

Calendar No. 73111TH CONGRESS
1ST SESSION**S. 1232**

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

JUNE 10, 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, Mrs. SHAHEEN, Ms. KLOBUCHAR, Mr. SPECTER, Mrs. BOXER, Mr. VITTER, and Mr. CONRAD) introduced the following bill; which was read the first time

JUNE 11, 2009

Read the second time and placed on the calendar

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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. FINDINGS.**

5 Congress finds that—

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

9 (2) the United States is the largest market for
10 pharmaceuticals in the world, yet American con-
11 sumers pay the highest prices for brand pharma-
12 ceuticals in the world;

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

15 (4) allowing and structuring the importation of
16 prescription drugs to ensure access to safe and af-
17 fordable drugs approved by the Food and Drug Ad-
18 ministration will provide a level of safety to Amer-
19 ican consumers that they do not currently enjoy;

20 (5) American spend more than
21 \$200,000,000,000 on prescription drugs every year;

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

1 (7) promoting competitive market pricing would
2 both contribute to health care savings and allow
3 greater access to therapy, improving health and sav-
4 ing lives.

5 **SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPOR-**
6 **TATION OF PRESCRIPTION DRUGS.**

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

10 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
11 **OF CERTAIN IMPORT RESTRICTIONS.**

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

16 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
17 **PRESCRIPTION DRUGS.**

18 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

19 “(1) IN GENERAL.—In the case of qualifying
20 drugs imported or offered for import into the United
21 States from registered exporters or by registered im-
22 porters—

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

1 “(B) the standards referred to in section
2 801(a) regarding admission of the drugs are
3 subject to subsection (g) of this section (includ-
4 ing with respect to qualifying drugs to which
5 section 801(d)(1) does not apply).

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

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

11 “(B) the drug is imported by an individual
12 for personal use or for the use of a family mem-
13 ber of the individual (not for resale) from a reg-
14 istered exporter.

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

19 “(A) by a registered importer; or

20 “(B) from a registered exporter to an indi-
21 vidual.

22 “(4) DEFINITIONS.—

23 “(A) REGISTERED EXPORTER; REG-
24 ISTERED IMPORTER.—For purposes of this sec-
25 tion:

1 “(i) The term ‘registered exporter’
2 means an exporter for which a registration
3 under subsection (b) has been approved
4 and is in effect.

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

10 “(iii) The term ‘registration condition’
11 means a condition that must exist for a
12 registration under subsection (b) to be ap-
13 proved.

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

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

21 “(i) with respect to a qualifying drug,
22 has the same active ingredient or ingredi-
23 ents, route of administration, dosage form,
24 and strength as the qualifying drug;

1 “(ii) with respect to the qualifying
2 drug, is manufactured by or for the person
3 that manufactures the qualifying drug;

4 “(iii) is approved under section
5 505(e); and

6 “(iv) is not—

7 “(I) a controlled substance, as
8 defined in section 102 of the Con-
9 trolled Substances Act (21 U.S.C.
10 802);

11 “(II) a biological product, as de-
12 fined in section 351 of the Public
13 Health Service Act (42 U.S.C. 262),
14 including—

15 “(aa) a therapeutic DNA
16 plasmid product;

17 “(bb) a therapeutic synthetic
18 peptide product;

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

21 “(dd) a therapeutic recom-
22 binant DNA-derived product;

23 “(III) an infused drug, including
24 a peritoneal dialysis solution;

25 “(IV) an injected drug;

1 “(V) a drug that is inhaled dur-
2 ing surgery;

3 “(VI) a drug that is the listed
4 drug referred to in 2 or more abbrevi-
5 ated new drug applications under
6 which the drug is commercially mar-
7 keted; or

8 “(VII) a sterile ophthalmic drug
9 intended for topical use on or in the
10 eye.

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

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

21 “(II) The Secretary shall designate a
22 permitted country under subparagraph (E)
23 (other than Canada) as a country from
24 which an exporter may export a drug to in-

1 individuals in the United States if the Sec-
2 retary determines that—

3 “(aa) the country has statutory
4 or regulatory standards that are
5 equivalent to the standards in the
6 United States and Canada with re-
7 spect to—

8 “(AA) the training of phar-
9 macists;

10 “(BB) the practice of phar-
11 macy; and

12 “(CC) the protection of the
13 privacy of personal medical infor-
14 mation; and

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

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

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

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

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

10 “(II) employs 1 or more phar-
11 macists.

12 “(v) The term ‘prescription drug’
13 means a drug that is described in section
14 503(b)(1).

15 “(vi) The term ‘wholesaler’—

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

20 “(II) does not include a person
21 authorized to import drugs under sec-
22 tion 801(d)(1).

23 “(E) PERMITTED COUNTRY.—The term
24 ‘permitted country’ means—

25 “(i) Australia;

1 “(ii) Canada;

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

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

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

18 “(iv) Japan;

19 “(v) New Zealand;

20 “(vi) Switzerland; and

21 “(vii) a country in which the Sec-
22 retary determines the following require-
23 ments are met:

24 “(I) The country has statutory or
25 regulatory requirements—

1 “(aa) that require the review
2 of drugs for safety and effective-
3 ness by an entity of the govern-
4 ment of the country;

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

20 “(cc) that require the meth-
21 ods used in, and the facilities and
22 controls used for the manufac-
23 ture, processing, and packing of
24 drugs in the country to be ade-

1 quate to preserve their identity,
2 quality, purity, and strength;

3 “(dd) for the reporting of
4 adverse reactions to drugs and
5 procedures to withdraw approval
6 and remove drugs found not to
7 be safe or effective; and

8 “(ee) that require the label-
9 ing and promotion of drugs to be
10 in accordance with the approval
11 of the drug.

12 “(II) The valid marketing au-
13 thorization system in the country is
14 equivalent to the systems in the coun-
15 tries described in clauses (i) through
16 (vi).

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

20 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
21 ERS.—

22 “(1) REGISTRATION OF IMPORTERS AND EX-
23 PORTERS.—A registration condition is that the im-
24 porter or exporter involved (referred to in this sub-

1 section as a ‘registrant’) submits to the Secretary a
2 registration containing the following:

3 “(A)(i) In the case of an exporter, the
4 name of the exporter and an identification of all
5 places of business of the exporter that relate to
6 qualifying drugs, including each warehouse or
7 other facility owned or controlled by, or oper-
8 ated for, the exporter.

9 “(ii) In the case of an importer, the name
10 of the importer and an identification of the
11 places of business of the importer at which the
12 importer initially receives a qualifying drug
13 after importation (which shall not exceed 3
14 places of business except by permission of the
15 Secretary).

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

20 “(i) in the case of an importer, sub-
21 sections (c), (d), (e), (g), and (j) (relating
22 to the sources of imported qualifying
23 drugs; the inspection of facilities of the im-
24 porter; the payment of fees; compliance
25 with the standards referred to in section

1 801(a); and maintenance of records and
2 samples); or

3 “(ii) in the case of an exporter, sub-
4 sections (c), (d), (f), (g), (h), (i), and (j)
5 (relating to the sources of exported quali-
6 fying drugs; the inspection of facilities of
7 the exporter and the marking of compliant
8 shipments; the payment of fees; and com-
9 pliance with the standards referred to in
10 section 801(a); being licensed as a phar-
11 macist; conditions for individual importa-
12 tion; and maintenance of records and sam-
13 ples).

14 “(C) An agreement by the registrant that
15 the registrant will not under subsection (a) im-
16 port or export any drug that is not a qualifying
17 drug.

18 “(D) An agreement by the registrant to—
19 “(i) notify the Secretary of a recall or
20 withdrawal of a qualifying drug distributed
21 in a permitted country that the registrant
22 has exported or imported, or intends to ex-
23 port or import, to the United States under
24 subsection (a);

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

3 “(iii) cease, or not begin, the expor-
4 tation or importation of such drug unless
5 the Secretary has notified the registrant
6 that exportation or importation of such
7 drug may proceed.

8 “(E) An agreement by the registrant to
9 ensure and monitor compliance with each reg-
10 istration condition, to promptly correct any
11 noncompliance with such a condition, and to
12 promptly report to the Secretary any such non-
13 compliance.

14 “(F) A plan describing the manner in
15 which the registrant will comply with the agree-
16 ment under subparagraph (E).

17 “(G) An agreement by the registrant to
18 enforce a contract under subsection (c)(3)(B)
19 against a party in the chain of custody of a
20 qualifying drug with respect to the authority of
21 the Secretary under clauses (ii) and (iii) of that
22 subsection.

23 “(H) An agreement by the registrant to
24 notify the Secretary not more than 30 days be-

1 fore the registrant intends to make the change,
2 of—

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

6 “(ii) any change that the registrant
7 intends to make in the compliance plan
8 under subparagraph (F).

9 “(I) In the case of an exporter:

10 “(i) An agreement by the exporter
11 that a qualifying drug will not under sub-
12 section (a) be exported to any individual
13 not authorized pursuant to subsection
14 (a)(2)(B) to be an importer of such drug.

15 “(ii) An agreement to post a bond,
16 payable to the Treasury of the United
17 States that is equal in value to the lesser
18 of—

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

23 “(II) \$1,000,000.

24 “(iii) An agreement by the exporter to
25 comply with applicable provisions of Cana-

1 dian law, or the law of the permitted coun-
2 try designated under subsection
3 (a)(4)(D)(i)(II) in which the exporter is lo-
4 cated, that protect the privacy of personal
5 information with respect to each individual
6 importing a prescription drug from the ex-
7 porter under subsection (a)(2)(B).

8 “(iv) An agreement by the exporter to
9 report to the Secretary—

10 “(I) not later than August 1 of
11 each fiscal year, the total price and
12 the total volume of drugs exported to
13 the United States by the exporter dur-
14 ing the 6-month period from January
15 1 through June 30 of that year; and

16 “(II) not later than January 1 of
17 each fiscal year, the total price and
18 the total volume of drugs exported to
19 the United States by the exporter dur-
20 ing the previous fiscal year.

21 “(J) In the case of an importer, an agree-
22 ment by the importer to report to the Sec-
23 retary—

24 “(i) not later than August 1 of each
25 fiscal year, the total price and the total

1 volume of drugs imported to the United
2 States by the importer during the 6-month
3 period from January 1 through June 30 of
4 that fiscal year; and

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

10 “(K) Such other provisions as the Sec-
11 retary may require by regulation to protect the
12 public health while permitting—

13 “(i) the importation by pharmacies,
14 groups of pharmacies, and wholesalers as
15 registered importers of qualifying drugs
16 under subsection (a); and

17 “(ii) importation by individuals of
18 qualifying drugs under subsection (a).

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

21 “(A) IN GENERAL.—Not later than 90
22 days after the date on which a registrant sub-
23 mits to the Secretary a registration under para-
24 graph (1), the Secretary shall notify the reg-
25 istrant whether the registration is approved or

1 is disapproved. The Secretary shall disapprove
2 a registration if there is reason to believe that
3 the registrant is not in compliance with one or
4 more registration conditions, and shall notify
5 the registrant of such reason. In the case of a
6 disapproved registration, the Secretary shall
7 subsequently notify the registrant that the reg-
8 istration is approved if the Secretary deter-
9 mines that the registrant is in compliance with
10 such conditions.

11 “(B) CHANGES IN REGISTRATION INFOR-
12 MATION.—Not later than 30 days after receiv-
13 ing a notice under paragraph (1)(H) from a
14 registrant, the Secretary shall determine wheth-
15 er the change involved affects the approval of
16 the registration of the registrant under para-
17 graph (1), and shall inform the registrant of
18 the determination.

19 “(3) PUBLICATION OF CONTACT INFORMATION
20 FOR REGISTERED EXPORTERS.—Through the Inter-
21 net website of the Food and Drug Administration
22 and a toll-free telephone number, the Secretary shall
23 make readily available to the public a list of reg-
24 istered exporters, including contact information for
25 the exporters. Promptly after the approval of a reg-

1 istration submitted under paragraph (1), the Sec-
2 retary shall update the Internet website and the in-
3 formation provided through the toll-free telephone
4 number accordingly.

5 “(4) SUSPENSION AND TERMINATION.—

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

9 “(i) Subject to clause (ii), the Sec-
10 retary may suspend the registration if the
11 Secretary determines, after notice and op-
12 portunity for a hearing, that the registrant
13 has failed to maintain substantial compli-
14 ance with a registration condition.

15 “(ii) If the Secretary determines that,
16 under color of the registration, the ex-
17 porter has exported a drug or the importer
18 has imported a drug that is not a quali-
19 fying drug, or a drug that does not comply
20 with subsection (g)(2)(A) or (g)(4), or has
21 exported a qualifying drug to an individual
22 in violation of subsection (i)(2)(F), the
23 Secretary shall immediately suspend the
24 registration. A suspension under the pre-
25 ceding sentence is not subject to the provi-

1 sion by the Secretary of prior notice, and
2 the Secretary shall provide to the reg-
3 istrant an opportunity for a hearing not
4 later than 10 days after the date on which
5 the registration is suspended.

6 “(iii) The Secretary may reinstate the
7 registration, whether suspended under
8 clause (i) or (ii), if the Secretary deter-
9 mines that the registrant has demonstrated
10 that further violations of registration con-
11 ditions will not occur.

12 “(B) TERMINATION.—The Secretary, after
13 notice and opportunity for a hearing, may ter-
14 minate the registration under paragraph (1) of
15 a registrant if the Secretary determines that
16 the registrant has engaged in a pattern or prac-
17 tice of violating 1 or more registration condi-
18 tions, or if on 1 or more occasions the Secretary
19 has under subparagraph (A)(ii) suspended the
20 registration of the registrant. The Secretary
21 may make the termination permanent, or for a
22 fixed period of not less than 1 year. During the
23 period in which the registration is terminated,
24 any registration submitted under paragraph (1)
25 by the registrant, or a person that is a partner

1 in the export or import enterprise, or a prin-
2 cipal officer in such enterprise, and any reg-
3 istration prepared with the assistance of the
4 registrant or such a person, has no legal effect
5 under this section.

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

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

16 “(B) failed to permit the Secretary to con-
17 duct an inspection described under subsection
18 (d).

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

24 “(1) The drug was manufactured in an estab-
25 lishment—

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

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

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

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

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

23 “(A) directly from the establishment; or

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

1 “(i) provides to the exporter or im-
2 porter a statement (in such form and con-
3 taining such information as the Secretary
4 may require) that, for the chain of custody
5 from the establishment, identifies each
6 prior sale, purchase, or trade of the drug
7 (including the date of the transaction and
8 the names and addresses of all parties to
9 the transaction);

10 “(ii) agrees to permit the Secretary to
11 inspect such statements and related
12 records to determine their accuracy;

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

21 “(iv) has ensured, through such con-
22 tractual relationships as may be necessary,
23 that the Secretary has the same authority
24 regarding other parties in the chain of cus-
25 tody from the establishment that the Sec-

1 retary has under clauses (ii) and (iii) re-
2 garding such entity.

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

6 “(B) The foreign country from which the ex-
7 porter will export the drug is the permitted country
8 in which the exporter is located.

9 “(5) During any period in which the drug was
10 not in the control of the manufacturer of the drug,
11 the drug did not enter any country that is not a per-
12 mitted country.

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

15 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
16 MENTS.—

17 “(1) INSPECTION OF FACILITIES.—A registra-
18 tion condition is that, for the purpose of assisting
19 the Secretary in determining whether the exporter
20 involved is in compliance with all other registration
21 conditions—

22 “(A) the exporter agrees to permit the Sec-
23 retary—

24 “(i) to conduct onsite inspections, in-
25 cluding monitoring on a day-to-day basis,

1 of places of business of the exporter that
2 relate to qualifying drugs, including each
3 warehouse or other facility owned or con-
4 trolled by, or operated for, the exporter;

5 “(ii) to have access, including on a
6 day-to-day basis, to—

7 “(I) records of the exporter that
8 relate to the export of such drugs, in-
9 cluding financial records; and

10 “(II) samples of such drugs;

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

13 “(iv) to carry out any other functions
14 determined by the Secretary to be nec-
15 essary regarding the compliance of the ex-
16 porter; and

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

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

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

12 “(B) include anticounterfeiting or track-
13 and-trace technologies, taking into account the
14 economic and technical feasibility of those tech-
15 nologies.

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

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

24 “(B) During the inspections under sub-
25 paragraph (A), verifying the chain of custody of

1 a statistically significant sample of qualifying
2 drugs from the establishment in which the drug
3 was manufactured to the exporter, which shall
4 be accomplished or supplemented by the use of
5 anticounterfeiting or track-and-trace tech-
6 nologies, taking into account the economic and
7 technical feasibility of those technologies, except
8 that a drug that lacks such technologies from
9 the point of manufacture shall not for that rea-
10 son be excluded from importation by an ex-
11 porter.

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

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

22 “(E) Inspecting as the Secretary deter-
23 mines is necessary the warehouses and other fa-
24 cilities, including records, of other parties in the
25 chain of custody of qualifying drugs.

1 “(F) Determining whether the exporter is
2 in compliance with all other registration condi-
3 tions.

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

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

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

17 “(C) the identity of the drug, including the
18 established name of the drug, the quantity of
19 the drug, and the lot number assigned by the
20 manufacturer;

21 “(D) the identity of the manufacturer of
22 the drug, including the identity of the establish-
23 ment at which the drug was manufactured;

24 “(E) the country from which the drug is
25 shipped;

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

3 “(G) anticipated arrival information, in-
4 cluding the port of arrival and crossing location
5 within that port, and the date and time;

6 “(H) a summary of the chain of custody of
7 the drug from the establishment in which the
8 drug was manufactured to the importer;

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

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

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

1 nology from the manufacturer of the drug. Markings
2 or other technology under the preceding sentence
3 shall—

4 “(A) be designed to prevent affixation of
5 the markings or other technology to any con-
6 tainer that is not authorized to bear the mark-
7 ings; and

8 “(B) shall include anticounterfeiting or
9 track-and-trace technologies, taking into ac-
10 count the economic and technical feasibility of
11 such technologies.

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

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

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 importer, 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 im-
6 porter.

7 “(C) Reviewing notices under paragraph
8 (4).

9 “(D) Inspecting as the Secretary deter-
10 mines is necessary the warehouses and other fa-
11 cilities, including records of other parties in the
12 chain of custody of qualifying drugs.

13 “(E) Determining whether the importer is
14 in compliance with all other registration condi-
15 tions.

16 “(e) IMPORTER FEES.—

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

22 “(2) INSPECTION FEE.—A registration condi-
23 tion is that the importer involved pays a fee to the
24 Secretary in accordance with this subsection. Such
25 fee shall be paid not later than October 1 and April

1 of each fiscal year in the amount provided for
2 under paragraph (3).

3 “(3) AMOUNT OF INSPECTION FEE.—

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

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

19 “(ii) developing, implementing, and
20 operating under such subsection an elec-
21 tronic system for submission and review of
22 the notices required under subsection
23 (d)(4) with respect to shipments of quali-
24 fying drugs under subsection (a) to assess
25 compliance with all registration conditions

1 when such shipments are offered for im-
2 port into the United States; and

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

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

15 “(C) TOTAL PRICE OF DRUGS.—

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

1 by each registered importer during the 6-
2 month period from January 1 through
3 June 30 of the previous fiscal year, as re-
4 ported to the Secretary by each registered
5 importer under subsection (b)(1)(J).

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

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

1 registered importer on April 1 of the sub-
2 sequent fiscal year so that the limitation
3 described in subparagraph (B) is observed.

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

13 “(4) USE OF FEES.—

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

1 and Border Protection until expended (without
2 fiscal year limitation).

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

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

16 “(f) EXPORTER FEES.—

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

22 “(2) INSPECTION FEE.—A registration condi-
23 tion is that the exporter involved pays a fee to the
24 Secretary in accordance with this subsection. Such
25 fee shall be paid not later than October 1 and April

1 of each fiscal year in the amount provided for
2 under paragraph (3).

3 “(3) AMOUNT OF INSPECTION FEE.—

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

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

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

1 “(iii) screening such markings, and
2 inspecting such shipments as necessary,
3 when offered for import into the United
4 States to determine if such a shipment
5 should be refused admission under sub-
6 section (g)(5).

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

14 “(C) TOTAL PRICE OF DRUGS.—

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

1 month period from January 1 through
2 June 30 of the previous fiscal year, as re-
3 ported to the Secretary by each registered
4 exporter under subsection (b)(1)(I)(iv).

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

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

1 quent fiscal year so that the limitation de-
2 scribed in subparagraph (B) is observed.

3 “(D) INDIVIDUAL EXPORTER 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 exporter shall be
7 an amount that is proportional to a reasonable
8 estimate by the Secretary of the semiannual
9 share of the exporter of the volume of quali-
10 fying drugs exported by exporters 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 “(g) COMPLIANCE WITH SECTION 801(a).—

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

23 “(2) SECTION 505; APPROVAL STATUS.—

24 “(A) IN GENERAL.—A qualifying drug that
25 is imported or offered for import under sub-

1 section (a) shall comply with the conditions es-
2 tablished in the approved application under sec-
3 tion 505(b) for the U.S. label drug as described
4 under this subsection.

5 “(B) NOTICE BY MANUFACTURER; GEN-
6 ERAL PROVISIONS.—

7 “(i) IN GENERAL.—The person that
8 manufactures a qualifying drug that is, or
9 will be, introduced for commercial distribu-
10 tion in a permitted country shall in accord-
11 ance with this paragraph submit to the
12 Secretary a notice that—

13 “(I) includes each difference in
14 the qualifying drug from a condition
15 established in the approved applica-
16 tion for the U.S. label drug beyond—

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

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

22 “(II) states that there is no dif-
23 ference in the qualifying drug from a
24 condition established in the approved

1 application for the U.S. label drug be-
2 yond—

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

5 “(bb) any difference in label-
6 ing (except ingredient labeling).

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

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

23 “(II) Information demonstrating
24 that the person submitting the notice
25 has also notified the government of

1 the permitted country in writing that
2 the person is submitting to the Sec-
3 retary a notice under clause (i)(I),
4 which notice describes the difference
5 in the qualifying drug from a condi-
6 tion established in the approved appli-
7 cation for the U.S. label drug.

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

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

24 “(I) the information provided in
25 the notice is complete and true; and

1 “(II) a copy of the notice has
2 been provided to the Federal Trade
3 Commission and to the State attor-
4 neys general.

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

20 “(v) TIMING OF SUBMISSION OF NO-
21 TICES.—

22 “(I) PRIOR APPROVAL NO-
23 TICES.—A notice under clause (i) to
24 which subparagraph (C) applies shall
25 be submitted to the Secretary not

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

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

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

24 “(vi) REVIEW BY SECRETARY.—

1 “(I) IN GENERAL.—In this para-
2 graph, the difference in a qualifying
3 drug that is submitted in a notice
4 under clause (i) from the U.S. label
5 drug shall be treated by the Secretary
6 as if it were a manufacturing change
7 to the U.S. label drug under section
8 506A.

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

18 “(III) BIOEQUIVALENCE.—If the
19 Secretary would approve the dif-
20 ference in a notice submitted under
21 clause (i) using the safe and effective
22 standard under section 506A and if
23 the Secretary determines that the
24 qualifying drug is not bioequivalent to

1 the U.S. label drug, the Secretary
2 shall—

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

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

20 “(IV) REVIEW BY THE SEC-
21 RETARY.—The Secretary shall review
22 and approve or disapprove the dif-
23 ference in a notice submitted under
24 clause (i), if required under section
25 506A, not later than 120 days after

1 the date on which the notice is sub-
2 mitted.

3 “(V) ESTABLISHMENT INSPEC-
4 TION.—If review of such difference
5 would require an inspection of the es-
6 tablishment in which the qualifying
7 drug is manufactured—

8 “(aa) such inspection by the
9 Secretary shall be authorized;
10 and

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

24 “(vii) PUBLICATION OF INFORMATION
25 ON NOTICES.—

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

8 “(II) CONTENTS.—The list under
9 subclause (I) shall include the date on
10 which a notice is submitted and
11 whether—

12 “(aa) a notice is under re-
13 view;

14 “(bb) the Secretary has or-
15 dered that importation of the
16 qualifying drug from a permitted
17 country cease; or

18 “(cc) the importation of the
19 drug is permitted under sub-
20 section (a).

21 “(III) UPDATE.—The Secretary
22 shall promptly update the Internet
23 website with any changes to the list.

24 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
25 ING PRIOR APPROVAL.—In the case of a notice

1 under subparagraph (B)(i) that includes a dif-
2 ference that would, under section 506A(c) or
3 (d)(3)(B)(i), require the approval of a supple-
4 mental application before the difference could
5 be made to the U.S. label drug the following
6 shall occur:

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

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

22 “(I) order that the importation of
23 the qualifying drug involved from the
24 permitted country not begin until the

1 Secretary completes review of the no-
2 tice; and

3 “(II) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 State attorneys general of the order.

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

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

16 “(II) notify the permitted coun-
17 try that approved the qualifying drug
18 for commercial distribution of the de-
19 termination; and

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

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

5 “(I) vacate the order under
6 clause (ii), if any;

7 “(II) consider the difference to
8 be a variation provided for in the ap-
9 proved application for the U.S. label
10 drug;

11 “(III) permit importation of the
12 qualifying drug under subsection (a);
13 and

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

19 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
20 QUIRING PRIOR APPROVAL.—In the case of a
21 notice under subparagraph (B)(i) that includes
22 a difference that would, under section
23 506A(d)(3)(B)(ii), not require the approval of a
24 supplemental application before the difference

1 could be made to the U.S. label drug the fol-
2 lowing shall occur:

3 “(i) During the period in which the
4 notice is being reviewed by the Secretary,
5 the authority under this subsection to im-
6 port the qualifying drug involved continues
7 in effect.

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

12 “(I) order that the importation of
13 the qualifying drug involved from the
14 permitted country cease;

15 “(II) notify the permitted coun-
16 try that approved the qualifying drug
17 for commercial distribution of the de-
18 termination; and

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

24 “(iii) If the Secretary determines that
25 such a supplemental application regarding

1 the U.S. label drug would be approved, the
2 difference shall be considered to be a vari-
3 ation provided for in the approved applica-
4 tion for the U.S. label drug.

5 “(E) NOTICE; DRUG DIFFERENCE NOT RE-
6 QUIRING APPROVAL; NO DIFFERENCE.—In the
7 case of a notice under subparagraph (B)(i) that
8 includes a difference for which, under section
9 506A(d)(1)(A), a supplemental application
10 would not be required for the difference to be
11 made to the U.S. label drug, or that states that
12 there is no difference, the Secretary—

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

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

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

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

24 “(i) IN GENERAL.—A person who
25 manufactures a drug approved under sec-

1 tion 505(b) shall submit an application
2 under section 505(b) for approval of an-
3 other drug that is manufactured for dis-
4 tribution in a permitted country by or for
5 the person that manufactures the drug ap-
6 proved under section 505(b) if—

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

17 “(II) each active ingredient of
18 the other drug is related to an active
19 ingredient of the drug approved under
20 section 505(b), as defined in clause
21 (v).

22 “(ii) APPLICATION UNDER SECTION
23 505(b).—The application under section
24 505(b) required under clause (i) shall—

1 “(I) request approval of the other
2 drug for the indication or indications
3 for which the drug approved under
4 section 505(b) is labeled;

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

17 “(III) include a right of reference
18 to the application for the drug ap-
19 proved under section 505(b); and

20 “(IV) include such additional in-
21 formation as the Secretary may re-
22 quire.

23 “(iii) TIMING OF SUBMISSION OF AP-
24 PPLICATION.—An application under section
25 505(b) required under clause (i) shall be

1 submitted to the Secretary not later than
2 the day on which the information referred
3 to in clause (ii)(II) is submitted to the gov-
4 ernment of the permitted country.

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

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

16 “(I) the same; or

17 “(II) different salts, esters, or
18 complexes of the same moiety.

19 “(3) SECTION 502; LABELING.—

20 “(A) IMPORTATION BY REGISTERED IM-
21 PORTER.—

22 “(i) IN GENERAL.—In the case of a
23 qualifying drug that is imported or offered
24 for import by a registered importer, such
25 drug shall be considered to be in compli-

1 ance with section 502 and the labeling re-
2 quirements under the approved application
3 for the U.S. label drug if the qualifying
4 drug bears—

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

10 “(II) the name of the manufac-
11 turer and location of the manufac-
12 turer;

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

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

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

21 “(ii) REQUEST FOR COPY OF THE LA-
22 BELING.—The Secretary shall provide such
23 copy to the registered importer involved,
24 upon request of the importer.

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

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

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

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

16 “(IV) if the inactive ingredients
17 of the qualifying drug are different
18 from the inactive ingredients for the
19 U.S. label drug, include—

20 “(aa) a prominent notice
21 that the ingredients of the quali-
22 fying drug differ from the ingre-
23 dients of the U.S. label drug and
24 that the qualifying drug must be
25 dispensed with an advisory to

1 people with allergies about this
2 difference and a list of ingredi-
3 ents; and

4 “(bb) a list of the ingredi-
5 ents of the qualifying drug as
6 would be required under section
7 502(e).

8 “(B) IMPORTATION BY INDIVIDUAL.—

9 “(i) IN GENERAL.—In the case of a
10 qualifying drug that is imported or offered
11 for import by a registered exporter to an
12 individual, such drug shall be considered to
13 be in compliance with section 502 and the
14 labeling requirements under the approved
15 application for the U.S. label drug if the
16 packaging and labeling of the qualifying
17 drug complies with all applicable regula-
18 tions promulgated under sections 3 and 4
19 of the Poison Prevention Packaging Act of
20 1970 (15 U.S.C. 1471 et seq.) and the la-
21 beling of the qualifying drug includes—

22 “(I) directions for use by the
23 consumer;

24 “(II) the lot number assigned by
25 the manufacturer;

1 “(III) the name and registration
2 number of the exporter;

3 “(IV) if required under para-
4 graph (2)(B)(vi)(III), a prominent ad-
5 visory that the drug is safe and effec-
6 tive but not bioequivalent to the U.S.
7 label drug;

8 “(V) if the inactive ingredients of
9 the drug are different from the inac-
10 tive ingredients for the U.S. label
11 drug—

12 “(aa) a prominent advisory
13 that persons with an allergy
14 should check the ingredient list
15 of the drug because the ingredi-
16 ents of the drug differ from the
17 ingredients of the U.S. label
18 drug; and

19 “(bb) a list of the ingredi-
20 ents of the drug as would be re-
21 quired under section 502(e); and

22 “(VI) a copy of any special label-
23 ing that would be required by the Sec-
24 retary had the U.S. label drug been
25 dispensed by a pharmacist in the

1 United States, without regard to
2 whether the special labeling bears any
3 trademark involved.

4 “(ii) PACKAGING.—A qualifying drug
5 offered for import to an individual by an
6 exporter under this section that is pack-
7 aged in a unit-of-use container (as those
8 items are defined in the United States
9 Pharmacopeia and National Formulary)
10 shall not be repackaged, provided that—

11 “(I) the packaging complies with
12 all applicable regulations under sec-
13 tions 3 and 4 of the Poison Preven-
14 tion Packaging Act of 1970 (15
15 U.S.C. 1471 et seq.); or

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

23 “(iii) REQUEST FOR COPY OF SPECIAL
24 LABELING AND INGREDIENT LIST.—The
25 Secretary shall provide to the registered

1 exporter involved a copy of the special la-
2 beling, the advisory, and the ingredient list
3 described under clause (i), upon request of
4 the exporter.

5 “(iv) REQUESTED LABELING AND IN-
6 GREDIENT LIST.—The labeling and ingre-
7 dient list provided by the Secretary under
8 clause (iii) shall—

9 “(I) include the established
10 name, as defined in section 502(e)(3),
11 for each active ingredient in the drug;
12 and

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

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

21 “(5) STANDARDS FOR REFUSING ADMISSION.—
22 A drug exported under subsection (a) from a reg-
23 istered exporter or imported by a registered importer
24 may be refused admission into the United States if
25 1 or more of the following applies:

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

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

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

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

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

13 “(F) The Secretary becomes aware that—

14 “(i) the drug may be counterfeit;

15 “(ii) the drug may have been pre-
16 pared, packed, or held under insanitary
17 conditions; or

18 “(iii) the methods used in, or the fa-
19 cilities or controls used for, the manufac-
20 turing, processing, packing, or holding of
21 the drug do not conform to good manufac-
22 turing practice.

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

1 “(H) The Secretary has under section
2 505(e) withdrawn approval of the drug.

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

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

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

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

15 “(ii) The markings on the shipping
16 container appear to be counterfeit.

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

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

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

1 “(2) the exporter employs persons that are li-
2 censed under the law of the permitted country in
3 which the exporter is located to dispense prescription
4 drugs in sufficient number to dispense safely the
5 drugs exported by the exporter to individuals, and
6 the exporter assigns to those persons responsibility
7 for dispensing such drugs to individuals.

8 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
9 TION.—

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

14 “(A) The drug is accompanied by a copy of
15 a prescription for the drug, which prescrip-
16 tion—

17 “(i) is valid under applicable Federal
18 and State laws; and

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

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

6 “(C) The copies referred to in subpara-
7 graphs (A)(i) and (B) are marked in a manner
8 sufficient—

9 “(i) to indicate that the prescription,
10 and the equivalent document in the per-
11 mitted country in which the exporter is lo-
12 cated, have been filled; and

13 “(ii) to prevent a duplicative filling by
14 another pharmacist.

15 “(D) The individual has provided to the
16 registered exporter a complete list of all drugs
17 used by the individual for review by the individ-
18 uals who dispense the drug.

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

21 “(F) The drug is not an ineligible subpart
22 H drug. For purposes of this section, a pre-
23 scription drug is an ‘ineligible subpart H drug’
24 if the drug was approved by the Secretary
25 under subpart H of part 314 of title 21, Code

1 of Federal Regulations (relating to accelerated
2 approval), with restrictions under section 520 of
3 such part to assure safe use, and the Secretary
4 has published in the Federal Register a notice
5 that the Secretary has determined that good
6 cause exists to prohibit the drug from being im-
7 ported pursuant to this subsection.

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

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

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

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

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

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

4 “(A) in the case of an importer, at the
5 place of business of the importer at which the
6 importer initially receives the qualifying drug
7 after importation; or

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

11 “(k) DRUG RECALLS.—

12 “(1) MANUFACTURERS.—A person that manu-
13 factures a qualifying drug imported from a per-
14 mitted country under this section shall promptly in-
15 form the Secretary—

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

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

20 “(C) the reason for the recall or with-
21 drawal.

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

24 “(A) enter into an agreement with the gov-
25 ernment of the country to receive information

1 about recalls and withdrawals of qualifying
2 drugs in the country; or

3 “(B) monitor recalls and withdrawals of
4 qualifying drugs in the country using any infor-
5 mation that is available to the public in any
6 media.

7 “(3) NOTICE.—The Secretary may notify, as
8 appropriate, registered exporters, registered import-
9 ers, wholesalers, pharmacies, or the public of a recall
10 or withdrawal of a qualifying drug in a permitted
11 country.

12 “(1) DRUG LABELING AND PACKAGING.—

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

23 “(A) The lot number assigned by the man-
24 ufacturer.

1 “(B) The name and registration number of
2 the importer.

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

7 “(D) If the inactive ingredients of the drug
8 are different from the inactive ingredients for
9 the U.S. label drug—

10 “(i) a prominent advisory that persons
11 with allergies should check the ingredient
12 list of the drug because the ingredients of
13 the drug differ from the ingredients of the
14 U.S. label drug; and

15 “(ii) a list of the ingredients of the
16 drug as would be required under section
17 502(e).

18 “(2) PACKAGING.—A qualifying drug that is
19 packaged in a unit-of-use container (as those terms
20 are defined in the United States Pharmacopeia and
21 National Formulary) shall not be repackaged, pro-
22 vided that—

23 “(A) the packaging complies with all appli-
24 cable regulations under sections 3 and 4 of the

1 Poison Prevention Packaging Act of 1970 (15
2 U.S.C. 1471 et seq.); or

3 “(B) the consumer consents to waive the
4 requirements of such Act, after being informed
5 that the packaging does not comply with such
6 Act and that the pharmacist will provide the
7 drug in packaging that is compliant at no addi-
8 tional cost.

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

17 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
18 TICES.—

19 “(1) IN GENERAL.—It is unlawful for a manu-
20 facturer, directly or indirectly (including by being a
21 party to a licensing agreement or other agreement),
22 to—

23 “(A) discriminate by charging a higher
24 price for a prescription drug sold to a registered
25 exporter or other person in a permitted country

1 that exports a qualifying drug to the United
2 States under this section than the price that is
3 charged, inclusive of rebates or other incentives
4 to the permitted country or other person, to an-
5 other person that is in the same country and
6 that does not export a qualifying drug into the
7 United States under this section;

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

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

1 “(D) discriminate by publicly, privately, or
2 otherwise refusing to do business with a reg-
3 istered exporter or other person in a permitted
4 country that exports a qualifying drug to the
5 United States under this section or with a reg-
6 istered importer or other person that distrib-
7 utes, sells, or uses a qualifying drug imported
8 into the United States under this section;

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

21 “(F) knowingly fail to submit an applica-
22 tion required under subsection (g)(2)(F), know-
23 ingly fail to submit such an application on or
24 before the date specified in subsection
25 (g)(2)(F)(ii), knowingly submit such an applica-

1 tion that makes a materially false, fictitious, or
2 fraudulent statement, or knowingly fail to pro-
3 vide promptly any information requested by the
4 Secretary to review such an application;

5 “(G) cause there to be a difference (includ-
6 ing a difference in active ingredient, route of
7 administration, dosage form, strength, formula-
8 tion, manufacturing establishment, manufac-
9 turing process, or person that manufactures the
10 drug) between a prescription drug for distribu-
11 tion in the United States and the drug for dis-
12 tribution in a permitted country;

13 “(H) refuse to allow an inspection author-
14 ized under this section of an establishment that
15 manufactures a qualifying drug that is, or will
16 be, introduced for commercial distribution in a
17 permitted country;

18 “(I) fail to conform to the methods used
19 in, or the facilities used for, the manufacturing,
20 processing, packing, or holding of a qualifying
21 drug that is, or will be, introduced for commer-
22 cial distribution in a permitted country to good
23 manufacturing practice under this Act;

24 “(J) become a party to a licensing agree-
25 ment or other agreement related to a qualifying

1 drug that fails to provide for compliance with
2 all requirements of this section with respect to
3 such drug;

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

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

10 “(M) engage in any other action that the
11 Federal Trade Commission determines to dis-
12 criminate against a person that engages or at-
13 tempts to engage in the importation of a quali-
14 fying drug under this section.

15 “(2) REFERRAL OF POTENTIAL VIOLATIONS.—
16 The Secretary shall promptly refer to the Federal
17 Trade Commission each potential violation of sub-
18 paragraph (E), (F), (G), (H), or (I) of paragraph
19 (1) that becomes known to the Secretary.

20 “(3) AFFIRMATIVE DEFENSE.—

21 “(A) DISCRIMINATION.—It shall be an af-
22 firmative defense to a charge that a manufac-
23 turer has discriminated under subparagraph
24 (A), (B), (C), (D), or (M) of paragraph (1) that
25 the higher price charged for a prescription drug

1 sold to a person, the denial, restriction, or delay
2 of supplies of a prescription drug to a person,
3 the refusal to do business with a person, or
4 other discriminatory activity against a person,
5 is not based, in whole or in part, on—

6 “(i) the person exporting or importing
7 a qualifying drug into the United States
8 under this section; or

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

12 “(B) DRUG DIFFERENCES.—It shall be an
13 affirmative defense to a charge that a manufac-
14 turer has caused there to be a difference de-
15 scribed in subparagraph (G) of paragraph (1)
16 that—

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

19 “(ii) the Secretary has determined
20 that the difference was necessary to im-
21 prove the safety or effectiveness of the
22 drug;

23 “(iii) the person manufacturing the
24 drug for distribution in the United States
25 has given notice to the Secretary under

1 subsection (g)(2)(B)(i) that the drug for
2 distribution in the United States is not dif-
3 ferent from a drug for distribution in per-
4 mitted countries whose combined popu-
5 lation represents at least 50 percent of the
6 total population of all permitted countries;
7 or

8 “(iv) the difference was not caused, in
9 whole or in part, for the purpose of re-
10 stricting importation of the drug into the
11 United States under this section.

12 “(4) EFFECT OF SUBSECTION.—

13 “(A) SALES IN OTHER COUNTRIES.—This
14 subsection applies only to the sale or distribu-
15 tion of a prescription drug in a country if the
16 manufacturer of the drug chooses to sell or dis-
17 tribute the drug in the country. Nothing in this
18 subsection shall be construed to compel the
19 manufacturer of a drug to distribute or sell the
20 drug in a country.

21 “(B) DISCOUNTS TO INSURERS, HEALTH
22 PLANS, PHARMACY BENEFIT MANAGERS, AND
23 COVERED ENTITIES.—Nothing in this sub-
24 section shall be construed to—

1 “(i) prevent or restrict a manufac-
2 turer of a prescription drug from providing
3 discounts to an insurer, health plan, phar-
4 macy benefit manager in the United
5 States, or covered entity in the drug dis-
6 count program under section 340B of the
7 Public Health Service Act (42 U.S.C.
8 256b) in return for inclusion of the drug
9 on a formulary;

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

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

17 “(C) CHARITABLE CONTRIBUTIONS.—

18 Nothing in this subsection shall be construed
19 to—

20 “(i) prevent a manufacturer from do-
21 nating a prescription drug, or supplying a
22 prescription drug at nominal cost, to a
23 charitable or humanitarian organization,
24 including the United Nations and affli-

1 ates, or to a government of a foreign coun-
2 try; or

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

5 “(5) ENFORCEMENT.—

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

12 “(B) ACTIONS BY THE COMMISSION.—The
13 Federal Trade Commission—

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

22 “(ii) may seek monetary relief three-
23 fold the damages sustained, in addition to
24 any other remedy available to the Federal
25 Trade Commission under the Federal

1 Trade Commission Act (15 U.S.C. 41 et
2 seq.).

3 “(6) ACTIONS BY STATES.—

4 “(A) IN GENERAL.—

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

16 “(I) enjoin that practice;

17 “(II) enforce compliance with
18 this subsection;

19 “(III) obtain damages, restitu-
20 tion, or other compensation on behalf
21 of residents of the State and persons
22 doing business in the State, including
23 threefold the damages; or

1 “(IV) obtain such other relief as
2 the court may consider to be appro-
3 priate.

4 “(ii) NOTICE.—

5 “(I) IN GENERAL.—Before filing
6 an action under clause (i), the attor-
7 ney general of the State involved shall
8 provide to the Federal Trade Commis-
9 sion—

10 “(aa) written notice of that
11 action; and

12 “(bb) a copy of the com-
13 plaint for that action.

14 “(II) EXEMPTION.—Subclause
15 (I) shall not apply with respect to the
16 filing of an action by an attorney gen-
17 eral of a State under this paragraph,
18 if the attorney general determines
19 that it is not feasible to provide the
20 notice described in that subclause be-
21 fore filing of the action. In such case,
22 the attorney general of a State shall
23 provide notice and a copy of the com-
24 plaint to the Federal Trade Commis-

1 sion at the same time as the attorney
2 general files the action.

3 “(B) INTERVENTION.—

4 “(i) IN GENERAL.—On receiving no-
5 tice under subparagraph (A)(ii), the Fed-
6 eral Trade Commission shall have the right
7 to intervene in the action that is the sub-
8 ject of the notice.

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

13 “(I) to be heard with respect to
14 any matter that arises in that action;
15 and

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

17 “(C) CONSTRUCTION.—For purposes of
18 bringing any civil action under subparagraph
19 (A), nothing in this subsection shall be con-
20 strued to prevent an attorney general of a State
21 from exercising the powers conferred on the at-
22 torney general by the laws of that State to—

23 “(i) conduct investigations;

24 “(ii) administer oaths or affirmations;

25 or

1 “(iii) compel the attendance of wit-
2 nesses or the production of documentary
3 and other evidence.

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

12 “(E) VENUE.—Any action brought under
13 subparagraph (A) may be brought in the dis-
14 trict court of the United States that meets ap-
15 plicable requirements relating to venue under
16 section 1391 of title 28, United States Code.

17 “(F) SERVICE OF PROCESS.—In an action
18 brought under subparagraph (A), process may
19 be served in any district in which the defend-
20 ant—

21 “(i) is an inhabitant; or

22 “(ii) may be found.

23 “(G) MEASUREMENT OF DAMAGES.—In
24 any action under this paragraph to enforce a
25 cause of action under this subsection in which

1 there has been a determination that a defend-
2 ant has violated a provision of this subsection,
3 damages may be proved and assessed in the ag-
4 gregate by statistical or sampling methods, by
5 the computation of illegal overcharges or by
6 such other reasonable system of estimating ag-
7 gregate damages as the court in its discretion
8 may permit without the necessity of separately
9 proving the individual claim of, or amount of
10 damage to, persons on whose behalf the suit
11 was brought.

12 “(H) EXCLUSION ON DUPLICATIVE RE-
13 LIEF.—The district court shall exclude from the
14 amount of monetary relief awarded in an action
15 under this paragraph brought by the attorney
16 general of a State any amount of monetary re-
17 lief which duplicates amounts which have been
18 awarded for the same injury.

19 “(7) EFFECT ON ANTITRUST LAWS.—Nothing
20 in this subsection shall be construed to modify, im-
21 pair, or supersede the operation of the antitrust
22 laws. For the purpose of this subsection, the term
23 ‘antitrust laws’ has the meaning given it in the first
24 section of the Clayton Act, except that it includes
25 section 5 of the Federal Trade Commission Act to

1 the extent that such section 5 applies to unfair
2 methods of competition.

3 “(8) MANUFACTURER.—In this subsection, the
4 term ‘manufacturer’ means any entity, including any
5 affiliate or licensee of that entity, that is engaged
6 in—

7 “(A) the production, preparation, propaga-
8 tion, compounding, conversion, or processing of
9 a prescription drug, either directly or indirectly
10 by extraction from substances of natural origin,
11 or independently by means of chemical syn-
12 thesis, or by a combination of extraction and
13 chemical synthesis; or

14 “(B) the packaging, repackaging, labeling,
15 relabeling, or distribution of a prescription
16 drug.”.

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

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

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

1 “(A) a sale at retail made pursuant to dis-
2 pensing the drug to a customer of the pharmacist or
3 organization; or

4 “(B) a sale or trade of the drug to a pharmacy
5 or a wholesaler registered to import drugs under sec-
6 tion 804.

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

10 “(3) The making of a materially false, fictitious, or
11 fraudulent statement or representation, or a material
12 omission, in a notice under clause (i) of section
13 804(g)(2)(B) or in an application required under section
14 804(g)(2)(F), or the failure to submit such a notice or
15 application.

16 “(4) The importation of a drug in violation of a reg-
17 istration condition or other requirement under section
18 804, the falsification of any record required to be main-
19 tained, or provided to the Secretary, under such section,
20 or the violation of any registration condition or other re-
21 quirement under such section.”; and

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

24 “(6) Notwithstanding subsection (a), any person that
25 knowingly violates section 301(i) (2) or (3) or section

1 301(aa)(4) shall be imprisoned not more than 10 years,
2 or fined in accordance with title 18, United States Code,
3 or both.”.

4 (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

9 “(g) With respect to a prescription drug that is im-
10 ported or offered for import into the United States by an
11 individual who is not in the business of such importation,
12 that is not shipped by a registered exporter under section
13 804, and that is refused admission under subsection (a),
14 the Secretary shall notify the individual that—

15 “(1) the drug has been refused admission be-
16 cause the drug was not a lawful import under sec-
17 tion 804;

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

20 “(3) the individual may under section 804 law-
21 fully import certain prescription drugs from export-
22 ers registered with the Secretary under section 804;
23 and

24 “(4) the individual can find information about
25 such importation, including a list of registered ex-

1 porters, on the Internet website of the Food and
2 Drug Administration or through a toll-free telephone
3 number required under section 804.”.

4 (2) ESTABLISHMENT REGISTRATION.—Section
5 510(i) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360(i)) is amended in paragraph (1) by
7 inserting after “import into the United States” the
8 following: “, including a drug that is, or may be, im-
9 ported or offered for import into the United States
10 under section 804,”.

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

14 (d) EXHAUSTION.—

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

17 (A) by redesignating subsections (h) and

18 (i) as (i) and (j), respectively; and

19 (B) by inserting after subsection (g) the

20 following:

21 “(h) It shall not be an act of infringement to use,
22 offer to sell, or sell within the United States or to import
23 into the United States any patented invention under sec-
24 tion 804 of the Federal Food, Drug, and Cosmetic Act

1 that was first sold abroad by or under authority of the
2 owner or licensee of such patent.”.

3 (2) RULE OF CONSTRUCTION.—Nothing in the
4 amendment made by paragraph (1) shall be con-
5 strued to affect the ability of a patent owner or li-
6 censee to enforce their patent, subject to such
7 amendment.

8 (e) EFFECT OF SECTION 804.—

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

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

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

22 (2) REVIEW OF REGISTRATION BY CERTAIN EX-
23 PORTERS.—

24 (A) REVIEW PRIORITY.—In the review of
25 registrations submitted under subsection (b) of

1 such section 804, registrations submitted by en-
2 tities in Canada that are significant exporters
3 of prescription drugs to individuals in the
4 United States as of the date of enactment of
5 this Act will have priority during the 90 day pe-
6 riod that begins on such date of enactment.

7 (B) PERIOD FOR REVIEW.—During such
8 90-day period, the reference in subsection
9 (b)(2)(A) of such section 804 to 90 days (relat-
10 ing to approval or disapproval of registrations)
11 is, as applied to such entities, deemed to be 30
12 days.

13 (C) LIMITATION.—That an exporter in
14 Canada exports, or has exported, prescription
15 drugs to individuals in the United States on or
16 before the date that is 90 days after the date
17 of enactment of this Act shall not serve as a
18 basis, in whole or in part, for disapproving a
19 registration under such section 804 from the
20 exporter.

21 (D) FIRST YEAR LIMIT ON NUMBER OF
22 EXPORTERS.—During the 1-year period begin-
23 ning on the date of enactment of this Act, the
24 Secretary of Health and Human Services (re-
25 ferred to in this section as the “Secretary”)

1 may limit the number of registered exporters
2 under such section 804 to not less than 50, so
3 long as the Secretary gives priority to those ex-
4 porters with demonstrated ability to process a
5 high volume of shipments of drugs to individ-
6 uals in the United States.

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

17 (F) FURTHER LIMIT ON NUMBER OF EX-
18 PORTERS.—During any 1-year period beginning
19 on a date that is 2 or more years after the date
20 of enactment of this Act, the Secretary may
21 limit the number of registered exporters under
22 such section 804 to not less than 25 more than
23 the number of such exporters during the pre-
24 vious 1-year period, so long as the Secretary
25 gives priority to those exporters with dem-

1 onstrated ability to process a high volume of
2 shipments of drugs to individuals in the United
3 States.

4 (3) LIMITS ON NUMBER OF IMPORTERS.—

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

18 (B) SECOND YEAR LIMIT ON NUMBER OF
19 IMPORTERS.—During the 1-year period begin-
20 ning on the date that is 2 years after the date
21 of enactment of this Act, the Secretary may
22 limit the number of registered importers under
23 such section 804 to not less than 200 (of which
24 at least a significant number shall be groups of
25 pharmacies, to the extent feasible given the ap-

1 plications submitted by such groups), so long as
2 the Secretary gives priority to those importers
3 with demonstrated ability to process a high vol-
4 ume of shipments of drugs into the United
5 States.

6 (C) FURTHER LIMIT ON NUMBER OF IM-
7 PORTERS.—During any 1-year period beginning
8 on a date that is 3 or more years after the date
9 of enactment of this Act, the Secretary may
10 limit the number of registered importers under
11 such section 804 to not less than 50 more (of
12 which at least a significant number shall be
13 groups of pharmacies, to the extent feasible
14 given the applications submitted by such
15 groups) than the number of such importers
16 during the previous 1-year period, so long as
17 the Secretary gives priority to those importers
18 with demonstrated ability to process a high vol-
19 ume of shipments of drugs to the United
20 States.

21 (4) NOTICES FOR DRUGS FOR IMPORT FROM
22 CANADA.—The notice with respect to a qualifying
23 drug introduced for commercial distribution in Can-
24 ada as of the date of enactment of this Act that is
25 required under subsection (g)(2)(B)(i) of such sec-

1 tion 804 shall be submitted to the Secretary not
2 later than 30 days after the date of enactment of
3 this Act if—

4 (A) the U.S. label drug (as defined in such
5 section 804) for the qualifying drug is 1 of the
6 100 prescription drugs with the highest dollar
7 volume of sales in the United States based on
8 the 12 calendar month period most recently
9 completed before the date of enactment of this
10 Act; or

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

13 (5) NOTICE FOR DRUGS FOR IMPORT FROM
14 OTHER COUNTRIES.—The notice with respect to a
15 qualifying drug introduced for commercial distribu-
16 tion in a permitted country other than Canada as of
17 the date of enactment of this Act that is required
18 under subsection (g)(2)(B)(i) of such section 804
19 shall be submitted to the Secretary not later than
20 180 days after the date of enactment of this Act
21 if—

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

1 that is first completed on the date that is 120
2 days after the date of enactment of this Act; or

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

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

6 (A) GUIDANCE ON SUBMISSION DATES.—

7 The Secretary shall by guidance establish a se-
8 ries of submission dates for the notices under
9 subsection (g)(2)(B)(i) of such section 804 with
10 respect to qualifying drugs introduced for com-
11 mercial distribution as of the date of enactment
12 of this Act and that are not required to be sub-
13 mitted under paragraph (4) or (5).

14 (B) CONSISTENT AND EFFICIENT USE OF

15 RESOURCES.—The Secretary shall establish the
16 dates described under subparagraph (A) so that
17 such notices described under subparagraph (A)
18 are submitted and reviewed at a rate that al-
19 lows consistent and efficient use of the re-
20 sources and staff available to the Secretary for
21 such reviews. The Secretary may condition the
22 requirement to submit such a notice, and the
23 review of such a notice, on the submission by a
24 registered exporter or a registered importer to
25 the Secretary of a notice that such exporter or

1 importer intends to import such qualifying drug
2 to the United States under such section 804.

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

11 (7) NOTICES FOR DRUGS APPROVED AFTER EF-
12 FECTIVE DATE.—The notice required under sub-
13 section (g)(2)(B)(i) of such section 804 for a quali-
14 fying drug first introduced for commercial distribu-
15 tion in a permitted country (as defined in such sec-
16 tion 804) after the date of enactment of this Act
17 shall be submitted to and reviewed by the Secretary
18 as provided under subsection (g)(2)(B) of such sec-
19 tion 804, without regard to paragraph (4), (5), or
20 (6).

21 (8) REPORT.—Beginning with the first full fis-
22 cal year after the date of enactment of this Act, not
23 later than 90 days after the end of each fiscal year
24 during which the Secretary reviews a notice referred
25 to in paragraph (4), (5), or (6), the Secretary shall

1 submit a report to Congress concerning the progress
2 of the Food and Drug Administration in reviewing
3 the notices referred to in paragraphs (4), (5), and
4 (6).

5 (9) USER FEES.—

6 (A) EXPORTERS.—When establishing an
7 aggregate total of fees to be collected from ex-
8 porters under subsection (f)(2) of such section
9 804, the Secretary shall, under subsection
10 (f)(3)(C)(i) of such section 804, estimate the
11 total price of drugs imported under subsection
12 (a) of such section 804 into the United States
13 by registered exporters during the first fiscal
14 year in which this Act takes effect to be an
15 amount equal to the amount which bears the
16 same ratio to \$1,000,000,000 as the number of
17 days in such fiscal year during which this Act
18 is effective bears to 365.

19 (B) IMPORTERS.—When establishing an
20 aggregate total of fees to be collected from im-
21 porters under subsection (e)(2) of such section
22 804, the Secretary shall, under subsection
23 (e)(3)(C)(i) of such section 804, estimate the
24 total price of drugs imported under subsection

1 (a) of such section 804 into the United States
2 by registered importers during—

3 (i) the first fiscal year in which this
4 Act takes effect to be an amount equal to
5 the amount which bears the same ratio to
6 \$1,000,000,000 as the number of days in
7 such fiscal year during which this Act is
8 effective bears to 365; and

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

11 (C) SECOND YEAR ADJUSTMENT.—

12 (i) REPORTS.—Not later than Feb-
13 ruary 20 of the second fiscal year in which
14 this Act is in effect, registered importers
15 shall report to the Secretary the total price
16 and the total volume of drugs imported to
17 the United States by the importer during
18 the 4-month period from October 1
19 through January 31 of such fiscal year.

20 (ii) REESTIMATE.—Notwithstanding
21 subsection (e)(3)(C)(ii) of such section 804
22 or subparagraph (B), the Secretary shall
23 reestimate the total price of qualifying
24 drugs imported under subsection (a) of
25 such section 804 into the United States by

1 registered importers during the second fis-
2 cal year in which this Act is in effect. Such
3 reestimate shall be equal to—

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

8 (II) 3.

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

20 (D) FAILURE TO PAY FEES.—Notwith-
21 standing any other provision of this section, the
22 Secretary may prohibit a registered importer or
23 exporter that is required to pay user fees under
24 subsection (e) or (f) of such section 804 and
25 that fails to pay such fees within 30 days after

1 the date on which it is due, from importing or
2 offering for importation a qualifying drug under
3 such section 804 until such fee is paid.

4 (E) ANNUAL REPORT.—

5 (i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the
6 end of each fiscal year during which fees
7 are collected under subsection (e), (f), or
8 (g)(2)(B)(iv) of such section 804, the Sec-
9 retary shall prepare and submit to the
10 House of Representatives and the Senate a
11 report on the implementation of the au-
12 thority for such fees during such fiscal
13 year and the use, by the Food and Drug
14 Administration, of the fees collected for the
15 fiscal year for which the report is made
16 and credited to the Food and Drug Admin-
17 istration.

18 (ii) CUSTOMS AND BORDER CON-
19 TROL.—Not later than 180 days after the
20 end of each fiscal year during which fees
21 are collected under subsection (e) or (f) of
22 such section 804, the Secretary of Home-
23 land Security, in consultation with the Sec-
24 retary of the Treasury, shall prepare and
25

1 submit to the House of Representatives
2 and the Senate a report on the use, by the
3 Bureau of Customs and Border Protection,
4 of the fees, if any, transferred by the Sec-
5 retary to the Bureau of Customs and Bor-
6 der Protection for the fiscal year for which
7 the report is made.

8 (10) SPECIAL RULE REGARDING IMPORTATION
9 BY INDIVIDUALS.—

10 (A) IN GENERAL.—Notwithstanding any
11 provision of this Act (or an amendment made
12 by this Act), the Secretary shall expedite the
13 designation of any additional countries from
14 which an individual may import a qualifying
15 drug into the United States under such section
16 804 if any action implemented by the Govern-
17 ment of Canada has the effect of limiting or
18 prohibiting the importation of qualifying drugs
19 into the United States from Canada.

20 (B) TIMING AND CRITERIA.—The Sec-
21 retary shall designate such additional countries
22 under subparagraph (A)—

23 (i) not later than 6 months after the
24 date of the action by the Government of

1 Canada described under such subpara-
2 graph; and

3 (ii) using the criteria described under
4 subsection (a)(4)(D)(i)(II) of such section
5 804.

6 (f) IMPLEMENTATION OF SECTION 804.—

7 (1) INTERIM RULE.—The Secretary may pro-
8 mulgate an interim rule for implementing section
9 804 of the Federal Food, Drug, and Cosmetic Act,
10 as added by subsection (a) of this section.

11 (2) NO NOTICE OF PROPOSED RULEMAKING.—
12 The interim rule described under paragraph (1) may
13 be developed and promulgated by the Secretary with-
14 out providing general notice of proposed rulemaking.

15 (3) FINAL RULE.—Not later than 1 year after
16 the date on which the Secretary promulgates an in-
17 terim rule under paragraph (1), the Secretary shall,
18 in accordance with procedures under section 553 of
19 title 5, United States Code, promulgate a final rule
20 for implementing such section 804, which may incor-
21 porate by reference provisions of the interim rule
22 provided for under paragraph (1), to the extent that
23 such provisions are not modified.

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

1 (1) with regard to the availability of qualifying
2 drugs for import for personal use from an exporter
3 registered with and approved by the Food and Drug
4 Administration under section 804 of the Federal
5 Food, Drug, and Cosmetic Act, as added by this sec-
6 tion, including information on how to verify whether
7 an exporter is registered and approved by use of the
8 Internet website of the Food and Drug Administra-
9 tion and the toll-free telephone number required by
10 this Act;

11 (2) that drugs that consumers attempt to im-
12 port from an exporter that is not registered with and
13 approved by the Food and Drug Administration can
14 be seized by the United States Customs Service and
15 destroyed, and that such drugs may be counterfeit,
16 unapproved, unsafe, or ineffective;

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

20 (4) with regard to the availability at domestic
21 retail pharmacies of qualifying drugs imported under
22 such section 804 by domestic wholesalers and phar-
23 macies registered with and approved by the Food
24 and Drug Administration.

1 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-
2 withstanding any provision of this Act (and the amend-
3 ments made by this Act), the practices and policies of the
4 Food and Drug Administration and Bureau of Customs
5 and Border Protection, in effect on January 1, 2004, with
6 respect to the importation of prescription drugs into the
7 United States by an individual, on the person of such indi-
8 vidual, for personal use, shall remain in effect.

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

16 **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
17 **SION INTO UNITED STATES.**

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

22 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
23 **MISSION.**

24 “(a) IN GENERAL.—The Secretary of Homeland Se-
25 curity shall deliver to the Secretary a shipment of drugs

1 that is imported or offered for import into the United
2 States if—

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

5 “(2)(A) the shipping container for such drugs
6 does not bear the markings required under section
7 804(d)(2); or

8 “(B) the Secretary has requested delivery of
9 such shipment of drugs.

10 “(b) NO BOND OR EXPORT.—Section 801(b) does
11 not authorize the delivery to the owner or consignee of
12 drugs delivered to the Secretary under subsection (a) pur-
13 suant to the execution of a bond, and such drugs may not
14 be exported.

15 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
16 Secretary shall destroy a shipment of drugs delivered by
17 the Secretary of Homeland Security to the Secretary
18 under subsection (a) if—

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

23 “(2) in the case of drugs that are not imported
24 or offered for import from a registered exporter

1 under section 804, the drugs are in violation of a
2 standard referred to in section 801(a) or 801(d)(1).

3 “(d) CERTAIN PROCEDURES.—

4 “(1) IN GENERAL.—The delivery and destruc-
5 tion of drugs under this section may be carried out
6 without notice to the importer, owner, or consignee
7 of the drugs except as required by section 801(g) or
8 section 804(i)(2). The issuance of receipts for the
9 drugs, and recordkeeping activities regarding the
10 drugs, may be carried out on a summary basis.

11 “(2) OBJECTIVE OF PROCEDURES.—Procedures
12 promulgated under paragraph (1) shall be designed
13 toward the objective of ensuring that, with respect to
14 efficiently utilizing Federal resources available for
15 carrying out this section, a substantial majority of
16 shipments of drugs subject to described in sub-
17 section (c) are identified and destroyed.

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

23 “(f) RULE OF CONSTRUCTION.—This section may
24 not be construed as having any legal effect on applicable
25 law with respect to a shipment of drugs that is imported

1 or offered for import into the United States and has a
2 declared value equal to or greater than \$10,000.”.

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

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

10 **SEC. 6. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
11 **MENTS REGARDING PRIOR SALE, PURCHASE,**
12 **OR TRADE.**

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

17 (1) in paragraph (1)—

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

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

23 (C) by striking subparagraph (B) and in-
24 serting the following:

1 “(B) The fact that a drug subject to subsection (b)
2 is exported from the United States does not with respect
3 to such drug exempt any person that is engaged in the
4 business of the wholesale distribution of the drug from
5 providing the statement described in subparagraph (A) to
6 the person that receives the drug pursuant to the export
7 of the drug.

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

23 “(ii) When the Secretary promulgates a final rule to
24 establish such alternative requirements, the final rule in
25 addition shall, with respect to the registration condition

1 established in clause (i) of section 804(c)(3)(B), establish
2 a condition equivalent to the alternative requirements, and
3 such equivalent condition may be met in lieu of the reg-
4 istration condition established in such clause (i).”;

5 (2) in paragraph (2)(A), by adding at the end
6 the following: “The preceding sentence may not be
7 construed as having any applicability with respect to
8 a registered exporter under section 804.”; and

9 (3) in paragraph (3), by striking “and sub-
10 section (d)—” in the matter preceding subparagraph
11 (A) and all that follows through “the term ‘whole-
12 sale distribution’ means” in subparagraph (B) and
13 inserting the following: “and subsection (d), the
14 term ‘wholesale distribution’ means”.

15 (b) CONFORMING AMENDMENT.—Section 503(d) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 353(d)) is amended by adding at the end the following:

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

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

25 (c) EFFECTIVE DATE.—

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

4 (2) DRUGS IMPORTED BY REGISTERED IMPORT-
5 ERS UNDER SECTION 804.—Notwithstanding para-
6 graph (1), the amendments made by paragraphs (1)
7 and (3) of subsection (a) and by subsection (b) shall
8 take effect on the date that is 90 days after the date
9 of enactment of this Act with respect to qualifying
10 drugs imported under section 804 of the Federal
11 Food, Drug, and Cosmetic Act, as added by section
12 4.

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

17 (4) ALTERNATIVE REQUIREMENTS.—The Sec-
18 retary shall issue regulations to establish the alter-
19 native requirements, referred to in the amendment
20 made by subsection (a)(1), that take effect not later
21 than January 1, 2012.

22 (5) INTERMEDIATE REQUIREMENTS.—The Sec-
23 retary shall by regulation require the use of stand-
24 ardized anti-counterfeiting or track-and-trace tech-
25 nologies on prescription drugs at the case and pallet

1 level effective not later than 1 year after the date of
2 enactment of this Act.

3 (6) ADDITIONAL REQUIREMENTS.—

4 (A) IN GENERAL.—Notwithstanding any
5 other provision of this section, the Secretary
6 shall, not later than 18 months after the date
7 of enactment of this Act, require that the pack-
8 aging of any prescription drug incorporates—

9 (i) a standardized numerical identifier
10 unique to each package of such drug, ap-
11 plied at the point of manufacturing and re-
12 packaging (in which case the numerical
13 identifier shall be linked to the numerical
14 identifier applied at the point of manufac-
15 turing); and

16 (ii)(I) overt optically variable counter-
17 feit-resistant technologies that—

18 (aa) are visible to the naked eye,
19 providing for visual identification of
20 product authenticity without the need
21 for readers, microscopes, lighting de-
22 vices, or scanners;

23 (bb) are similar to that used by
24 the Bureau of Engraving and Printing
25 to secure United States currency;

1 (cc) are manufactured and dis-
2 tributed in a highly secure, tightly
3 controlled environment; and

4 (dd) incorporate additional layers
5 of nonvisible covert security features
6 up to and including forensic capa-
7 bility, as described in subparagraph
8 (B); or

9 (II) technologies that have a function
10 of security comparable to that described in
11 subclause (I), as determined by the Sec-
12 retary.

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

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

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

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

2 “(a) REQUIREMENTS REGARDING INFORMATION ON
3 INTERNET SITE.—

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

7 “(A) the purchaser of the drug submitted
8 the purchase order for the drug, or conducted
9 any other part of the sales transaction for the
10 drug, through an Internet site;

11 “(B) the person dispenses the drug to the
12 purchaser by mailing or shipping the drug to
13 the purchaser; and

14 “(C) such site, or any other Internet site
15 used by such person for purposes of sales of a
16 prescription drug, fails to meet each of the re-
17 quirements specified in paragraph (2), other
18 than a site or pages on a site that—

19 “(i) are not intended to be accessed
20 by purchasers or prospective purchasers; or

21 “(ii) provide an Internet information
22 location tool within the meaning of section
23 231(e)(5) of the Communications Act of
24 1934 (47 U.S.C. 231(e)(5)).

25 “(2) REQUIREMENTS.—With respect to an
26 Internet site, the requirements referred to in sub-

1 paragraph (C) of paragraph (1) for a person to
2 whom such paragraph applies are as follows:

3 “(A) Each page of the site shall include ei-
4 ther the following information or a link to a
5 page that provides the following information:

6 “(i) The name of such person.

7 “(ii) Each State in which the person
8 is authorized by law to dispense prescrip-
9 tion drugs.

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

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

22 “(v) If the person provides for medical
23 consultations through the site for purposes
24 of providing prescriptions, the name of
25 each individual who provides such con-

1 sultations; each State in which the indi-
2 vidual is licensed or otherwise authorized
3 by law to provide such consultations or
4 practice medicine; and the type or types of
5 health professions for which the individual
6 holds such licenses or other authorizations.

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

12 “(b) INTERNET SALES WITHOUT APPROPRIATE
13 MEDICAL RELATIONSHIPS.—

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

17 “(A) for purposes of such dispensing or
18 sale, the purchaser communicated with the per-
19 son through the Internet;

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

24 “(C) pursuant to such communications, the
25 person provided for the involvement of a practi-

1 tioner, or an individual represented by the per-
2 son as a practitioner, and the practitioner or
3 such individual issued a prescription for the
4 drug that was purchased;

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

10 “(E) the person received payment for the
11 dispensing or sale of the drug.

12 For purposes of subparagraph (E), payment is re-
13 ceived if money or other valuable consideration is re-
14 ceived.

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

17 “(A) the dispensing or selling of a pre-
18 scription drug pursuant to telemedicine prac-
19 tices sponsored by—

20 “(i) a hospital that has in effect a
21 provider agreement under title XVIII of
22 the Social Security Act (relating to the
23 Medicare program); or

24 “(ii) a group practice that has not
25 fewer than 100 physicians who have in ef-

1 fect provider agreements under such title;
2 or

3 “(B) the dispensing or selling of a pre-
4 scription drug pursuant to practices that pro-
5 mote the public health, as determined by the
6 Secretary by regulation.

7 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

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

13 “(i) at least one in-person medical
14 evaluation of the patient has been con-
15 ducted by the practitioner; or

16 “(ii) the practitioner conducts a med-
17 ical evaluation of the patient as a covering
18 practitioner.

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

20 A medical evaluation by a practitioner is an in-
21 person medical evaluation for purposes of this
22 section if the practitioner is in the physical
23 presence of the patient as part of conducting
24 the evaluation, without regard to whether por-

1 tions of the evaluation are conducted by other
2 health professionals.

3 “(C) COVERING PRACTITIONER.—With re-
4 spect to a patient, a practitioner is a covering
5 practitioner for purposes of this section if the
6 practitioner conducts a medical evaluation of
7 the patient at the request of a practitioner who
8 has conducted at least one in-person medical
9 evaluation of the patient and is temporarily un-
10 available to conduct the evaluation of the pa-
11 tient. A practitioner is a covering practitioner
12 without regard to whether the practitioner has
13 conducted any in-person medical evaluation of
14 the patient involved.

15 “(4) RULES OF CONSTRUCTION.—

16 “(A) INDIVIDUALS REPRESENTED AS
17 PRACTITIONERS.—A person who is not a practi-
18 tioner (as defined in subsection (e)(1)) lacks
19 legal capacity under this section to have a
20 qualifying medical relationship with any patient.

21 “(B) STANDARD PRACTICE OF PHAR-
22 MACY.—Paragraph (1) may not be construed as
23 prohibiting any conduct that is a standard prac-
24 tice in the practice of pharmacy.

1 “(C) APPLICABILITY OF REQUIRE-
2 MENTS.—Paragraph (3) may not be construed
3 as having any applicability beyond this section,
4 and does not affect any State law, or interpre-
5 tation of State law, concerning the practice of
6 medicine.

7 “(c) ACTIONS BY STATES.—

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

23 “(2) NOTICE.—The State shall serve prior writ-
24 ten notice of any civil action under paragraph (1) or
25 (5)(B) upon the Secretary and provide the Secretary

1 with a copy of its complaint, except that if it is not
2 feasible for the State to provide such prior notice,
3 the State shall serve such notice immediately upon
4 instituting such action. Upon receiving a notice re-
5 specting a civil action, the Secretary shall have the
6 right—

7 “(A) to intervene in such action;

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

10 “(C) to file petitions for appeal.

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

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

1 any district in which the defendant is an inhabitant
2 or in which the defendant may be found.

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

4 “(A) Nothing contained in this section
5 shall prohibit an authorized State official from
6 proceeding in State court on the basis of an al-
7 leged violation of any civil or criminal statute of
8 such State.

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

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

18 “(e) GENERAL DEFINITIONS.—For purposes of this
19 section:

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

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

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

4 “(f) INTERNET-RELATED DEFINITIONS.—

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

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

16 “(B) The term ‘link’, with respect to the
17 Internet, means one or more letters, words,
18 numbers, symbols, or graphic items that appear
19 on a page of an Internet site for the purpose
20 of serving, when activated, as a method for exe-
21 cuting an electronic command—

22 “(i) to move from viewing one portion
23 of a page on such site to another portion
24 of the page;

1 “(ii) to move from viewing one page
2 on such site to another page on such site;
3 or

4 “(iii) to move from viewing a page on
5 one Internet site to a page on another
6 Internet site.

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

10 “(D)(i) The terms ‘site’ and ‘address’, with
11 respect to the Internet, mean a specific location
12 on the Internet that is determined by Internet
13 Protocol numbers. Such term includes the do-
14 main name, if any.

15 “(ii) The term ‘domain name’ means a
16 method of representing an Internet address
17 without direct reference to the Internet Protocol
18 numbers for the address, including methods
19 that use designations such as ‘.com’, ‘.edu’,
20 ‘.gov’, ‘.net’, or ‘.org’.

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

24 “(2) AUTHORITY OF SECRETARY.—The Sec-
25 retary may by regulation modify any definition

1 under paragraph (1) to take into account changes in
2 technology.

3 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
4 TISING.—No provider of an interactive computer service,
5 as defined in section 230(f)(2) of the Communications Act
6 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
7 shall be liable under this section for dispensing or selling
8 prescription drugs in violation of this section on account
9 of another person’s selling or dispensing such drugs, pro-
10 vided that the provider of the interactive computer service
11 or of advertising services does not own or exercise cor-
12 porate control over such person.”.

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

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

19 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
20 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
21 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
22 NESSES.—In carrying out section 503C of the Federal
23 Food, Drug, and Cosmetic Act (as added by subsection
24 (a) of this section), the Secretary of Health and Human
25 Services shall take into consideration the practices and

1 procedures of public or private entities that certify that
2 businesses selling prescription drugs through Internet
3 sites are legitimate businesses, including practices and
4 procedures regarding disclosure formats and verification
5 programs.

6 (d) REPORTS REGARDING INTERNET-RELATED VIO-
7 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
8 OF DRUGS.—

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

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

20 (B) reporting such sites to State medical
21 licensing boards and State pharmacy licensing
22 boards, and to the Attorney General and the
23 Secretary, for further investigation; and

24 (C) submitting, for each fiscal year for
25 which the award under this subsection is made,

1 a report to the Secretary describing investiga-
2 tions undertaken with respect to violations de-
3 scribed in subparagraph (A).

4 (2) AUTHORIZATION OF APPROPRIATIONS.—For
5 the purpose of carrying out paragraph (1), there is
6 authorized to be appropriated \$100,000 for each of
7 the first 3 fiscal years in which this section is in ef-
8 fect.

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

18 **SEC. 8. PROHIBITING PAYMENTS TO UNREGISTERED FOR-**
19 **EIGN PHARMACIES.**

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

23 “(h) RESTRICTED TRANSACTIONS.—

24 “(1) IN GENERAL.—The introduction of re-
25 stricted transactions into a payment system or the

1 completion of restricted transactions using a pay-
2 ment system is prohibited.

3 “(2) PAYMENT SYSTEM.—

4 “(A) IN GENERAL.—The term ‘payment
5 system’ means a system used by a person de-
6 scribed in subparagraph (B) to effect a credit
7 transaction, electronic fund transfer, or money
8 transmitting service that may be used in con-
9 nection with, or to facilitate, a restricted trans-
10 action, and includes—

11 “(i) a credit card system;

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

17 “(iii) any other system that is cen-
18 trally managed and is primarily engaged in
19 the transmission and settlement of credit
20 transactions, electronic fund transfers, or
21 money transmitting services.

22 “(B) PERSONS DESCRIBED.—A person re-
23 ferred to in subparagraph (A) is—

24 “(i) a creditor;

25 “(ii) a credit card issuer;

1 “(iii) a financial institution;

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

5 “(v) a money transmitting business;
6 or

7 “(vi) a participant in an international,
8 national, regional, or local network used to
9 effect a credit transaction, electronic fund
10 transfer, or money transmitting service.

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

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

22 “(B) an electronic fund transfer or funds
23 transmitted by or through a money transmit-
24 ting business, or the proceeds of an electronic
25 fund transfer or money transmitting service,

1 from or on behalf of the individual for the pur-
2 pose of the unlawful drug importation request;

3 “(C) a check, draft, or similar instrument
4 which is drawn by or on behalf of the individual
5 for the purpose of the unlawful drug importa-
6 tion request and is drawn on or payable at or
7 through any financial institution; or

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

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

23 “(5) UNREGISTERED FOREIGN PHARMACY.—
24 The term ‘unregistered foreign pharmacy’ means a

1 person in a country other than the United States
2 that is not a registered exporter under section 804.

3 “(6) OTHER DEFINITIONS.—

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

5 The terms ‘credit’, ‘creditor’, and ‘credit card’
6 have the meanings given the terms in section
7 103 of the Truth in Lending Act (15 U.S.C.
8 1602).

9 “(B) ACCESS DEVICE; ELECTRONIC FUND

10 TRANSFER.—The terms ‘access device’ and
11 ‘electronic fund transfer’—

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

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

19 “(C) FINANCIAL INSTITUTION.—The term

20 ‘financial institution’—

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

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

4 “(D) MONEY TRANSMITTING BUSINESS;
5 MONEY TRANSMITTING SERVICE.—The terms
6 ‘money transmitting business’ and ‘money
7 transmitting service’ have the meaning given
8 the terms in section 5330(d) of title 31, United
9 States Code.

10 “(E) BOARD.—The term ‘Board’ means
11 the Board of Governors of the Federal Reserve
12 System.

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

15 “(A) REGULATIONS.—The Board shall
16 promulgate regulations requiring—

17 “(i) an operator of a credit card sys-
18 tem;

19 “(ii) an operator of an international,
20 national, regional, or local network used to
21 effect a credit transaction, an electronic
22 fund transfer, or a money transmitting
23 service;

24 “(iii) an operator of any other pay-
25 ment system that is centrally managed and

1 is primarily engaged in the transmission
2 and settlement of credit transactions, elec-
3 tronic transfers or money transmitting
4 services where at least one party to the
5 transaction or transfer is an individual;
6 and

7 “(iv) any other person described in
8 paragraph (2)(B) and specified by the
9 Board in such regulations,
10 to establish policies and procedures that are
11 reasonably designed to prevent the introduction
12 of a restricted transaction into a payment sys-
13 tem or the completion of a restricted trans-
14 action using a payment system

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

18 “(i) identify types of policies and pro-
19 cedures, including nonexclusive examples,
20 that shall be considered to be reasonably
21 designed to prevent the introduction of re-
22 stricted transactions into a payment sys-
23 tem or the completion of restricted trans-
24 actions using a payment system; and

1 “(ii) to the extent practicable, permit
2 any payment system, or person described
3 in paragraph (2)(B), as applicable, to
4 choose among alternative means of pre-
5 venting the introduction or completion of
6 restricted transactions.

7 “(C) NO LIABILITY FOR BLOCKING OR RE-
8 FUSING TO HONOR RESTRICTED TRANS-
9 ACTION.—

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

21 “(ii) COMPLIANCE.—A person de-
22 scribed in paragraph (2)(B) meets the re-
23 quirements of this subsection if the person
24 relies on and complies with the policies and
25 procedures of a payment system of which

1 the person is a member or in which the
2 person is a participant, and such policies
3 and procedures of the payment system
4 comply with the requirements of the regu-
5 lations promulgated under subparagraph
6 (A).

7 “(D) ENFORCEMENT.—

8 “(i) IN GENERAL.—This section shall
9 be enforced by the Federal functional regu-
10 lators and the Federal Trade Commission
11 under applicable law in the manner pro-
12 vided in section 505(a) of the Gramm-
13 Leach-Bliley Act (15 U.S.C. 6805(a)).

14 “(ii) FACTORS TO BE CONSIDERED.—
15 In considering any enforcement action
16 under this subsection against a payment
17 system or person described in paragraph
18 (2)(B), the Federal functional regulators
19 and the Federal Trade Commission shall
20 consider the following factors:

21 “(I) The extent to which the pay-
22 ment system or person knowingly per-
23 mits restricted transactions.

1 “(II) The history of the payment
2 system or person in connection with
3 permitting restricted transactions.

4 “(III) The extent to which the
5 payment system or person has estab-
6 lished and is maintaining policies and
7 procedures in compliance with regula-
8 tions prescribed under this subsection.

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

21 “(9) RELATION TO STATE LAWS.—No require-
22 ment, prohibition, or liability may be imposed on a
23 payment system, or a person described in paragraph
24 (2)(B) that is subject to a regulation issued under
25 this subsection, under the laws of any state with re-

1 spect to any payment transaction by an individual
2 because the payment transaction involves a payment
3 to a foreign pharmacy.

4 “(10) TIMING OF REQUIREMENTS.—A payment
5 system, or a person described in paragraph (2)(B)
6 that is subject to a regulation issued under this sub-
7 section, must adopt policies and procedures reason-
8 ably designed to comply with any regulations re-
9 quired under paragraph (7) within 60 days after
10 such regulations are issued in final form.”.

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

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

20 **SEC. 9. IMPORTATION EXEMPTION UNDER CONTROLLED**
21 **SUBSTANCES IMPORT AND EXPORT ACT.**

22 Section 1006(a)(2) of the Controlled Substances Im-
23 port and Export Act (21 U.S.C. 956(a)(2)) is amended
24 by striking “not import the controlled substance into the
25 United States in an amount that exceeds 50 dosage units

1 of the controlled substance.” and inserting “import into
2 the United States not more than 10 dosage units com-
3 bined of all such controlled substances.”.

4 **SEC. 10. SEVERABILITY.**

5 If any provision of this Act, an amendment by this
6 Act, or the application of such provision or amendment
7 to any person or circumstance is held to be unconstitu-
8 tional, the remainder of this Act, the amendments made
9 by this Act, and the application of the provisions of such
10 to any person or circumstance shall not affected thereby.

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111TH CONGRESS
1ST Session

S. 1232

A BILL

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

JUNE 11, 2009

Read the second time and placed on the calendar