

111TH CONGRESS
1ST SESSION

S. 525

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 4, 2009

Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. KENNEDY, Mr. MCCAIN, Ms. STABENOW, Mr. BINGAMAN, Ms. COLLINS, Mr. DURBIN, Mr. NELSON of Florida, Mr. KOHL, Mr. LEVIN, Mr. LEAHY, Mr. SANDERS, Mr. KERRY, Mr. BROWN, Mr. FEINGOLD, Mr. JOHNSON, Mr. INOUE, Mr. TESTER, Mr. CASEY, Mrs. MCCASKILL, Mr. THUNE, Mr. BEGICH, and Mrs. SHAHEEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Mar-
5 ket Access and Drug Safety Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

4 (2) the United States is the largest market for
5 pharmaceuticals in the world, yet American con-
6 sumers pay the highest prices for brand pharma-
7 ceuticals in the world;

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

10 (4) allowing and structuring the importation of
11 prescription drugs to ensure access to safe and af-
12 fordable drugs approved by the Food and Drug Ad-
13 ministration will provide a level of safety to Amer-
14 ican consumers that they do not currently enjoy;

15 (5) American spend more than
16 \$200,000,000,000 on prescription drugs every year;

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

21 (7) promoting competitive market pricing would
22 both contribute to health care savings and allow
23 greater access to therapy, improving health and sav-
24 ing lives.

1 **SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPOR-**
 2 **TATION OF PRESCRIPTION DRUGS.**

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

6 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
 7 **OF CERTAIN IMPORT RESTRICTIONS.**

8 (a) IN GENERAL.—Chapter VIII of the Federal
 9 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
 10 as amended by section 3, is further amended by inserting
 11 after section 803 the following:

12 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
 13 **PRESCRIPTION DRUGS.**

14 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

15 “(1) IN GENERAL.—In the case of qualifying
 16 drugs imported or offered for import into the United
 17 States from registered exporters or by registered im-
 18 porters—

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

21 “(B) the standards referred to in section
 22 801(a) regarding admission of the drugs are
 23 subject to subsection (g) of this section (includ-
 24 ing with respect to qualifying drugs to which
 25 section 801(d)(1) does not apply).

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

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

6 “(B) the drug is imported by an individual
7 for personal use or for the use of a family mem-
8 ber of the individual (not for resale) from a reg-
9 istered exporter.

10 “(3) RULE OF CONSTRUCTION.—This section
11 shall apply only with respect to a drug that is im-
12 ported or offered for import into the United
13 States—

14 “(A) by a registered importer; or

15 “(B) from a registered exporter to an indi-
16 vidual.

17 “(4) DEFINITIONS.—

18 “(A) REGISTERED EXPORTER; REG-
19 ISTERED IMPORTER.—For purposes of this sec-
20 tion:

21 “(i) The term ‘registered exporter’
22 means an exporter for which a registration
23 under subsection (b) has been approved
24 and is in effect.

1 “(ii) The term ‘registered importer’
2 means a pharmacy, group of pharmacies,
3 or a wholesaler for which a registration
4 under subsection (b) has been approved
5 and is in effect.

6 “(iii) The term ‘registration condition’
7 means a condition that must exist for a
8 registration under subsection (b) to be ap-
9 proved.

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

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

17 “(i) with respect to a qualifying drug,
18 has the same active ingredient or ingredi-
19 ents, route of administration, dosage form,
20 and strength as the qualifying drug;

21 “(ii) with respect to the qualifying
22 drug, is manufactured by or for the person
23 that manufactures the qualifying drug;

24 “(iii) is approved under section
25 505(c); and

1 “(iv) is not—

2 “(I) a controlled substance, as
3 defined in section 102 of the Con-
4 trolled Substances Act (21 U.S.C.
5 802);

6 “(II) a biological product, as de-
7 fined in section 351 of the Public
8 Health Service Act (42 U.S.C. 262),
9 including—

10 “(aa) a therapeutic DNA
11 plasmid product;

12 “(bb) a therapeutic synthetic
13 peptide product;

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

16 “(dd) a therapeutic recom-
17 binant DNA-derived product;

18 “(III) an infused drug, including
19 a peritoneal dialysis solution;

20 “(IV) an injected drug;

21 “(V) a drug that is inhaled dur-
22 ing surgery;

23 “(VI) a drug that is the listed
24 drug referred to in 2 or more abbrev-
25 viated new drug applications under

1 which the drug is commercially mar-
2 keted; or

3 “(VII) a sterile opthlamic drug
4 intended for topical use on or in the
5 eye.

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

8 “(i)(I) The term ‘exporter’ means a
9 person that is in the business of exporting
10 a drug to individuals in the United States
11 from Canada or from a permitted country
12 designated by the Secretary under sub-
13 clause (II), or that, pursuant to submitting
14 a registration under subsection (b), seeks
15 to be in such business.

16 “(II) The Secretary shall designate a
17 permitted country under subparagraph (E)
18 (other than Canada) as a country from
19 which an exporter may export a drug to in-
20 dividuals in the United States if the Sec-
21 retary determines that—

22 “(aa) the country has statutory
23 or regulatory standards that are
24 equivalent to the standards in the

1 United States and Canada with re-
2 spect to—

3 “(AA) the training of phar-
4 macists;

5 “(BB) the practice of phar-
6 macy; and

7 “(CC) the protection of the
8 privacy of personal medical infor-
9 mation; and

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

14 “(ii) The term ‘importer’ means a
15 pharmacy, a group of pharmacies, or a
16 wholesaler that is in the business of im-
17 porting a drug into the United States or
18 that, pursuant to submitting a registration
19 under subsection (b), seeks to be in such
20 business.

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

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

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

6 “(II) employs 1 or more phar-
7 macists.

8 “(v) The term ‘prescription drug’
9 means a drug that is described in section
10 503(b)(1).

11 “(vi) The term ‘wholesaler’—

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

16 “(II) does not include a person
17 authorized to import drugs under sec-
18 tion 801(d)(1).

19 “(E) PERMITTED COUNTRY.—The term
20 ‘permitted country’ means—

21 “(i) Australia;

22 “(ii) Canada;

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

1 “(I) the country’s Annex to the
 2 Treaty of Accession to the European
 3 Union 2003 includes a transitional
 4 measure for the regulation of human
 5 pharmaceutical products that has not
 6 expired; or

7 “(II) the Secretary determines
 8 that the requirements described in
 9 subclauses (I) and (II) of clause (vii)
 10 will not be met by the date on which
 11 such transitional measure for the reg-
 12 ulation of human pharmaceutical
 13 products expires;

14 “(iv) Japan;

15 “(v) New Zealand;

16 “(vi) Switzerland; and

17 “(vii) a country in which the Sec-
 18 retary determines the following require-
 19 ments are met:

20 “(I) The country has statutory or
 21 regulatory requirements—

22 “(aa) that require the review
 23 of drugs for safety and effective-
 24 ness by an entity of the govern-
 25 ment of the country;

1 “(bb) that authorize the ap-
2 proval of only those drugs that
3 have been determined to be safe
4 and effective by experts employed
5 by or acting on behalf of such en-
6 tity and qualified by scientific
7 training and experience to evalu-
8 ate the safety and effectiveness of
9 drugs on the basis of adequate
10 and well-controlled investigations,
11 including clinical investigations,
12 conducted by experts qualified by
13 scientific training and experience
14 to evaluate the safety and effec-
15 tiveness of drugs;

16 “(cc) that require the meth-
17 ods used in, and the facilities and
18 controls used for the manufac-
19 ture, processing, and packing of
20 drugs in the country to be ade-
21 quate to preserve their identity,
22 quality, purity, and strength;

23 “(dd) for the reporting of
24 adverse reactions to drugs and
25 procedures to withdraw approval

1 and remove drugs found not to
 2 be safe or effective; and

3 “(ee) that require the label-
 4 ing and promotion of drugs to be
 5 in accordance with the approval
 6 of the drug.

7 “(II) The valid marketing au-
 8 thorization system in the country is
 9 equivalent to the systems in the coun-
 10 tries described in clauses (i) through
 11 (vi).

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

15 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
 16 ERS.—

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

22 “(A)(i) In the case of an exporter, the
 23 name of the exporter and an identification of all
 24 places of business of the exporter that relate to
 25 qualifying drugs, including each warehouse or

1 other facility owned or controlled by, or oper-
2 ated for, the exporter.

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

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

14 “(i) in the case of an importer, sub-
15 sections (c), (d), (e), (g), and (j) (relating
16 to the sources of imported qualifying
17 drugs; the inspection of facilities of the im-
18 porter; the payment of fees; compliance
19 with the standards referred to in section
20 801(a); and maintenance of records and
21 samples); or

22 “(ii) in the case of an exporter, sub-
23 sections (c), (d), (f), (g), (h), (i), and (j)
24 (relating to the sources of exported quali-
25 fying drugs; the inspection of facilities of

1 the exporter and the marking of compliant
2 shipments; the payment of fees; and com-
3 pliance with the standards referred to in
4 section 801(a); being licensed as a phar-
5 macist; conditions for individual importa-
6 tion; and maintenance of records and sam-
7 ples).

8 “(C) An agreement by the registrant that
9 the registrant will not under subsection (a) im-
10 port or export any drug that is not a qualifying
11 drug.

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

13 “(i) notify the Secretary of a recall or
14 withdrawal of a qualifying drug distributed
15 in a permitted country that the registrant
16 has exported or imported, or intends to ex-
17 port or import, to the United States under
18 subsection (a);

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

21 “(iii) cease, or not begin, the expor-
22 tation or importation of such drug unless
23 the Secretary has notified the registrant
24 that exportation or importation of such
25 drug may proceed.

1 “(E) An agreement by the registrant to
2 ensure and monitor compliance with each reg-
3 istration condition, to promptly correct any
4 noncompliance with such a condition, and to
5 promptly report to the Secretary any such non-
6 compliance.

7 “(F) A plan describing the manner in
8 which the registrant will comply with the agree-
9 ment under subparagraph (E).

10 “(G) An agreement by the registrant to
11 enforce a contract under subsection (c)(3)(B)
12 against a party in the chain of custody of a
13 qualifying drug with respect to the authority of
14 the Secretary under clauses (ii) and (iii) of that
15 subsection.

16 “(H) An agreement by the registrant to
17 notify the Secretary not more than 30 days be-
18 fore the registrant intends to make the change,
19 of—

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

23 “(ii) any change that the registrant
24 intends to make in the compliance plan
25 under subparagraph (F).

1 “(I) In the case of an exporter:

2 “(i) An agreement by the exporter
3 that a qualifying drug will not under sub-
4 section (a) be exported to any individual
5 not authorized pursuant to subsection
6 (a)(2)(B) to be an importer of such drug.

7 “(ii) An agreement to post a bond,
8 payable to the Treasury of the United
9 States that is equal in value to the lesser
10 of—

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

15 “(II) \$1,000,000.

16 “(iii) An agreement by the exporter to
17 comply with applicable provisions of Cana-
18 dian law, or the law of the permitted coun-
19 try designated under subsection
20 (a)(4)(D)(i)(II) in which the exporter is lo-
21 cated, that protect the privacy of personal
22 information with respect to each individual
23 importing a prescription drug from the ex-
24 porter under subsection (a)(2)(B).

1 “(iv) An agreement by the exporter to
2 report to the Secretary—

3 “(I) not later than August 1 of
4 each fiscal year, the total price and
5 the total volume of drugs exported to
6 the United States by the exporter dur-
7 ing the 6-month period from January
8 1 through June 30 of that year; and

9 “(II) not later than January 1 of
10 each fiscal year, the total price and
11 the total volume of drugs exported to
12 the United States by the exporter dur-
13 ing the previous fiscal year.

14 “(J) In the case of an importer, an agree-
15 ment by the importer to report to the Sec-
16 retary—

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

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

1 States by the importer during the previous
2 fiscal year.

3 “(K) Such other provisions as the Sec-
4 retary may require by regulation to protect the
5 public health while permitting—

6 “(i) the importation by pharmacies,
7 groups of pharmacies, and wholesalers as
8 registered importers of qualifying drugs
9 under subsection (a); and

10 “(ii) importation by individuals of
11 qualifying drugs under subsection (a).

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

14 “(A) IN GENERAL.—Not later than 90
15 days after the date on which a registrant sub-
16 mits to the Secretary a registration under para-
17 graph (1), the Secretary shall notify the reg-
18 istrant whether the registration is approved or
19 is disapproved. The Secretary shall disapprove
20 a registration if there is reason to believe that
21 the registrant is not in compliance with one or
22 more registration conditions, and shall notify
23 the registrant of such reason. In the case of a
24 disapproved registration, the Secretary shall
25 subsequently notify the registrant that the reg-

1 istration is approved if the Secretary deter-
2 mines that the registrant is in compliance with
3 such conditions.

4 “(B) CHANGES IN REGISTRATION INFOR-
5 MATION.—Not later than 30 days after receiv-
6 ing a notice under paragraph (1)(H) from a
7 registrant, the Secretary shall determine wheth-
8 er the change involved affects the approval of
9 the registration of the registrant under para-
10 graph (1), and shall inform the registrant of
11 the determination.

12 “(3) PUBLICATION OF CONTACT INFORMATION
13 FOR REGISTERED EXPORTERS.—Through the Inter-
14 net website of the Food and Drug Administration
15 and a toll-free telephone number, the Secretary shall
16 make readily available to the public a list of reg-
17 istered exporters, including contact information for
18 the exporters. Promptly after the approval of a reg-
19 istration submitted under paragraph (1), the Sec-
20 retary shall update the Internet website and the in-
21 formation provided through the toll-free telephone
22 number accordingly.

23 “(4) SUSPENSION AND TERMINATION.—

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

4 “(i) Subject to clause (ii), the Sec-
5 retary may suspend the registration if the
6 Secretary determines, after notice and op-
7 portunity for a hearing, that the registrant
8 has failed to maintain substantial compli-
9 ance with a registration condition.

10 “(ii) If the Secretary determines that,
11 under color of the registration, the ex-
12 porter has exported a drug or the importer
13 has imported a drug that is not a quali-
14 fying drug, or a drug that does not comply
15 with subsection (g)(2)(A) or (g)(4), or has
16 exported a qualifying drug to an individual
17 in violation of subsection (i)(2)(F), the
18 Secretary shall immediately suspend the
19 registration. A suspension under the pre-
20 ceding sentence is not subject to the provi-
21 sion by the Secretary of prior notice, and
22 the Secretary shall provide to the reg-
23 istrant an opportunity for a hearing not
24 later than 10 days after the date on which
25 the registration is suspended.

1 “(iii) The Secretary may reinstate the
2 registration, whether suspended under
3 clause (i) or (ii), if the Secretary deter-
4 mines that the registrant has demonstrated
5 that further violations of registration con-
6 ditions will not occur.

7 “(B) TERMINATION.—The Secretary, after
8 notice and opportunity for a hearing, may ter-
9 minate the registration under paragraph (1) of
10 a registrant if the Secretary determines that
11 the registrant has engaged in a pattern or prac-
12 tice of violating 1 or more registration condi-
13 tions, or if on 1 or more occasions the Secretary
14 has under subparagraph (A)(ii) suspended the
15 registration of the registrant. The Secretary
16 may make the termination permanent, or for a
17 fixed period of not less than 1 year. During the
18 period in which the registration is terminated,
19 any registration submitted under paragraph (1)
20 by the registrant, or a person that is a partner
21 in the export or import enterprise, or a prin-
22 cipal officer in such enterprise, and any reg-
23 istration prepared with the assistance of the
24 registrant or such a person, has no legal effect
25 under this section.

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

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

11 “(B) failed to permit the Secretary to con-
12 duct an inspection described under subsection
13 (d).

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

19 “(1) The drug was manufactured in an estab-
20 lishment—

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

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

24 “(ii) for which the Secretary has elected to
25 rely on a satisfactory report of a good manufac-

1 turing practice inspection of the establishment
2 from a permitted country whose regulatory sys-
3 tem the Secretary recognizes as equivalent
4 under a mutual recognition agreement, as pro-
5 vided for under section 510(i)(3), section 803,
6 or part 26 of title 21, Code of Federal Regula-
7 tions (or any corresponding successor rule or
8 regulation).

9 “(2) The establishment is located in any coun-
10 try, and the establishment manufactured the drug
11 for distribution in the United States or for distribu-
12 tion in 1 or more of the permitted countries (without
13 regard to whether in addition the drug is manufac-
14 tured for distribution in a foreign country that is
15 not a permitted country).

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

18 “(A) directly from the establishment; or

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

21 “(i) provides to the exporter or im-
22 porter a statement (in such form and con-
23 taining such information as the Secretary
24 may require) that, for the chain of custody
25 from the establishment, identifies each

1 prior sale, purchase, or trade of the drug
2 (including the date of the transaction and
3 the names and addresses of all parties to
4 the transaction);

5 “(ii) agrees to permit the Secretary to
6 inspect such statements and related
7 records to determine their accuracy;

8 “(iii) agrees, with respect to the quali-
9 fying drugs involved, to permit the Sec-
10 retary to inspect warehouses and other fa-
11 cilities, including records, of the entity for
12 purposes of determining whether the facili-
13 ties are in compliance with any standards
14 under this Act that are applicable to facili-
15 ties of that type in the United States; and

16 “(iv) has ensured, through such con-
17 tractual relationships as may be necessary,
18 that the Secretary has the same authority
19 regarding other parties in the chain of cus-
20 tody from the establishment that the Sec-
21 retary has under clauses (ii) and (iii) re-
22 garding such entity.

23 “(4)(A) The foreign country from which the im-
24 porter will import the drug is a permitted country;
25 or

1 “(B) The foreign country from which the ex-
 2 porter will export the drug is the permitted country
 3 in which the exporter is located.

4 “(5) During any period in which the drug was
 5 not in the control of the manufacturer of the drug,
 6 the drug did not enter any country that is not a per-
 7 mitted country.

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

10 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
 11 MENTS.—

12 “(1) INSPECTION OF FACILITIES.—A registra-
 13 tion condition is that, for the purpose of assisting
 14 the Secretary in determining whether the exporter
 15 involved is in compliance with all other registration
 16 conditions—

17 “(A) the exporter agrees to permit the Sec-
 18 retary—

19 “(i) to conduct onsite inspections, in-
 20 cluding monitoring on a day-to-day basis,
 21 of places of business of the exporter that
 22 relate to qualifying drugs, including each
 23 warehouse or other facility owned or con-
 24 trolled by, or operated for, the exporter;

1 “(ii) to have access, including on a
2 day-to-day basis, to—

3 “(I) records of the exporter that
4 relate to the export of such drugs, in-
5 cluding financial records; and

6 “(II) samples of such drugs;

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

9 “(iv) to carry out any other functions
10 determined by the Secretary to be nec-
11 essary regarding the compliance of the ex-
12 porter; and

13 “(B) the Secretary has assigned 1 or more
14 employees of the Secretary to carry out the
15 functions described in this subsection for the
16 Secretary randomly, but not less than 12 times
17 annually, on the premises of places of busi-
18 nesses referred to in subparagraph (A)(i), and
19 such an assignment remains in effect on a con-
20 tinuous basis.

21 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
22 registration condition is that the exporter involved
23 agrees to affix to each shipping container of quali-
24 fying drugs exported under subsection (a) such
25 markings as the Secretary determines to be nec-

1 essary to identify the shipment as being in compli-
2 ance with all registration conditions. Markings under
3 the preceding sentence shall—

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

7 “(B) include anticounterfeiting or track-
8 and-trace technologies, taking into account the
9 economic and technical feasibility of those tech-
10 nologies.

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

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

19 “(B) During the inspections under sub-
20 paragraph (A), verifying the chain of custody of
21 a statistically significant sample of qualifying
22 drugs from the establishment in which the drug
23 was manufactured to the exporter, which shall
24 be accomplished or supplemented by the use of
25 anticounterfeiting or track-and-trace tech-

1 nologies, taking into account the economic and
2 technical feasibility of those technologies, except
3 that a drug that lacks such technologies from
4 the point of manufacture shall not for that rea-
5 son be excluded from importation by an ex-
6 porter.

7 “(C) Randomly reviewing records of ex-
8 ports to individuals for the purpose of deter-
9 mining whether the drugs are being imported
10 by the individuals in accordance with the condi-
11 tions under subsection (i). Such reviews shall be
12 conducted in a manner that will result in a sta-
13 tistically significant determination of compli-
14 ance with all such conditions.

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

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

21 “(F) Determining whether the exporter is
22 in compliance with all other registration condi-
23 tions.

24 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-
25 istration condition is that, not less than 8 hours and

1 not more than 5 days in advance of the time of the
2 importation of a shipment of qualifying drugs, the
3 importer involved agrees to submit to the Secretary
4 a notice with respect to the shipment of drugs to be
5 imported or offered for import into the United
6 States under subsection (a). A notice under the pre-
7 ceding sentence shall include—

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

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

12 “(C) the identity of the drug, including the
13 established name of the drug, the quantity of
14 the drug, and the lot number assigned by the
15 manufacturer;

16 “(D) the identity of the manufacturer of
17 the drug, including the identity of the establish-
18 ment at which the drug was manufactured;

19 “(E) the country from which the drug is
20 shipped;

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

23 “(G) anticipated arrival information, in-
24 cluding the port of arrival and crossing location
25 within that port, and the date and time;

1 “(H) a summary of the chain of custody of
2 the drug from the establishment in which the
3 drug was manufactured to the importer;

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

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

10 “(5) MARKING OF COMPLIANT SHIPMENTS.—A
11 registration condition is that the importer involved
12 agrees, before wholesale distribution (as defined in
13 section 503(e)) of a qualifying drug that has been
14 imported under subsection (a), to affix to each con-
15 tainer of such drug such markings or other tech-
16 nology as the Secretary determines necessary to
17 identify the shipment as being in compliance with all
18 registration conditions, except that the markings or
19 other technology shall not be required on a drug
20 that bears comparable, compatible markings or tech-
21 nology from the manufacturer of the drug. Markings
22 or other technology under the preceding sentence
23 shall—

24 “(A) be designed to prevent affixation of
25 the markings or other technology to any con-

1 tainer that is not authorized to bear the mark-
2 ings; and

3 “(B) shall include anticounterfeiting or
4 track-and-trace technologies, taking into ac-
5 count the economic and technical feasibility of
6 such technologies.

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

10 “(A) Inspecting, randomly, but not less
11 than 12 times annually, the places of business
12 of the importer at which a qualifying drug is
13 initially received after importation.

14 “(B) During the inspections under sub-
15 paragraph (A), verifying the chain of custody of
16 a statistically significant sample of qualifying
17 drugs from the establishment in which the drug
18 was manufactured to the importer, which shall
19 be accomplished or supplemented by the use of
20 anticounterfeiting or track-and-trace tech-
21 nologies, taking into account the economic and
22 technical feasibility of those technologies, except
23 that a drug that lacks such technologies from
24 the point of manufacture shall not for that rea-

1 son be excluded from importation by an im-
 2 porter.

3 “(C) Reviewing notices under paragraph
 4 (4).

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

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

12 “(e) IMPORTER FEES.—

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

18 “(2) INSPECTION FEE.—A registration condi-
 19 tion is that the importer involved pays a fee to the
 20 Secretary in accordance with this subsection. Such
 21 fee shall be paid not later than October 1 and April
 22 1 of each fiscal year in the amount provided for
 23 under paragraph (3).

24 “(3) AMOUNT OF INSPECTION FEE.—

1 “(A) AGGREGATE TOTAL OF FEES.—Not
2 later than 30 days before the start of each fis-
3 cal year, the Secretary, in consultation with the
4 Secretary of Homeland Security and the Sec-
5 retary of the Treasury, shall establish an aggre-
6 gate total of fees to be collected under para-
7 graph (2) for importers for that fiscal year that
8 is sufficient, and not more than necessary, to
9 pay the costs for that fiscal year of admin-
10 istering this section with respect to registered
11 importers, including the costs associated with—

12 “(i) inspecting the facilities of reg-
13 istered importers, and of other entities in
14 the chain of custody of a qualifying drug
15 as necessary, under subsection (d)(6);

16 “(ii) developing, implementing, and
17 operating under such subsection an elec-
18 tronic system for submission and review of
19 the notices required under subsection
20 (d)(4) with respect to shipments of quali-
21 fying drugs under subsection (a) to assess
22 compliance with all registration conditions
23 when such shipments are offered for im-
24 port into the United States; and

1 “(iii) inspecting such shipments as
2 necessary, when offered for import into the
3 United States to determine if such a ship-
4 ment should be refused admission under
5 subsection (g)(5).

6 “(B) LIMITATION.—Subject to subpara-
7 graph (C), the aggregate total of fees collected
8 under paragraph (2) for a fiscal year shall not
9 exceed 2.5 percent of the total price of quali-
10 fying drugs imported during that fiscal year
11 into the United States by registered importers
12 under subsection (a).

13 “(C) TOTAL PRICE OF DRUGS.—

14 “(i) ESTIMATE.—For the purposes of
15 complying with the limitation described in
16 subparagraph (B) when establishing under
17 subparagraph (A) the aggregate total of
18 fees to be collected under paragraph (2)
19 for a fiscal year, the Secretary shall esti-
20 mate the total price of qualifying drugs im-
21 ported into the United States by registered
22 importers during that fiscal year by adding
23 the total price of qualifying drugs imported
24 by each registered importer during the 6-
25 month period from January 1 through

1 June 30 of the previous fiscal year, as re-
2 ported to the Secretary by each registered
3 importer under subsection (b)(1)(J).

4 “(ii) CALCULATION.—Not later than
5 March 1 of the fiscal year that follows the
6 fiscal year for which the estimate under
7 clause (i) is made, the Secretary shall cal-
8 culate the total price of qualifying drugs
9 imported into the United States by reg-
10 istered importers during that fiscal year by
11 adding the total price of qualifying drugs
12 imported by each registered importer dur-
13 ing that fiscal year, as reported to the Sec-
14 retary by each registered importer under
15 subsection (b)(1)(J).

16 “(iii) ADJUSTMENT.—If the total
17 price of qualifying drugs imported into the
18 United States by registered importers dur-
19 ing a fiscal year as calculated under clause
20 (ii) is less than the aggregate total of fees
21 collected under paragraph (2) for that fis-
22 cal year, the Secretary shall provide for a
23 pro-rata reduction in the fee due from each
24 registered importer on April 1 of the sub-

1 sequent fiscal year so that the limitation
2 described in subparagraph (B) is observed.

3 “(D) INDIVIDUAL IMPORTER FEE.—Sub-
4 ject to the limitation described in subparagraph
5 (B), the fee under paragraph (2) to be paid on
6 October 1 and April 1 by an importer shall be
7 an amount that is proportional to a reasonable
8 estimate by the Secretary of the semiannual
9 share of the importer of the volume of quali-
10 fying drugs imported by importers under sub-
11 section (a).

12 “(4) USE OF FEES.—

13 “(A) IN GENERAL.—Subject to appropria-
14 tions Acts, fees collected by the Secretary under
15 paragraphs (1) and (2) shall be credited to the
16 appropriation account for salaries and expenses
17 of the Food and Drug Administration until ex-
18 pended (without fiscal year limitation), and the
19 Secretary may, in consultation with the Sec-
20 retary of Homeland Security and the Secretary
21 of the Treasury, transfer some proportion of
22 such fees to the appropriation account for sala-
23 ries and expenses of the Bureau of Customs
24 and Border Protection until expended (without
25 fiscal year limitation).

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

7 “(5) COLLECTION OF FEES.—In any case where
 8 the Secretary does not receive payment of a fee as-
 9 sessed under paragraph (1) or (2) within 30 days
 10 after it is due, such fee shall be treated as a claim
 11 of the United States Government subject to sub-
 12 chapter II of chapter 37 of title 31, United States
 13 Code.

14 “(f) EXPORTER FEES.—

15 “(1) REGISTRATION FEE.—A registration con-
 16 dition is that the exporter involved pays to the Sec-
 17 retary a fee of \$10,000 due on the date on which
 18 the exporter first submits that registration to the
 19 Secretary under subsection (b).

20 “(2) INSPECTION FEE.—A registration condi-
 21 tion is that the exporter involved pays a fee to the
 22 Secretary in accordance with this subsection. Such
 23 fee shall be paid not later than October 1 and April
 24 1 of each fiscal year in the amount provided for
 25 under paragraph (3).

1 “(3) AMOUNT OF INSPECTION FEE.—

2 “(A) AGGREGATE TOTAL OF FEES.—Not
3 later than 30 days before the start of each fis-
4 cal year, the Secretary, in consultation with the
5 Secretary of Homeland Security and the Sec-
6 retary of the Treasury, shall establish an aggre-
7 gate total of fees to be collected under para-
8 graph (2) for exporters for that fiscal year that
9 is sufficient, and not more than necessary, to
10 pay the costs for that fiscal year of admin-
11 istering this section with respect to registered
12 exporters, including the costs associated with—

13 “(i) inspecting the facilities of reg-
14 istered exporters, and of other entities in
15 the chain of custody of a qualifying drug
16 as necessary, under subsection (d)(3);

17 “(ii) developing, implementing, and
18 operating under such subsection a system
19 to screen marks on shipments of qualifying
20 drugs under subsection (a) that indicate
21 compliance with all registration conditions,
22 when such shipments are offered for im-
23 port into the United States; and

24 “(iii) screening such markings, and
25 inspecting such shipments as necessary,

1 when offered for import into the United
2 States to determine if such a shipment
3 should be refused admission under sub-
4 section (g)(5).

5 “(B) LIMITATION.—Subject to subpara-
6 graph (C), the aggregate total of fees collected
7 under paragraph (2) for a fiscal year shall not
8 exceed 2.5 percent of the total price of quali-
9 fying drugs imported during that fiscal year
10 into the United States by registered exporters
11 under subsection (a).

12 “(C) TOTAL PRICE OF DRUGS.—

13 “(i) ESTIMATE.—For the purposes of
14 complying with the limitation described in
15 subparagraph (B) when establishing under
16 subparagraph (A) the aggregate total of
17 fees to be collected under paragraph (2)
18 for a fiscal year, the Secretary shall esti-
19 mate the total price of qualifying drugs im-
20 ported into the United States by registered
21 exporters during that fiscal year by adding
22 the total price of qualifying drugs exported
23 by each registered exporter during the 6-
24 month period from January 1 through
25 June 30 of the previous fiscal year, as re-

ported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

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

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

1 “(D) INDIVIDUAL EXPORTER FEE.—Sub-
2 ject to the limitation described in subparagraph
3 (B), the fee under paragraph (2) to be paid on
4 October 1 and April 1 by an exporter shall be
5 an amount that is proportional to a reasonable
6 estimate by the Secretary of the semiannual
7 share of the exporter of the volume of quali-
8 fying drugs exported by exporters under sub-
9 section (a).

10 “(4) USE OF FEES.—

11 “(A) IN GENERAL.—Subject to appropria-
12 tions Acts, fees collected by the Secretary under
13 paragraphs (1) and (2) shall be credited to the
14 appropriation account for salaries and expenses
15 of the Food and Drug Administration until ex-
16 pended (without fiscal year limitation), and the
17 Secretary may, in consultation with the Sec-
18 retary of Homeland Security and the Secretary
19 of the Treasury, transfer some proportion of
20 such fees to the appropriation account for sala-
21 ries and expenses of the Bureau of Customs
22 and Border Protection until expended (without
23 fiscal year limitation).

24 “(B) SOLE PURPOSE.—Fees collected by
25 the Secretary under paragraphs (1) and (2) are

only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

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

“(g) COMPLIANCE WITH SECTION 801(a).—

“(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection (a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

“(2) SECTION 505; APPROVAL STATUS.—

“(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under sec-

tion 505(b) for the U.S. label drug as described
under this subsection.

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

“(i) IN GENERAL.—The person that
manufactures a qualifying drug that is, or
will be, introduced for commercial distribu-
tion in a permitted country shall in accord-
ance 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 applica-
tion for the U.S. label drug beyond—

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

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

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

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

3 “(bb) any difference in label-
4 ing (except ingredient labeling).

5 “(ii) INFORMATION IN NOTICE.—A
6 notice under clause (i)(I) shall include the
7 information that the Secretary may require
8 under section 506A, any additional infor-
9 mation the Secretary may require (which
10 may include data on bioequivalence if such
11 data are not required under section 506A),
12 and, with respect to the permitted country
13 that approved the qualifying drug for com-
14 mercial distribution, or with respect to
15 which such approval is sought, include the
16 following:

17 “(I) The date on which the quali-
18 fying drug with such difference was,
19 or will be, introduced for commercial
20 distribution in the permitted country.

21 “(II) Information demonstrating
22 that the person submitting the notice
23 has also notified the government of
24 the permitted country in writing that
25 the person is submitting to the Sec-

1 retary a notice under clause (i)(I),
2 which notice describes the difference
3 in the qualifying drug from a condi-
4 tion established in the approved appli-
5 cation for the U.S. label drug.

6 “(III) The information that the
7 person submitted or will submit to the
8 government of the permitted country
9 for purposes of obtaining approval for
10 commercial distribution of the drug in
11 the country which, if in a language
12 other than English, shall be accom-
13 panied by an English translation
14 verified to be complete and accurate,
15 with the name, address, and a brief
16 statement of the qualifications of the
17 person that made the translation.

18 “(iii) CERTIFICATIONS.—The chief ex-
19 ecutive officer and the chief medical officer
20 of the manufacturer involved shall each
21 certify in the notice under clause (i) that—

22 “(I) the information provided in
23 the notice is complete and true; and

24 “(II) a copy of the notice has
25 been provided to the Federal Trade

1 Commission and to the State attor-
2 neys general.

3 “(iv) FEE.—If a notice submitted
4 under clause (i) includes a difference that
5 would, under section 506A, require the
6 submission of a supplemental application if
7 made as a change to the U.S. label drug,
8 the person that submits the notice shall
9 pay to the Secretary a fee in the same
10 amount as would apply if the person were
11 paying a fee pursuant to section
12 736(a)(1)(A)(ii). Subject to appropriations
13 Acts, fees collected by the Secretary under
14 the preceding sentence are available only to
15 the Secretary and are for the sole purpose
16 of paying the costs of reviewing notices
17 submitted under clause (i).

18 “(v) TIMING OF SUBMISSION OF NO-
19 TICES.—

20 “(I) PRIOR APPROVAL NO-
21 TICES.—A notice under clause (i) to
22 which subparagraph (C) applies shall
23 be submitted to the Secretary not
24 later than 120 days before the quali-
25 fying drug with the difference is intro-

1 duced for commercial distribution in a
2 permitted country, unless the country
3 requires that distribution of the quali-
4 fying drug with the difference begin
5 less than 120 days after the country
6 requires the difference.

7 “(II) OTHER APPROVAL NO-
8 TICES.—A notice under clause (i) to
9 which subparagraph (D) applies shall
10 be submitted to the Secretary not
11 later than the day on which the quali-
12 fying drug with the difference is intro-
13 duced for commercial distribution in a
14 permitted country.

15 “(III) OTHER NOTICES.—A no-
16 tice under clause (i) to which subpara-
17 graph (E) applies shall be submitted
18 to the Secretary on the date that the
19 qualifying drug is first introduced for
20 commercial distribution in a permitted
21 country and annually thereafter.

22 “(vi) REVIEW BY SECRETARY.—

23 “(I) IN GENERAL.—In this para-
24 graph, the difference in a qualifying
25 drug that is submitted in a notice

1 under clause (i) from the U.S. label
2 drug shall be treated by the Secretary
3 as if it were a manufacturing change
4 to the U.S. label drug under section
5 506A.

6 “(II) STANDARD OF REVIEW.—

7 Except as provided in subclause (III),
8 the Secretary shall review and approve
9 or disapprove the difference in a no-
10 tice submitted under clause (i), if re-
11 quired under section 506A, using the
12 safe and effective standard for ap-
13 proving or disapproving a manufac-
14 turing change under section 506A.

15 “(III) BIOEQUIVALENCE.—If the

16 Secretary would approve the dif-
17 ference in a notice submitted under
18 clause (i) using the safe and effective
19 standard under section 506A and if
20 the Secretary determines that the
21 qualifying drug is not bioequivalent to
22 the U.S. label drug, the Secretary
23 shall—

24 “(aa) include in the labeling

25 provided under paragraph (3) a

1 prominent advisory that the
2 qualifying drug is safe and effec-
3 tive but is not bioequivalent to
4 the U.S. label drug if the Sec-
5 retary determines that such an
6 advisory is necessary for health
7 care practitioners and patients to
8 use the qualifying drug safely
9 and effectively; or

10 “(bb) decline to approve the
11 difference if the Secretary deter-
12 mines that the availability of
13 both the qualifying drug and the
14 U.S. label drug would pose a
15 threat to the public health.

16 “(IV) REVIEW BY THE SEC-
17 RETARY.—The Secretary shall review
18 and approve or disapprove the dif-
19 ference in a notice submitted under
20 clause (i), if required under section
21 506A, not later than 120 days after
22 the date on which the notice is sub-
23 mitted.

24 “(V) ESTABLISHMENT INSPEC-
25 TION.—If review of such difference

1 would require an inspection of the es-
2 tablishment in which the qualifying
3 drug is manufactured—

4 “(aa) such inspection by the
5 Secretary shall be authorized;
6 and

7 “(bb) the Secretary may rely
8 on a satisfactory report of a good
9 manufacturing practice inspec-
10 tion of the establishment from a
11 permitted country whose regu-
12 latory system the Secretary rec-
13 ognizes as equivalent under a
14 mutual recognition agreement, as
15 provided under section 510(i)(3),
16 section 803, or part 26 of title
17 21, Code of Federal Regulations
18 (or any corresponding successor
19 rule or regulation).

20 “(vii) PUBLICATION OF INFORMATION
21 ON NOTICES.—

22 “(I) IN GENERAL.—Through the
23 Internet website of the Food and
24 Drug Administration and a toll-free
25 telephone number, the Secretary shall

1 readily make available to the public a
 2 list of notices submitted under clause
 3 (i).

4 “(II) CONTENTS.—The list under
 5 subclause (I) shall include the date on
 6 which a notice is submitted and
 7 whether—

8 “(aa) a notice is under re-
 9 view;

10 “(bb) the Secretary has or-
 11 dered that importation of the
 12 qualifying drug from a permitted
 13 country cease; or

14 “(cc) the importation of the
 15 drug is permitted under sub-
 16 section (a).

17 “(III) UPDATE.—The Secretary
 18 shall promptly update the Internet
 19 website with any changes to the list.

20 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
 21 ING PRIOR APPROVAL.—In the case of a notice
 22 under subparagraph (B)(i) that includes a dif-
 23 ference that would, under section 506A(c) or
 24 (d)(3)(B)(i), require the approval of a supple-
 25 mental application before the difference could

1 be made to the U.S. label drug the following
2 shall occur:

3 “(i) Promptly after the notice is sub-
4 mitted, the Secretary shall notify reg-
5 istered exporters, registered importers, the
6 Federal Trade Commission, and the State
7 attorneys general that the notice has been
8 submitted with respect to the qualifying
9 drug involved.

10 “(ii) If the Secretary has not made a
11 determination whether such a supple-
12 mental application regarding the U.S. label
13 drug would be approved or disapproved by
14 the date on which the qualifying drug in-
15 volved is to be introduced for commercial
16 distribution in a permitted country, the
17 Secretary shall—

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country not begin until the
21 Secretary completes review of the no-
22 tice; and

23 “(II) promptly notify registered
24 exporters, registered importers, the

1 Federal Trade Commission, and the
2 State attorneys general of the order.

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

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

12 “(II) notify the permitted coun-
13 try that approved the qualifying drug
14 for commercial distribution of the de-
15 termination; and

16 “(III) promptly notify registered
17 exporters, registered importers, the
18 Federal Trade Commission, and the
19 State attorneys general of the deter-
20 mination.

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

1 “(I) vacate the order under
2 clause (ii), if any;

3 “(II) consider the difference to
4 be a variation provided for in the ap-
5 proved application for the U.S. label
6 drug;

7 “(III) permit importation of the
8 qualifying drug under subsection (a);
9 and

10 “(IV) promptly notify registered
11 exporters, registered importers, the
12 Federal Trade Commission, and the
13 State attorneys general of the deter-
14 mination.

15 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
16 QUIRING PRIOR APPROVAL.—In the case of a
17 notice under subparagraph (B)(i) that includes
18 a difference that would, under section
19 506A(d)(3)(B)(ii), not require the approval of a
20 supplemental application before the difference
21 could be made to the U.S. label drug the fol-
22 lowing shall occur:

23 “(i) During the period in which the
24 notice is being reviewed by the Secretary,
25 the authority under this subsection to im-

1 port the qualifying drug involved continues
2 in effect.

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

7 “(I) order that the importation of
8 the qualifying drug involved from the
9 permitted country cease;

10 “(II) notify the permitted coun-
11 try that approved the qualifying drug
12 for commercial distribution of the de-
13 termination; and

14 “(III) promptly notify registered
15 exporters, registered importers, the
16 Federal Trade Commission, and the
17 State attorneys general of the deter-
18 mination.

19 “(iii) If the Secretary determines that
20 such a supplemental application regarding
21 the U.S. label drug would be approved, the
22 difference shall be considered to be a vari-
23 ation provided for in the approved applica-
24 tion for the U.S. label drug.

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

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

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

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

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

“(i) IN GENERAL.—A person who
 manufactures a drug approved under sec-
 tion 505(b) shall submit an application
 under section 505(b) for approval of an-
 other drug that is manufactured for dis-
 tribution in a permitted country by or for

1 the person that manufactures the drug ap-
2 proved under section 505(b) if—

3 “(I) there is no qualifying drug
4 in commercial distribution in per-
5 mitted countries whose combined pop-
6 ulation represents at least 50 percent
7 of the total population of all permitted
8 countries with the same active ingre-
9 dient or ingredients, route of adminis-
10 tration, dosage form, and strength as
11 the drug approved under section
12 505(b); and

13 “(II) each active ingredient of
14 the other drug is related to an active
15 ingredient of the drug approved under
16 section 505(b), as defined in clause
17 (v).

18 “(ii) APPLICATION UNDER SECTION
19 505(b).—The application under section
20 505(b) required under clause (i) shall—

21 “(I) request approval of the other
22 drug for the indication or indications
23 for which the drug approved under
24 section 505(b) is labeled;

1 “(II) include the information that
2 the person submitted to the govern-
3 ment of the permitted country for
4 purposes of obtaining approval for
5 commercial distribution of the other
6 drug in that country, which if in a
7 language other than English, shall be
8 accompanied by an English trans-
9 lation verified to be complete and ac-
10 curate, with the name, address, and a
11 brief statement of the qualifications of
12 the person that made the translation;

13 “(III) include a right of reference
14 to the application for the drug ap-
15 proved under section 505(b); and

16 “(IV) include such additional in-
17 formation as the Secretary may re-
18 quire.

19 “(iii) TIMING OF SUBMISSION OF AP-
20 PPLICATION.—An application under section
21 505(b) required under clause (i) shall be
22 submitted to the Secretary not later than
23 the day on which the information referred
24 to in clause (ii)(II) is submitted to the gov-
25 ernment of the permitted country.

1 “(iv) NOTICE OF DECISION ON APPLI-
2 CATION.—The Secretary shall promptly no-
3 tify registered exporters, registered import-
4 ers, the Federal Trade Commission, and
5 the State attorneys general of a determina-
6 tion to approve or to disapprove an appli-
7 cation under section 505(b) required under
8 clause (i).

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

12 “(I) the same; or

13 “(II) different salts, esters, or
14 complexes of the same moiety.

15 “(3) SECTION 502; LABELING.—

16 “(A) IMPORTATION BY REGISTERED IM-
17 PORTER.—

18 “(i) IN GENERAL.—In the case of a
19 qualifying drug that is imported or offered
20 for import by a registered importer, such
21 drug shall be considered to be in compli-
22 ance with section 502 and the labeling re-
23 quirements under the approved application
24 for the U.S. label drug if the qualifying
25 drug bears—

1 “(I) a copy of the labeling ap-
2 proved for the U.S. label drug under
3 section 505, without regard to wheth-
4 er the copy bears any trademark in-
5 volved;

6 “(II) the name of the manufac-
7 turer and location of the manufac-
8 turer;

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

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

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

17 “(ii) REQUEST FOR COPY OF THE LA-
18 BELING.—The Secretary shall provide such
19 copy to the registered importer involved,
20 upon request of the importer.

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

24 “(I) include the established
25 name, as defined in section 502(e)(3),

1 for each active ingredient in the quali-
2 fying drug;

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

6 “(III) if required under para-
7 graph (2)(B)(vi)(III), a prominent ad-
8 visory that the qualifying drug is safe
9 and effective but not bioequivalent to
10 the U.S. label drug; and

11 “(IV) if the inactive ingredients
12 of the qualifying drug are different
13 from the inactive ingredients for the
14 U.S. label drug, include—

15 “(aa) a prominent notice
16 that the ingredients of the quali-
17 fying drug differ from the ingre-
18 dients of the U.S. label drug and
19 that the qualifying drug must be
20 dispensed with an advisory to
21 people with allergies about this
22 difference and a list of ingredi-
23 ents; and

24 “(bb) a list of the ingredi-
25 ents of the qualifying drug as

1 would be required under section
2 502(e).

3 “(B) IMPORTATION BY INDIVIDUAL.—

4 “(i) IN GENERAL.—In the case of a
5 qualifying drug that is imported or offered
6 for import by a registered exporter to an
7 individual, such drug shall be considered to
8 be in compliance with section 502 and the
9 labeling requirements under the approved
10 application for the U.S. label drug if the
11 packaging and labeling of the qualifying
12 drug complies with all applicable regula-
13 tions promulgated under sections 3 and 4
14 of the Poison Prevention Packaging Act of
15 1970 (15 U.S.C. 1471 et seq.) and the la-
16 beling of the qualifying drug includes—

17 “(I) directions for use by the
18 consumer;

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

21 “(III) the name and registration
22 number of the exporter;

23 “(IV) if required under para-
24 graph (2)(B)(vi)(III), a prominent ad-
25 visory that the drug is safe and effec-

1 tive but not bioequivalent to the U.S.
2 label drug;

3 “(V) if the inactive ingredients of
4 the drug are different from the inac-
5 tive ingredients for the U.S. label
6 drug—

7 “(aa) a prominent advisory
8 that persons with an allergy
9 should check the ingredient list
10 of the drug because the ingredi-
11 ents of the drug differ from the
12 ingredients of the U.S. label
13 drug; and

14 “(bb) a list of the ingredi-
15 ents of the drug as would be re-
16 quired under section 502(e); and

17 “(VI) a copy of any special label-
18 ing that would be required by the Sec-
19 retary had the U.S. label drug been
20 dispensed by a pharmacist in the
21 United States, without regard to
22 whether the special labeling bears any
23 trademark involved.

24 “(ii) PACKAGING.—A qualifying drug
25 offered for import to an individual by an

1 exporter under this section that is pack-
2 aged in a unit-of-use container (as those
3 items are defined in the United States
4 Pharmacopeia and National Formulary)
5 shall not be repackaged, provided that—

6 “(I) the packaging complies with
7 all applicable regulations under sec-
8 tions 3 and 4 of the Poison Preven-
9 tion Packaging Act of 1970 (15
10 U.S.C. 1471 et seq.); or

11 “(II) the consumer consents to
12 waive the requirements of such Act,
13 after being informed that the pack-
14 aging does not comply with such Act
15 and that the exporter will provide the
16 drug in packaging that is compliant at
17 no additional cost.

18 “(iii) REQUEST FOR COPY OF SPECIAL
19 LABELING AND INGREDIENT LIST.—The
20 Secretary shall provide to the registered
21 exporter involved a copy of the special la-
22 beling, the advisory, and the ingredient list
23 described under clause (i), upon request of
24 the exporter.

1 “(iv) REQUESTED LABELING AND IN-
2 GREDIENT LIST.—The labeling and ingre-
3 dient list provided by the Secretary under
4 clause (iii) shall—

5 “(I) include the established
6 name, as defined in section 502(e)(3),
7 for each active ingredient in the drug;
8 and

9 “(II) not include the proprietary
10 name of the U.S. label drug or any
11 active ingredient thereof.

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

17 “(5) STANDARDS FOR REFUSING ADMISSION.—
18 A drug exported under subsection (a) from a reg-
19 istered exporter or imported by a registered importer
20 may be refused admission into the United States if
21 1 or more of the following applies:

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

23 “(B) A notice for the drug required under
24 paragraph (2)(B) has not been submitted to the
25 Secretary.

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

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

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

9 “(F) The Secretary becomes aware that—

10 “(i) the drug may be counterfeit;

11 “(ii) the drug may have been pre-
12 pared, packed, or held under insanitary
13 conditions; or

14 “(iii) the methods used in, or the fa-
15 cilities or controls used for, the manufac-
16 turing, processing, packing, or holding of
17 the drug do not conform to good manufac-
18 turing practice.

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

22 “(H) The Secretary has under section
23 505(e) withdrawn approval of the drug.

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

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

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

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

11 “(ii) The markings on the shipping
 12 container appear to be counterfeit.

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

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

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

22 “(2) the exporter employs persons that are li-
 23 censed under the law of the permitted country in
 24 which the exporter is located to dispense prescription
 25 drugs in sufficient number to dispense safely the

1 drugs exported by the exporter to individuals, and
 2 the exporter assigns to those persons responsibility
 3 for dispensing such drugs to individuals.

4 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
 5 TION.—

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

10 “(A) The drug is accompanied by a copy of
 11 a prescription for the drug, which prescrip-
 12 tion—

13 “(i) is valid under applicable Federal
 14 and State laws; and

15 “(ii) was issued by a practitioner who,
 16 under the law of a State of which the indi-
 17 vidual is a resident, or in which the indi-
 18 vidual receives care from the practitioner
 19 who issues the prescription, is authorized
 20 to administer prescription drugs.

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

1 “(C) The copies referred to in subpara-
2 graphs (A)(i) and (B) are marked in a manner
3 sufficient—

4 “(i) to indicate that the prescription,
5 and the equivalent document in the per-
6 mitted country in which the exporter is lo-
7 cated, have been filled; and

8 “(ii) to prevent a duplicative filling by
9 another pharmacist.

10 “(D) The individual has provided to the
11 registered exporter a complete list of all drugs
12 used by the individual for review by the individ-
13 uals who dispense the drug.

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

16 “(F) The drug is not an ineligible subpart
17 H drug. For purposes of this section, a pre-
18 scription drug is an ‘ineligible subpart H drug’
19 if the drug was approved by the Secretary
20 under subpart H of part 314 of title 21, Code
21 of Federal Regulations (relating to accelerated
22 approval), with restrictions under section 520 of
23 such part to assure safe use, and the Secretary
24 has published in the Federal Register a notice
25 that the Secretary has determined that good

1 cause exists to prohibit the drug from being im-
2 ported pursuant to this subsection.

3 “(2) NOTICE REGARDING DRUG REFUSED AD-
4 MISSION.—If a registered exporter ships a drug to
5 an individual pursuant to subsection (a)(2)(B) and
6 the drug is refused admission to the United States,
7 a written notice shall be sent to the individual and
8 to the exporter that informs the individual and the
9 exporter of such refusal and the reason for the re-
10 fusal.

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

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

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

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

19 “(2) PLACE OF RECORD MAINTENANCE.—The
20 records described under paragraph (1) shall be
21 maintained—

22 “(A) in the case of an importer, at the
23 place of business of the importer at which the
24 importer initially receives the qualifying drug
25 after importation; or

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

4 “(k) DRUG RECALLS.—

5 “(1) MANUFACTURERS.—A person that manu-
6 factures a qualifying drug imported from a per-
7 mitted country under this section shall promptly in-
8 form the Secretary—

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

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

13 “(C) the reason for the recall or with-
14 drawal.

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

17 “(A) enter into an agreement with the gov-
18 ernment of the country to receive information
19 about recalls and withdrawals of qualifying
20 drugs in the country; or

21 “(B) monitor recalls and withdrawals of
22 qualifying drugs in the country using any infor-
23 mation that is available to the public in any
24 media.

1 “(3) NOTICE.—The Secretary may notify, as
2 appropriate, registered exporters, registered import-
3 ers, wholesalers, pharmacies, or the public of a recall
4 or withdrawal of a qualifying drug in a permitted
5 country.

6 “(1) DRUG LABELING AND PACKAGING.—

7 “(1) IN GENERAL.—When a qualifying drug
8 that is imported into the United States by an im-
9 porter under subsection (a) is dispensed by a phar-
10 macist to an individual, the pharmacist shall provide
11 that the packaging and labeling of the drug complies
12 with all applicable regulations promulgated under
13 sections 3 and 4 of the Poison Prevention Packaging
14 Act of 1970 (15 U.S.C. 1471 et seq.) and shall in-
15 clude with any other labeling provided to the indi-
16 vidual the following:

17 “(A) The lot number assigned by the man-
18 ufacturer.

19 “(B) The name and registration number of
20 the importer.

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

1 “(D) If the inactive ingredients of the drug
2 are different from the inactive ingredients for
3 the U.S. label drug—

4 “(i) a prominent advisory that persons
5 with allergies should check the ingredient
6 list of the drug because the ingredients of
7 the drug differ from the ingredients of the
8 U.S. label drug; and

9 “(ii) a list of the ingredients of the
10 drug as would be required under section
11 502(e).

12 “(2) PACKAGING.—A qualifying drug that is
13 packaged in a unit-of-use container (as those terms
14 are defined in the United States Pharmacopeia and
15 National Formulary) shall not be repackaged, pro-
16 vided that—

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

21 “(B) the consumer consents to waive the
22 requirements of such Act, after being informed
23 that the packaging does not comply with such
24 Act and that the pharmacist will provide the

1 drug in packaging that is compliant at no addi-
2 tional cost.

3 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-
4 standing any other provision of this section, this section
5 does not authorize the importation into the United States
6 of a qualifying drug donated or otherwise supplied for free
7 or at nominal cost by the manufacturer of the drug to
8 a charitable or humanitarian organization, including the
9 United Nations and affiliates, or to a government of a for-
10 eign country.

11 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
12 TICES.—

13 “(1) IN GENERAL.—It is unlawful for a manu-
14 facturer, directly or indirectly (including by being a
15 party to a licensing agreement or other agreement),
16 to—

17 “(A) discriminate by charging a higher
18 price for a prescription drug sold to a registered
19 exporter or other person in a permitted country
20 that exports a qualifying drug to the United
21 States under this section than the price that is
22 charged, inclusive of rebates or other incentives
23 to the permitted country or other person, to an-
24 other person that is in the same country and

1 that does not export a qualifying drug into the
2 United States under this section;

3 “(B) discriminate by charging a higher
4 price for a prescription drug sold to a registered
5 importer or other person that distributes, sells,
6 or uses a qualifying drug imported into the
7 United States under this section than the price
8 that is charged to another person in the United
9 States that does not import a qualifying drug
10 under this section, or that does not distribute,
11 sell, or use such a drug;

12 “(C) discriminate by denying, restricting,
13 or delaying supplies of a prescription drug to a
14 registered exporter or other person in a per-
15 mitted country that exports a qualifying drug to
16 the United States under this section or to a
17 registered importer or other person that distrib-
18 utes, sells, or uses a qualifying drug imported
19 into the United States under this section;

20 “(D) discriminate by publicly, privately, or
21 otherwise refusing to do business with a reg-
22 istered exporter or other person in a permitted
23 country that exports a qualifying drug to the
24 United States under this section or with a reg-
25 istered importer or other person that distrib-

1 utes, sells, or uses a qualifying drug imported
2 into the United States under this section;

3 “(E) knowingly fail to submit a notice
4 under subsection (g)(2)(B)(i), knowingly fail to
5 submit such a notice on or before the date spec-
6 ified in subsection (g)(2)(B)(v) or as otherwise
7 required under subsection (e) (3), (4), and (5)
8 of section 4 of the Pharmaceutical Market Ac-
9 cess and Drug Safety Act of 2009, knowingly
10 submit such a notice that makes a materially
11 false, fictitious, or fraudulent statement, or
12 knowingly fail to provide promptly any informa-
13 tion requested by the Secretary to review such
14 a notice;

15 “(F) knowingly fail to submit an applica-
16 tion required under subsection (g)(2)(F), know-
17 ingly fail to submit such an application on or
18 before the date specified in subsection
19 (g)(2)(F)(ii), knowingly submit such an applica-
20 tion that makes a materially false, fictitious, or
21 fraudulent statement, or knowingly fail to pro-
22 vide promptly any information requested by the
23 Secretary to review such an application;

24 “(G) cause there to be a difference (includ-
25 ing a difference in active ingredient, route of

1 administration, dosage form, strength, formula-
2 tion, manufacturing establishment, manufac-
3 turing process, or person that manufactures the
4 drug) between a prescription drug for distribu-
5 tion in the United States and the drug for dis-
6 tribution in a permitted country;

7 “(H) refuse to allow an inspection author-
8 ized under this section of an establishment that
9 manufactures a qualifying drug that is, or will
10 be, introduced for commercial distribution in a
11 permitted country;

12 “(I) fail to conform to the methods used
13 in, or the facilities used for, the manufacturing,
14 processing, packing, or holding of a qualifying
15 drug that is, or will be, introduced for commer-
16 cial distribution in a permitted country to good
17 manufacturing practice under this Act;

18 “(J) become a party to a licensing agree-
19 ment or other agreement related to a qualifying
20 drug that fails to provide for compliance with
21 all requirements of this section with respect to
22 such drug;

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

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

4 “(M) engage in any other action that the
5 Federal Trade Commission determines to dis-
6 criminate against a person that engages or at-
7 tempts to engage in the importation of a quali-
8 fying drug under this section.

9 “(2) REFERRAL OF POTENTIAL VIOLATIONS.—
10 The Secretary shall promptly refer to the Federal
11 Trade Commission each potential violation of sub-
12 paragraph (E), (F), (G), (H), or (I) of paragraph
13 (1) that becomes known to the Secretary.

14 “(3) AFFIRMATIVE DEFENSE.—

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

1 “(i) the person exporting or importing
2 a qualifying drug into the United States
3 under this section; or

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

7 “(B) DRUG DIFFERENCES.—It shall be an
8 affirmative defense to a charge that a manufac-
9 turer has caused there to be a difference de-
10 scribed in subparagraph (G) of paragraph (1)
11 that—

12 “(i) the difference was required by the
13 country in which the drug is distributed;

14 “(ii) the Secretary has determined
15 that the difference was necessary to im-
16 prove the safety or effectiveness of the
17 drug;

18 “(iii) the person manufacturing the
19 drug for distribution in the United States
20 has given notice to the Secretary under
21 subsection (g)(2)(B)(i) that the drug for
22 distribution in the United States is not dif-
23 ferent from a drug for distribution in per-
24 mitted countries whose combined popu-
25 lation represents at least 50 percent of the

total population of all permitted countries;
or

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

“(4) EFFECT OF SUBSECTION.—

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

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

“(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the

Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

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

“(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

“(C) CHARITABLE CONTRIBUTIONS.—

Nothing in this subsection shall be construed to—

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

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

“(5) ENFORCEMENT.—

“(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be

1 treated as a violation of a rule defining an un-
 2 fair or deceptive act or practice prescribed
 3 under section 18(a)(1)(B) of the Federal Trade
 4 Commission Act (15 U.S.C. 57a(a)(1)(B)).

5 “(B) ACTIONS BY THE COMMISSION.—The
 6 Federal Trade Commission—

7 “(i) shall enforce this subsection in
 8 the same manner, by the same means, and
 9 with the same jurisdiction, powers, and du-
 10 ties as though all applicable terms and pro-
 11 visions of the Federal Trade Commission
 12 Act (15 U.S.C. 41 et seq.) were incor-
 13 porated into and made a part of this sec-
 14 tion; and

15 “(ii) may seek monetary relief three-
 16 fold the damages sustained, in addition to
 17 any other remedy available to the Federal
 18 Trade Commission under the Federal
 19 Trade Commission Act (15 U.S.C. 41 et
 20 seq.).

21 “(6) ACTIONS BY STATES.—

22 “(A) IN GENERAL.—

23 “(i) CIVIL ACTIONS.—In any case in
 24 which the attorney general of a State has
 25 reason to believe that an interest of the

1 residents of that State have been adversely
2 affected by any manufacturer that violates
3 paragraph (1), the attorney general of a
4 State may bring a civil action on behalf of
5 the residents of the State, and persons
6 doing business in the State, in a district
7 court of the United States of appropriate
8 jurisdiction to—

9 “(I) enjoin that practice;

10 “(II) enforce compliance with
11 this subsection;

12 “(III) obtain damages, restitu-
13 tion, or other compensation on behalf
14 of residents of the State and persons
15 doing business in the State, including
16 threefold the damages; or

17 “(IV) obtain such other relief as
18 the court may consider to be appro-
19 priate.

20 “(ii) NOTICE.—

21 “(I) IN GENERAL.—Before filing
22 an action under clause (i), the attor-
23 ney general of the State involved shall
24 provide to the Federal Trade Commis-
25 sion—

1 “(aa) written notice of that
2 action; and

3 “(bb) a copy of the com-
4 plaint for that action.

5 “(II) EXEMPTION.—Subclause
6 (I) shall not apply with respect to the
7 filing of an action by an attorney gen-
8 eral of a State under this paragraph,
9 if the attorney general determines
10 that it is not feasible to provide the
11 notice described in that subclause be-
12 fore filing of the action. In such case,
13 the attorney general of a State shall
14 provide notice and a copy of the com-
15 plaint to the Federal Trade Commis-
16 sion at the same time as the attorney
17 general files the action.

18 “(B) INTERVENTION.—

19 “(i) IN GENERAL.—On receiving no-
20 tice under subparagraph (A)(ii), the Fed-
21 eral Trade Commission shall have the right
22 to intervene in the action that is the sub-
23 ject of the notice.

24 “(ii) EFFECT OF INTERVENTION.—If
25 the Federal Trade Commission intervenes

1 in an action under subparagraph (A), it
2 shall have the right—

3 “(I) to be heard with respect to
4 any matter that arises in that action;
5 and

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

7 “(C) CONSTRUCTION.—For purposes of
8 bringing any civil action under subparagraph
9 (A), nothing in this subsection shall be con-
10 strued to prevent an attorney general of a State
11 from exercising the powers conferred on the at-
12 torney general by the laws of that State to—

13 “(i) conduct investigations;

14 “(ii) administer oaths or affirmations;

15 or

16 “(iii) compel the attendance of wit-
17 nesses or the production of documentary
18 and other evidence.

19 “(D) ACTIONS BY THE COMMISSION.—In
20 any case in which an action is instituted by or
21 on behalf of the Federal Trade Commission for
22 a violation of paragraph (1), a State may not,
23 during the pendency of that action, institute an
24 action under subparagraph (A) for the same

1 violation against any defendant named in the
2 complaint in that action.

3 “(E) VENUE.—Any action brought under
4 subparagraph (A) may be brought in the dis-
5 trict court of the United States that meets ap-
6 plicable requirements relating to venue under
7 section 1391 of title 28, United States Code.

8 “(F) SERVICE OF PROCESS.—In an action
9 brought under subparagraph (A), process may
10 be served in any district in which the defend-
11 ant—

12 “(i) is an inhabitant; or

13 “(ii) may be found.

14 “(G) MEASUREMENT OF DAMAGES.—In
15 any action under this paragraph to enforce a
16 cause of action under this subsection in which
17 there has been a determination that a defend-
18 ant has violated a provision of this subsection,
19 damages may be proved and assessed in the ag-
20 gregate by statistical or sampling methods, by
21 the computation of illegal overcharges or by
22 such other reasonable system of estimating ag-
23 gregate damages as the court in its discretion
24 may permit without the necessity of separately
25 proving the individual claim of, or amount of

1 damage to, persons on whose behalf the suit
2 was brought.

3 “(H) EXCLUSION ON DUPLICATIVE RE-
4 LIEF.—The district court shall exclude from the
5 amount of monetary relief awarded in an action
6 under this paragraph brought by the attorney
7 general of a State any amount of monetary re-
8 lief which duplicates amounts which have been
9 awarded for the same injury.

10 “(7) EFFECT ON ANTITRUST LAWS.—Nothing
11 in this subsection shall be construed to modify, im-
12 pair, or supersede the operation of the antitrust
13 laws. For the purpose of this subsection, the term
14 ‘antitrust laws’ has the meaning given it in the first
15 section of the Clayton Act, except that it includes
16 section 5 of the Federal Trade Commission Act to
17 the extent that such section 5 applies to unfair
18 methods of competition.

19 “(8) MANUFACTURER.—In this subsection, the
20 term ‘manufacturer’ means any entity, including any
21 affiliate or licensee of that entity, that is engaged
22 in—

23 “(A) the production, preparation, propaga-
24 tion, compounding, conversion, or processing of
25 a prescription drug, either directly or indirectly

1 by extraction from substances of natural origin,
 2 or independently by means of chemical syn-
 3 thesis, or by a combination of extraction and
 4 chemical synthesis; or

5 “(B) the packaging, repackaging, labeling,
 6 relabeling, or distribution of a prescription
 7 drug.”.

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

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

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

16 “(A) a sale at retail made pursuant to dis-
 17 pensing the drug to a customer of the pharmacist or
 18 organization; or

19 “(B) a sale or trade of the drug to a pharmacy
 20 or a wholesaler registered to import drugs under sec-
 21 tion 804.

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

1 “(3) The making of a materially false, fictitious, or
2 fraudulent statement or representation, or a material
3 omission, in a notice under clause (i) of section
4 804(g)(2)(B) or in an application required under section
5 804(g)(2)(F), or the failure to submit such a notice or
6 application.

7 “(4) The importation of a drug in violation of a reg-
8 istration condition or other requirement under section
9 804, the falsification of any record required to be main-
10 tained, or provided to the Secretary, under such section,
11 or the violation of any registration condition or other re-
12 quirement under such section.”; and

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

15 “(6) Notwithstanding subsection (a), any person that
16 knowingly violates section 301(i) (2) or (3) or section
17 301(aa)(4) shall be imprisoned not more than 10 years,
18 or fined in accordance with title 18, United States Code,
19 or both.”.

20 (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

1 “(g) With respect to a prescription drug that is im-
2 ported or offered for import into the United States by an
3 individual who is not in the business of such importation,
4 that is not shipped by a registered exporter under section
5 804, and that is refused admission under subsection (a),
6 the Secretary shall notify the individual that—

7 “(1) the drug has been refused admission be-
8 cause the drug was not a lawful import under sec-
9 tion 804;

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

12 “(3) the individual may under section 804 law-
13 fully import certain prescription drugs from export-
14 ers registered with the Secretary under section 804;
15 and

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

21 (2) ESTABLISHMENT REGISTRATION.—Section
22 510(i) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 360(i)) is amended in paragraph (1) by
24 inserting after “import into the United States” the
25 following: “, including a drug that is, or may be, im-

1 ported or offered for import into the United States
2 under section 804,”.

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

6 (d) EXHAUSTION.—

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

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

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

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

19 (2) RULE OF CONSTRUCTION.—Nothing in the
20 amendment made by paragraph (1) shall be con-
21 strued to affect the ability of a patent owner or li-
22 censee to enforce their patent, subject to such
23 amendment.

24 (e) EFFECT OF SECTION 804.—

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

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

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

14 (2) REVIEW OF REGISTRATION BY CERTAIN EX-
15 PORTERS.—

16 (A) REVIEW PRIORITY.—In the review of
17 registrations submitted under subsection (b) of
18 such section 804, registrations submitted by en-
19 tities in Canada that are significant exporters
20 of prescription drugs to individuals in the
21 United States as of the date of enactment of
22 this Act will have priority during the 90-day pe-
23 riod that begins on such date of enactment.

24 (B) PERIOD FOR REVIEW.—During such
25 90-day period, the reference in subsection

1 (b)(2)(A) of such section 804 to 90 days (relat-
2 ing to approval or disapproval of registrations)
3 is, as applied to such entities, deemed to be 30
4 days.

5 (C) LIMITATION.—That an exporter in
6 Canada exports, or has exported, prescription
7 drugs to individuals in the United States on or
8 before the date that is 90 days after the date
9 of enactment of this Act shall not serve as a
10 basis, in whole or in part, for disapproving a
11 registration under such section 804 from the
12 exporter.

13 (D) FIRST YEAR LIMIT ON NUMBER OF
14 EXPORTERS.—During the 1-year period begin-
15 ning on the date of enactment of this Act, the
16 Secretary of Health and Human Services (re-
17 ferred to in this section as the “Secretary”)
18 may limit the number of registered exporters
19 under such section 804 to not less than 50, so
20 long as the Secretary gives priority to those ex-
21 porters with demonstrated ability to process a
22 high volume of shipments of drugs to individ-
23 uals in the United States.

24 (E) SECOND YEAR LIMIT ON NUMBER OF
25 EXPORTERS.—During the 1-year period begin-

1 ning on the date that is 1 year after the date
2 of enactment of this Act, the Secretary may
3 limit the number of registered exporters under
4 such section 804 to not less than 100, so long
5 as the Secretary gives priority to those export-
6 ers with demonstrated ability to process a high
7 volume of shipments of drugs to individuals in
8 the United States.

9 (F) FURTHER LIMIT ON NUMBER OF EX-
10 PORTERS.—During any 1-year period beginning
11 on a date that is 2 or more years after the date
12 of enactment of this Act, the Secretary may
13 limit the number of registered exporters under
14 such section 804 to not less than 25 more than
15 the number of such exporters during the pre-
16 vious 1-year period, so long as the Secretary
17 gives priority to those exporters with dem-
18 onstrated ability to process a high volume of
19 shipments of drugs to individuals in the United
20 States.

21 (3) LIMITS ON NUMBER OF IMPORTERS.—

22 (A) FIRST YEAR LIMIT ON NUMBER OF IM-
23 PORTERS.—During the 1-year period beginning
24 on the date that is 1 year after the date of en-
25 actment of this Act, the Secretary may limit the

1 number of registered importers under such sec-
2 tion 804 to not less than 100 (of which at least
3 a significant number shall be groups of phar-
4 macies, to the extent feasible given the applica-
5 tions submitted by such groups), so long as the
6 Secretary gives priority to those importers with
7 demonstrated ability to process a high volume
8 of shipments of drugs imported into the United
9 States.

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

23 (C) FURTHER LIMIT ON NUMBER OF IM-
24 PORTERS.—During any 1-year period beginning
25 on a date that is 3 or more years after the date

1 of enactment of this Act, the Secretary may
2 limit the number of registered importers under
3 such section 804 to not less than 50 more (of
4 which at least a significant number shall be
5 groups of pharmacies, to the extent feasible
6 given the applications submitted by such
7 groups) than the number of such importers
8 during the previous 1-year period, so long as
9 the Secretary gives priority to those importers
10 with demonstrated ability to process a high vol-
11 ume of shipments of drugs to the United
12 States.

13 (4) NOTICES FOR DRUGS FOR IMPORT FROM
14 CANADA.—The notice with respect to a qualifying
15 drug introduced for commercial distribution in Can-
16 ada as of the date of enactment of this Act that is
17 required under subsection (g)(2)(B)(i) of such sec-
18 tion 804 shall be submitted to the Secretary not
19 later than 30 days after the date of enactment of
20 this Act if—

21 (A) the U.S. label drug (as defined in such
22 section 804) for the qualifying drug is 1 of the
23 100 prescription drugs with the highest dollar
24 volume of sales in the United States based on
25 the 12 calendar month period most recently

1 completed before the date of enactment of this
 2 Act; or

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

5 (5) NOTICE FOR DRUGS FOR IMPORT FROM
 6 OTHER COUNTRIES.—The notice with respect to a
 7 qualifying drug introduced for commercial distribu-
 8 tion in a permitted country other than Canada as of
 9 the date of enactment of this Act that is required
 10 under subsection (g)(2)(B)(i) of such section 804
 11 shall be submitted to the Secretary not later than
 12 180 days after the date of enactment of this Act
 13 if—

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

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

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

23 (A) GUIDANCE ON SUBMISSION DATES.—
 24 The Secretary shall by guidance establish a se-
 25 ries of submission dates for the notices under

1 subsection (g)(2)(B)(i) of such section 804 with
2 respect to qualifying drugs introduced for com-
3 mercial distribution as of the date of enactment
4 of this Act and that are not required to be sub-
5 mitted under paragraph (4) or (5).

6 (B) CONSISTENT AND EFFICIENT USE OF
7 RESOURCES.—The Secretary shall establish the
8 dates described under subparagraph (A) so that
9 such notices described under subparagraph (A)
10 are submitted and reviewed at a rate that al-
11 lows consistent and efficient use of the re-
12 sources and staff available to the Secretary for
13 such reviews. The Secretary may condition the
14 requirement to submit such a notice, and the
15 review of such a notice, on the submission by a
16 registered exporter or a registered importer to
17 the Secretary of a notice that such exporter or
18 importer intends to import such qualifying drug
19 to the United States under such section 804.

20 (C) PRIORITY FOR DRUGS WITH HIGHER
21 SALES.—The Secretary shall establish the dates
22 described under subparagraph (A) so that the
23 Secretary reviews the notices described under
24 such subparagraph with respect to qualifying
25 drugs with higher dollar volume of sales in the

1 United States before the notices with respect to
2 drugs with lower sales in the United States.

3 (7) NOTICES FOR DRUGS APPROVED AFTER EF-
4 FECTIVE DATE.—The notice required under sub-
5 section (g)(2)(B)(i) of such section 804 for a quali-
6 fying drug first introduced for commercial distribu-
7 tion in a permitted country (as defined in such sec-
8 tion 804) after the date of enactment of this Act
9 shall be submitted to and reviewed by the Secretary
10 as provided under subsection (g)(2)(B) of such sec-
11 tion 804, without regard to paragraph (4), (5), or
12 (6).

13 (8) REPORT.—Beginning with the first full fis-
14 cal year after the date of enactment of this Act, not
15 later than 90 days after the end of each fiscal year
16 during which the Secretary reviews a notice referred
17 to in paragraph (4), (5), or (6), the Secretary shall
18 submit a report to Congress concerning the progress
19 of the Food and Drug Administration in reviewing
20 the notices referred to in paragraphs (4), (5), and
21 (6).

22 (9) USER FEES.—

23 (A) EXPORTERS.—When establishing an
24 aggregate total of fees to be collected from ex-
25 porters under subsection (f)(2) of such section

1 804, the Secretary shall, under subsection
2 (f)(3)(C)(i) of such section 804, estimate the
3 total price of drugs imported under subsection
4 (a) of such section 804 into the United States
5 by registered exporters during the first fiscal
6 year in which this Act takes effect to be an
7 amount equal to the amount which bears the
8 same ratio to \$1,000,000,000 as the number of
9 days in such fiscal year during which this Act
10 is effective bears to 365.

11 (B) IMPORTERS.—When establishing an
12 aggregate total of fees to be collected from im-
13 porters under subsection (e)(2) of such section
14 804, the Secretary shall, under subsection
15 (e)(3)(C)(i) of such section 804, estimate the
16 total price of drugs imported under subsection
17 (a) of such section 804 into the United States
18 by registered importers during—

19 (i) the first fiscal year in which this
20 Act takes effect to be an amount equal to
21 the amount which bears the same ratio to
22 \$1,000,000,000 as the number of days in
23 such fiscal year during which this Act is
24 effective bears to 365; and

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

3 (C) SECOND YEAR ADJUSTMENT.—

4 (i) REPORTS.—Not later than Feb-
5 ruary 20 of the second fiscal year in which
6 this Act is in effect, registered importers
7 shall report to the Secretary the total price
8 and the total volume of drugs imported to
9 the United States by the importer during
10 the 4-month period from October 1
11 through January 31 of such fiscal year.

12 (ii) REESTIMATE.—Notwithstanding
13 subsection (e)(3)(C)(ii) of such section 804
14 or subparagraph (B), the Secretary shall
15 reestimate the total price of qualifying
16 drugs imported under subsection (a) of
17 such section 804 into the United States by
18 registered importers during the second fis-
19 cal year in which this Act is in effect. Such
20 reestimate shall be equal to—

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

25 (II) 3.

1 (iii) ADJUSTMENT.—The Secretary
2 shall adjust the fee due on April 1 of the
3 second fiscal year in which this Act is in
4 effect, from each importer so that the ag-
5 gregate total of fees collected under sub-
6 section (e)(2) for such fiscal year does not
7 exceed the total price of qualifying drugs
8 imported under subsection (a) of such sec-
9 tion 804 into the United States by reg-
10 istered importers during such fiscal year as
11 reestimated under clause (ii).

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

21 (E) ANNUAL REPORT.—

22 (i) FOOD AND DRUG ADMINISTRA-
23 TION.—Not later than 180 days after the
24 end of each fiscal year during which fees
25 are collected under subsection (e), (f), or

1 (g)(2)(B)(iv) of such section 804, the Sec-
2 retary shall prepare and submit to the
3 House of Representatives and the Senate a
4 report on the implementation of the au-
5 thority for such fees during such fiscal
6 year and the use, by the Food and Drug
7 Administration, of the fees collected for the
8 fiscal year for which the report is made
9 and credited to the Food and Drug Admin-
10 istration.

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

1 (10) SPECIAL RULE REGARDING IMPORTATION
2 BY INDIVIDUALS.—

3 (A) IN GENERAL.—Notwithstanding any
4 provision of this Act (or an amendment made
5 by this Act), the Secretary shall expedite the
6 designation of any additional countries from
7 which an individual may import a qualifying
8 drug into the United States under such section
9 804 if any action implemented by the Govern-
10 ment of Canada has the effect of limiting or
11 prohibiting the importation of qualifying drugs
12 into the United States from Canada.

13 (B) TIMING AND CRITERIA.—The Sec-
14 retary shall designate such additional countries
15 under subparagraph (A)—

16 (i) not later than 6 months after the
17 date of the action by the Government of
18 Canada described under such subpara-
19 graph; and

20 (ii) using the criteria described under
21 subsection (a)(4)(D)(i)(II) of such section
22 804.

23 (f) IMPLEMENTATION OF SECTION 804.—

24 (1) INTERIM RULE.—The Secretary may pro-
25 mulgate an interim rule for implementing section

1 804 of the Federal Food, Drug, and Cosmetic Act,
2 as added by subsection (a) of this section.

3 (2) NO NOTICE OF PROPOSED RULEMAKING.—

4 The interim rule described under paragraph (1) may
5 be developed and promulgated by the Secretary with-
6 out providing general notice of proposed rulemaking.

7 (3) FINAL RULE.—Not later than 1 year after
8 the date on which the Secretary promulgates an in-
9 terim rule under paragraph (1), the Secretary shall,
10 in accordance with procedures under section 553 of
11 title 5, United States Code, promulgate a final rule
12 for implementing such section 804, which may incor-
13 porate by reference provisions of the interim rule
14 provided for under paragraph (1), to the extent that
15 such provisions are not modified.

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

18 (1) with regard to the availability of qualifying
19 drugs for import for personal use from an exporter
20 registered with and approved by the Food and Drug
21 Administration under section 804 of the Federal
22 Food, Drug, and Cosmetic Act, as added by this sec-
23 tion, including information on how to verify whether
24 an exporter is registered and approved by use of the
25 Internet website of the Food and Drug Administra-

1 tion and the toll-free telephone number required by
2 this Act;

3 (2) that drugs that consumers attempt to im-
4 port from an exporter that is not registered with and
5 approved by the Food and Drug Administration can
6 be seized by the United States Customs Service and
7 destroyed, and that such drugs may be counterfeit,
8 unapproved, unsafe, or ineffective;

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

12 (4) with regard to the availability at domestic
13 retail pharmacies of qualifying drugs imported under
14 such section 804 by domestic wholesalers and phar-
15 macies registered with and approved by the Food
16 and Drug Administration.

17 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-
18 withstanding any provision of this Act (and the amend-
19 ments made by this Act), the practices and policies of the
20 Food and Drug Administration and Bureau of Customs
21 and Border Protection, in effect on January 1, 2004, with
22 respect to the importation of prescription drugs into the
23 United States by an individual, on the person of such indi-
24 vidual, for personal use, shall remain in effect.

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

8 **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
 9 **SION INTO UNITED STATES.**

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

14 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
 15 **MISSION.**

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

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

22 “(2)(A) the shipping container for such drugs
 23 does not bear the markings required under section
 24 804(d)(2); or

1 “(B) the Secretary has requested delivery of
2 such shipment of drugs.

3 “(b) NO BOND OR EXPORT.—Section 801(b) does
4 not authorize the delivery to the owner or consignee of
5 drugs delivered to the Secretary under subsection (a) pur-
6 suant to the execution of a bond, and such drugs may not
7 be exported.

8 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
9 Secretary shall destroy a shipment of drugs delivered by
10 the Secretary of Homeland Security to the Secretary
11 under subsection (a) if—

12 “(1) in the case of drugs that are imported or
13 offered for import from a registered exporter under
14 section 804, the drugs are in violation of any stand-
15 ard described in section 804(g)(5); or

16 “(2) in the case of drugs that are not imported
17 or offered for import from a registered exporter
18 under section 804, the drugs are in violation of a
19 standard referred to in section 801(a) or 801(d)(1).

20 “(d) CERTAIN PROCEDURES.—

21 “(1) IN GENERAL.—The delivery and destruc-
22 tion of drugs under this section may be carried out
23 without notice to the importer, owner, or consignee
24 of the drugs except as required by section 801(g) or
25 section 804(i)(2). The issuance of receipts for the

1 drugs, and recordkeeping activities regarding the
2 drugs, may be carried out on a summary basis.

3 “(2) OBJECTIVE OF PROCEDURES.—Procedures
4 promulgated under paragraph (1) shall be designed
5 toward the objective of ensuring that, with respect to
6 efficiently utilizing Federal resources available for
7 carrying out this section, a substantial majority of
8 shipments of drugs subject to described in sub-
9 section (c) are identified and destroyed.

10 “(e) EVIDENCE EXCEPTION.—Drugs may not be de-
11 stroyed under subsection (c) to the extent that the Attor-
12 ney General of the United States determines that the
13 drugs should be preserved as evidence or potential evi-
14 dence with respect to an offense against the United States.

15 “(f) RULE OF CONSTRUCTION.—This section may
16 not be construed as having any legal effect on applicable
17 law with respect to a shipment of drugs that is imported
18 or offered for import into the United States and has a
19 declared value equal to or greater than \$10,000.”.

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

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

4 **SEC. 6. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
 5 **MENTS REGARDING PRIOR SALE, PURCHASE,**
 6 **OR TRADE.**

7 (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO
 8 REGISTERED EXPORTERS.—Section 503(e) of the Federal
 9 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is
 10 amended—

11 (1) in paragraph (1)—

12 (A) by striking “and who is not the manu-
 13 facturer or an authorized distributor of record
 14 of such drug”;

15 (B) by striking “to an authorized dis-
 16 tributor of record or”; and

17 (C) by striking subparagraph (B) and in-
 18 serting the following:

19 “(B) The fact that a drug subject to subsection (b)
 20 is exported from the United States does not with respect
 21 to such drug exempt any person that is engaged in the
 22 business of the wholesale distribution of the drug from
 23 providing the statement described in subparagraph (A) to
 24 the person that receives the drug pursuant to the export
 25 of the drug.

1 “(C)(i) The Secretary shall by regulation establish re-
 2 quirements that supersede subparagraph (A) (referred to
 3 in this subparagraph as ‘alternative requirements’) to
 4 identify the chain of custody of a drug subject to sub-
 5 section (b) from the manufacturer of the drug throughout
 6 the wholesale distribution of the drug to a pharmacist who
 7 intends to sell the drug at retail if the Secretary deter-
 8 mines that the alternative requirements, which may in-
 9 clude standardized anti-counterfeiting or track-and-trace
 10 technologies, will identify such chain of custody or the
 11 identity of the discrete package of the drug from which
 12 the drug is dispensed with equal or greater certainty to
 13 the requirements of subparagraph (A), and that the alter-
 14 native requirements are economically and technically fea-
 15 sible.

16 “(ii) When the Secretary promulgates a final rule to
 17 establish such alternative requirements, the final rule in
 18 addition shall, with respect to the registration condition
 19 established in clause (i) of section 804(c)(3)(B), establish
 20 a condition equivalent to the alternative requirements, and
 21 such equivalent condition may be met in lieu of the reg-
 22 istration condition established in such clause (i).”;

23 (2) in paragraph (2)(A), by adding at the end
 24 the following: “The preceding sentence may not be

1 construed as having any applicability with respect to
 2 a registered exporter under section 804.”; and

3 (3) in paragraph (3), by striking “and sub-
 4 section (d)—” in the matter preceding subparagraph
 5 (A) and all that follows through “the term ‘whole-
 6 sale distribution’ means” in subparagraph (B) and
 7 inserting the following: “and subsection (d), the
 8 term ‘wholesale distribution’ means”.

9 (b) CONFORMING AMENDMENT.—Section 503(d) of
 10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 11 353(d)) is amended by adding at the end the following:

12 “(4) Each manufacturer of a drug subject to sub-
 13 section (b) shall maintain at its corporate offices a current
 14 list of the authorized distributors of record of such drug.

15 “(5) For purposes of this subsection, the term ‘au-
 16 thorized distributors of record’ means those distributors
 17 with whom a manufacturer has established an ongoing re-
 18 lationship to distribute such manufacturer’s products.”.

19 (c) EFFECTIVE DATE.—

20 (1) IN GENERAL.—The amendments made by
 21 paragraphs (1) and (3) of subsection (a) and by sub-
 22 section (b) shall take effect on January 1, 2012.

23 (2) DRUGS IMPORTED BY REGISTERED IMPORT-
 24 ERS UNDER SECTION 804.—Notwithstanding para-
 25 graph (1), the amendments made by paragraphs (1)

1 and (3) of subsection (a) and by subsection (b) shall
2 take effect on the date that is 90 days after the date
3 of enactment of this Act with respect to qualifying
4 drugs imported under section 804 of the Federal
5 Food, Drug, and Cosmetic Act, as added by section
6 4.

7 (3) EFFECT WITH RESPECT TO REGISTERED
8 EXPORTERS.—The amendment made by subsection
9 (a)(2) shall take effect on the date that is 90 days
10 after the date of enactment of this Act.

11 (4) ALTERNATIVE REQUIREMENTS.—The Sec-
12 retary shall issue regulations to establish the alter-
13 native requirements, referred to in the amendment
14 made by subsection (a)(1), that take effect not later
15 than January 1, 2012.

16 (5) INTERMEDIATE REQUIREMENTS.—The Sec-
17 retary shall by regulation require the use of stand-
18 ardized anti-counterfeiting or track-and-trace tech-
19 nologies on prescription drugs at the case and pallet
20 level effective not later than 1 year after the date of
21 enactment of this Act.

22 (6) ADDITIONAL REQUIREMENTS.—

23 (A) IN GENERAL.—Notwithstanding any
24 other provision of this section, the Secretary
25 shall, not later than 18 months after the date

1 of enactment of this Act, require that the pack-
2 aging of any prescription drug incorporates—

3 (i) a standardized numerical identifier
4 unique to each package of such drug, ap-
5 plied at the point of manufacturing and re-
6 packaging (in which case the numerical
7 identifier shall be linked to the numerical
8 identifier applied at the point of manufac-
9 turing); and

10 (ii)(I) overt optically variable counter-
11 feit-resistant technologies that—

12 (aa) are visible to the naked eye,
13 providing for visual identification of
14 product authenticity without the need
15 for readers, microscopes, lighting de-
16 vices, or scanners;

17 (bb) are similar to that used by
18 the Bureau of Engraving and Printing
19 to secure United States currency;

20 (cc) are manufactured and dis-
21 tributed in a highly secure, tightly
22 controlled environment; and

23 (dd) incorporate additional layers
24 of nonvisible covert security features
25 up to and including forensic capa-

1 bility, as described in subparagraph
2 (B); or

3 (II) technologies that have a function
4 of security comparable to that described in
5 subclause (I), as determined by the Sec-
6 retary.

7 (B) STANDARDS FOR PACKAGING.—For
8 the purpose of making it more difficult to coun-
9 terfeit the packaging of drugs subject to this
10 paragraph, the manufacturers of such drugs
11 shall incorporate the technologies described in
12 subparagraph (A) into at least 1 additional ele-
13 ment of the physical packaging of the drugs, in-
14 cluding blister packs, shrink wrap, package la-
15 bels, package seals, bottles, and boxes.

16 **SEC. 7. INTERNET SALES OF PRESCRIPTION DRUGS.**

17 (a) IN GENERAL.—Chapter V of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
19 ed by inserting after section 503B the following:

20 **“SEC. 503C. INTERNET SALES OF PRESCRIPTION DRUGS.**

21 “(a) REQUIREMENTS REGARDING INFORMATION ON
22 INTERNET SITE.—

23 “(1) IN GENERAL.—A person may not dispense
24 a prescription drug pursuant to a sale of the drug
25 by such person if—

1 “(A) the purchaser of the drug submitted
2 the purchase order for the drug, or conducted
3 any other part of the sales transaction for the
4 drug, through an Internet site;

5 “(B) the person dispenses the drug to the
6 purchaser by mailing or shipping the drug to
7 the purchaser; and

8 “(C) such site, or any other Internet site
9 used by such person for purposes of sales of a
10 prescription drug, fails to meet each of the re-
11 quirements specified in paragraph (2), other
12 than a site or pages on a site that—

13 “(i) are not intended to be accessed
14 by purchasers or prospective purchasers; or

15 “(ii) provide an Internet information
16 location tool within the meaning of section
17 231(e)(5) of the Communications Act of
18 1934 (47 U.S.C. 231(e)(5)).

19 “(2) REQUIREMENTS.—With respect to an
20 Internet site, the requirements referred to in sub-
21 paragraph (C) of paragraph (1) for a person to
22 whom such paragraph applies are as follows:

23 “(A) Each page of the site shall include ei-
24 ther the following information or a link to a
25 page that provides the following information:

1 “(i) The name of such person.

2 “(ii) Each State in which the person
3 is authorized by law to dispense prescrip-
4 tion drugs.

5 “(iii) The address and telephone num-
6 ber of each place of business of the person
7 with respect to sales of prescription drugs
8 through the Internet, other than a place of
9 business that does not mail or ship pre-
10 scription drugs to purchasers.

11 “(iv) The name of each individual who
12 serves as a pharmacist for prescription
13 drugs that are mailed or shipped pursuant
14 to the site, and each State in which the in-
15 dividual is authorized by law to dispense
16 prescription drugs.

17 “(v) If the person provides for medical
18 consultations through the site for purposes
19 of providing prescriptions, the name of
20 each individual who provides such con-
21 sultations; each State in which the indi-
22 vidual is licensed or otherwise authorized
23 by law to provide such consultations or
24 practice medicine; and the type or types of

1 health professions for which the individual
 2 holds such licenses or other authorizations.

3 “(B) A link to which paragraph (1) applies
 4 shall be displayed in a clear and prominent
 5 place and manner, and shall include in the cap-
 6 tion for the link the words ‘licensing and con-
 7 tact information’.

8 “(b) INTERNET SALES WITHOUT APPROPRIATE
 9 MEDICAL RELATIONSHIPS.—

10 “(1) IN GENERAL.—Except as provided in para-
 11 graph (2), a person may not dispense a prescription
 12 drug, or sell such a drug, if—

13 “(A) for purposes of such dispensing or
 14 sale, the purchaser communicated with the per-
 15 son through the Internet;

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

20 “(C) pursuant to such communications, the
 21 person provided for the involvement of a practi-
 22 tioner, or an individual represented by the per-
 23 son as a practitioner, and the practitioner or
 24 such individual issued a prescription for the
 25 drug that was purchased;

1 “(D) the person knew, or had reason to
 2 know, that the practitioner or the individual re-
 3 ferred to in subparagraph (C) did not, when
 4 issuing the prescription, have a qualifying med-
 5 ical relationship with the patient; and

6 “(E) the person received payment for the
 7 dispensing or sale of the drug.

8 For purposes of subparagraph (E), payment is re-
 9 ceived if money or other valuable consideration is re-
 10 ceived.

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

13 “(A) the dispensing or selling of a pre-
 14 scription drug pursuant to telemedicine prac-
 15 tices sponsored by—

16 “(i) a hospital that has in effect a
 17 provider agreement under title XVIII of
 18 the Social Security Act (relating to the
 19 Medicare program); or

20 “(ii) a group practice that has not
 21 fewer than 100 physicians who have in ef-
 22 fect provider agreements under such title;
 23 or

24 “(B) the dispensing or selling of a pre-
 25 scription drug pursuant to practices that pro-

1 mote the public health, as determined by the
2 Secretary by regulation.

3 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

4 “(A) IN GENERAL.—With respect to
5 issuing a prescription for a drug for a patient,
6 a practitioner has a qualifying medical relation-
7 ship with the patient for purposes of this sec-
8 tion if—

9 “(i) at least one in-person medical
10 evaluation of the patient has been con-
11 ducted by the practitioner; or

12 “(ii) the practitioner conducts a med-
13 ical evaluation of the patient as a covering
14 practitioner.

15 “(B) IN-PERSON MEDICAL EVALUATION.—

16 A medical evaluation by a practitioner is an in-
17 person medical evaluation for purposes of this
18 section if the practitioner is in the physical
19 presence of the patient as part of conducting
20 the evaluation, without regard to whether por-
21 tions of the evaluation are conducted by other
22 health professionals.

23 “(C) COVERING PRACTITIONER.—With re-
24 spect to a patient, a practitioner is a covering
25 practitioner for purposes of this section if the

practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

“(4) RULES OF CONSTRUCTION.—

“(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

“(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

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

1 “(c) ACTIONS BY STATES.—

2 “(1) IN GENERAL.—Whenever an attorney gen-
3 eral of any State has reason to believe that the in-
4 terests of the residents of that State have been or
5 are being threatened or adversely affected because
6 any person has engaged or is engaging in a pattern
7 or practice that violates section 301(l), the State
8 may bring a civil action on behalf of its residents in
9 an appropriate district court of the United States to
10 enjoin such practice, to enforce compliance with such
11 section (including a nationwide injunction), to obtain
12 damages, restitution, or other compensation on be-
13 half of residents of such State, to obtain reasonable
14 attorneys fees and costs if the State prevails in the
15 civil action, or to obtain such further and other relief
16 as the court may deem appropriate.

17 “(2) NOTICE.—The State shall serve prior writ-
18 ten notice of any civil action under paragraph (1) or
19 (5)(B) upon the Secretary and provide the Secretary
20 with a copy of its complaint, except that if it is not
21 feasible for the State to provide such prior notice,
22 the State shall serve such notice immediately upon
23 instituting such action. Upon receiving a notice re-
24 specting a civil action, the Secretary shall have the
25 right—

1 “(A) to intervene in such action;

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

4 “(C) to file petitions for appeal.

5 “(3) CONSTRUCTION.—For purposes of bring-
6 ing any civil action under paragraph (1), nothing in
7 this chapter shall prevent an attorney general of a
8 State from exercising the powers conferred on the
9 attorney general by the laws of such State to con-
10 duct investigations or to administer oaths or affir-
11 mations or to compel the attendance of witnesses or
12 the production of documentary and other evidence.

13 “(4) VENUE; SERVICE OF PROCESS.—Any civil
14 action brought under paragraph (1) in a district
15 court of the United States may be brought in the
16 district in which the defendant is found, is an inhab-
17 itant, or transacts business or wherever venue is
18 proper under section 1391 of title 28, United States
19 Code. Process in such an action may be served in
20 any district in which the defendant is an inhabitant
21 or in which the defendant may be found.

22 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

23 “(A) Nothing contained in this section
24 shall prohibit an authorized State official from
25 proceeding in State court on the basis of an al-

1 leged violation of any civil or criminal statute of
2 such State.

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

9 “(d) EFFECT OF SECTION.—This section shall not
10 apply to a person that is a registered exporter under sec-
11 tion 804.

12 “(e) GENERAL DEFINITIONS.—For purposes of this
13 section:

14 “(1) The term ‘practitioner’ means a practi-
15 tioner referred to in section 503(b)(1) with respect
16 to issuing a written or oral prescription.

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

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

22 “(f) INTERNET-RELATED DEFINITIONS.—

23 “(1) IN GENERAL.—For purposes of this sec-
24 tion:

1 “(A) The term ‘Internet’ means collectively
2 the myriad of computer and telecommunications
3 facilities, including equipment and operating
4 software, which comprise the interconnected
5 world-wide network of networks that employ the
6 transmission control protocol/internet protocol,
7 or any predecessor or successor protocols to
8 such protocol, to communicate information of
9 all kinds by wire or radio.

10 “(B) The term ‘link’, with respect to the
11 Internet, means one or more letters, words,
12 numbers, symbols, or graphic items that appear
13 on a page of an Internet site for the purpose
14 of serving, when activated, as a method for exe-
15 cuting an electronic command—

16 “(i) to move from viewing one portion
17 of a page on such site to another portion
18 of the page;

19 “(ii) to move from viewing one page
20 on such site to another page on such site;
21 or

22 “(iii) to move from viewing a page on
23 one Internet site to a page on another
24 Internet site.

1 “(C) The term ‘page’, with respect to the
2 Internet, means a document or other file
3 accessed at an Internet site.

4 “(D)(i) The terms ‘site’ and ‘address’, with
5 respect to the Internet, mean a specific location
6 on the Internet that is determined by Internet
7 Protocol numbers. Such term includes the do-
8 main name, if any.

9 “(ii) The term ‘domain name’ means a
10 method of representing an Internet address
11 without direct reference to the Internet Protocol
12 numbers for the address, including methods
13 that use designations such as ‘.com’, ‘.edu’,
14 ‘.gov’, ‘.net’, or ‘.org’.

15 “(iii) The term ‘Internet Protocol num-
16 bers’ includes any successor protocol for deter-
17 mining a specific location on the Internet.

18 “(2) AUTHORITY OF SECRETARY.—The Sec-
19 retary may by regulation modify any definition
20 under paragraph (1) to take into account changes in
21 technology.

22 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
23 TISING.—No provider of an interactive computer service,
24 as defined in section 230(f)(2) of the Communications Act
25 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services

1 shall be liable under this section for dispensing or selling
 2 prescription drugs in violation of this section on account
 3 of another person's selling or dispensing such drugs, pro-
 4 vided that the provider of the interactive computer service
 5 or of advertising services does not own or exercise cor-
 6 porate control over such person.”.

7 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
 8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 9 331) is amended by inserting after paragraph (k) the fol-
 10 lowing:

11 “(l) The dispensing or selling of a prescription drug
 12 in violation of section 503C.”.

13 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
 14 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
 15 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
 16 NESSES.—In carrying out section 503C of the Federal
 17 Food, Drug, and Cosmetic Act (as added by subsection
 18 (a) of this section), the Secretary of Health and Human
 19 Services shall take into consideration the practices and
 20 procedures of public or private entities that certify that
 21 businesses selling prescription drugs through Internet
 22 sites are legitimate businesses, including practices and
 23 procedures regarding disclosure formats and verification
 24 programs.

1 (d) REPORTS REGARDING INTERNET-RELATED VIO-
 2 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
 3 OF DRUGS.—

4 (1) IN GENERAL.—The Secretary of Health and
 5 Human Services (referred to in this subsection as
 6 the “Secretary”) shall, pursuant to the submission
 7 of an application meeting the criteria of the Sec-
 8 retary, make an award of a grant or contract to the
 9 National Clearinghouse on Internet Prescribing (op-
 10 erated by the Federation of State Medical Boards)
 11 for the purpose of—

12 (A) identifying Internet sites that appear
 13 to be in violation of Federal or State laws con-
 14 cerning the dispensing of drugs;

15 (B) reporting such sites to State medical
 16 licensing boards and State pharmacy licensing
 17 boards, and to the Attorney General and the
 18 Secretary, for further investigation; and

19 (C) submitting, for each fiscal year for
 20 which the award under this subsection is made,
 21 a report to the Secretary describing investiga-
 22 tions undertaken with respect to violations de-
 23 scribed in subparagraph (A).

24 (2) AUTHORIZATION OF APPROPRIATIONS.—For
 25 the purpose of carrying out paragraph (1), there is

1 authorized to be appropriated \$100,000 for each of
 2 the first 3 fiscal years in which this section is in ef-
 3 fect.

4 (e) EFFECTIVE DATE.—The amendments made by
 5 subsections (a) and (b) take effect 90 days after the date
 6 of enactment of this Act, without regard to whether a final
 7 rule to implement such amendments has been promulgated
 8 by the Secretary of Health and Human Services under
 9 section 701(a) of the Federal Food, Drug, and Cosmetic
 10 Act. The preceding sentence may not be construed as af-
 11 fecting the authority of such Secretary to promulgate such
 12 a final rule.

13 **SEC. 8. PROHIBITING PAYMENTS TO UNREGISTERED FOR-**
 14 **EIGN PHARMACIES.**

15 (a) IN GENERAL.—Section 303 of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
 17 adding at the end the following:

18 “(h) RESTRICTED TRANSACTIONS.—

19 “(1) IN GENERAL.—The introduction of re-
 20 stricted transactions into a payment system or the
 21 completion of restricted transactions using a pay-
 22 ment system is prohibited.

23 “(2) PAYMENT SYSTEM.—

24 “(A) IN GENERAL.—The term ‘payment
 25 system’ means a system used by a person de-

scribed in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

“(i) a credit card system;

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

“(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

“(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

“(i) a creditor;

“(ii) a credit card issuer;

“(iii) a financial institution;

“(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

1 “(v) a money transmitting business;

2 or

3 “(vi) a participant in an international,
4 national, regional, or local network used to
5 effect a credit transaction, electronic fund
6 transfer, or money transmitting service.

7 “(3) RESTRICTED TRANSACTION.—The term
8 ‘restricted transaction’ means a transaction or trans-
9 mittal, on behalf of an individual who places an un-
10 lawful drug importation request to any person en-
11 gaged in the operation of an unregistered foreign
12 pharmacy, of—

13 “(A) credit, or the proceeds of credit, ex-
14 tended to or on behalf of the individual for the
15 purpose of the unlawful drug importation re-
16 quest (including credit extended through the
17 use of a credit card);

18 “(B) an electronic fund transfer or funds
19 transmitted by or through a money transmit-
20 ting business, or the proceeds of an electronic
21 fund transfer or money transmitting service,
22 from or on behalf of the individual for the pur-
23 pose of the unlawful drug importation request;

24 “(C) a check, draft, or similar instrument
25 which is drawn by or on behalf of the individual

1 for the purpose of the unlawful drug importa-
 2 tion request and is drawn on or payable at or
 3 through any financial institution; or

4 “(D) the proceeds of any other form of fi-
 5 nancial transaction (identified by the Board by
 6 regulation) that involves a financial institution
 7 as a payor or financial intermediary on behalf
 8 of or for the benefit of the individual for the
 9 purpose of the unlawful drug importation re-
 10 quest.

11 “(4) UNLAWFUL DRUG IMPORTATION RE-
 12 QUEST.—The term ‘unlawful drug importation re-
 13 quest’ means the request, or transmittal of a re-
 14 quest, made to an unregistered foreign pharmacy for
 15 a prescription drug by mail (including a private car-
 16 rier), facsimile, phone, or electronic mail, or by a
 17 means that involves the use, in whole or in part, of
 18 the Internet.

19 “(5) UNREGISTERED FOREIGN PHARMACY.—
 20 The term ‘unregistered foreign pharmacy’ means a
 21 person in a country other than the United States
 22 that is not a registered exporter under section 804.

23 “(6) OTHER DEFINITIONS.—

24 “(A) CREDIT; CREDITOR; CREDIT CARD.—

25 The terms ‘credit’, ‘creditor’, and ‘credit card’

1 have the meanings given the terms in section
2 103 of the Truth in Lending Act (15 U.S.C.
3 1602).

4 “(B) ACCESS DEVICE; ELECTRONIC FUND
5 TRANSFER.—The terms ‘access device’ and
6 ‘electronic fund transfer’—

7 “(i) have the meaning given the term
8 in section 903 of the Electronic Fund
9 Transfer Act (15 U.S.C. 1693a); and

10 “(ii) the term ‘electronic fund trans-
11 fer’ also includes any fund transfer covered
12 under Article 4A of the Uniform Commer-
13 cial Code, as in effect in any State.

14 “(C) FINANCIAL INSTITUTION.—The term
15 ‘financial institution’—

16 “(i) has the meaning given the term
17 in section 903 of the Electronic Transfer
18 Fund Act (15 U.S.C. 1693a); and

19 “(ii) includes a financial institution
20 (as defined in section 509 of the Gramm-
21 Leach-Bliley Act (15 U.S.C. 6809)).

22 “(D) MONEY TRANSMITTING BUSINESS;
23 MONEY TRANSMITTING SERVICE.—The terms
24 ‘money transmitting business’ and ‘money
25 transmitting service’ have the meaning given

1 the terms in section 5330(d) of title 31, United
2 States Code.

3 “(E) BOARD.—The term ‘Board’ means
4 the Board of Governors of the Federal Reserve
5 System.

6 “(7) POLICIES AND PROCEDURES REQUIRED TO
7 PREVENT RESTRICTED TRANSACTIONS.—

8 “(A) REGULATIONS.—The Board shall
9 promulgate regulations requiring—

10 “(i) an operator of a credit card sys-
11 tem;

12 “(ii) an operator of an international,
13 national, regional, or local network used to
14 effect a credit transaction, an electronic
15 fund transfer, or a money transmitting
16 service;

17 “(iii) an operator of any other pay-
18 ment system that is centrally managed and
19 is primarily engaged in the transmission
20 and settlement of credit transactions, elec-
21 tronic transfers or money transmitting
22 services where at least one party to the
23 transaction or transfer is an individual;
24 and

1 “(iv) any other person described in
2 paragraph (2)(B) and specified by the
3 Board in such regulations,
4 to establish policies and procedures that are
5 reasonably designed to prevent the introduction
6 of a restricted transaction into a payment sys-
7 tem or the completion of a restricted trans-
8 action using a payment system.

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

12 “(i) identify types of policies and pro-
13 cedures, including nonexclusive examples,
14 that shall be considered to be reasonably
15 designed to prevent the introduction of re-
16 stricted transactions into a payment sys-
17 tem or the completion of restricted trans-
18 actions using a payment system; and

19 “(ii) to the extent practicable, permit
20 any payment system, or person described
21 in paragraph (2)(B), as applicable, to
22 choose among alternative means of pre-
23 venting the introduction or completion of
24 restricted transactions.

1 “(C) NO LIABILITY FOR BLOCKING OR RE-
2 FUSING TO HONOR RESTRICTED TRANS-
3 ACTION.—

4 “(i) IN GENERAL.—A payment sys-
5 tem, or a person described in paragraph
6 (2)(B) that is subject to a regulation
7 issued under this subsection, and any par-
8 ticipant in such payment system that pre-
9 vents or otherwise refuses to honor trans-
10 actions in an effort to implement the poli-
11 cies and procedures required under this
12 subsection or to otherwise comply with this
13 subsection shall not be liable to any party
14 for such action.

15 “(ii) COMPLIANCE.—A person de-
16 scribed in paragraph (2)(B) meets the re-
17 quirements of this subsection if the person
18 relies on and complies with the policies and
19 procedures of a payment system of which
20 the person is a member or in which the
21 person is a participant, and such policies
22 and procedures of the payment system
23 comply with the requirements of the regu-
24 lations promulgated under subparagraph
25 (A).

1 “(D) ENFORCEMENT.—

2 “(i) IN GENERAL.—This section shall
3 be enforced by the Federal functional regu-
4 lators and the Federal Trade Commission
5 under applicable law in the manner pro-
6 vided in section 505(a) of the Gramm-
7 Leach-Bliley Act (15 U.S.C. 6805(a)).

8 “(ii) FACTORS TO BE CONSIDERED.—
9 In considering any enforcement action
10 under this subsection against a payment
11 system or person described in paragraph
12 (2)(B), the Federal functional regulators
13 and the Federal Trade Commission shall
14 consider the following factors:

15 “(I) The extent to which the pay-
16 ment system or person knowingly per-
17 mits restricted transactions.

18 “(II) The history of the payment
19 system or person in connection with
20 permitting restricted transactions.

21 “(III) The extent to which the
22 payment system or person has estab-
23 lished and is maintaining policies and
24 procedures in compliance with regula-
25 tions prescribed under this subsection.

1 “(8) TRANSACTIONS PERMITTED.—A payment
2 system, or a person described in paragraph (2)(B)
3 that is subject to a regulation issued under this sub-
4 section, is authorized to engage in transactions with
5 foreign pharmacies in connection with investigating
6 violations or potential violations of any rule or re-
7 quirement adopted by the payment system or person
8 in connection with complying with paragraph (7). A
9 payment system, or such a person, and its agents
10 and employees shall not be found to be in violation
11 of, or liable under, any Federal, State or other law
12 by virtue of engaging in any such transaction.

13 “(9) RELATION TO STATE LAWS.—No require-
14 ment, prohibition, or liability may be imposed on a
15 payment system, or a person described in paragraph
16 (2)(B) that is subject to a regulation issued under
17 this subsection, under the laws of any State with re-
18 spect to any payment transaction by an individual
19 because the payment transaction involves a payment
20 to a foreign pharmacy.

21 “(10) TIMING OF REQUIREMENTS.—A payment
22 system, or a person described in paragraph (2)(B)
23 that is subject to a regulation issued under this sub-
24 section, must adopt policies and procedures reason-
25 ably designed to comply with any regulations re-

1 quired under paragraph (7) within 60 days after
2 such regulations are issued in final form.”.

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

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

12 **SEC. 9. IMPORTATION EXEMPTION UNDER CONTROLLED**
13 **SUBSTANCES IMPORT AND EXPORT ACT.**

14 Section 1006(a)(2) of the Controlled Substances Im-
15 port and Export Act (21 U.S.C. 956(a)(2)) is amended
16 by striking “not import the controlled substance into the
17 United States in an amount that exceeds 50 dosage units
18 of the controlled substance.” and inserting “import into
19 the United States not more than 10 dosage units com-
20 bined of all such controlled substances.”.

21 **SEC. 10. SEVERABILITY.**

22 If any provision of this Act, an amendment by this
23 Act, or the application of such provision or amendment
24 to any person or circumstance is held to be unconstitu-
25 tional, the remainder of this Act, the amendments made

1 by this Act, and the application of the provisions of such
2 to any person or circumstance shall not affected thereby.

