevant directives and with other guidelines under the Federal Sentencing Guidelines;
(IV) account for any aggravating or mitigating circumstances that might justify exceptions, including circumstances for which the Federal Sentencing Guidelines, as in effect on the date of enactment of this Act, provide sentencing enhancements;
(V) make any necessary conforming changes to the Federal Sentencing Guidelines; and
(VI) ensure that the Federal Sentencing Guidelines adequately meet the purposes of sentencing.

(B) INTENT REQUIREMENT FOR HEALTH CARE FRAUD.—Section 1347 of title 18, United States Code, is amended—
(I) by inserting “(a)” before “Whoever knowingly”; and
(ii) by adding at the end the following:
“(b) With respect to violations of this section, it shall be a defense that the defendant had no actual knowledge of this section or specific intent to commit a violation of this section.”.

(C) HEALTH CARE FRAUD OFFENSE.—Section 2(a) of title 18, United States Code, is amended—
(I) in paragraph (1), by striking the semicolon and inserting “or section 1126B of the Social Security Act (42 U.S.C. 1320d-7b); or”;
and
(ii) in paragraph (2)—
(I) by inserting “1349,” after “1343,”; and

(D) SUBPOENA AUTHORITY RELATING TO HEALTH CARE.—
(I) SUBPOENAS UNDER THE CIVIL RIGHTS OF INSTITUTIONALIZED PERSONS ACT.—The Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997 et seq.) is amended by inserting after section 1510 the following:
“SEC. 3A. SUBPOENA AUTHORITY.
“(a) AUTHORITY.—The Attorney General, or at the direction of the Attorney General, any officer or employee of the Department of Justice may require by subpoena access to any institution that is the subject of an investigation under this Act and to any document, record, material, file, report, memorandum, polyclinic information, video or audio recording, or quality assurance report relating to any institution that is the subject of an investigation under this Act to determine whether there are conditions which deprive persons residing in or confined to the institution of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States.
“(b) ISSUANCE AND ENFORCEMENT OF SUBPOENAS.—
“(1) ISSUANCE.—Subpoenas issued under this section—
“(A) shall bear the signature of the Attorney General or designated officer or employee of the Department of Justice as designated by the Attorney General; and
“(B) shall be served by any person or class of persons designated by the Attorney General or a designated officer or employee for that purpose.
“(2) ENFORCEMENT.—In the case of contumacy or failure to obey a subpoena issued under this section—
“(A) the court for the judicial district in which the violation occurred or in which the person resides or is employed may fine not more than $10,000 or imprison not more than one year or both; and
“(B) the court for the judicial district in which the grand jury is sitting or in which the grand jury was convened or in which the grand jury subpoena was issued under this section may fine not more than $10,000 or imprison not more than one year or both.
“(3) RULE OF CONSTRUCTION.—This section shall be applied in a manner so as to prevent the disclosure of any personally identifiable information.

SA 2793. Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Ms. KLOBUCHAR, Mr. BROWN, Mrs. SHAHEEN, Mr. VITTER, Mr. KOHL, Mr. LEAHY, Mr. FEINGOLD, and Mr. NELSON of Florida) submitted an amendment to the amendment previously proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the military and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE X—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 10001. SHORT TITLE.
This title may be cited as the “Pharmaceutical Market Access and Drug Safety Act of 2009”.

SEC. 10002. FINDINGS.
Congress finds that—
(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;
(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;
(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;
(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;
(5) American spend more than $200,000,000,000 on prescription drugs every year;
(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and
(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. 10003. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

SEC. 10004. IMPORTATION OF PRESCRIPTION DRUGS: WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is further amended by inserting after section 803 the following:
“SEC. 804. COMMERCIAL AND PERSONAL IMPOR TATION OF PRESCRIPTION DRUGS.
“(a) IMPORTATION OF PRESCRIPTION DRUGS.—
“(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—
“(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or
“(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.
“(2) RULE OF CONSTRUCTION.—This section shall apply only to drugs that is imported or offered for import into the United States—
“(A) by a registered importer; or
“(B) from a registered exporter to an individual.
“(3) DEFINITIONS.—
“(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section—
“(i) the term ‘registered exporter’ means an exporter for which a registration under

December 1, 2009
subsection (b) has been approved and is in effect.

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

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

(B) QUALIFYING DRUG.—For purposes of this section, the term ‘qualifying drug’ means a drug for which there is a corresponding U.S. label drug.

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

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

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

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

(iv) is not—

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

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

(aa) a therapeutic DNA plasmid product;

(bb) a therapeutic synthetic peptide product;

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

(dd) a therapeutic recombinant DNA-derived product;

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

(iv) an injected drug;

(V) a drug that is inhaled during surgery;

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

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

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

(I) The term ‘exporter’ means a person that is in the business of exporting a drug to individuals in a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

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

(A) the training of pharmacists;

(BB) the practice of pharmacy; and

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

(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

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

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

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

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

(ii) employs 1 or more pharmacists.

(IV) An ‘FDA-labeled drug’ means a drug that is described in section 503(b)(1).

(V) The term ‘wholesaler’—

(I) means a person licensed as a wholesaler or a distributor of prescription drugs in the United States under section 801(a)(1); and

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

( VI) PERMITTED COUNTRY.—The term ‘permitted country’ means—

(I) Australia;

(ii) Canada;

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

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

(B) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

(iv) Japan;

(iv) New Zealand;

(v) Switzerland; and

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

(I) The country has statutory or regulatory requirements—

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

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

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

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

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

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

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

(IV) The registration of importers and exporters, including those of other than prescription drugs, to the Secretary a registration containing the following:

(A) The name of the exporter, the name and address of the importer and an identification of all places of business of the exporter that relate to quality activities, including any warehouse, retail store, house or other facility owned or controlled by, or operated for, the exporter.

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

(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

(i) in the case of an importer, subsections (c)(4), (e)(4), and (g)(4) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; and compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

(ii) in the case of an exporter, subsections (c)(4), (e)(4), (f)(4), (g)(4), (h)(4), (i)(4), and (j)(4) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

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

(IV) An agreement by the registrant to—

(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed from a permitted country; (2) an agreement by the registrant to provide the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

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

(F) A plan describing the manner in which the registrant will comply with the agreements under subsections (a)(2)(A) through (J) (relating to the approval of only qualifying drugs; the protection of the privacy of personal medical information; and the payment of fees; and compliance with the standards referred to in sections 801(a); and maintenance of records and samples).

(G) An agreement by the registrant to enforce a contract under subsection (a)(3)(B) regarding the use of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

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

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

(ii) any change that the registrant intends to make regarding information provided under subparagraph (F).

(III) In the case of an exporter:

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

(J) An agreement by the exporter to post a bond, payable to the Treasury of the United States that is in a permitted country equivalent to the Secretary, in the amount of—

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

(ii) $1,000,000.

(K) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country.
proven if the Secretary determines that the registration is not in compliance with one or more registration conditions. Markings under the preceding sentence shall—

(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration. The Secretary may make such determination if the registrant has not complied with a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration condition is that, for the purpose of as-

(C) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

(1) INSPECTION OF FACILITIES.—A registration condition is that the exporter or importer agrees to permit the Secretary to conduct an inspection described under subsection (d) of this section at any establishment that is a part of the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter or importer of qualifying drugs under subsection (a) or (ii), if the Secretary determines that the registration has demonstrated that further violations of registration conditions will not occur.

(3) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer obtained the drug that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i), or

(4) DEFAULT OF BOND.—A bond required to be posted pursuant to paragraph (1)(A)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportu-

nity for an informal hearing, the Sec-

retary determines that the exporter has—

(A) failed to permit the Secretary to conduct an inspection described under subsection (d); or

(B) failed to pay a registration fee not later than 10 days after the date on which the registration is suspended.

(5) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under the preceding sentence is not sub-

ject to the provision of the Secretary of prior notice, and the Secretary shall provide a notice to the registrant not later than 10 days after the date on which the registration is suspended.

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

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

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

(K) Such other provisions as the Sec-

retary determines to be necessary to identify the drug will under subsection (a) be exported or imported by the registrant, or a person that is a part-

ner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(1) INSPECTION OF FACILITIES.—A registrant shall—

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

(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a reg-

nistrant, the Secretary shall determine whether the registrant is in compliance with subsection (g)(2)(A), (g)(4), or (i), or

(ii) importation by individuals of qualifying drugs under subsection (a); and

(2) APPROVAL OR DISAPPROVAL OF REG-

ISTRATION.—

(A) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

(1) INSPECTION OF FACILITIES.—A registration condition is that the exporter or importer involved is in compliance with all other registration conditions—

(A) the exporter agrees to permit the Sec-

retary—

(i) to conduct onsite inspections, includ-

ing monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, or a warehouse or other facility owned or controlled by, or operated for, the exporter; and

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

day basis, to—

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

(ii) samples of such drugs;

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

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

(B) the Secretary has assigned 1 or more employees of the Secretary to carry out any other functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping con-

tainer of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

(A) directly from the establishment; or

(B) directly from an entity that, by con-

tract with the exporter or importer—

(1) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establish-

ment, sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

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

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

(iv) has ensured, through such contrac-

tual relationships as may be necessary, that the Secretary has the same authority regard-

ing other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

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

(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is loc-

ated.

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

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

(7) INSPECTION OF FACILITIES.—

(1) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

(A) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of as-

suring the operation of the Secretary to carry out any other functions de-

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

(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping con-

tainer of qualifying drugs exported under subsection (a) such markings as the Sec-

retary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—
“(B) include anticonteuring or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

(ii) PARTICULARS RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following: 

(A) Inspecting, randomly, but not less than twice annually, the place of business of the exporter at which qualifying drugs are shipped or labeled to be shipped;

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

(C) Randomly reviewing records of exporters for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

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

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

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

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

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

(B) the drug, except for drugs that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (g)(2), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable information from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

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

(2) be included in or on the drug, including the identity of the establishment in which the drug was manufactured to the importer, in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticonteuring or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that the importer involved pays a fee to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

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

(4) Estimating the total price of drugs imported during that fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

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

(4) USE OF FEES.—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, 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).

(5) Available for.—Fees collected by the Secretary under paragraphs (2) and (3) shall be available to 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).

(8) Availability.—Fees collected by the Secretary under paragraphs (1) and (2) shall be 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).

(9) COLLECTION OF FEES.—In any case where a registrant fails to submit 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 under chapter II of section 3751 of title 31, United States Code.

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

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

"(3) Registration fee.—

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

"(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

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

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

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

"(C) Total price of drugs.—

"(i) Estimate.—For the purposes of complying with the limitation described in subparagraph (b) when establishing under sub-paragraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the aggregate total price of qualifying drugs imported into the United States by registered exporters that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

"(ii) Calculation.—Not later than March 1 of the fiscal year following the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters that fiscal year as calculated under subparagraph (i) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary may require a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (b) is met.

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

"(4) Use of fees.—

"(A) In general.—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, and may be transferred without fiscal year limitation, and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer 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) Availability.—Fees collected by the Secretary under paragraphs (1) and (2) shall be available to the Food and Drug Administration.

"(C) 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).

"(D) 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.

"(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.

"(A) In general.—A registration condition is that each qualifying drug exported under subsection (a) by the registered importer involved is in compliance with all registration conditions.

"(B) Notice by manufacturer; general provisions.—

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

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

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

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

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

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

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

"(ii) Information in notice.—A notice under clause (i)(I) shall include the information described in subparagraph (C) of subsection 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not available), and such other information as the Secretary may require with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to which such approval is sought, include the following:

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

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

"(III) The information that the person submitting the notice has also notified the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

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

"(1) the information provided in the notice is complete and true; and

"(2) a copy of the notice has been provided to the Federal Trade Commission and to the States attorney general.

"(iv) Fee.—

"(A) In general.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made and change to the status of the U.S. label drug, the Secretary that admits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 780a(a)(1)(A)(ii). Fees collected by the Secretary under the preceding sentence are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

"(B) Fee amount for certain years.—If no fee amount is in effect under section 780a(a)(1)(A)(ii) for the fiscal year, the amount paid by a person under subclause (i) shall—

"(aa) for the first fiscal year in which no fee amount is in effect under subsection (a), be equal to the fee amount under section 780a(a)(1)(A)(ii) for the most recent fiscal year for which such section was in effect, adjusted in accordance with section 780c; and

"(bb) for each subsequent fiscal year in which no fee amount under such section is in effect, be equal to the applicable fee amount for the previous fiscal year, adjusted in accordance with section 780c.

"(C) Timing of submission of notices.—

"(1) Prior approval notices.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the date on which the notice is submitted to the Secretary.

"(2) Other notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary when the difference in the qualifying drug with the difference begins less than 120 days after the date on which the notice is submitted to the Secretary.

"(D) Other notices.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the
date that the qualifying drug is first intro-
duced for commercial distribution in a per-
mitted country and annually thereafter.

(vi) REVIEW BY SECRETARY.—The Sec-
retary shall review and approve or disapprove the dif-
ference in a notice submitted under clause (i) if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

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

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

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

(bb) decline to approve the difference if the Secretary determines that the avail-
ability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

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

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

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

(bb) the Secretary may rely on a satisfac-
tory report of a good manufacturing practice inspection of the establishment from a per-
mitted country whose regulatory system the Secretary determines is equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 21 of Title 21, Code of Federal Regulations (or any corresponding successor rule or regula-
tion).

(vii) PUBLICATION OF INFORMATION ON NOT-
ICES.—

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

(ii) CONTENTS.—The list under subclause (I) shall include—

(bb) the Secretary has ordered that im-
portation of the qualifying drug from a per-
mitted country cease; or

(cc) the importation of the drug is per-
mitted under subclause (a).

(iii) The Secretary shall promptly update the Internet website with any changes to the list.

(C) NOTICE; DRUG DIFFERENCE REQUI-
RING PRIOR APPROVAL.—In the case of a notice submitted under subparagraph (B)(i) that includes a dif-
fERENCE that would, under subclause (c) or (d)(3)(B)(i) of section 506A, require the appro-
priate notice for the U.S. label drug to be submitted to the government of the permitted country, the difference could be made to the U.S. label drug the following shall occur:

(i) Promptly after the notice is sub-
mitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

(ii) The Secretary shall order that the importation of the qualifying drug involved from the permitted country cease; or

(iii) The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission and the State attorneys general of the notice; and

(iv) The Secretary completes review of the notice; and

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

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

(i) during the period in which the notice is being reviewed by the Secretary, the auth-
orized notice for the U.S. label drug to be submitted to the government of the permitted country;

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

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

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

(F) DIFFERENCES IN ACTIVE INGREDIENTS.

(i) In general.—A person who manufac-
tures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country for the same active ingredient, dosage form, and strength as the drug approved under section 505(b); and

(ii) each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b), as defined in clause (v).

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

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

(ii) include the information that the per-
son submitted to the government of the per-
mitted country for purposes of obtaining ap-
proval for commercial distribution of the other drug in that country in a language other than English, shall be accom-
panied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifi-
cations of the person that made the trans-
lation.

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

(v) TIMING OF SUBMISSION OF APPLICA-
tions.—An application under section 505(b) re-
quired under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii) is submitted to the government of the permitted country.

(vi) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify reg-
istered exporters, registered importers, the Federal Trade Commission, and the State at-
orneys general of a determination to ap-
prove or to disapprove an application under section 505(b) required under clause (i).

(vii) RELATED ACTIVITIES.—For pur-
poses of clause (i), 2 active ingredients are relat-
ed if they are—

(1) the same; or

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

(C) SECTION 502; LABELING.—

(A) IMPORTATION BY REGISTERED IM-
PORTER.—

(1) In general.—In the case of a qual-
ifying drug that is imported or offered for im-
port by a registered importer, such drug shall be considered to be in compliance with this provision if the importer complies with any requirements under the approved application for the U.S. label drug if the qualifying drug bears—
“(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

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

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

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

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

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

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

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

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

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

“( iv) if the inactive ingredients of the qualifying drug differ from the inactive ingredients for the U.S. label drug, include—

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

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

“(B) IMPORTATION BY INDIVIDUAL.—

“(I) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), and the labeling of the qualifying drug includes—

“(aa) directions for use by the consumer;

“(bb) the lot number assigned by the manufacturer;

“(cc) the name and registration number of the exporting manufacturer;

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

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

“(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

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

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

“(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and Na-
`(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or 

`(B) at the place of business of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

`(2) In this section—

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

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

`(ii) how the drug may be identified, including—

`(I) the reason for the recall or withdrawal.

`(B) SECRETARY.—With respect to each permitted country, the Secretary shall—

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

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

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

`(D) Drug Labeling and Packaging.—

`(I) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), and shall include with any other labeling provided to the individual the following:

`(a) The lot number assigned by the manufacturer;

`(b) The name and registration number of the importer.

`(C) If required under paragraph (2) of section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

`(D) If the inactive ingredients of the drug are different, a prominent advisory to this effect for the U.S. label drug—

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

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

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

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

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

`(3) MANUFACTURER CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, the United Nations, or affiliates, or to a government of a foreign country.

`(4) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

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

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

`(b) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section, or that does not distribute, sell, or use such a drug;

`(c) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section;

`(d) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section; or

`(e) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under paragraphs (3), (4), and (5) of section 10004(e) of the Pharmaceutical Market Access and Drug Safety Act of 2009, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent representation, or knowingly submit such a notice on or before the date specified in subsection (g)(2)(B)(v), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F) or knowingly fail to submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

`(f) knowingly fail to submit an application required under subsection (g)(2)(F), and knowing fail to submit such an application on or before the date specified in subsection (g)(2)(F), and knowingly fail to provide promptly any information requested by the Secretary to review such an application;

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

`(h) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

`(i) fail to provide an observation period related to a prescription drug under this section;

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

`(k) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section.

`(4) EFFECT OF SUBSECTION.—

`(a) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in that 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 AND OTHER AGREEMENTS.—Nothing in this subsection shall be construed to—

`(i) require or prevent the manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity.

`(5) DISCRIMINATION.—It shall be an unfair and discriminatory act and practice for a manufacturer, or a person engaging in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

`(6) REFERRAL OF POTENTIAL VIOLATIONS.—

`(A) The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

`(B) DISCRIMINATION.—It shall be an unfair and discriminatory act and practice for a manufacturer to charge a person, including a manufacturer, a materially different price for a prescription drug sold to a person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other price reductions permitted by country or other person, to another person that is in the same country and that does not export a qualifying drug to the United States under this section.

`(7) AFFIRMATIVE DEFENSE.—

`(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has engaged in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section, and that—

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

`(ii) the person, being a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug; or

`(III) of paragraph (1) that becomes known to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

`(B) Sales in Other Countries.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in that country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

`(C) Discounts and Other Agreements.—Nothing in this subsection shall be construed to—

`(I) require or prevent the manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity.

`(D) Unfair and Discriminatory Acts and Practices.—

`(E) Sale or Distribution in Other Countries.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in that country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.
the damages sustained, in addition to any
compensation on behalf of residents of the
States of appropriate jurisdiction to—

(A) an individual action brought under
paragraph (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;

(B) SERVICE OF PROCESS.—In an
action brought under subparagraph (A), process
may be served in any district in which the
defendant—

(1) is an inhabitant; or

(2) may be found.

(C) MEASUREMENT OF DAMAGES.—In any
action under this paragraph to enforce a
cause of action under this subsection in which
there has been a determination that a
defendant has violated a provision of this
subsection, damages may be proved and as-
essed in the aggregate by statistical or sam-
ping methods, by the computation of illegal
 profits, or by 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,
without the consent of the Attorney General,
bring a civil action on behalf of the residents
of that State have been adversely affected by
a violation of this subsection.

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

(F) SERVICE OF PROCESS.—In an
action brought under subparagraph (A), process
may be served in any district in which the
defendant—

(1) is an inhabitant; or

(2) may be found.

(G) MEASUREMENT OF DAMAGES.—In any
action under this paragraph to enforce a
cause of action under this subsection in which
there has been a determination that a
defendant has violated a provision of this
subsection, damages may be proved and as-
essed in the aggregate by statistical or sam-
ping methods, by the computation of illegal
 profits, or by the production of documentary
and other evidence.

(H) EXCLUSION ON DILUTIVE RELIEF.—
The district court shall exclude from the
amount of monetary relief awarded in an ac-
tion under this paragraph brought by the at-
torney general of a State any amount of
monetary relief which duplicates amounts
which have been awarded for the same in-
jury.

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

(B) MANUFACTURER.—In this subsection,
the term ‘manufacturer’ means any entity,
including any affiliate or licensee of that en-
tity, that is engaged in—

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

(B) the packaging, repackaging, labeling,
relabeling, or distribution of a prescription
drug;—

(B) The sale or trade by an individual of a
prescription drug to a customer of the phar-
macist or organization; or

(2) The sale or trade by a pharmacist
or the sale or trade of a drug to a phar-
macist or organization; or

(3) The making of a materially false, fic-
titious, or fraudulent statement or repre-
sentation, or a materially omission, in a notice
under clause (i) of section 804(g)(2)(B) or
an application required under section
804(g)(2)(F), or the failure to submit such a
notice or application.

(4) The importation of a drug in violation
of a registration condition or other require-
ment under section 804, the falsification of
any record required to be maintained, or pro-
vided to the Secretary, under such section,
or the violation of any registration condition
or other requirement under such section;—
and

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

Notwithstanding subsection (a), any
person that knowingly violates section 301(1)
(2) or (3) or section 303(aa)(4) shall be impris-
oned not more than 10 years, or fined in ac-
cordance with title 18, United States Code,
or both.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—The Federal Food, Drug,
and Cosmetic Act (21 U.S.C. 331) is amended
by striking paragraph (6) and inserting the fol-
lowing:

With respect to a prescription drug
that is imported or offered for import into
the United States by a person who

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

(3) the individual may under section 804
lawfully import certain prescription drugs
from foreign countries under the Secretary
under section 804; and

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

(2) ESTABLISHMENT REGISTRATION.—Section
510(i) of the Federal Food, Drug, and Cos-
metic Act (21 U.S.C. 351(i)) is amended by
inserting a certification of the Food and
Drug Administration or through a toll-free telephone number re-
quired under section 804.

(3) EXHAUSTION.—The amendments
made by this subsection shall take effect on
the date that is 90 days after the date of en-
actment of this Act.

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

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

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

(2) The sale or trade by a pharmacist
or organization; or

(3) The making of a materially false, fic-
titious, or fraudulent statement or repre-
sentation, or a materially omission, in a notice
under clause (i) of section 804(g)(2)(B) or
an application required under section
804(g)(2)(F), or the failure to submit such a
notice or application.

(4) The importation of a drug in violation
of a registration condition or other require-
ment under section 804, the falsification of
any record required to be maintained, or pro-
vided to the Secretary, under such section,
or the violation of any registration condition
or other requirement under such section;—
and

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

Notwithstanding subsection (a), any
person that knowingly violates section 301(1)
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by striking paragraph (6) and inserting the fol-
lowing:

With respect to a prescription drug
that is imported or offered for import into
the United States by a person who

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

(3) the individual may under section 804
lawfully import certain prescription drugs
from foreign countries under the Secretary
under section 804; and

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

(2) ESTABLISHMENT REGISTRATION.—Section
510(i) of the Federal Food, Drug, and Cos-
metic Act (21 U.S.C. 351(i)) is amended by
inserting a certification of the Food and
Drug Administration or through a toll-free telephone number re-
quired under section 804.

(3) EXHAUSTION.—The amendments
made by this subsection shall take effect on
the date that is 90 days after the date of en-
actment of this Act.

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

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

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

(2) The sale or trade by a pharmacist
or organization; or

(3) The making of a materially false, fic-
titious, or fraudulent statement or repre-
sentation, or a materially omission, in a notice
under clause (i) of section 804(g)(2)(B) or
an application required under section
804(g)(2)(F), or the failure to submit such a
notice or application.

(4) The importation of a drug in violation
of a registration condition or other require-
ment under section 804, the falsification of
any record required to be maintained, or pro-
vided to the Secretary, under such section,
or the violation of any registration condition
or other requirement under such section;—
and

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

Notwithstanding subsection (a), any
person that knowingly violates section 301(1)
(2) or (3) or section 303(aa)(4) shall be impris-
oned not more than 10 years, or fined in ac-
cordance with title 18, United States Code,
or both.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—The Federal Food, Drug,
and Cosmetic Act (21 U.S.C. 331) is amended
by striking paragraph (6) and inserting the fol-
lowing:

With respect to a prescription drug
that is imported or offered for import into
the United States by a person who

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

(3) the individual may under section 804
lawfully import certain prescription drugs
from foreign countries under the Secretary
under section 804; and

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

(2) ESTABLISHMENT REGISTRATION.—Section
510(i) of the Federal Food, Drug, and Cos-
metic Act (21 U.S.C. 351(i)) is amended by
inserting a certification of the Food and
Drug Administration or through a toll-free telephone number re-
quired under section 804.

(3) EXHAUSTION.—The amendments
made by this subsection shall take effect on
the date that is 90 days after the date of en-
actment of this Act.

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

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

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

(e) EFFECT OF SECTION 804.—

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

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

(B) from permitted countries, as defined in such section 804, by importers registered under such section 804 on the date that is 1 year after the date of enactment of this Act;

(D) priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States;

(E) S ECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 3 or more years after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this Act shall be submitted to the Secretary not later than 90 days after the date of enactment of this Act, and that are not registered importers under subsection (a) of such section 804 into the United States by the importer during the 4-month period from October 1 through January 31 of such fiscal year.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the total price of drugs imported to the United States by the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered importer under subsection (a) of such section 804 of a notice to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 90 days after the date of enactment of this Act if—

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

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

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act if—

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

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

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

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

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A) are submitted at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered importer under subsection (a) of such section 804 of a notice to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

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

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (g)(2)(A) of such section 804, the Secretary shall, under subsection (i)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (g)(2)(B) of such section 804, the Secretary shall, under subsection (i)(3)(C)(iv) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(C) ESTIMATE.—The Secretary shall estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(D) SECOND YEAR ADJUSTMENT.—

(1) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect to be the second fiscal year in which this title is effective, the Secretary shall submit to Congress the report described in paragraph (E) of such section 804 of the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered importer under subsection (a) of such section 804 of a notice to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(2) LIMITATION.—That an exporter in Canada or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this Act shall not serve as a basis for approving a registration under such section 804 from the exporter.

(A) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the first fiscal year in which this title is in effect to be $3,000,000,000.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 2,500 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.
(1) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by
(ii) 3.

(3) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees for each fiscal year as reestimated under clause (ii).

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

(E) ANNUAL REPORT.—

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

(2) and submit to the House of Representatives and the Senate a report on the implementa-

tion of any registration of a registered importer or exporter under such section 804; and

(3) with regard to the suspension and termina-

tion of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at doc-

umentation as evidence of drugs which have been imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(b) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of drugs, shall remain in effect.

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

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by this section (a), shall be established not later than 90 days after the date of the enactment of this Act.

(c) ANNEXATION.—Title VI of the Internal Revenue Code is amended by striking subparagraph (b) and inserting in its stead—

Sec. 6006. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRICKING OF EXEMPTIONABILITY TO REGISTERED IMPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) by striking—

(A) in general—

''(a) IN GENERAL.—The Secretary shall designate such additional permitted countries under subparagraph (A)...

(2) and (ii) not later than 6 months after the date of the action by the Government of Canada described in this subparagraph; and

(3) and (ii) using the criteria described under subsection (a)(4)(d)(I)(II) of such section 804.

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

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

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at documentation as evidence of drugs which have been imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of drugs, shall remain in effect.

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

Sec. 10006. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRICKING OF EXEMPTIONABILITY TO REGISTERED IMPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) by striking—

(A) in general—

''(a) IN GENERAL.—The Secretary shall designate such additional permitted countries under subparagraph (A)...

(2) and (ii) not later than 6 months after the date of the action by the Government of Canada described in this subparagraph; and

(3) and (ii) using the criteria described under subsection (a)(4)(d)(I)(II) of such section 804.

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

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

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at documentation as evidence of drugs which have been imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of drugs, shall remain in effect.

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

Sec. 10006. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRICKING OF EXEMPTIONABILITY TO REGISTERED IMPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) by striking—

(A) in general—

''(a) IN GENERAL.—The Secretary shall designate such additional permitted countries under subparagraph (A)...

(2) and (ii) not later than 6 months after the date of the action by the Government of Canada described in this subparagraph; and

(3) and (ii) using the criteria described under subsection (a)(4)(d)(I)(II) of such section 804.

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

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

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termina-

tion of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at documentation as evidence of drugs which have been imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of drugs, shall remain in effect.

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

Sec. 10006. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.
from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible for which the manufacturer has established an ongoing relationship with the distributors of record of such drug.

(2) In paragraph (2)(A), by adding at the end the following:

"(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 504(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i)."

(3) In paragraph (3), by striking "and subsection (d)—" in the matter preceding subparagraph (A) and all that follows through "the term ‘wholesale distribution’ means” in subparagraph (B) and inserting the following: "and subsection (d), the term ‘wholesale distribution’ means”.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding after subsection (a) the following:

"(4) Each manufacturer of a drug subject to subsection (d) shall maintain at its corporate headquarters a list of the authorized distributors of record of such drug.

"(5) For purposes of this subsection, the term ‘authorized distributors of record’ means a person who has established an ongoing relationship to distribute such manufacturer’s products to purchasers.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) take effect on January 1, 2012.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (a) and the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) take effect on the date that is 90 days after the date of enactment of this Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 503B of this Act, and with respect to the following requirements, the final rule in addition shall, with respect to the registration condition established in paragraph (1), the amendments made by subsection (a) apply at the point of manufacturing; and

"(ii) incorporate additional layers of non-visible convert security features up to and including forensic capability, as described in subparagraph (B) or (II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(3) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug,

"(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

"(B) the patient from whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

"(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

"(D) for purposes of such dispensing or sale, the person has reasonable reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

"(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

(2) EXCEPTIONS.—Paragraph (1) does not apply to—

"(i) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

"(I) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program);

"(II) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title;

"(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary.

(3) QUALIFYING MEDICAL RELATIONSHIP.—

"(A) IN GENERAL.—With respect to issuing a prescription for a drug to a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if—

"(i) the practitioner conducts a medical evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner conducts any in-person medical evaluation of the patient and is temporarily unavailable to conduct the medical evaluation of the patient.

"(B) COVERING PRACTITIONER.—With respect to an in-person medical evaluation by a practitioner, there 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 or not the evaluation is conducted by other health professionals.

"(C) QUALIFYING MEDICAL RELATIONSHIP.—With respect to the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary.

(4) NOTIFICATION.—With respect to a prescription drug, the terms under this section is received.

"(I) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

"(II) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title;

"(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary.

"(C) QUALIFYING MEDICAL RELATIONSHIP.—With respect to issuing a prescription for a drug to a patient, a practitioner has a qualifying medical relationship 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; and

"(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 or not the patient has been conducted by other health professionals.

"(C) COVERING PRACTITIONER.—With respect to a prescription for a drug to a patient, there 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, and the patient, or the practitioner, or an individual represented by the practitioner, has been conducted by other health professionals.
"(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 to have a standard practice in the practice of medicine. (B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting that which is a standard practice in the practice of pharmacy.

"(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having application beyond this section and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

"(d) ACTIONS BY STATES.—

"(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(i), the State shall bring actions in such State on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enjoin such practice of medicine.

"(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall:

"(A) to intervene in such action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses to obtain evidence relevant to the production of documentary and other evidence.

"(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business whenever such a defendant is an inhabitant of the United States. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

"(5) ACTIONS BY OTHER STATE OFFICIALS.—

"(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

"(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

"(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered foreign pharmacy.

"(e) GENERAL DEFINITIONS.—For purposes of this section:

"(1) The term ‘practitioner’ means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

"(2) The term ‘prescription drug’ means a drug that is described in section 503(b)(1).

"(3) The term ‘qualifying medical relationship’, with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

"(4) ‘INTERNET-RELATED DEFINITIONS.—

"(1) IN GENERAL.—For purposes of this section:

"(A) The term ‘Internet’ means collectively the myriad of computer and telecommunication facilities, including equipment, software, services, or networks which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(B) The term ‘link’, with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing such a link, to obtain information, to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State is adjudged to have the proper, or to obtain such further and other relief as the court may deem appropriate.

"(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall:

"(A) to intervene in such action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses to obtain evidence relevant to the production of documentary and other evidence.

"(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business whenever such a defendant is an inhabitant of the United States. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

"(5) ACTIONS BY OTHER STATE OFFICIALS.—

"(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

"(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

"(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered foreign pharmacy.

"(e) GENERAL DEFINITIONS.—For purposes of this section:

"(1) The term ‘practitioner’ means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

"(2) The term ‘prescription drug’ means a drug that is described in section 503(b)(1).

"(3) The term ‘qualifying medical relationship’, with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

"(4) ‘INTERNET-RELATED DEFINITIONS.—

"(1) IN GENERAL.—For purposes of this section:

"(A) The term ‘Internet’ means collectively the myriad of computer and telecommunication facilities, including equipment, software, services, or networks which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(B) The term ‘link’, with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing such a link, to obtain information, to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State is adjudged to have the proper, or to obtain such further and other relief as the court may deem appropriate.

"(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall:

"(A) to intervene in such action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses to obtain evidence relevant to the production of documentary and other evidence.

"(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business whenever such a defendant is an inhabitant of the United States. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

"(5) ACTIONS BY OTHER STATE OFFICIALS.—

"(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

"(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

"(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered foreign pharmacy.

"(e) GENERAL DEFINITIONS.—For purposes of this section:
transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

"(B) PERSONS DESCRIBED.—A person referred to in paragraph (A) is—

"(i) a creditor;

"(ii) a credit card issuer;

"(iii) a financial institution;

"(iv) an operator of an electronic fund transfer system or a money transmitting service 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) TRANSACTION.—The term ‘restricted transaction’ means a transaction or remittance, on behalf of an individual who places an unlawful drug importation request for an individual for the purpose of the unlawful drug importation request.

"(4) UNAUTHORIZED DRUG IMPORTATION REQUEST.—The term ‘unlawful drug importation request’ means the request, or remittance, of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

"(5) UNREGISTERED FOREIGN PHARMACY.—The term ‘unregistered foreign pharmacy’ means an entity that is not a registered foreign pharmacy as defined in section 5330(a) of title 31, United States Code.

"(6) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms ‘access device’ and ‘electronic fund transfer’ have the meanings given in the operation of an unregistered foreign pharmacy, of—

"(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

"(B) an electronic fund transfer or funds transmitted through a money transmitting service, or from or on behalf of the individual for the purpose of the unlawful drug importation request;

"(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request; and

"(D) the proceeds of any other form of financial transaction (identifying the Board by regulation) that involves a financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

"(7) MONEY TRANSMITTING BUSINESS.—The term ‘money transmitting business’ includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

"(8) ACQUIRED.—The term ‘acquired’ includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

"(9) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING BUSINESS.—The terms ‘money transmitting business’ and ‘money transmitting service’ have the meanings given in the terms in section 5330(d) of title 31, United States Code.

"(10) BOARD.—The term ‘Board’ means the Board of Governors of the Federal Reserve System.

"(11) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

"(A) REGULATIONS.—The Board shall promulgate regulations to—

"(i) an operator of a credit card system;

"(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or a money transmitting service;

"(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

"(iv) any party described in paragraph (2)(B) and specified by the Board in such regulations, to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system;

"(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

"(i) identify types of policies and procedures, including nonexclusive examples, that shall be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system;

"(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

"(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

"(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection, or otherwise complies with this subsection shall not be liable to any party for such action.

"(ii) COMPLIANCE.—A person described in paragraph (2)(B) that is subject to a regulation issued under this subsection shall, in connection with complying with paragraph (1)—

"(A) adopt or rely on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system;

"(B) be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

"(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

"(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, shall adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 90 days after such regulations are issued in final form.

"(11) COMPLIANCE.—A payment system, and any person described in paragraph (2)(B), shall not be deemed to be in violation of paragraph (1).

"(A)(i) if an alleged violation of paragraph (1) occurs prior to the mandatory compliance date of the regulations issued under paragraph (7); and

"(ii) such entity has adopted or relied on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system.

"(B)(i) if an alleged violation of paragraph (1) occurs after the mandatory compliance date of such regulations; and

"(ii) such entity is in compliance with such regulations.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (h)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this Act.

SEC. 10009. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking "not import the controlled substances" and inserting "not import into the United States not to exceed 10 dosage units of the controlled substance."
made by this title, and the application of the provisions of such to any person or circumstance shall not affect thereby.

SA 2794. Mr. LEAHY submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986, to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1266, between lines 17 and 18, insert the following:

SEC. 4403. EXTENSION OF MEDICAL MALPRACTICE COVERAGE TO FREE CLINICS.

(a) In General.—Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended—

(1) in subsection (g), by striking paragraph (4) and inserting the following:

"(4) An entity described in this paragraph is—

"(A) a public or non-profit private entity receiving Federal funds under section 330; or

"(B) a free clinic defined under subsection (o)(3)(A); and

(2) in subsection (o)(6)(A), by inserting "and employees, and contractors of free clinics" after "free clinic health professionals";

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act and apply to any act or omission which occurs on or after that date.

SA 2795. Mr. LEAHY (for himself, Mr. REID, Mr. KERRY, Mr. ROCKEFELLER, Mr. LIEBERMAN, Mrs. FEINSTEIN, Mr. FENGOID, Mr. WYDEN, Mr. SCHUMER, Ms. CANTWELL, Mr. LAUTENBERG, Mrs. McCASKILL, Mr. WHITEHOUSE, Mr. BURRIS, Mr. KAUFMAN, Mr. BENNETT, and Mr. FRANKEN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 377, after line 14, insert the following:

SEC. 1561A. HEALTH INSURANCE INDUSTRY ANTICOMPETITIVE ACT ENFORCEMENT ACT OF 2009.

(a) SHORT TITLE.—This section may be cited as the "Health Insurance Industry Antitrust Enforcement Act of 2009".

(b) PURPOSE.—The purpose of this section is to ensure that health insurance issuers and medical malpractice insurance issuers cannot engage in any form of price fixing, bid rigging, or market allocations in connection with the conduct of the business of providing health insurance coverage (as defined in such section) or contracts for medical malpractice claims or actions.

(d) APPLICATION TO ACTIVITIES OF STATE COMMISSIONS OF INSURANCE AND OTHER STATE REGULATORY AGENCIES.—Nothing in this section shall apply to the information gathering and rate setting activities of any State commission of insurance, or any other State regulatory entity with authority to set insurance rates.

SA 2797. Mr. DURBIN (for Mr. WYDEN) proposed an amendment to the resolution S. Res. 71, condemning the Government of Iran for its state-sponsored persecution of the Baha'i minority in Iran and its continued violation of the International Covenants on Human Rights; as follows:

Strike all after the resolving clause and insert the following:

That the Senate—

(1) condemns the Government of Iran for its state-sponsored persecution of the Baha'i minority in Iran and its continued violation of the International Covenants on Human Rights;

(2) calls on the Government of Iran to immediately release the seven leaders and all other prisoners held solely on account of their religion, including Mrs. Fariba Kamalabadi, Mr. Jamaloddin Khanjani, Mr. Afif Naemi, Mr. Saeid Rezaie, Mr. Behrouz Tavakkoli, Mrs. Mahvash Sabet, and Mr. Vahid Tizfahm, the members of the coordinating group for the Baha'i community in Iran;

Whereas these seven leaders have been imprisoned for well over a year and are yet to stand trial, the trial having been delayed multiple times;

Whereas official Iranian media has announced that they will face charges of "espionage for Israel, insulting religious sanctities and propaganda against the Islamic Republic";

Whereas these seven Baha'i leaders were targeted solely on the basis of their religion; and

Whereas the Government of Iran is party to the International Covenants on Human Rights: Now, therefore, be it

NOTICE OF HEARING
COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled before the Subcommittee on Energy. The hearing will be held on Tuesday, December 8, 2009, at 2:30 p.m., in room SD-366 of the Dirksen Senate Office Building.

The purpose of the hearing is to receive testimony on the following bills: H.R. 957, Green Energy Education Act of 2009; H.R. 2729, To authorize the designation of National Environmental Research Parks by the Secretary of Energy, and for other purposes; H.R. 3165, Wind Energy Research and Development Act of 2009; H.R. 3246, Advanced Vehicle Technology Act of 2009; H.R. 3855, Solar Technology Roadmap Act; S. 737, A bill to amend the Energy Independence and Security Act of 2007 to require the authorizing the Secretaries of Energy to conduct research, development, and demonstration to make biofuels more compatible with small non-road engines, and for other purposes; S. 1617, To require the Secretary of Commerce to establish a program for the award of grants to States to establish revolving loan funds for small and medium-sized manufacturers to improve energy efficiency and produce clean energy technology, and for other purposes; S. 2744, A bill to amend the Energy Policy Act of 2005 to expand the authority for awarding technology prizes by the Secretary of Energy to include a financial award for separation of carbon dioxide from dilute sources; and S. 2773, A bill to require the Secretary of Energy to carry out a program to support research, demonstration, and development of commercial applications for offshore wind energy, and for other purposes.