

108TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. DORGAN (for himself, Ms. SNOWE, Mr. KENNEDY, Mr. MCCAIN, Mr. DASCHLE, Mr. LOTT, Ms. STABENOW, Mr. JOHNSON, Mr. PRYOR, and Mr. FEINGOLD) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Mar-
5 ket Access and Drug Safety Act of 2004”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

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

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

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

15 (5) American seniors alone will spend
16 \$1,800,000,000,000 on pharmaceuticals over the
17 next 10 years; and

18 (6) allowing open pharmaceutical markets could
19 save American consumers at least \$38,000,000,000
20 each year.

21 **SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPOR-**
22 **TATION OF PRESCRIPTION DRUGS.**

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

1 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
2 **OF CERTAIN IMPORT RESTRICTIONS.**

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

7 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
8 **PRESCRIPTION DRUGS.**

9 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

10 “(1) IN GENERAL.—The Secretary shall in ac-
11 cordance with this section provide by regulation
12 that, in the case of qualifying drugs imported or of-
13 fered for import into the United States from reg-
14 istered exporters or by registered importers—

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

17 “(B) the standards referred to in section
18 801(a) regarding admission of the drugs are
19 subject to subsection (g) of this section (includ-
20 ing with respect to qualifying drugs to which
21 section 801(d)(1) does not apply).

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

24 “(A) the drug is imported by a pharmacy
25 or a wholesaler that is a registered importer; or

1 “(B) the drug is imported by an individual
2 for personal use or for the use of a family mem-
3 ber of the individual (not for resale) from a reg-
4 istered exporter.

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

9 “(A) by a registered importer; or

10 “(B) from a registered exporter to an indi-
11 vidual.

12 “(4) DEFINITIONS.—

13 “(A) REGISTERED EXPORTER; REG-
14 ISTERED IMPORTER.—For purposes of this sec-
15 tion:

16 “(i) The term ‘registered exporter’
17 means an exporter for which a registration
18 under subsection (b) has been approved
19 and is in effect.

20 “(ii) The term ‘registered importer’
21 means a pharmacy, group of pharmacies,
22 or a wholesaler for which a registration
23 under subsection (b) has been approved
24 and is in effect.

1 “(iii) The term ‘registration condition’
2 means a condition that must exist for a
3 registration under subsection (b) to be ap-
4 proved.

5 “(B) QUALIFYING DRUG.—For purposes of
6 this section, the term ‘qualifying drug’ means a
7 prescription drug, other than any of the fol-
8 lowing:

9 “(i) A controlled substance, as defined
10 in section 102 of the Controlled Sub-
11 stances Act (21 U.S.C. 802).

12 “(ii) A biological product, as defined
13 in section 351 of the Public Health Service
14 Act (42 U.S.C. 262).

15 “(iii) An infused drug, including a
16 peritoneal dialysis solution.

17 “(iv) An intravenously injected drug.

18 “(v) A drug that is inhaled during
19 surgery.

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

22 “(i) The term ‘exporter’ means a per-
23 son that is in the business of exporting a
24 drug from Canada to individuals in the
25 United States or that, pursuant to submit-

1 ting a registration under subsection (b),
2 seeks to be in such business.

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

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

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

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

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

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

24 “(vi) The term ‘wholesaler’—

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

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

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

10 “(i) Australia;

11 “(ii) Canada;

12 “(iii) a member country of the Euro-
13 pean Union as of January 1, 2003;

14 “(iv) Japan;

15 “(v) New Zealand; and

16 “(vi) Switzerland.

17 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
18 ERS.—

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

24 “(A) The name of the registrant and an
25 identification of all places of business of the

1 “(C) An agreement by the registrant that
2 the registrant will not under subsection (a) im-
3 port or export any drug that is not a qualifying
4 drug.

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

6 “(i) notify the Secretary of a recall or
7 withdrawal of a drug distributed in a per-
8 mitted country that the registrant has ex-
9 ported or imported, or intends to export or
10 import, to the United States under sub-
11 section (a);

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

14 “(iii) cease, or not begin, the expor-
15 tation or importation of such drug unless
16 the Secretary has notified the registrant
17 that exportation or importation of such
18 drug may proceed.

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

1 “(F) A plan describing the manner in
2 which the registrant will comply with the agree-
3 ment under subparagraph (E).

4 “(G) An agreement by the registrant to
5 enforce a contract under subsection (c)(3)(B)
6 against a party in the chain of custody of a
7 qualifying drug with respect to the authority of
8 the Secretary under clauses (ii) and (iii) of that
9 subsection.

10 “(H) An agreement by the registrant to
11 notify the Secretary of—

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

15 “(ii) any change that the registrant
16 intends to make in the compliance plan
17 under subparagraph (F).

18 “(I) In the case of an exporter—

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

24 “(ii) An agreement to post a bond,
25 payable to the Treasury of the United

1 States if, after opportunity for an informal
2 hearing, the Secretary determines that the
3 exporter has exported a drug to the United
4 States that is not a qualifying drug or that
5 is not in compliance with subsections (g)
6 or (i), that is equal in value to the lesser
7 of—

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

12 “(II) \$1,000,000.

13 “(J) Such other provisions as the Sec-
14 retary may require to protect the public health
15 while permitting—

16 “(i) the importation by pharmacies,
17 groups of pharmacies, wholesalers as reg-
18 istered importers of qualifying drugs under
19 subsection (a); and

20 “(ii) importation by individuals of
21 qualifying drugs under subsection (a).

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

24 “(A) IN GENERAL.—Not later than 90
25 days after the date on which a registrant sub-

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

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

22 “(3) PUBLICATION OF CONTACT INFORMATION
23 FOR REGISTERED EXPORTERS.—Through the Inter-
24 net website of the Food and Drug Administration,
25 the Secretary shall make readily available to the

1 public a list of registered exporters, including con-
2 tact information for the exporters. Promptly after
3 the approval of a registration submitted under para-
4 graph (1), the Secretary shall update the Internet
5 website accordingly.

6 “(4) SUSPENSION AND TERMINATION.—

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

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

16 “(ii) If the Secretary determines that,
17 under color of the registration, the ex-
18 porter has exported a drug or the importer
19 has imported a drug that is not a quali-
20 fying drug, or a drug that does not meet
21 the criteria under subsection (g)(2)(A), or
22 has exported a qualifying drug to an indi-
23 vidual in violation of subsection (i)(1)(F),
24 the Secretary shall immediately suspend
25 the registration. A suspension under the

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

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

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

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

7 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
8 tion condition is that the exporter or importer involved
9 agrees that a qualifying drug will under subsection (a) be
10 exported or imported to the United States only if there
11 is compliance with the following:

12 “(1) The drug was manufactured in an estab-
13 lishment—

14 “(A) required to register under subsection
15 (h) or (i) of section 510; or

16 “(B) inspected by the Secretary as pro-
17 vided by this section.

18 “(2) The establishment is located in the United
19 States or in any foreign country, and the establish-
20 ment manufactured the drug for distribution in the
21 United States or for distribution in 1 or more of the
22 permitted countries (without regard to whether in
23 addition the drug was manufactured for distribution
24 in a foreign country that is not a permitted coun-
25 try).

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

3 “(A) directly from the establishment; or

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

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

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

18 “(iii) agrees, with respect to the quali-
19 fying drugs involved, to permit the Sec-
20 retary to inspect warehouses and other fa-
21 cilities of the entity for purposes of deter-
22 mining whether the facilities are in compli-
23 ance with any standards under this Act
24 that are applicable to facilities of that type
25 in the United States; and

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

8 “(4) The foreign country from which the im-
9 porter will import the drug is a permitted country.

10 “(5) The foreign country from which the ex-
11 porter will export the drug is Canada.

12 “(6) During any period in which the drug was
13 not in the control of the manufacturer of the drug,
14 the drug did not enter any country that is not a per-
15 mitted country.

16 “(7) The exporter or importer retains a sample
17 of each lot of the drug sufficient for testing by the
18 Secretary.

19 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
20 MENTS.—

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

1 “(A) the exporter agrees to permit the Sec-
2 retary—

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

9 “(ii) to have access, including on a
10 day-to-day basis, to—

11 “(I) records of the exporter that
12 relate to the export of such drugs, in-
13 cluding financial records; and

14 “(II) samples of such drugs;

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

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

21 “(B) the Secretary has assigned 1 or more
22 employees of the Secretary to carry out the
23 functions described in this subsection for the
24 Secretary not less than every 3 weeks on the
25 premises of places of businesses referred to in

1 subparagraph (A)(i), and such an assignment
2 remains in effect on a continuous basis.

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

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

14 “(B) may include anti-counterfeiting or
15 track-and-trace technologies.

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) Verifying the chain of custody of a
20 statistically significant sample of qualifying
21 drugs from the establishment in which the drug
22 was manufactured to the exporter, which may
23 be accomplished by the use of anticounterfeiting
24 or track-and-trace technologies, if available.

1 “(B) Randomly reviewing records of ex-
2 ports to individuals for the purpose of deter-
3 mining whether the drugs are being imported
4 by the individuals in accordance with the condi-
5 tions under subsection (i). Such reviews shall be
6 conducted in a manner that will result in a sta-
7 tistically significant determination of compli-
8 ance with all such conditions.

9 “(C) Monitoring the affixing of markings
10 under paragraph (2).

11 “(D) Inspect as the Secretary determines
12 is necessary the warehouses and other facilities
13 of other parties in the chain of custody of quali-
14 fying drugs.

15 “(E) Determine whether the exporter is in
16 compliance with all other registration condi-
17 tions.

18 “(4) CERTAIN DUTIES RELATING TO IMPORT-
19 ERS.—Duties of the Secretary with respect to an im-
20 porter include the following:

21 “(A) As authorized under section 704, in-
22 spect not less than every 3 weeks, the places of
23 business of the importer that relate to the re-
24 ceipt and distribution of a qualifying drug, in-
25 cluding each warehouse or other facility owned

1 or controlled by, or operated for, the importer
2 at which qualifying drugs are received or from
3 which they are distributed to pharmacies.

4 “(B) During the inspections under sub-
5 paragraph (A), verify the chain of custody of a
6 statistically significant sample of qualifying
7 drugs from the establishment in which the drug
8 was manufactured to the importer, which may
9 be accomplished by the use of anticounterfeiting
10 or track-and-trace technologies, if available.

11 “(C) Inspect as the Secretary determines
12 is necessary the warehouses and other facilities
13 of other parties in the chain of custody of quali-
14 fying drugs.

15 “(D) Determine whether the importer is in
16 compliance with all other registration condi-
17 tions.

18 “(e) IMPORTER FEES.—

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

24 “(2) INSPECTION FEE.—A registration condi-
25 tion is that the importer involved pays to the Sec-

1 retary in accordance with this subsection a fee on a
2 semiannual basis, with the first fee due on the date
3 that is 6 months after the date on which the reg-
4 istration of the importer under subsection (b) is first
5 approved by the Secretary.

6 “(3) AMOUNT OF INSPECTION FEE.—

7 “(A) AGGREGATE TOTAL OF FEES.—The
8 Secretary shall ensure that the aggregate total
9 of fees collected under paragraph (2) for a fis-
10 cal year from all importers is sufficient, and no
11 more than necessary, to pay the costs of admin-
12 istering this section with respect to registered
13 importers for a fiscal year, including—

14 “(i) inspection of the facilities of im-
15 porters under subsection (d)(4);

16 “(ii) reviewing qualifying drugs of-
17 fered for import to importers; and

18 “(iii) determining the compliance of
19 importers with registration conditions.

20 “(B) LIMITATION.—The aggregate total of
21 fees collected under paragraph (2) shall not ex-
22 ceed 1 percent of the total price of drugs im-
23 ported annually to the United States by reg-
24 istered importers under this section

1 “(C) INDIVIDUAL IMPORTER FEE.—Sub-
2 ject to the limitation described in subparagraph
3 (B), a fee under paragraph (2) for an importer
4 shall be an amount that is a reasonable esti-
5 mate by the Secretary of the semiannual share
6 of the importer of the volume of drugs imported
7 by importers under this section.

8 “(D) ADJUSTMENT OF FEE.—The Sec-
9 retary shall annually adjust the fees under
10 paragraph (2) to ensure that the fees accurately
11 reflect the actual costs referred to in subpara-
12 graph (A) and do not exceed, in the aggregate,
13 1 percent of the total price of drugs imported
14 annually to the United States under this sec-
15 tion.

16 “(4) USE OF FEES.—Subject to appropriations
17 Acts, fees collected by the Secretary under para-
18 graphs (1) and (2) are available only to the Sec-
19 retary and are for the sole purpose of paying the
20 costs referred to in paragraph (3)(A).

21 “(f) EXPORTER FEES.—

22 “(1) REGISTRATION FEE.—A registration con-
23 dition is that the exporter involved pays to the Sec-
24 retary a fee of \$10,000 due on the date on which

1 the exporter first submits that registration to the
2 Secretary under subsection (b).

3 “(2) INSPECTION FEE.—A registration condi-
4 tion is that the exporter involved pays to the Sec-
5 retary in accordance with this subsection a fee on a
6 semiannual basis, with the first fee due on the date
7 that is 6 months after the date on which the reg-
8 istration of the exporter under subsection (b) is first
9 approved by the Secretary.

10 “(3) AMOUNT OF INSPECTION FEE.—

11 “(A) AGGREGATE TOTAL OF FEES.—The
12 Secretary shall ensure that the aggregate total
13 of fees collected under paragraph (2) for a fis-
14 cal year from all exporters is sufficient, and not
15 more than necessary, to pay the costs of admin-
16 istering this section with respect to registered
17 exporters for a fiscal year, including—

18 “(i) monitoring foreign facilities under
19 subsection (d);

20 “(ii) developing, implementing, and
21 maintaining under such subsection a sys-
22 tem to mark shipments to indicate compli-
23 ance with all registration conditions; and

24 “(iii) conducting under such sub-
25 section inspections within the United

1 States to determine compliance with condi-
2 tions under subsections (h) and (i).

3 “(B) LIMITATION.—The aggregate total of
4 fees collected under paragraph (2) shall not ex-
5 ceed 1 percent of the total price of drugs im-
6 ported annually to the United States by reg-
7 istered exporters under this section

8 “(C) INDIVIDUAL EXPORTER FEE.—Sub-
9 ject to the limitation described in subparagraph
10 (B), a fee under paragraph (2) for an exporter
11 shall be an amount that is a reasonable esti-
12 mate by the Secretary of the semiannual share
13 of the exporter of the volume of drugs exported
14 by exporters under this section.

15 “(D) ADJUSTMENT OF FEE.—The Sec-
16 retary shall annually adjust the fees under
17 paragraph (2) to ensure that the fees accurately
18 reflect the actual costs referred to in subpara-
19 graph (A) and do not exceed, in the aggregate,
20 1 percent of the total price of drugs imported
21 annually to the United States under this sec-
22 tion.

23 “(4) USE OF FEES.—Subject to appropriations
24 Acts, fees collected by the Secretary under para-
25 graphs (1) and (2) are only available to the Sec-

1 retary and are for the sole purpose of paying the
2 costs referred to in paragraph (3)(A).

3 “(g) COMPLIANCE WITH SECTION 801(a).—

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

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

13 “(A) IN GENERAL.—For purposes of ad-
14 ministrative and judicial procedure, there is a
15 presumption that a drug proposed for export or
16 import under subsection (a) is an approved
17 drug under section 505(b) if the following cri-
18 teria are met:

19 “(i) The drug proposed for export or
20 import is in compliance with subsection
21 (c).

22 “(ii) The drug proposed for export or
23 import has the same active ingredient or
24 ingredients, route of administration, dos-
25 age form, and strength, according to infor-

1 mation provided by the labeling of the drug
2 proposed for export or import, as a drug
3 (referred to in this subsection as a ‘U.S.
4 label drug’) that—

5 “(I) is manufactured by or for
6 the person that manufactures the
7 drug proposed for export or import;
8 and

9 “(II) is approved under section
10 505(b).

11 “(B) IMPORTATION.—Subject to subpara-
12 graphs (D) and (E), a drug meeting the criteria
13 described in subparagraph (A) may, in accord-
14 ance with the other subsections of this section,
15 be imported into the United States.

16 “(C) NOTICE BY MANUFACTURER; GEN-
17 ERAL PROVISIONS.—

18 “(i) IN GENERAL.—The person that
19 manufactures a drug that may be imported
20 under subsection (a) shall in accordance
21 with this paragraph submit to the Sec-
22 retary a notice that—

23 “(I) includes each difference in
24 the drug from a condition established
25 in the approved application for the

1 U.S. label drug beyond the variations
2 provided for in the application, any
3 difference in labeling, the date on
4 which the drug with such difference
5 was, or will be, introduced for com-
6 mercial distribution in a permitted
7 country, and such additional informa-
8 tion as the Secretary may require; or

9 “(II) states that there is no dif-
10 ference in the drug from a condition
11 established in the approved applica-
12 tion for the U.S. label drug beyond
13 the variations provided for in the ap-
14 plication and differences in labeling.

15 “(ii) INFORMATION REGARDING FOR-
16 EIGN GOVERNMENT.—A notice under
17 clause (i)(I) shall with respect to the per-
18 mitted country that approved the drug for
19 commercial distribution, or with respect to
20 which such approval is sought, include the
21 following:

22 “(I) Information demonstrating
23 that the person submitting the notice
24 has also notified the government of
25 the permitted country in writing that

1 the person is submitting to the Sec-
2 retary a notice under clause (i)(I),
3 which notice describes the difference
4 in the drug from a condition estab-
5 lished in the approved application for
6 the U.S. label drug.

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

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

23 “(I) the information provided in
24 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 Assistant At-
4 torney General in charge of the Anti-
5 trust Division of the Department of
6 Justice (referred to in this subsection
7 as the ‘Assistant Attorney General’).

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

23 “(v) TIMING OF SUBMISSION OF NO-
24 TICES.—

1 “(I) PRIOR APPROVAL NO-
2 TICES.—A notice under clause (i) to
3 which subparagraph (D) applies shall
4 be submitted to the Secretary not
5 later than 120 days before the drug
6 with the difference is introduced for
7 commercial distribution in a permitted
8 country, unless the country requires
9 that distribution of the drug with the
10 difference begin less than 120 days
11 after the country requires the dif-
12 ference.

13 “(II) OTHER APPROVAL NO-
14 TICES.—A notice under clause (i) to
15 which subparagraph (E) applies shall
16 be submitted to the Secretary not
17 later than the day on which the drug
18 with the difference is introduced for
19 commercial distribution in a permitted
20 country.

21 “(III) OTHER NOTICES.—A no-
22 tice under clause (i) to which subpara-
23 graph (F) applies shall be submitted
24 to the Secretary on the date that the
25 drug is first introduced for commer-

1 cial distribution in a permitted coun-
2 try and annually thereafter.

3 “(vi) REVIEW BY SECRETARY.—

4 “(I) IN GENERAL.—In this para-
5 graph, the difference in a drug that
6 may be imported under subsection (a)
7 from the U.S. label drug shall be
8 treated by the Secretary as if it was
9 a manufacturing change to the U.S.
10 label drug under section 506A.

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

19 “(III) ESTABLISHMENT INSPEC-
20 TION.—If review of such difference
21 would require an inspection by the
22 Secretary of the establishment in
23 which the drug is manufactured, such
24 inspection shall be authorized by sec-
25 tion 704.

1 “(vii) PUBLICATION OF INFORMATION
2 ON NOTICES.—

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

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

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

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

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

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

1 the Secretary completes review of the
2 notice; and

3 “(II) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 Attorney 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 drug involved from the permitted
13 country cease, or provide that an
14 order under clause (ii), if any, re-
15 mains in effect;

16 “(II) notify the permitted coun-
17 try that approved the drug for com-
18 mercial distribution of the determina-
19 tion; and

20 “(III) promptly notify registered
21 exporters, registered importers, the
22 Federal Trade Commission, and the
23 Assistant Attorney General of the de-
24 termination.

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 vacate the order under
5 clause (ii), if any, permit importation of
6 the drug under subsection (a), and
7 promptly notify registered exporters, reg-
8 istered importers, the Federal Trade Com-
9 mission, and the Assistant Attorney Gen-
10 eral of the determination.

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

19 “(i) During the period in which the
20 notice is being reviewed by the Secretary,
21 the authority under this subsection to im-
22 port the drug involved continues in effect.

23 “(ii) If the Secretary determines that
24 such a supplemental application regarding
25 the U.S. label drug would not be approved,

1 the Secretary shall order that the importa-
2 tion of the drug involved from the per-
3 mitted country cease, shall notify the per-
4 mitted country that approved the drug for
5 commercial distribution of the determina-
6 tion, and shall promptly notify registered
7 exporters, registered importers, the Fed-
8 eral Trade Commission, and the Assistant
9 Attorney General of the determination.

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

18 “(i) may not order that the importa-
19 tion of the drug involved cease; and

20 “(ii) shall promptly notify registered
21 exporters and registered importers.

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

1 “(i) IN GENERAL.—A person who
2 manufactures a U.S. label drug shall sub-
3 mit an application under section 505(b) for
4 a drug that is manufactured for distribu-
5 tion in a permitted country by or for the
6 person that manufactures the U.S. label
7 drug if—

8 “(I) there is no drug for export
9 from at least half of the permitted
10 countries with the same active ingre-
11 dient or ingredients, route of adminis-
12 tration, dosage form, and strength as
13 the U.S. label drug; and

14 “(II) each active ingredient of
15 the drug is related to an active ingre-
16 dient of the U.S. label drug, as de-
17 fined in clause (v).

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

21 “(I) request approval of the drug
22 for the indication or indications for
23 which the U.S. label drug is approved
24 under section 505;

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

13 “(III) include a right of reference
14 to the application under section
15 505(b) for the U.S. label drug; and

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

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

1 505, without regard to whether the
2 copy bears the trademark involved;

3 “(II) the name of the manufac-
4 turer and location of the manufac-
5 turer;

6 “(III) the lot number assigned by
7 the manufacturer; and

8 “(IV) the name, location, and
9 registration number of the importer.

10 “(ii) REQUEST FOR COPY OF THE LA-
11 BELING.—The Secretary shall provide such
12 copy to the registered importer involved,
13 upon request of the importer.

14 “(B) IMPORTATION BY INDIVIDUAL.—In
15 the case of a qualifying drug that is imported
16 or offered for import by a registered exporter to
17 an individual, such drug shall be considered to
18 be in compliance with section 502 if the drug
19 bears a label providing the directions for use by
20 the consumer, and bears a copy of any special
21 labeling that would be required by the Secretary
22 had the drug been dispensed by a pharmacist in
23 the United States, without regard to whether
24 the special labeling bears the trademark in-
25 volved. The Secretary shall provide to the reg-

1 “(III) the methods used in, or
2 the facilities or controls used for, the
3 manufacturing, processing, packing,
4 or holding of the drug do not conform
5 to good manufacturing practice.

6 “(iii) The Secretary has obtained an
7 injunction under section 302 that prohibits
8 the distribution of the drug in interstate
9 commerce.

10 “(iv) The Secretary has under section
11 505(e) withdrawn approval of the drug.

12 “(v) The manufacturer of the drug
13 has instituted a recall of the drug.

14 “(vi) If the qualifying drug is ex-
15 ported from a registered exporter to an in-
16 dividual and 1 or more of the following ap-
17 plies:

18 “(I) The shipping container for
19 such drug does not bear the markings
20 required subsection (d)(2).

21 “(II) The markings on the ship-
22 ping container appear to be counter-
23 feit.

1 “(III) The shipping container or
2 markings appear to have been tam-
3 pered with.

4 “(h) LICENSING AS PHARMACIST.—A registration
5 condition is that the exporter involved agrees that a quali-
6 fying drug will be exported to an individual only if the
7 Secretary has verified that—

8 “(1) the exporter is authorized under Canadian
9 law to dispense prescription drugs; and

10 “(2) the exporter employs persons that are li-
11 censed under Canadian law to dispense prescription
12 drugs in sufficient number to dispense safely the
13 qualifying drugs exported by the exporter to individ-
14 uals, and the exporter assigns to those persons re-
15 sponsibility for dispensing such qualifying drugs to
16 individuals.

17 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION
18 FROM CANADA.—

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

23 “(A) The drug is accompanied by a copy of
24 a prescription for the drug, which prescrip-
25 tion—

1 “(i) is valid under applicable Federal
2 and State laws; and

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

9 “(B) The drug is accompanied by a copy
10 of the documentation that was required under
11 the law or regulations of Canada as a condition
12 of dispensing the drug to the individual.

13 “(C) The copies referred to in subpara-
14 graphs (A)(i) and (B) are marked in a manner
15 sufficient—

16 “(i) to indicate that the prescription,
17 and the equivalent document in Canada,
18 have been filled; and

19 “(ii) to prevent a duplicative filling by
20 another pharmacist.

21 “(D) The individual has provided to the
22 registered exporter a complete list of all drugs
23 used by the individual for review by the individ-
24 uals who dispense the drug.

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

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

15 “(2) NOTICE REGARDING DRUG REFUSED AD-
16 MISSION.—If a registered exporter ships a drug to
17 an individual pursuant to subsection (a)(2)(B) and
18 the drug is refused admission to the United States,
19 a written notice shall be sent to the individual and
20 to the exporter that informs the individual and the
21 exporter of such refusal and the reason for the re-
22 fusal.

23 “(j) MAINTENANCE OF RECORDS AND SAMPLES.—A
24 registration condition is that the importer or exporter in-
25 volved shall—

1 “(1) maintain records required under this sec-
2 tion for not less than 2 years; and

3 “(2) maintain samples of each lot of a drug re-
4 quired under this section for not less than 2 years.

5 “(k) DRUG RECALLS.—

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

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

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

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

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

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

22 “(B) monitor recalls and withdrawals of
23 prescription drugs in the country using any in-
24 formation that is available to the public in any
25 media.

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

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

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

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

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

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

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

23 “(3) The making of a materially false, fictitious, or
24 fraudulent statement or representation, or a material
25 omission, in a notice under clause (i) of section

1 804(g)(2)(C) or in an application required under section
2 804(g)(2)(G), or the failure to submit such a notice or
3 application.

4 “(4) The importation of a drug in violation of a re-
5 quirement under section 804.”; and

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

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

12 (c) IMPLEMENTATION.—

13 (1) RULEMAKING.—

14 (A) IN GENERAL.—

15 (i) PROMULGATION BY SECRETARY.—

16 Not later than 90 days after the date of
17 the enactment of this Act, the Secretary of
18 Health and Human Services shall promul-
19 gate an interim rule for implementing sec-
20 tion 804 of the Federal Food, Drug, and
21 Cosmetic Act, as added by subsection (a)
22 of this section. Such rule shall be devel-
23 oped and promulgated by the Secretary
24 without providing general notice of pro-
25 posed rulemaking. Not later than 1 year

1 after the date on which the interim rule is
2 promulgated, the Secretary shall, in ac-
3 cordance with procedures under section
4 553 of title 5, United States Code, promul-
5 gate a final rule for implementing such
6 section 804, which may incorporate by ref-
7 erence provisions of the interim rule, to the
8 extent that such provisions are not modi-
9 fied.

10 (ii) EFFECT OF RULES.—The rules
11 promulgated under clause (i) shall permit
12 the importation of prescription drugs—

13 (I) from registered exporters by
14 individuals effective on the date of the
15 promulgation of the interim rule;

16 (II) from Canada by registered
17 importers effective on the date of the
18 promulgation of the interim rule; and

19 (III) from Australia, a member
20 country of the European Union as of
21 January 1, 2003, Japan, New Zea-
22 land, or Switzerland by registered im-
23 porters on the date that is 1 year
24 after the date of the enactment of this
25 Act.

1 (B) CERTAIN EXPORTERS.—The interim
2 rule under subparagraph (A) shall provide that,
3 in the review of registrations submitted under
4 subsection (b) of the section 804 referred to in
5 such subparagraph, registrations submitted by
6 entities in Canada that are significant exporters
7 of prescription drugs to individuals in the
8 United States as of the date of the enactment
9 of this Act will have priority during the period
10 in which the interim rule under subparagraph
11 (A) is in effect. During such period, the refer-
12 ence in subsection (b)(2)(A) of such section
13 804 to 90 days (relating to approval or dis-
14 approval of registrations) is, as applied to such
15 entities, deemed to be 30 days.

16 (C) DRUGS FOR IMPORT FROM CANADA.—
17 The notices with respect to drugs to be im-
18 ported from Canada that are required under
19 subsection (g)(2)(C)(i)(I) of such section 804
20 and that require approval under subsection
21 (g)(2)(D) or (E) of such section 804 shall be
22 submitted to the Secretary not later than 30
23 days after the date of enactment of this Act.
24 The notices with respect to drugs to be im-
25 ported from Canada that are required under

1 subsection (g)(2)(C)(i) of such section 804 and
2 that do not require approval under subsection
3 (g)(2)(D) or (E) of such section 804 shall be
4 submitted to the Secretary not later than 90
5 days after the date of enactment of this Act.

6 (D) DRUGS FOR IMPORT FROM OTHER
7 COUNTRIES.—The notices with respect to drugs
8 to be imported from Australia, a member coun-
9 try of the European Union as of January 1,
10 2003, Japan, New Zealand, or Switzerland that
11 are required under subsection (g)(2)(C)(i)(I) of
12 such section 804 and that require approval
13 under subsection (g)(2)(D) or (E) of such sec-
14 tion 804 shall be submitted to the Secretary not
15 later than 180 days after the date of enactment
16 of this Act. The notices with respect to drugs
17 to be imported from such countries that are re-
18 quired under subsection (g)(2)(C)(i)(II) of such
19 section 804 and that do not require approval
20 under subsection (g)(2)(D) or (E) of such sec-
21 tion 804 shall be submitted to the Secretary not
22 later than 270 days after the date of enactment
23 of this Act.

24 (2) PERSONAL IMPORTATION FROM CANADA.—
25 Until the expiration of the 60-day period beginning

1 on the date on which the interim rule under para-
2 graph (1)(A) is promulgated, an individual may im-
3 port a prescription drug from Canada for personal
4 use or for the use of a family member of the indi-
5 vidual (rather than for resale), subject to compliance
6 with the following conditions:

7 (A) The drug is not—

8 (i) a controlled substance, as defined
9 in section 102 of the Controlled Sub-
10 stances Act (21 U.S.C. 802);

11 (ii) a biological product, as defined in
12 section 351 of the Public Health Service
13 Act (42 U.S.C. 262);

14 (iii) an infused drug, including a peri-
15 toneal dialysis solution;

16 (iv) an intravenously injected drug;

17 (v) a drug that is inhaled during sur-
18 gery; or

19 (vi) a drug approved by the Secretary
20 under subpart H of part 314 of title 21,
21 Code of Federal Regulations (relating to
22 accelerated approval) with restrictions
23 under section 520 of such part to assure
24 safe use.

1 (B) The drug is dispensed by a person li-
2 censed in Canada to dispense such drugs.

3 (C) The drug is accompanied by a copy of
4 the prescription for the drug, which prescrip-
5 tion—

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

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

14 (D) The drug is accompanied by a copy of
15 the document that was required in Canada as
16 a condition of dispensing the drug to the indi-
17 vidual.

18 (E) The copies referred to in subpara-
19 graphs (C) and (D) are marked in a manner
20 sufficient—

21 (i) to indicate that the prescription,
22 and the equivalent document in Canada,
23 have been filled; and

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

1 (F) The quantity of the drug does not ex-
2 ceed a 90-day supply.

3 (3) FACILITATION OF CANADIAN IMPORTS.—

4 Not less than 15 days after the enactment of this
5 Act and until the expiration of the 60-day period
6 that begins on the date on which the interim rule
7 under paragraph (1)(A) is promulgated, the Sec-
8 retary shall, through the Internet website of the
9 Food and Drug Administration, make readily avail-
10 able to the public a list of persons licensed in Can-
11 ada to dispense prescription drugs who are willing to
12 export drugs under paragraph (2) to individuals in
13 the United States.

14 (4) EFFECT OF PROVISIONS.—The amendments
15 made in subsection (d), section 6, and section 7 of
16 this Act shall have no effect with respect to imports
17 made under paragraph (2).

18 (d) AMENDMENT OF CERTAIN PROVISION.—Section
19 801 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 381) is amended by striking subsection (g) and in-
21 serting the following:

22 “(g) With respect to a prescription drug that is im-
23 ported or offered for import into the United States by an
24 individual who is not in the business of such importation,
25 that is not shipped by a registered exporter under section

1 804, and that is refused admission under subsection (a),
2 the Secretary shall notify the individual that—

3 “(1) the drug has been refused admission be-
4 cause the drug was not a lawful import under sec-
5 tion 804;

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

8 “(3) the individual may under section 804 law-
9 fully import certain prescription drugs from Cana-
10 dian exporters registered with the Secretary; and

11 “(4) the individual can find information about
12 such importation, including a list of registered ex-
13 porters, on the Internet website of the Food and
14 Drug Administration.”.

15 (e) ANTICOMPETITIVE PRACTICES RELATING TO IM-
16 PORTING AND EXPORTING DRUGS TO THE UNITED
17 STATES.—

18 (1) IN GENERAL.—The Clayton Act (15 U.S.C.
19 12 et seq.) is amended by adding at the end the fol-
20 lowing:

21 **“SEC. 27. RESTRAINT OF TRADE REGARDING PRESCRIP-**
22 **TION DRUGS.**

23 “(a) IN GENERAL.—It shall be unlawful for any per-
24 son engaged in commerce, directly or indirectly to—

1 “(1) charge a higher price for prescription
2 drugs sold to a registered exporter or other person
3 that exports prescription drugs to the United States
4 under section 804 of the Federal Food, Drug, and
5 Cosmetic Act than the price that is charged to an-
6 other person that is in the same country and that
7 does not export prescription drugs into the United
8 States under section 804 of such Act;

9 “(2) charge a higher price for prescription
10 drugs sold to a registered importer or other person
11 that distributes, sells, or uses prescription drugs im-
12 ported to the United States under section 804 of
13 such Act than the price that is charged to another
14 person in the United States that does not import
15 prescription drugs under section 804 of such Act, or
16 that does not distribute, sell, or use such drugs;

17 “(3) deny supplies of prescription drugs to a
18 registered exporter or other person that exports pre-
19 scription drugs to the United States under section
20 804 of such Act or to a registered importer or other
21 person that distributes, sells, or uses prescription
22 drugs imported to the United States under section
23 804 of such Act;

24 “(4) publicly, privately, or otherwise refuse to
25 do business with a registered exporter or other per-

1 son that exports prescription drugs to the United
2 States under section 804 of such Act or with a reg-
3 istered importer or other person that distributes,
4 sells, or uses prescription drugs imported to the
5 United States under section 804 of such Act;

6 “(5) specifically restrict supplies of prescription
7 drugs to a registered exporter or other person that
8 exports prescription drugs to the United States
9 under section 804 of such Act or to a registered im-
10 porter or other person that distributes, sells, or uses
11 prescription drugs imported to the United States
12 under section 804 of such Act;

13 “(6) fail to submit a notice under subsection
14 (g)(2)(C)(i) of section 804 of such Act, fail to sub-
15 mit such a notice on or before the date specified in
16 subsection (g)(2)(C)(v) of section 804 of such Act,
17 submit such a notice that makes a materially false,
18 fictitious, or fraudulent statement, or fail to provide
19 promptly any information requested by the Secretary
20 of Health and Human Services to review such a no-
21 tice;

22 “(7) fail to submit an application required
23 under subsection (g)(2)(G) of section 804 of such
24 Act, fail to submit such an application on or before
25 the date specified in subsection (g)(2)(G)(ii) of sec-

1 tion 804 of such Act, submit such an application
2 that makes a materially false, fictitious, or fraudu-
3 lent statement, or fail to provide promptly any infor-
4 mation requested by the Secretary of Health and
5 Human Services to review such an application;

6 “(8) cause there to be a difference (including a
7 difference in active ingredient, route of administra-
8 tion, dosage form, strength, formulation, manufac-
9 turing establishment, manufacturing process, or per-
10 son that manufactures the drug) between a prescrip-
11 tion drug for distribution in the United States and
12 a prescription drug for distribution in Australia,
13 Canada, a member country of the European Union
14 as of January 1, 2003, Japan, New Zealand, or
15 Switzerland for the purpose of restricting importa-
16 tion of the drug to the United States under section
17 804 of such Act;

18 “(9) refuse to allow an inspection authorized
19 under section 804 of such Act of an establishment
20 that manufactures a prescription drug that is of-
21 fered for import under such section;

22 “(10) fail to conform to the methods used in,
23 or the facilities used for, the manufacturing, proc-
24 essing, packing, or holding of a prescription drug of-

1 ferred for import under section 804 to good manufac-
2 turing practice under such Act; or

3 “(11) engage in any other action that the Fed-
4 eral Trade Commission determines to unfairly re-
5 strict competition under section 804 of such Act.

6 “(b) PRESUMPTION.—A difference (including a dif-
7 ference in active ingredient, route of administration, dos-
8 age form, strength, formulation, manufacturing establish-
9 ment, manufacturing process, or person that manufac-
10 tures the drug) between a prescription drug for distribu-
11 tion in the United States and a prescription drug for dis-
12 tribution in Australia, Canada, a member country of the
13 European Union as of January 1, 2003, Japan, New Zea-
14 land, or Switzerland made after January 1, 2004, shall
15 be presumed to be for the purpose of restricting importa-
16 tion of the drug to the United States under section 804
17 of the Federal Food, Drug, and Cosmetic Act unless—

18 “(1) the person manufacturing the drug for dis-
19 tribution in the United States proves that the dif-
20 ference was required by the country in which the
21 drug is distributed;

22 “(2) the Secretary of Health and Human Serv-
23 ices, acting through the Commissioner of Food and
24 Drug, determines that the difference was necessary
25 to improve the safety or efficacy of the drug; or

1 “(3) the person manufacturing the drug for dis-
2 tribution in the United States has given notice to
3 the Secretary of Health and Human Services under
4 subsection (g)(2)(C)(i) of section 804 of such Act
5 that the drug for distribution in the United States
6 is not different from a drug for distribution in not
7 fewer than half of those countries.

8 “(c) AFFIRMATIVE DEFENSE.—It shall be an affirm-
9 ative defense to a charge that a person has violated para-
10 graph (1), (2), (3), (4), or (5) of subsection (a) that the
11 higher prices charged for prescription drugs sold to a per-
12 son, the denial of supplies of prescription drugs to a per-
13 son, the refusal to do business with a person, or the spe-
14 cific restriction or delay of supplies to a person is not
15 based, in whole or in part, on—

16 “(1) the person exporting or importing pre-
17 scription drugs to the United States under section
18 804 of the Federal Food, Drug, and Cosmetic Act;
19 or

20 “(2) the person distributing, selling, or using
21 prescription drugs imported to the United States
22 under section 804 of such Act.

23 “(d) DEFINITIONS.—In this section:

24 “(1) PRESCRIPTION DRUG.—The term ‘pre-
25 scription drug’ means a drug that is described in

1 section 503(b)(1) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 353(b)(1)).

3 “(2) REGISTERED IMPORTER.—The term ‘reg-
4 istered importer’ has the meaning given such term
5 in section 804 of the Federal Food, Drug, and Cos-
6 metic Act.

7 “(3) REGISTERED EXPORTER.—The term ‘reg-
8 istered exporter’ has the same meaning as in section
9 804 of the Federal Food, Drug, and Cosmetic Act.”.

10 (2) APPLICABILITY OF AMENDMENTS TO IM-
11 PORTATION UNDER THE PHARMACEUTICAL MARKET
12 ACCESS AND FAIR TRADE ACT OF 2004.—

13 (A) PERSONAL IMPORTATION FROM CAN-
14 ADA.—Paragraphs (1) through (5) and (11) of
15 subsection (a) of section 27 of the Clayton Act
16 (15 U.S.C. et seq.) (as amended by paragraph
17 (1)) shall apply with respect to the importation
18 of drugs from Canada under subsection (c)(2).

19 (B) NOTICES RESPECTING DRUG FOR IM-
20 PORT.—Paragraph (6) of subsection (a) of sec-
21 tion 27 of the Clayton Act (15 U.S.C. et seq.)
22 (as amended by paragraph (1)) shall apply with
23 respect to notices required under section
24 804(g)(2)(C)(i) of the Federal Food Drug and
25 Cosmetic Act (21 U.S.C. 384(g)(2)(C)(i)) that

1 are not submitted by the dates required under
2 subsections (c)(1)(C) and (D).

3 (f) EXHAUSTION.—

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

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

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

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

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

1 **SEC. 5. ADDITIONAL WAIVERS REGARDING PERSONAL IM-**
2 **PORTATION; ENFORCEMENT POLICIES OF**
3 **SECRETARY.**

4 (a) IN GENERAL.—Section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6 adding at the end the following:

7 “(p)(1) Waivers under this subsection are in addition
8 to, and independent of, the waiver pursuant to section
9 804(a)(2)(B).

10 “(2) With respect to the standards referred to in sub-
11 section (d)(1), the Secretary shall establish by regulation
12 a waiver of such standards in the case of the importation
13 by an individual of a drug into the United States in the
14 following circumstances:

15 “(A) The drug was dispensed to the individual
16 while the individual was in the United States, the
17 drug was dispensed by a pharmacist or by a practi-
18 tioner licensed by law to administer the drug, and
19 the individual traveled from the United States with
20 the drug.

21 “(B) The individual is entering the United
22 States and the drug accompanies the individual at
23 the time of entry.

24 “(C) The drug does not appear to the Secretary
25 to be adulterated.

1 “(D) The quantity of the drug does not exceed
2 a 90-day supply.

3 “(E) The drug is accompanied by a statement
4 that the individual seeks to import the drug into the
5 United States under a personal importation waiver.

6 “(F) Such additional standards as the Sec-
7 retary determines to be appropriate to protect the
8 public health.

9 “(3) With respect to the standards referred to in sub-
10 sections (a) and (d)(1), the Secretary shall establish by
11 regulation a waiver of such standards in the case of the
12 importation by an individual of a drug into the United
13 States in the following circumstances:

14 “(A) The drug was dispensed to the individual
15 while the individual was in a foreign country, and
16 the drug was dispensed in accordance with the laws
17 and regulations of such country.

18 “(B) The individual is entering the United
19 States and the drug accompanies the individual at
20 the time of entry.

21 “(C) The drug is approved for commercial dis-
22 tribution in the foreign country in which the drug
23 was obtained.

24 “(D) The drug does not appear to the Secretary
25 to be adulterated.

1 “(E) The quantity of the drug does not ex-
2 ceed—

3 “(i) a 90-day supply if the drug is dis-
4 pensed in Australia, Canada, a member country
5 of the European Union as of January 1, 2003,
6 Japan, New Zealand, or Switzerland; or

7 “(ii) a 14-day supply otherwise.

8 “(F) The drug is accompanied by a statement
9 that the individual seeks to import the drug into the
10 United States under a personal importation waiver.

11 “(G) Such additional standards as the Sec-
12 retary determines to be appropriate to protect the
13 public health.

14 “(q) The Secretary may not administer any enforce-
15 ment policy that has the effect of permitting the importa-
16 tion of a prescription drug into the United States in viola-
17 tion of this Act or section 351 of the Public Health Service
18 Act.”.

19 (b) ADDITIONAL WAIVER.—This Act and the amend-
20 ments made by this Act shall not be construed as limiting
21 the authority of the Secretary of Health and Human Serv-
22 ices to establish a waiver of the standards referred to in
23 section 801(a) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 381(a)) with respect to the importation
25 by an individual of a drug into the United States that does

1 not meet such standards, provided that such waiver is no
2 more permissive than the guidance, as in effect on Janu-
3 ary 1, 2004, that is provided in the item numbered 2 (re-
4 lating to a specific situation, consisting of conditions (a)
5 through (d)) under the heading “Drugs, Biologics, and
6 Devices” in chapter 9 of the FDA/ORA Regulatory Proce-
7 dures Manual (relating to import operations/actions), in
8 the subchapter relating to coverage of personal importa-
9 tions.

10 **SEC. 6. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
11 **SION INTO UNITED STATES.**

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 of this Act, is further amended
15 by adding at the end the following section:

16 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
17 **MISSION.**

18 “(a) IN GENERAL.—The Secretary of Homeland Se-
19 curity shall refuse admission to a shipment of drugs that
20 is imported or offered for import into the United States
21 if the shipment has a declared value of less than \$10,000
22 and the drugs are in violation of any standard referred
23 to in section 801(a) or 801(d)(1), including any drugs im-
24 ported or offered for import under enforcement policies
25 prohibited under section 801(q).

1 “(b) IMPORTATION UNDER SECTION 804.—In the
2 case of a drug that under section 804 is imported or of-
3 fered for import from a registered exporter, the reference
4 in subsection (a) to standards referred to in section 801(a)
5 or 801(d)(1) shall be considered a reference to standards
6 referred to in section 804(g)(4)(B).

7 “(c) DESTRUCTION OF VIOLATIVE SHIPMENTS.—
8 Drugs refused admission under subsection (a) or (b) shall
9 be destroyed, subject to subsection (e). Section 801(b)
10 does not authorize the delivery of the drugs pursuant to
11 the execution of a bond, and the drugs may not be ex-
12 ported.

13 “(d) CERTAIN PROCEDURES.—

14 “(1) IN GENERAL.—The refusal of admission
15 and destruction of drugs under this section may be
16 carried out without notice to the importer, owner, or
17 consignee of the drugs except as required by section
18 801(g) or section 804(i)(2). The issuance of receipts
19 for the drugs, and recordkeeping activities regarding
20 the drugs, may be carried out on a summary basis.

21 “(2) OBJECTIVE OF PROCEDURES.—Procedures
22 promulgated under paragraph (1) shall be designed
23 toward the objective of ensuring that, with respect to
24 efficiently utilizing Federal resources available for
25 carrying out this section, a substantial majority of

1 shipments of drugs subject to subsection (a) or (b)
2 are identified and refused admission and destroyed.

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

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

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

17 **SEC. 7. CIVIL ACTIONS REGARDING PROPERTY.**

18 Section 303 of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 333) is amended by adding at the end the
20 following subsection:

21 “(g)(1) If a person is alienating or disposing of prop-
22 erty, or intends to alienate or dispose of property, that
23 is obtained as a result of or is traceable to a drug imported
24 in violation of section 801(a) or 801(d), the Attorney Gen-
25 eral may commence a civil action in any Federal court—

1 “(A) to enjoin such alienation or disposition of
2 property; or

3 “(B) for a restraining order to—

4 “(i) prohibit any person from withdrawing,
5 transferring, removing, dissipating, or disposing
6 of any such property or property of equivalent
7 value; and

8 “(ii) appoint a temporary receiver to ad-
9 minister such restraining order.

10 “(2) Proceedings under paragraph (1) shall be car-
11 ried out in the same manner as applies under section 1345
12 of title 18, United States Code.”.

13 **SEC. 8. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
14 **MENTS REGARDING PRIOR SALE, PURCHASE,**
15 **OR TRADE.**

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

20 (1) in paragraph (1)—

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

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

1 (C) by striking subparagraph (B) and in-
2 serting the following:

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

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

23 “(ii) If the Secretary promulgates a final rule to es-
24 tablish such alternative requirements, the final rule in ad-
25 dition shall, with respect to the registration condition es-

1 tablished in clause (i) of section 804(c)(3)(B), establish
2 a condition equivalent to the alternative requirements, and
3 such equivalent condition supersedes such clause (i).”;

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

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

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

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

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

1 **SEC. 9. REPEAL OF IMPORTATION EXEMPTION UNDER CON-**
2 **TROLLED SUBSTANCES IMPORT AND EXPORT**
3 **ACT.**

4 Section 1006 of the Controlled Substances Import
5 and Export Act (21 U.S.C. 956) is repealed.