

108TH CONGRESS
2D SESSION

S. 2493

To amend the Federal Food, Drug, and Cosmetic Act to protect the public health from the unsafe importation of prescription drugs and from counterfeit prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 2, 2004

Mr. GREGG (for himself, Mr. SMITH, Ms. COLLINS, Mr. COLEMAN, Mr. SESSIONS, Mr. LOTT, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to protect the public health from the unsafe importation of prescription drugs and from counterfeit 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Safe Importation of Medical Products and Other Rx
6 Therapies Act of 2004” or the “Safe IMPORT Act of
7 2004”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Importation.
- Sec. 3. Protection against adulterated prescription drugs.
- Sec. 4. Internet pharmacies.
- Sec. 5. Administrative detention and temporary hold.
- Sec. 6. Suspension.
- Sec. 7. Debarment for repeated or serious prescription drug importation viola-
 tions.
- Sec. 8. Registration of prescription drug importation facilities.
- Sec. 9. Maintenance and inspection of records for prescription drugs.
- Sec. 10. Advance notice of imported prescription drug shipments.
- Sec. 11. Authority to mark prescription drugs refused admission into the
 United States.
- Sec. 12. Prohibition of port shopping.
- Sec. 13. Authority to commission other Federal and State officials to conduct
 inspections.
- Sec. 14. User fees relating to prescription drug importation.
- Sec. 15. Anticounterfeiting provisions.
- Sec. 16. Conforming amendments.

3 **SEC. 2. IMPORTATION.**

4 (a) IN GENERAL.—Chapter VIII of the Federal
 5 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
 6 is amended—

7 (1) by inserting after the chapter heading the
 8 following:

9 “SUBCHAPTER A—GENERAL PROVISIONS”; and

10 (2) by adding at the end the following:

11 “SUBCHAPTER B—IMPORTATION OF
 12 PRESCRIPTION DRUGS

13 **“SEC. 811. DEFINITIONS.**

14 “In this subchapter:

15 “(1) DRUG IMPORTATION FACILITY.—The term
 16 ‘drug importation facility’ means a person, other

1 than an individual importing a prescription drug
2 under section 812, located outside the United States
3 (other than a transporter) that engages in the dis-
4 tribution or dispensing of a prescription drug that is
5 imported or offered for importation into the United
6 States.

7 “(2) INTERNET PHARMACY.—The term ‘Inter-
8 net pharmacy’ means a person, other than an indi-
9 vidual importing a prescription drug under section
10 812, that offers to dispense in the United States a
11 prescription drug through an Internet website in
12 interstate commerce, regardless of whether the phys-
13 ical location of the principal place of business of the
14 Internet pharmacy is in the United States or in an-
15 other country.

16 “(3) PHARMACY.—The term ‘pharmacy’ means
17 a person, other than an individual importing a pre-
18 scription drug under section 812, licensed by a State
19 to dispense prescription drugs or to provide pharma-
20 ceutical care.

21 “(4) PERMITTED COUNTRY.—

22 “(A) IN GENERAL.—The term ‘permitted
23 country’ means a country that—

24 “(i) was a member of the European
25 Union as of December 31, 2003; and

1 “(ii) is designated by the Secretary as
2 a permitted country under subparagraph
3 (B).

4 “(B) REPORT.—Three years after the date
5 of enactment of this subchapter, the Secretary
6 shall submit to the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate and
8 to the Committee on Energy and Commerce of
9 the House of Representatives a report that in-
10 cludes—

11 “(i) a list of countries under subpara-
12 graph (A)(i) designated by the Secretary
13 from which a prescription drug shall be
14 permitted to be imported into the United
15 States under this subchapter, and the basis
16 for the Secretary’s determination that the
17 importation of a prescription drug from
18 such countries would not present an in-
19 creased risk to the public health;

20 “(ii) a list of countries under subpara-
21 graph (A)(i) from which a prescription
22 drug shall not be permitted to be imported
23 into the United States under this sub-
24 chapter, and the basis for Secretary’s de-
25 termination that the importation of a pre-

1 prescription drug from such countries would
2 present an increased risk to the public
3 health;

4 “(iii) for countries identified in clause
5 (i), any additional measures that could be
6 taken to ensure that there will be no in-
7 creased risk to the public health; and

8 “(iv) for countries identified in clause
9 (ii), any additional measures that could be
10 taken to a avoid, reduce, or mitigate such
11 increased risk to the public health.

12 “(C) DETERMINATION.—The Secretary
13 may determine whether to designate a per-
14 mitted country at any time after submission of
15 the report under subparagraph (B).

16 “(5) PRESCRIPTION DRUG.—

17 “(A) IN GENERAL.—The term ‘prescription
18 drug’ means a drug described in section 503(b)
19 that is approved by the Secretary under section
20 505.

21 “(B) EXCLUSIONS.—The term ‘prescrip-
22 tion drug’ does not include—

23 “(i) a controlled substance (as defined
24 in section 102 of the Controlled Sub-
25 stances Act (21 U.S.C. 802));

1 “(ii) a biological product (as defined
2 in section 351 of the Public Health Service
3 Act (42 U.S.C. 262));

4 “(iii) an infused drug (including a
5 peritoneal dialysis solution);

6 “(iv) an intravenously injected drug;

7 “(v) a drug that is inhaled during sur-
8 gery;

9 “(vi) a parenteral drug;

10 “(vii) a drug manufactured through 1
11 or more biotechnology processes, includ-
12 ing—

13 “(I) a therapeutic DNA plasmid
14 product;

15 “(II) a therapeutic synthetic
16 peptide product of not more than 40
17 amino acids;

18 “(III) a monoclonal antibody
19 product for in vivo use; and

20 “(IV) a therapeutic recombinant
21 DNA-derived product;

22 “(viii) a drug required to be refrig-
23 erated at any time during manufacturing,
24 packing, processing, or holding; or

25 “(ix) a photoreactive drug.

1 “(6) TREATING PROVIDER.—The term ‘treating
2 provider’ means a licensed health care provider
3 that—

4 “(A)(i) performs a documented patient
5 evaluation (including a patient history and
6 physical examination) of an individual to estab-
7 lish the diagnosis for which a prescription drug
8 is prescribed;

9 “(ii) discusses with the individual the
10 treatment options of the individual and the
11 risks and benefits of treatment; and

12 “(iii) maintains contemporaneous medical
13 records concerning the individual; or

14 “(B) provides care to an individual as part
15 of an on-call or cross-coverage arrangement
16 with a health care provider described in sub-
17 paragraph (A).

18 “(7) WHOLESALER.—

19 “(A) IN GENERAL.—The term ‘wholesaler’
20 means a person licensed as a wholesaler or dis-
21 tributor of prescription drugs in the United
22 States as described in section 503(e)(2).

23 “(B) EXCLUSION.—The term ‘wholesaler’
24 does not include—

1 “(i) a person authorized to import
2 drugs under section 801(d)(1); or

3 “(ii) an individual importing a pre-
4 scription drug under section 812.

5 **“SEC. 812. PERSONAL IMPORTATION.**

6 “(a) IN GENERAL.—An individual may import a pre-
7 scription drug from Canada or a permitted country into
8 the United States for personal use (not for resale), subject
9 to subsections (b) and (c).

10 “(b) IMPORTATION.—An individual may import a
11 prescription drug if—

12 “(1) the prescription drug is purchased from a
13 licensed pharmacy in Canada or a licensed pharmacy
14 in a permitted country and dispensed in compliance
15 with the applicable laws of Canada or the permitted
16 country regarding the practice of pharmacy;

17 “(2) the prescription drug is imported for per-
18 sonal use (not for resale) by the individual;

19 “(3) the prescription drug is imported from
20 Canada or a permitted country into the United
21 States;

22 “(4) the prescription drug is imported by the
23 individual on the person of the individual;

1 “(5) the quantity of the prescription drug im-
2 ported does not exceed a 90-day supply during any
3 90-day period; and

4 “(6) the prescription drug is accompanied by—

5 “(A) a copy of a prescription valid in a
6 State and cosigned by a prescribing physician
7 in Canada or the permitted country; or

8 “(B) if the prescription drug is available in
9 Canada or the permitted country without a pre-
10 scription, a copy of the valid prescription signed
11 by a pharmacist licensed in Canada or the per-
12 mitted country.

13 “(c) COMPASSIONATE USE.—The Secretary may per-
14 mit an individual to import an up to a 90-day supply of
15 a drug that is not approved by the Secretary under section
16 505 if the importation is for continuation of personal use
17 by the individual for treatment, begun in a foreign coun-
18 try, of a serious medical condition.

19 **“SEC. 813. PHARMACY AND WHOLESALE IMPORTATION OF**
20 **PRESCRIPTION DRUGS.**

21 “(a) IN GENERAL.—

22 “(1) IMPORTATION.—A drug importation facil-
23 ity, pharmacy, Internet pharmacy, or wholesaler may
24 import a prescription drug from Canada or a per-
25 mitted country into the United States for dispensing

1 in the United States in accordance with this sub-
2 chapter.

3 “(2) LIMITATION TO CERTAIN PORTS.—The
4 Secretary may limit the ports of entry in the United
5 States through which a prescription drug may be
6 imported under this section to a reasonable number
7 of ports designated by the Secretary.

8 “(b) REQUIREMENTS.—Each prescription drug im-
9 ported under this subchapter shall—

10 “(1) be approved under section 505;

11 “(2) comply with sections 501 and 502;

12 “(3) be in a container that bears a label stat-
13 ing, in prominent and conspicuous type—

14 “(A) the lot number of the prescription
15 drug;

16 “(B) the name, address and phone number
17 of the drug importation facility;

18 “(C) the following: ‘This drug has been im-
19 ported from _____.’, with the name of the
20 permitted country from which the prescription
21 drug is imported in the blank space; and

22 “(D) a unique identifier code provided by
23 the Secretary that modifies the national drug
24 code of the prescription drug to indicate that
25 the drug has been imported; and

1 “(4) comply with any other applicable require-
2 ment of this Act.

3 “(c) APPROVED LABELING.—

4 “(1) IN GENERAL.—A drug importation facility
5 that offers for importation a prescription drug under
6 this subchapter shall submit to the Secretary an ap-
7 plication for approval that demonstrates that the la-
8 beling of the prescription drug to be imported into
9 the United States complies with the requirements of
10 sections 502 and 503.

11 “(2) PROCEDURE.—Not later than 60 days
12 after receipt of a completed application under para-
13 graph (1), the Secretary shall—

14 “(A) approve or deny the application con-
15 sistent with the requirements of sections 502
16 and 503; and

17 “(B) notify the applicant of the decision of
18 the Secretary and, if the application is denied,
19 the reason for the denial.

20 “(3) LISTS.—

21 “(A) APPLICATIONS.—The Secretary shall
22 maintain an updated list of applications pend-
23 ing, applications approved, and applications de-
24 nied under this subsection.

1 “(B) PORTS.—The Secretary shall main-
2 tain an updated list of ports through which a
3 prescription drug may be imported under this
4 section and make the list available to the public
5 on an Internet website.

6 “(d) PROHIBITION OF IMPORTATION OF A PRESCRIP-
7 TION DRUG THAT ENTERS OTHER COUNTRIES.—

8 “(1) IN GENERAL.—A drug importation facility,
9 pharmacy, Internet pharmacy, or wholesaler shall
10 not import a prescription drug if, during any period
11 in which the prescription drug was not in the control
12 of the manufacturer, the prescription drug entered a
13 country other than—

14 “(A) Canada; or

15 “(B) subject to paragraph (2), a country
16 that was a member of the European Union as
17 of December 31, 2003.

18 “(2) LIMITATION.—The Secretary may exclude
19 1 or more of the countries under subparagraph (B)
20 of paragraph (1) from the application of that sub-
21 paragraph if the Secretary determines that allowing
22 a prescription drug to be imported into the United
23 States after having entered that country outside con-
24 trol of a manufacturer would present a risk to the
25 public health.

1 “(e) PROHIBITION OF COMMINGLING.—

2 “(1) IN GENERAL.—A drug importation facility,
3 pharmacy, Internet pharmacy, or wholesaler shall
4 not commingle a prescription drug imported into the
5 United States under this subchapter with a prescrip-
6 tion drug that is not imported from Canada or a
7 permitted country.

8 “(2) LABEL.—A pharmacy or Internet phar-
9 macy that dispenses a prescription drug imported
10 from Canada or a permitted country shall affix on
11 each dispensed container of the prescription drug
12 the label required under subsection (b)(3) unless
13 such a label is already affixed to the container.

14 “(f) DRUG RECALLS.—On receipt of notification
15 from the manufacturer of a prescription drug imported
16 from Canada or a permitted country under this section
17 that the prescription drug has been recalled or withdrawn
18 from the market in Canada or a permitted country, a drug
19 importation facility shall promptly provide the Secretary
20 and any person to whom the prescription drug was distrib-
21 uted a notice that the drug has been recalled or withdrawn
22 from the market and that includes—

23 “(1) information (including the lot number)
24 that identifies the prescription drug; and

1 “(2) a statement of the reason for the recall or
2 withdrawal.

3 “(g) CHARITABLE CONTRIBUTIONS.—Notwith-
4 standing any other provision of this section, section
5 801(d)(1) continues to apply to a prescription drug that
6 is donated or otherwise supplied at no charge or a nominal
7 charge by the manufacturer of the prescription drug to
8 a charitable or humanitarian organization (including the
9 United Nations and affiliates) or to a government of a
10 foreign country.

11 “(h) JURISDICTION.—The district courts of the
12 United States shall have jurisdiction in an action brought
13 by the United States against a person importing or offer-
14 ing for importation a prescription drug in violation of the
15 requirements of this section.

16 “(i) EFFECT OF SECTION.—Nothing in this section
17 limits the authority of the Secretary relating to the impor-
18 tation of prescription drugs (including the interdiction of
19 prescription drugs that are unapproved, adulterated, or
20 misbranded), other than with respect to section 801(d)(1)
21 as provided in subsection (g).”.

22 (b) REGULATIONS.—

23 (1) PERSONAL IMPORTATION.—

24 (A) IN GENERAL.—The Secretary of
25 Health and Human Services may promulgate

1 regulations to carry out section 812 of the Fed-
2 eral Food, Drug, and Cosmetic Act (as added
3 by this section).

4 (B) EFFECTIVE DATE.—Section 812 of the
5 Federal Food, Drug, and Cosmetic Act shall
6 take effect on the date of enactment of this Act,
7 without regard to whether the Secretary of
8 Health and Human Services has promulgated
9 regulations under paragraph (1).

10 (2) PHARMACY AND WHOLESALER IMPORTA-
11 TION OF PRESCRIPTION DRUGS.—

12 (A) IN GENERAL.—The Secretary of
13 Health and Human Services shall promulgate
14 interim final regulations to carry out section
15 813 of the Federal Food, Drug, and Cosmetic
16 Act (as added by this section).

17 (B) EFFECTIVE DATE.—Section 813 of the
18 Federal Food, Drug, and Cosmetic Act shall
19 take effect on the date that is 1 year after the
20 date of enactment of this Act, without regard to
21 whether the Secretary of Health and Human
22 Services has promulgated regulations under
23 paragraph (1).

1 (c) PROHIBITED ACT.—Section 301 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
3 ed by adding at the end the following:

4 “(hh) Dispensing or offering to dispense a prescrip-
5 tion drug imported into the United States in violation of
6 the requirements of section 813.”.

7 **SEC. 3. PROTECTION AGAINST ADULTERATED PRESCRIP-**
8 **TION DRUGS.**

9 Section 801(h) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 381(h)) is amended—

11 (1) in paragraph (2)—

12 (A) by inserting “and prescription drugs”
13 after “related to foods”;

14 (B) by inserting “and of prescription
15 drugs” after “adulteration of food,”; and

16 (C) by inserting “and prescription drugs”
17 after “importation of food”; and

18 (2) in paragraph (3), by inserting “and for en-
19 suring the safety of imported prescription drugs”
20 after “food safety”.

21 **SEC. 4. INTERNET PHARMACIES.**

22 (a) INTERNET PHARMACIES.—Chapter V of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
24 seq.) is amended by inserting after section 510 the fol-
25 lowing:

1 **“SEC. 511. INTERNET PHARMACIES.**

2 “(a) DEFINITIONS.—In this section:

3 “(1) ADVERTISING SERVICE PROVIDER.—The
4 term ‘advertising service provider’ means an adver-
5 tising company that contracts with a provider of an
6 interactive computer service (as defined in section
7 230(f) of the Communications Act of 1934 (47
8 U.S.C. 230(f)) to provide advertising on the Inter-
9 net.

10 “(2) DESIGNATED PAYMENT SYSTEM.—

11 “(A) IN GENERAL.—The term ‘designated
12 payment system’ means a system used by a per-
13 son to effect a credit transaction, electronic
14 transfer, or money transmitting service de-
15 scribed in subparagraph (B) that the Federal
16 functional regulators determine, by regulation
17 or order, could be used in connection with, or
18 to facilitate, a restricted transaction.

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

21 “(i) a creditor;

22 “(ii) a credit card issuer;

23 “(iii) a financial institution;

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

1 “(v) a money transmitting business;

2 or

3 “(vi)(I) an international, national, re-
4 gional, or local network used to effect a
5 credit transaction, electronic fund transfer,
6 or money transmitting service; or

7 “(II) any participant in a network de-
8 scribed in subclause (I).

9 “(3) FEDERAL FUNCTIONAL REGULATOR.—The
10 term ‘Federal functional regulator’ has the meaning
11 given the term in section 509 of the Gramm-Leach-
12 Bliley Act (15 U.S.C. 6809).

13 “(4) PRESCRIPTION DRUG.—The term ‘pre-
14 scription drug’ means a drug described in section
15 503(b) that is approved by the Secretary under sec-
16 tion 505.

17 “(5) INTERNET PHARMACY.—The term ‘Inter-
18 net pharmacy’ means a person that dispenses or of-
19 fers to dispense a prescription drug through an
20 Internet website in interstate commerce in the
21 United States regardless of whether the physical lo-
22 cation of the principal place of business of the Inter-
23 net pharmacy is in the United States or in another
24 country.

1 “(6) RESTRICTED TRANSACTION.—The term
2 ‘restricted transaction’ means a transaction or trans-
3 mittal, on behalf of a individual who places an un-
4 lawful Internet pharmacy request to any person en-
5 gaged in the operation of an unlicensed Internet
6 pharmacy, of—

7 “(A) credit, or the proceeds of credit, ex-
8 tended to or on behalf of the individual who
9 placed the unlawful Internet request (including
10 credit extended through the use of a credit
11 card);

12 “(B) an electronic fund transfer or funds
13 transmitted by or through a money transmit-
14 ting business, or the proceeds of an electronic
15 fund transfer or money transmitting service,
16 from or on behalf of the individual who placed
17 the unlawful Internet request;

18 “(C) a check, draft, or similar instrument
19 which is drawn by or on behalf of the individual
20 who placed the unlawful Internet request and is
21 drawn on or payable at or through any financial
22 institution; or

23 “(D) the proceeds of any other form of fi-
24 nancial transaction (identified by the Federal
25 functional regulators by regulation) that in-

1 volves a financial institution as a payor or fi-
2 nancial intermediary on behalf of or for the
3 benefit of the individual who placed the unlaw-
4 ful Internet request.

5 “(7) UNLAWFUL INTERNET PHARMACY RE-
6 QUEST.—The term ‘unlawful Internet pharmacy re-
7 quest’ means the request, or transmittal of a re-
8 quest, made to an unlicensed Internet pharmacy for
9 a prescription drug by mail (including a private car-
10 rier), facsimile, phone, or electronic mail, or by a
11 means that involves the use, in whole or in part, of
12 the Internet.

13 “(8) OTHER DEFINITIONS.—

14 “(A) CREDIT; CREDITOR; CREDIT CARD.—
15 The terms ‘credit’, ‘creditor’; and ‘credit card’
16 have the meanings given the terms in section
17 103 of the Truth in Lending Act (15 U.S.C.
18 1602).

19 “(B) ELECTRONIC FUND TRANSFER.—The
20 term ‘electronic fund transfer’—

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

1 “(ii) includes any fund transfer cov-
2 ered under Article 4A of the Uniform Com-
3 mercial Code, as in effect in any State.

4 “(C) FINANCIAL INSTITUTION.—The term
5 ‘financial institution’—

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

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

12 “(D) MONEY TRANSMITTING BUSINESS;
13 MONEY TRANSMITTING SERVICE.—The terms
14 ‘money transmitting business’ and ‘money
15 transmitting service’ have the meaning given
16 the terms in section 5330(d) of title 31, United
17 States Code.

18 “(b) IN GENERAL.—An Internet pharmacy may only
19 dispense or offer to dispense a prescription drug to a per-
20 son in the United States in accordance with this section.

21 “(c) LICENSING OF INTERNET PHARMACIES.—

22 “(1) IN GENERAL.—To be licensed under this
23 section an Internet pharmacy shall—

1 “(A) have its principal place of business in
2 the United States, Canada, or a permitted
3 country; and

4 “(B) be licensed by the Secretary in ac-
5 cordance with this section prior to dispensing a
6 prescription drug to an individual.

7 “(2) CONDITIONS FOR LICENSING.—

8 “(A) APPLICATION REQUIREMENTS.—An
9 Internet pharmacy shall submit to the Sec-
10 retary an application that includes—

11 “(i)(I) in the case of an Internet
12 pharmacy located in the United States,
13 verification that, in each State in which
14 the Internet pharmacy engages in dis-
15 pensing or offering to dispense prescription
16 drugs, the Internet pharmacy, and all em-
17 ployees and agents of the Internet phar-
18 macy, is in compliance with applicable
19 Federal and State laws regarding—

20 “(aa) the practice of pharmacy,
21 including licensing laws and inspec-
22 tion requirements; and

23 “(bb) the manufacturing and dis-
24 tribution of controlled substances, in-
25 cluding with respect to mailing or

1 shipping controlled substances to con-
2 sumers; or

3 “(II) in the case of an Internet phar-
4 macy located in Canada or a permitted
5 country, verification that—

6 “(aa) all employees and agents of
7 the Internet pharmacy are in compli-
8 ance with applicable laws of Canada
9 or the permitted country regarding
10 the practice of pharmacy, including li-
11 censing laws and inspection require-
12 ments; and

13 “(bb) the Internet pharmacy is in
14 compliance with applicable Federal
15 and State laws regarding the practice
16 of pharmacy, including licensing laws
17 and inspection requirements;

18 “(ii) verification that the person that
19 owns the Internet pharmacy has not had a
20 license for an Internet pharmacy termi-
21 nated by the Secretary, and that no other
22 Internet pharmacy owned by the person
23 has had a license under this subsection
24 that has been terminated by the Secretary;

1 “(iii) verification from the person that
2 owns the Internet pharmacy that the per-
3 son will permit inspection of the facilities
4 and business practices of the Internet
5 pharmacy by the Secretary to the extent
6 necessary to determine whether the Inter-
7 net pharmacy is in compliance with this
8 subsection; and

9 “(iv) in the case of an agreement be-
10 tween a patient and an Internet pharmacy
11 that releases the Internet pharmacy, and
12 any employee or agent of the Internet
13 pharmacy, from liability for damages aris-
14 ing out of the negligence of the Internet
15 pharmacy, an assurance that such a limita-
16 tion of liability shall be null and void.

17 “(B) IDENTIFICATION REQUIREMENTS.—
18 An Internet pharmacy shall provide to any per-
19 son that accesses the Internet pharmacy
20 website, on each page of the website of the
21 Internet pharmacy or by a link to a separate
22 page, the following information:

23 “(i) The street address, city, ZIP
24 Code or comparable mail code, State (or

1 comparable entity), country, and telephone
2 number of—

3 “(I) each place of business of the
4 Internet pharmacy; and

5 “(II) the name of the supervising
6 pharmacist of the Internet pharmacy
7 and each individual who serves as a
8 pharmacist for purposes of the Inter-
9 net pharmacy website.

10 “(ii) The names of all States or coun-
11 tries, as appropriate, in which the Internet
12 pharmacy and the pharmacists employed
13 by the Internet pharmacy are licensed or
14 otherwise authorized to dispense prescrip-
15 tion drugs.

16 “(iii) If the Internet pharmacy makes
17 referrals to, or solicits on behalf of, a
18 health care practitioner or group of practi-
19 tioners in the United States for prescrip-
20 tion services—

21 “(I) the name, street address,
22 city, ZIP Code or comparable mail
23 code, State, and telephone number of
24 the practitioner or group; and

1 “(II) the name of each State in
2 which each practitioner is licensed or
3 otherwise authorized to prescribe
4 drugs.

5 “(iv) A statement that the Internet
6 pharmacy will dispense prescription drugs
7 only after receipt of a valid prescription.

8 “(C) PROFESSIONAL SERVICES REQUIRE-
9 MENTS.—An Internet pharmacy shall carry out
10 the following:

11 “(i) Maintain patient medication pro-
12 files and other related data in a readily ac-
13 cessible format organized to facilitate con-
14 sultation with treating providers, care-
15 givers, and patients.

16 “(ii) Conduct prospective drug use re-
17 views before dispensing medications or
18 medical devices.

19 “(iii) Ensure patient confidentiality
20 and the protection of patient identity and
21 patient-specific information, in accordance
22 with the regulations promulgated under
23 section 264(c) of the Health Insurance
24 Portability and Accountability Act of 1996
25 (42 U.S.C. 1320d–2 note).

1 “(iv) Offer interactive and meaningful
2 consultation by a licensed pharmacist to
3 the caregiver or patient prior to and subse-
4 quent to the time at which the Internet
5 pharmacy dispenses the drug.

6 “(v)(I) Establish a mechanism for pa-
7 tients to report errors and suspected ad-
8 verse drug reactions.

9 “(II) Document in the reporting
10 mechanism the response of the Internet
11 pharmacy to those reports.

12 “(vi) Develop a system to inform care-
13 givers and patients about drug recalls.

14 “(vii) Educate caregivers and patients
15 about the appropriate means of disposing
16 of expired, damaged, or unusable medica-
17 tions.

18 “(viii) Assure that the sale of a pre-
19 scription drug is in accordance with a pre-
20 scription from the treating provider of the
21 individual.

22 “(ix)(I) Verify the validity of the pre-
23 scription of an individual by using 1 of the
24 following methods:

1 “(aa) Receiving from the indi-
2 vidual or treating provider of the indi-
3 vidual the prescription of the indi-
4 vidual by mail (including a private
5 carrier), or receiving from the treating
6 provider of the individual the prescrip-
7 tion of the individual by electronic
8 mail.

9 “(bb) If the prescription is for a
10 controlled substance (as defined in
11 section 102 of the Controlled Sub-
12 stances Act (21 U.S.C. 802)), con-
13 firming with the treating provider the
14 information in subclause (II).

15 “(II) When seeking verification of a
16 prescription of an individual under sub-
17 clause (I)(bb), an Internet pharmacy shall
18 provide to the treating provider the fol-
19 lowing information:

20 “(aa) The full name and address
21 of the individual.

22 “(bb) Identification of the pre-
23 scription drug.

24 “(cc) The quantity of the pre-
25 scription drug to be dispensed.

1 “(dd) The date on which the in-
2 dividual presented the prescription to
3 the Internet pharmacy.

4 “(ee) The date and time of the
5 verification request.

6 “(ff) The name of a contact per-
7 son at the Internet pharmacy, includ-
8 ing a voice telephone number, elec-
9 tronic mail address, and facsimile tele-
10 phone number.

11 “(III) A prescription is verified under
12 subclause (I)(bb) only if 1 of the following
13 occurs:

14 “(aa) The treating provider con-
15 firms, by direct communication with
16 the Internet pharmacy, that the pre-
17 scription is accurate.

18 “(bb) The treating provider in-
19 forms the Internet pharmacy that the
20 prescription is inaccurate and provides
21 the accurate prescription.

22 “(IV) An Internet pharmacy shall not
23 fill a prescription if—

24 “(aa) a treating provider informs
25 the Internet pharmacy within 72

1 hours after receipt of a communica-
2 tion under subclause (I)(bb) that the
3 prescription is inaccurate or expired;
4 or

5 “(bb) the treating provider does
6 not respond within that time.

7 “(x) Maintain, for such period of time
8 as the Secretary shall prescribe by regula-
9 tion, a record of all direct communications
10 with a treating provider regarding the dis-
11 pensing of a prescription drug, including
12 verification of the prescription.

13 “(3) LICENSURE PROCEDURE.—

14 “(A) ACTION BY SECRETARY.—On receipt
15 of a completed licensing application under para-
16 graph (3), the Secretary shall—

17 “(i) assign an identification number
18 to each Internet pharmacy;

19 “(ii) notify the applicant of the receipt
20 of the licensure application; and

21 “(iii) not later than 60 days after re-
22 ceipt of the licensure application, issue a li-
23 cense if the Internet pharmacy is in com-
24 pliance with conditions under paragraph
25 (3).

1 “(B) ELECTRONIC FILING.—

2 “ (i) IN GENERAL.—For the purpose
3 of reducing paperwork and reporting bur-
4 dens, the Secretary shall require the use of
5 electronic methods of submitting to the
6 Secretary a licensure application required
7 under this section and provide for elec-
8 tronic methods of receiving the applica-
9 tions.

10 “(ii) AUTHENTICATION.—In providing
11 for the electronic submission of such licen-
12 sure applications under this section, the
13 Secretary shall ensure that adequate au-
14 thentication protocols are used to allow
15 identification of the Internet pharmacy and
16 validation of the data as appropriate.

17 “(4) LIST.—

18 “(A) IN GENERAL.—The Secretary shall
19 compile, maintain, and periodically update a list
20 of licensees.

21 “(B) AVAILABILITY.—The Secretary shall
22 make the list described under subparagraph (A)
23 and information submitted by the licensee
24 under paragraph (2)(B) available to the public

1 on an Internet website and through a toll-free
2 telephone number.

3 “(5) LICENSING FEE.—The Secretary shall es-
4 tablish a licensing fee that an Internet pharmacy li-
5 censed by the Secretary under this section shall be
6 required to pay to the Secretary.

7 “(A) COLLECTION.—

8 “(i) COLLECTION OF INITIAL YEAR LI-
9 CENSING FEE.—A licensing fee of \$5,000
10 shall be payable for the fiscal year in which
11 the Internet pharmacy first submits a li-
12 censing application under this section.

13 “(ii) COLLECTION IN SUBSEQUENT
14 YEARS.—After the licensing fee is paid for
15 the first fiscal year, the fee, as modified
16 under subparagraph (B), shall be payable
17 on or before October 1 of each year.

18 “(iii) ONE FEE PER INTERNET PHAR-
19 MACY.—The licensing fee shall be paid
20 only once for each Internet pharmacy for
21 a fiscal year in which the fee is payable.

22 “(B) FEE AMOUNT.—The amount of the
23 licensing fee shall be determined each year by
24 the Secretary based on the anticipated costs to

1 the Secretary of enforcing the requirements of
2 this section in the subsequent fiscal year.

3 “(C) ANNUAL FEE DETERMINATION.—

4 “(i) IN GENERAL.—Not later than 60
5 days before the beginning of each fiscal
6 year beginning after September 30, 2004,
7 the Secretary shall determine the licensing
8 fee for that fiscal year.

9 “(ii) PUBLICATION OF FEE
10 AMOUNT.—Not later than 60 days before
11 each fiscal year, the Secretary shall publish
12 the licensing fee under this section for that
13 fiscal year and provide for a period of 30
14 days for the public to provide written com-
15 ments on the fee.

16 “(D) USE OF FEES.—The licensing fees
17 collected under this section shall be used, with-
18 out further appropriation, to carry out this sec-
19 tion.

20 “(E) FAILURE TO PAY FEE.—

21 “(i) DUE DATE.—A licensing fee pay-
22 able under this section shall be paid by the
23 date that is 30 days after the date on
24 which the fee is due.

1 “(ii) FAILURE TO PAY.—If an Inter-
2 net pharmacy subject to a fee under this
3 section fails to pay the fee by the date
4 specified under clause (i), the Secretary
5 shall not permit the Internet pharmacy to
6 engage in the dispensing of drugs as de-
7 scribed under this section until all such
8 fees owed by the Internet pharmacy are
9 paid.

10 “(F) REPORTS.—Beginning with fiscal
11 year 2005, not later than 60 days after the end
12 of each fiscal year during which licensing fees
13 are collected under this section, the Secretary
14 shall submit to the Committee on Health, Edu-
15 cation, Labor, and Pensions of the Senate and
16 the Committee on Energy and Commerce of the
17 House of Representatives a report that de-
18 scribes—

19 “(i) implementation of the licensing
20 fee authority during the fiscal year; and

21 “(ii) the use by the Secretary of the
22 licensing fees collected during the fiscal
23 year for which the report is made.

24 “(6) TERMINATION OF LICENSE.—The Sec-
25 retary, upon the initiative of the Secretary, may ter-

1 minate a license issued under subsection (c), after
2 notice to the Internet pharmacy and an opportunity
3 for a hearing, and if the Secretary determines that
4 an Internet pharmacy—

5 “(A) has demonstrated a pattern of non-
6 compliance with this section;

7 “(B) has made an untrue statement of ma-
8 terial fact in its license application; or

9 “(C) is in violation of any applicable Fed-
10 eral or State law relating to the dispensing of
11 a prescription drug.

12 “(7) RENEWAL EVALUATION.—

13 “(A) IN GENERAL.—Before renewing a li-
14 cense of an Internet pharmacy under this sub-
15 section pursuant to the submission of a renewal
16 application, the Secretary shall conduct an eval-
17 uation to determine whether the Internet phar-
18 macy is in compliance with this section.

19 “(B) EVALUATION.—At the discretion of
20 the Secretary and as applicable, an evaluation
21 under subparagraph (A) may include testing of
22 the Internet pharmacy website or other systems
23 through which the Internet pharmacy commu-
24 nicates with consumers, and a physical inspec-

1 tion of the records and premises of the phar-
2 macy.

3 “(8) CONTRACT FOR OPERATION OF PRO-
4 GRAM.—

5 “(A) IN GENERAL.—The Secretary may
6 award a contract under this subsection for the
7 operation of the licensing program.

8 “(B) TERM.—The duration of a contract
9 under subparagraph (A) shall not exceed 5
10 years and may be renewable.

11 “(C) PERFORMANCE REVIEW.—The Sec-
12 retary shall annually review performance under
13 a contract under subparagraph (A).

14 “(d) PROVIDERS OF INTERACTIVE COMPUTER SERV-
15 ICES OR ADVERTISING SERVICES.—A provider of inter-
16 active computer services (as defined in section 230(f) of
17 the Communications Act of 1934 (47 U.S.C. 230(f))) or
18 an advertising service provider shall be liable under this
19 section for dispensing or selling prescription drugs in vio-
20 lation of this section on account of another person’s selling
21 or dispensing of a prescription drug if the provider of the
22 service—

23 “(1) accepts advertising for a prescription drug
24 from an unlicensed Internet pharmacy; or

1 “(2) accepts advertising stating that an indi-
2 vidual does not need a physician’s prescription to ob-
3 tain a prescription drug.

4 “(e) POLICIES AND PROCEDURES REQUIRED TO
5 PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHAR-
6 MACY REQUESTS.—

7 “(1) REGULATIONS.—Not later than 1 year
8 after the date of enactment of this section, the Fed-
9 eral functional regulators shall promulgate regula-
10 tions requiring a person described in subsection
11 (a)(2) to prevent restricted transactions by estab-
12 lishing policies and procedures that—

13 “(A)(i) are reasonably designed to allow
14 the payment system and any person involved in
15 the payment system to identify restricted trans-
16 actions by means of codes in authorization mes-
17 sages or by other means; and

18 “(ii) are reasonably designed to block re-
19 stricted transactions identified as a result of the
20 policies and procedures developed under clause
21 (i); or

22 “(B) prevent the acceptance of the prod-
23 ucts or services of the payment system in con-
24 nection with a restricted transaction.

1 “(2) REQUIREMENTS FOR POLICIES AND PRO-
2 CEDURES.—In promulgating regulations under para-
3 graph (1), the Federal functional regulators shall—

4 “(A) identify types of policies and proce-
5 dures, including nonexclusive examples, that
6 shall be considered to be reasonably designed to
7 identify and reasonably designed to block or to
8 prevent the acceptance of the products or serv-
9 ices in connection with each type of restricted
10 transaction, including—

11 “(i) identifying transactions by a code
12 or codes in the authorization message; and

13 “(ii) denying authorization of a credit
14 card transaction in response to an author-
15 ization message; and

16 “(B) to the extent practicable, permit any
17 participant in a designated payment system to
18 choose among alternative means of identifying
19 and blocking, or otherwise preventing the ac-
20 ceptance of the products or services of the des-
21 ignated payment system or participant in con-
22 nection with, restricted transactions.

23 “(3) COMPLIANCE WITH PAYMENT SYSTEM
24 POLICIES AND PROCEDURES.—A person described in

1 subsection (a)(2)(B) meets the requirement of para-
2 graph (1) if—

3 “(A) the person relies on and complies
4 with the policies and procedures of a designated
5 payment system of which the person is a mem-
6 ber or in which the person is a participant, to—

7 “(i) identify and block restricted
8 transactions; or

9 “(ii) otherwise prevent the acceptance
10 of the products or services of the payment
11 system, member, or participant in connec-
12 tion with restricted transactions; and

13 “(B) such policies and procedures of the
14 designated payment system comply with the re-
15 quirements of regulations promulgated under
16 paragraph (1).

17 “(4) NO LIABILITY FOR BLOCKING OR REFUS-
18 ING TO HONOR RESTRICTED TRANSACTION.—A per-
19 son that is subject to a regulation or an order issued
20 under this section and blocks or otherwise refuses to
21 honor a restricted transaction (or a transaction that
22 such person reasonably believes to be a restricted
23 transaction) or as a member of a designated pay-
24 ment system, relies on the policies and procedures of
25 the payment system in an effort to comply with reg-

1 ulations promulgated under this section, shall not be
2 liable to any party for such action.

3 “(5) ENFORCEMENT.—

4 “(A) IN GENERAL.—This section shall be
5 enforced by the Federal functional regulators
6 and the Federal Trade Commission under appli-
7 cable law in the manner provided in section
8 505(a) of the Gramm-Leach-Bliley Act (21
9 U.S.C. 6805(a)).

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

16 “(i) The extent to which the person is
17 extending credit or transmitting funds
18 knowing the transaction is in connection
19 with an unlawful Internet pharmacy re-
20 quest.

21 “(ii) The history of the person in ex-
22 tending credit or transmitting funds know-
23 ing the transaction is in connection with
24 an unlawful Internet pharmacy request.

1 “(iii) The extent to which the person
2 has established and is maintaining policies
3 and procedures in compliance with regula-
4 tions prescribed under this subsection.

5 “(iv) The feasibility that any specific
6 remedy prescribed can be implemented by
7 the person without substantial deviation
8 from normal business practice.

9 “(v) The costs and burdens the spe-
10 cific remedy will have on the person.

11 “(f) REPORTS REGARDING INTERNET-RELATED VIO-
12 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
13 OF DRUGS.—The Secretary shall, pursuant to the submis-
14 sion of an application meeting criteria prescribed by the
15 Secretary, make an award of a grant or contract to an
16 entity with experience in developing and maintaining sys-
17 tems for the purpose of—

18 “(1) identifying Internet pharmacy websites
19 that are not licensed or that appear to be operating
20 in violation of Federal or State laws concerning the
21 dispensing of drugs;

22 “(2) reporting such Internet pharmacy websites
23 to State medical licensing boards and State phar-
24 macy licensing boards, and to the Attorney General
25 and the Secretary, for further investigation; and

1 “(3) submitting, for each fiscal year for which
2 the award under this subsection is made, a report to
3 the Secretary describing investigations undertaken
4 with respect to violations described in paragraph
5 (1).”.

6 (b) PROHIBITED ACT.—Section 301 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
8 amended by section 2(b)) is amended by adding at the
9 end the following:

10 “(ii) The sale of a prescription drug, or the ownership
11 or operation of an Internet pharmacy, in violation of sec-
12 tion 511.

13 “(jj) The representation by advertisement, sales pres-
14 entation, direct communication (including telephone, fac-
15 simile, or electronic mail), or otherwise by an Internet
16 pharmacy, that a prescription drug may be obtained from
17 the Internet pharmacy without a prescription, in violation
18 of section 511.

19 “(kk) The acceptance of an advertisement from an
20 Internet pharmacy by the provider of an interactive com-
21 puter service, unless the provider has on file a copy of
22 the license issued to the Internet pharmacy under section
23 511.”.

24 (c) LINKS TO ILLEGAL INTERNET PHARMACIES.—
25 Section 302 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 332) is amended by adding at the end the fol-
2 lowing:

3 “(c)(1) In the case of a violation of section 511 relat-
4 ing to an illegal Internet pharmacy, the district courts of
5 the United States and the United States courts of the ter-
6 ritories shall have jurisdiction to order a provider of an
7 interactive computer service to remove, or disable access
8 to, a website violating that section that resides on a com-
9 puter server that the provider controls or operates.

10 “(2) Relief under paragraph (1)—

11 “(A) shall be available only after provision to
12 the provider of notice and an opportunity to appear;

13 “(B) shall not impose any obligation on the
14 provider to monitor its service or to affirmatively
15 seek facts indicating activity violating section 511;
16 and

17 “(C) shall specify the provider to which the re-
18 lief applies.”.

19 (d) REGULATIONS.—

20 (1) IN GENERAL.—Not later than 1 year after
21 the date of enactment of this Act, the Secretary of
22 Health and Human Services shall promulgate in-
23 terim final regulations that are consistent with the
24 Verified Internet Pharmacy Sites certification pro-
25 gram developed by the National Association of

1 Boards of Pharmacy to carry out the amendments
2 made by this section.

3 (2) EFFECTIVE DATE.—The requirement of li-
4 censure under section 511 of the Federal Food,
5 Drug, and Cosmetic Act (as added by this section)
6 shall take effect on the date determined by the Sec-
7 retary of Health and Human Services but in no
8 event later than 90 days after the effective date of
9 the interim final regulations under paragraph (1).

10 (e) RETURN TO SENDER.—Section 801 of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
12 amended by adding at the end the following:

13 “(p) UNLICENSED INTERNET PHARMACY.—If an
14 Internet pharmacy is not licensed by the Secretary in ac-
15 cordance with section 511, any shipment of a prescription
16 drug from such an Internet pharmacy to an individual
17 shall be refused admission into the United States and the
18 Secretary shall return the prescription drug, other than
19 a prescription drug that is required to be destroyed, to
20 the Internet pharmacy at the expense of the Internet phar-
21 macy.

22 “(q) LICENSED INTERNET PHARMACY.—If a ship-
23 ment of a prescription drug from an Internet pharmacy
24 licensed by the Secretary in accordance with section 511

1 to an individual is refused admission into the United
2 States, the Secretary shall—

3 “(1) return the prescription drug, other than a
4 prescription drug that is required to be destroyed, to
5 the Internet pharmacy at the expense of the Internet
6 pharmacy; and

7 “(2) provide the individual and the Internet
8 pharmacy with a written notice that informs the in-
9 dividual and the Internet pharmacy of the refusal
10 and of the reason for the refusal.”.

11 **SEC. 5. ADMINISTRATIVE DETENTION AND TEMPORARY**

12 **HOLD.**

13 (a) IN GENERAL.—The Federal Food, Drug, and
14 Cosmetic Act is amended by adding after section 815 (as
15 added by section 9) the following:

16 **“SEC. 816. ADMINISTRATIVE DETENTION.**

17 “(a) ADMINISTRATIVE DETENTION OF PRESCRIP-
18 TION DRUGS.—

19 “(1) DETENTION AUTHORITY.—

20 “(A) IN GENERAL.—An officer or qualified
21 employee of the Food and Drug Administration
22 may order the detention, in accordance with
23 this subsection, of any prescription drug that is
24 found during an inspection, examination, or in-
25 vestigation under this Act conducted by the of-

1 ficer or qualified employee, if the officer or
2 qualified employee has credible evidence or in-
3 formation indicating that the prescription drug
4 presents a risk to the public health.

5 “(B) APPROVAL.—A prescription drug
6 may be detained under subparagraph (A) only
7 if the Secretary or an official designated by the
8 Secretary approves the order of detention.

9 “(2) PERIOD OF DETENTION.—A prescription
10 drug may be detained under paragraph (1) for a
11 reasonable period, not to exceed 20 days, unless a
12 greater period, not to exceed 30 days, is necessary,
13 to enable the Secretary to commence an action
14 under this subsection or section 302.

15 “(3) SECURITY OF DETAINED ARTICLE.—

16 “(A) IN GENERAL.—An order under para-
17 graph (1) with respect to a prescription drug—

18 “(i) may require that the prescription
19 drug be labeled or marked as detained; and

20 “(ii) shall require that the prescrip-
21 tion drug be removed to a secure facility,
22 as appropriate.

23 “(B) NO TRANSFER.—A prescription drug
24 subject to an order under paragraph (1) shall
25 not be transferred by any person from the place

1 at which the prescription drug is ordered de-
2 tained or from the place to which the prescrip-
3 tion drug is removed, until released by the Sec-
4 retary or until the expiration of the detention
5 period applicable under the order, whichever oc-
6 curs first.

7 “(C) EFFECT OF PARAGRAPH.—This para-
8 graph does not authorize the delivery of a pre-
9 scription drug pursuant to the execution of a
10 bond while the prescription drug is subject to
11 an order under paragraph (1).

12 “(D) EFFECT OF BONDING PROVISION.—
13 Section 801(b) does not authorize the delivery
14 of a prescription drug pursuant to the execution
15 of a bond while the prescription drug is subject
16 to an order under paragraph (1).

17 “(4) APPEAL OF DETENTION ORDER.—

18 “(A) IN GENERAL.—With respect to a pre-
19 scription drug detained under paragraph (1),
20 any person that would be entitled to be a claim-
21 ant for the prescription drug if the prescription
22 drug were seized under paragraph (1) may ap-
23 peal the order of detention to the Secretary.

24 “(B) ACTION BY THE SECRETARY.—Not
25 later than 5 days after an appeal is filed, the

1 Secretary, after providing opportunity for an in-
2 formal hearing, shall confirm or terminate the
3 order, and confirmation by the Secretary shall
4 be considered to be a final agency action for
5 purposes of section 702 of title 5, United States
6 Code.

7 “(C) FAILURE TO ACT.—If, during the 5-
8 day period specified in subparagraph (B), the
9 Secretary fails to provide an opportunity for
10 hearing or to confirm or terminate the order,
11 the order shall be deemed to be terminated.

12 “(D) EFFECT OF COMMENCEMENT OF
13 COURT ACTION.—The process under this para-
14 graph for the appeal of an order under para-
15 graph (1) with respect to a prescription drug
16 terminates if the Secretary commences an ac-
17 tion under subsection (a) or section 302 regard-
18 ing the prescription drug.

19 “(b) EFFECT OF SECTION.—Nothing in this section
20 applies to a prescription drug imported by an individual
21 under section 812 or to a commercial transaction con-
22 ducted between an Internet pharmacy and an individual.”.

23 (b) TEMPORARY HOLD AT PORT OF ENTRY.—Sec-
24 tion 801 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 381) (as amended by section 4(e)) is amended
2 by adding at the end the following:

3 “(r) TEMPORARY HOLD AT PORT OF ENTRY.—

4 “(1) IN GENERAL.—If an officer or qualified
5 employee of the Food and Drug Administration has
6 credible evidence or information indicating that a
7 prescription drug presents a risk to the public
8 health, and the officer or qualified employee is un-
9 able to inspect, examine, or investigate the prescrip-
10 tion drug upon the prescription drug’s being offered
11 for import at a port of entry into the United States,
12 the officer or qualified employee shall request the
13 Secretary of the Treasury to hold the prescription
14 drug at the port of entry for a reasonable period of
15 time, not to exceed 24 hours, for the purpose of ena-
16 bling the Secretary to inspect, examine, or inves-
17 tigate the prescription drug as appropriate.

18 “(2) APPROVAL.—

19 “(A) IN GENERAL.—An officer or qualified
20 employee of the Food and Drug Administration
21 may make a request under paragraph (1) only
22 if the Secretary or an official designated by the
23 Secretary approves the request.

24 “(B) DESIGNEES.—An official may not be
25 designated under subparagraph (A) unless the

1 official is the director of the district under this
2 Act in which the prescription drug is located, or
3 is an official senior to that director.

4 “(3) NOTIFICATION.—With respect to a pre-
5 scription drug for which a request under paragraph
6 (1) is made, the Secretary, promptly after the re-
7 quest is made, shall notify the State in which the
8 port of entry involved is located that the request has
9 been made, and as applicable, that the prescription
10 drug, is being held under this subsection.

11 “(4) REMOVAL.—A prescription drug held
12 under paragraph (1) shall be removed to a secure fa-
13 cility, as appropriate.

14 “(5) NO TRANSFER.—During the period in
15 which a prescription drug is held under this sub-
16 section, the prescription drug shall not be trans-
17 ferred by any person from the port of entry into the
18 United States for the prescription drug or from the
19 secure facility to which the prescription drug has
20 been removed.

21 “(6) EFFECT OF BONDING PROVISION.—Sub-
22 section (b) does not authorize the delivery of a pre-
23 scription drug held under this subsection pursuant
24 to the execution of a bond while the prescription
25 drug is held under this subsection.

1 “(7) EFFECT OF SUBSECTION.—Nothing in this
2 subsection applies to a prescription drug imported
3 by an individual under section 812 or to a commer-
4 cial transaction conducted between an Internet phar-
5 macy and an individual.”.

6 (c) PROHIBITED ACT.—Section 301 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
8 amended by section 4(b)) is amended by adding at the
9 end the following:

10 “(11) The transfer of a prescription drug in violation
11 of an order under section 816, or the removal or alteration
12 of any mark or label required by the order to identify the
13 prescription drug as detained.”.

14 **SEC. 6. SUSPENSION.**

15 (a) IN GENERAL.—The Federal Food, Drug, and
16 Cosmetic Act is amended by adding after section 816 (as
17 added by section 5) the following:

18 **“SEC. 817. SUSPENSION OF IMPORTATION.**

19 “(a) PRESCRIPTION DRUG.—If the Secretary deter-
20 mines that the importation of a particular prescription
21 drug or particular dosage form of a prescription drug into
22 the United States presents a risk to the public health, the
23 Secretary may immediately order the suspension of the
24 importation of the particular prescription drug or par-
25 ticular dosage form of the prescription drug.

1 “(b) SUSPENSION.—If the Secretary determines that
2 a drug importation facility, pharmacy, Internet pharmacy,
3 or wholesaler is engaged in a pattern of importing or offer-
4 ing for importation a prescription drug into the United
5 States in violation of any of the requirements of this Act,
6 the Secretary may immediately order the suspension of
7 that person from engaging in the importation or offering
8 for importation of prescription drugs into the United
9 States.

10 “(c) CANADA OR PERMITTED COUNTRY.—If the Sec-
11 retary determines that there is a pattern of prescription
12 drugs being imported or offered for importation into the
13 United States from Canada or a permitted country in vio-
14 lation of any of the requirements of this Act, the Secretary
15 may immediately order the suspension of the importation
16 or offering for importation into the United States of pre-
17 scription drugs from Canada or that permitted country,
18 as appropriate.

19 “(d) APPEAL OF SUSPENSION ORDER.—

20 “(1) IN GENERAL.—

21 “(A) PRESCRIPTION DRUGS.—With respect
22 to the importation of a prescription drug, the
23 importation of which is suspended under sub-
24 section (a), any person that would be entitled to

1 be a claimant for the prescription drug may ap-
2 peal the suspension order to the Secretary.

3 “(B) SUSPENDED PERSONS.—With respect
4 to a drug importation facility, pharmacy, Inter-
5 net pharmacy, or wholesaler subject to a sus-
6 pension order under subsection (b) or (c), the
7 drug importation facility, pharmacy, Internet
8 pharmacy or wholesaler may appeal the suspen-
9 sion order to the Secretary.

10 “(2) ACTION BY THE SECRETARY.—Not later
11 than 30 days after an appeal is filed, the Secretary,
12 after providing opportunity for an informal hearing,
13 shall confirm or terminate the order.

14 “(3) FAILURE TO ACT.—If, during the 30-day
15 period specified in paragraph (2), the Secretary fails
16 to provide an opportunity for a hearing or to con-
17 firm or terminate the order, the order shall be
18 deemed to be terminated.

19 “(e) NO JUDICIAL REVIEW.—An order under this
20 section shall not be subject to judicial review.

21 “(f) EFFECT OF SECTION.—Nothing in this section
22 applies to a prescription drug imported by an individual
23 under section 812 or to a commercial transaction con-
24 ducted between an Internet pharmacy and an individual.”.

1 (b) PROHIBITED ACT.—Section 301 of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
 3 amended by section 5(c)) is amended by adding at the end
 4 the following:

5 “(mm) The importation or offering for importation
 6 of a prescription drug in violation of an order under sec-
 7 tion 817.”.

8 **SEC. 7. DEBARMENT FOR REPEATED OR SERIOUS PRE-**
 9 **SCRIPTION DRUG IMPORTATION VIOLA-**
 10 **TIONS.**

11 (a) DEBARMENT AUTHORITY.—

12 (1) PERMISSIVE DEBARMENT.—Section
 13 306(b)(1) of the Federal Food, Drug, and Cosmetic
 14 Act (21 U.S.C. 335a(b)(1)) is amended—

15 (A) in subparagraph (B), by striking “or”
 16 at the end;

17 (B) in subparagraph (C), by striking the
 18 period at the end and inserting “, or”; and

19 (C) by adding at the end the following:

20 “(D) a person from importing a prescrip-
 21 tion drug or offering a prescription drug for im-
 22 portation into the United States.”.

23 (2) AMENDMENT REGARDING DEBARMENT
 24 GROUNDS.—Section 306(b) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is
2 amended—

3 (A) by redesignating paragraph (4) as
4 paragraph (5); and

5 (B) by inserting after paragraph (3) the
6 following:

7 “(4) PERSONS SUBJECT TO PERMISSIVE DE-
8 BARMENT; PRESCRIPTION DRUG IMPORTATION.—

9 “(A) IN GENERAL.—A person is subject to
10 debarment under paragraph (1)(D) if—

11 “(i) the person has been convicted of
12 a felony for conduct relating to the impor-
13 tation into the United States of any pre-
14 scription drug; or

15 “(ii) the person has engaged in a pat-
16 tern of importing or offering for import a
17 prescription drug that presents a risk to
18 the public health.

19 “(B) EFFECT OF PARAGRAPH.—Nothing
20 in this paragraph applies to a prescription drug
21 imported by an individual under section 812 or
22 to a commercial transaction conducted between
23 an Internet pharmacy and an individual.”.

1 (b) CONFORMING AMENDMENTS.—Section 306 of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a)
3 is amended—

4 (1) in subsection (b), by striking the subsection
5 heading and inserting the following:

6 “(b) PERMISSIVE DEBARMENT; CERTAIN DRUG AP-
7 PPLICATIONS; IMPORTS.—”;

8 (2) in subsection (c)(2)(A)(iii), by striking
9 “paragraph (2) or (3) of subsection (b)” and insert-
10 ing “paragraph (2), (3), or (4) of subsection (b)”;
11 and

12 (3) in subsection (d)(3)—

13 (A) in subparagraph (A)(i), by striking “or
14 paragraph (2)(A) or (3) of subsection (b)” and
15 inserting “paragraph (2)(A), (3), or (4) of sub-
16 section (b)”;

17 (B) in clauses (i) and (ii) of subparagraph
18 (B), by striking “or subsection (b)(3)” and in-
19 serting “paragraph (3) or (4) of subsection
20 (b)”;

21 (C) in subparagraph (B)(ii), by striking
22 “or the food importation process, as the case
23 may be” and inserting “, or the food or pre-
24 scription drug importation process, as the case
25 may be”.

1 (c) EFFECTIVE DATE.—Section 306(l)(2) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 335a(l)(2))
3 is amended—

4 (1) in the first sentence, by striking “and sub-
5 section (b)(3)(A)” and inserting “subsection
6 (b)(3)(A), and subsection (b)(4)(A)”;

7 (2) in the second sentence, by inserting “, sub-
8 section (b)(4)(B),” after “subsection (b)(3)(B)”.

9 (d) PROHIBITED ACT.—Section 301 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
11 amended by section 6(b)) is amended by adding at the
12 end the following:

13 “(nn) The importing or offering for importation into
14 the United States of a prescription drug by, with the as-
15 sistance of, or at the direction of a person debarred under
16 section 306(b)(4).”.

17 (e) IMPORTATION BY DEBARRED PERSONS.—Section
18 801 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 381) (as amended by section 5(b)) is amended by
20 adding at the end the following:

21 “(s) IMPORTATION OF PRESCRIPTION DRUGS BY
22 DEBARRED PERSONS.—

23 “(1) IN GENERAL.—If a prescription drug is
24 imported or offered for importation into the United
25 States, and the importer, owner, or consignee of the

1 prescription drug is a person that has been debarred
2 under section 306(b)(4), the prescription drug—

3 “(A) shall be held at the port of entry for
4 the prescription drug; and

5 “(B) may not be delivered to the person.

6 “(2) EFFECT OF BONDING PROVISION.—Sub-
7 section (b) does not authorize the delivery of a pre-
8 scription drug pursuant to the execution of a bond
9 while the prescription drug is held under this sub-
10 section.

11 “(3) REMOVAL.—A prescription drug held
12 under this subsection shall be removed to a secure
13 facility, as appropriate.

14 “(4) NO TRANSFER.—During a period in which
15 a prescription drug is held under this subsection, the
16 prescription drug shall not be transferred by any
17 person from the port of entry into the United States
18 for the prescription drug or from the secure facility
19 to which the prescription drug has been removed.

20 “(5) PERMISSIBLE DELIVERY.—A prescription
21 drug held under this subsection may be delivered to
22 a person that is not a debarred person under section
23 306(b)(4) if the person affirmatively establishes, at
24 the expense of the person, that the prescription drug

1 complies with the requirements of this Act, as deter-
2 mined by the Secretary.”.

3 **SEC. 8. REGISTRATION OF PRESCRIPTION DRUG IMPORTA-**
4 **TION FACILITIES.**

5 (a) REGISTRATION OF CERTAIN IMPORTERS.—The
6 Federal Food, Drug, and Cosmetic Act is amended by
7 adding after section 813 (as added by section 2) the fol-
8 lowing:

9 **“SEC. 814. REGISTRATION OF CERTAIN IMPORTERS.**

10 “(a) IN GENERAL.—A drug importation facility,
11 pharmacy, Internet pharmacy, or wholesaler engaged in
12 the importation or offering for importation of prescription
13 drugs into the United States, or in the dispensing of such
14 drugs, shall register with the Secretary in accordance with
15 this section.

16 “(b) REGISTRATION.—

17 “(1) IN GENERAL.—To register, the owner, op-
18 erator, or agent in charge of a drug importation fa-
19 cility, pharmacy, Internet pharmacy, or wholesaler
20 shall submit to the Secretary a registration that dis-
21 closes—

22 “(A) the name and address of each drug
23 importation facility, pharmacy, Internet phar-
24 macy, or wholesaler at which, and all trade

1 names under which, the registrant conducts
2 business;

3 “(B) the name of each prescription drug to
4 be imported into the United States by each
5 drug importation facility, pharmacy, Internet
6 pharmacy, or wholesaler; and

7 “(C) the name and address of an agent for
8 service of process in the United States.

9 “(2) CHANGE IN INFORMATION.—The reg-
10 istrant shall notify the Secretary in a timely manner
11 of any change in the information provided under
12 paragraph (1).

13 “(3) PROCEDURE.—Not later than 60 days
14 after receipt of a completed registration under para-
15 graph (1), the Secretary shall—

16 “(A) assign a registration number to each
17 registered drug importation facility, pharmacy,
18 Internet pharmacy, and wholesaler; and

19 “(B) notify the registrant of the receipt of
20 the registration.

21 “(4) LIST.—

22 “(A) IN GENERAL.—The Secretary shall
23 compile, maintain, and periodically update a list
24 of registrants.

1 “(B) AVAILABILITY.—The Secretary shall
2 make the list described under subparagraph (A)
3 and information submitted by a registrant
4 under paragraph (1) available to the public on
5 an Internet website and through a toll-free tele-
6 phone number.

7 “(c) ELECTRONIC FILING.—

8 “(1) IN GENERAL.—For the purpose of reduc-
9 ing paperwork and reporting burdens, the Secretary
10 shall provide for, and require the use of, electronic
11 methods of submitting to the Secretary registrations
12 required under this section and shall provide for
13 electronic methods of receiving the registrations.

14 “(2) AUTHENTICATION.—In providing for the
15 electronic submission of such registrations under
16 this section, the Secretary shall ensure that ade-
17 quate authentication protocols are used to allow
18 identification of the registrant and validation of the
19 data as appropriate.

20 “(d) EFFECT OF SECTION.—

21 “(1) AUTHORITY.—Nothing in this section
22 authorizes the Secretary to require an applica-
23 tion, review, or licensing process for a drug im-
24 portation facility, pharmacy, or wholesaler.

1 “(2) IMPORTATION BY INDIVIDUALS.—
2 Nothing in this section applies to a prescription
3 drug imported by an individual under section
4 812 or to a commercial transaction conducted
5 between an Internet pharmacy and an indi-
6 vidual.”.

7 (b) REGULATIONS.—

8 (1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of this Act, the Secretary of
10 Health and Human Services shall promulgate regu-
11 lations to carry out section 814 of the Federal Food,
12 Drug, and Cosmetic Act (as added by this section).

13 (2) EFFECTIVE DATE.—The requirement of
14 registration under section 814 of the Federal Food,
15 Drug, and Cosmetic Act takes effect—

16 (A) on the effective date of the final regu-
17 lations under paragraph (1); or

18 (B) if the final regulations have not been
19 made effective as of the expiration of that pe-
20 riod, on the date that is 1 year after the date
21 of enactment of this Act, subject to compliance
22 with the final regulations when the final regula-
23 tions are made effective.

24 (c) IMPORTATION; FAILURE TO REGISTER.—Section
25 801 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 381) (as amended by section 7(e)) is amended by
2 adding at the end the following:

3 “(t) FAILURE TO REGISTER.—

4 “(1) IN GENERAL.—If a drug importation facil-
5 ity, pharmacy, Internet pharmacy, or wholesaler en-
6 gaged in the importation or offering for importation
7 of prescription drugs into the United States has not
8 submitted a registration to the Secretary in accord-
9 ance with section 814, a prescription drug that is
10 being imported or offered for importation into the
11 United States shall not be delivered to the importer,
12 owner, or consignee of the prescription drug until
13 the drug importation facility, pharmacy, Internet
14 pharmacy, or wholesaler is registered in accordance
15 with section 814.

16 “(2) EFFECT OF SUBSECTION (b).—Subsection
17 (b) does not authorize the delivery of the prescrip-
18 tion drug pursuant to the execution of a bond while
19 the prescription drug is held under this subsection.

20 “(3) REMOVAL.—A prescription drug held
21 under this subsection shall be removed to a secure
22 facility, as appropriate.

23 “(4) NO TRANSFER.—During the period in
24 which a prescription drug is held under this sub-
25 section, the prescription drug shall not be trans-

1 ferred by any person from the port of entry into the
2 United States for the prescription drug or from the
3 secure facility to which the prescription drug has
4 been removed.”.

5 (d) PROHIBITED ACT.—Section 301 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
7 amended by section 7(d)) is amended by adding at the
8 end the following:

9 “(oo) The failure of a drug importation facility, phar-
10 macy, Internet pharmacy, or wholesaler engaged in the
11 importation or offering for importation of prescription
12 drugs into the United States, or in the dispensing of such
13 drugs, to register in accordance with section 814.”.

14 **SEC. 9. MAINTENANCE AND INSPECTION OF RECORDS FOR**
15 **PRESCRIPTION DRUGS.**

16 The Federal Food, Drug, and Cosmetic Act is amend-
17 ed by adding after section 814 (as added by section 8)
18 the following:

19 **“SEC. 815. MAINTENANCE AND INSPECTION OF RECORDS**
20 **FOR PRESCRIPTION DRUGS.**

21 “(a) IN GENERAL.—The Secretary may by regulation
22 establish requirements relating to the establishment and
23 maintenance, for not longer than 2 years, of records by—

24 “(1) a drug importation facility, pharmacy,
25 Internet pharmacy, or wholesaler engaged in the im-

1 portation of prescription drugs into the United
2 States, or in the dispensing of such drugs; and

3 “(2) any person that processes, packages, dis-
4 tributes, receives, holds, or transports a prescription
5 drug imported under this subchapter.

6 “(b) INSPECTION.—

7 “(1) IN GENERAL.—If the Secretary has reason
8 to believe that a prescription drug imported under
9 this subchapter presents a risk to the public health,
10 the drug importation facility, pharmacy, Internet
11 pharmacy, or wholesaler that imports the prescrip-
12 tion drug, and each person that processes, packages,
13 distributes, receives, holds, or transports the pre-
14 scription drug shall, at the request of an officer or
15 employee duly designated by the Secretary, permit
16 the officer or employee, upon presentation of appro-
17 priate credentials and a written notice to such phar-
18 macy or person, at reasonable times, within reason-
19 able limits and in a reasonable manner, to have ac-
20 cess to and copy all records relating to the prescrip-
21 tion drug that are needed to enable the Secretary to
22 determine whether the prescription drug presents a
23 risk to the public health.

24 “(2) APPLICABILITY.—Paragraph (1) applies to
25 all records maintained by or on behalf of the drug

1 importation facility, pharmacy, Internet pharmacy,
 2 or wholesaler or such other person in any format
 3 (including paper and electronic formats) and at any
 4 location.

5 “(c) PROTECTION OF SENSITIVE INFORMATION.—
 6 The Secretary shall take appropriate measures to ensure
 7 that there are in effect effective procedures to prevent the
 8 unauthorized disclosure of any trade secret or confidential
 9 information that is obtained by the Secretary under this
 10 section or any commercial or financial information that
 11 is privileged or confidential.

12 “(d) EFFECT OF SECTION.—Nothing in this section
 13 applies to a prescription drug imported by an individual
 14 under section 812 or to a commercial transaction con-
 15 ducted between an Internet pharmacy and an individual.”.

16 **SEC. 10. ADVANCE NOTICE OF IMPORTED PRESCRIPTION**
 17 **DRUG SHIPMENTS.**

18 (a) IN GENERAL.—Section 801 of the Federal Food,
 19 Drug, and Cosmetic Act (as amended by section 8(b)) is
 20 amended by adding at the end the following:

21 “(u) ADVANCE NOTICE OF IMPORTED PRESCRIPTION
 22 DRUG SHIPMENTS.—

23 “(1) IN GENERAL.—For purposes of enabling
 24 the Secretary to inspect at ports of entry a prescrip-
 25 tion drug that is being imported or offered for im-

1 portation into the United States, the person import-
2 ing or offering for importation the prescription drug
3 shall, in advance, provide to the Secretary a notice
4 that includes—

5 “(A) the established name (as defined by
6 section 502(e)), dosage form, and quantity of
7 the prescription drug;

8 “(B) the name of the shipper of the pre-
9 scription drug;

10 “(C) the name of the country from which
11 the prescription drug originates;

12 “(D) the country from which the prescrip-
13 tion drug is shipped;

14 “(E) the name of the port of entry of the
15 prescription drug;

16 “(F) documentation from the drug impor-
17 tation facility located in Canada or a permitted
18 country specifying—

19 “(i) the original source of the pre-
20 scription drug; and

21 “(ii) the quantity of each lot of the
22 prescription drug originally received by the
23 facility from that source;

1 “(G) the lot or control number assigned to
2 the prescription drug by the manufacturer of
3 the prescription drug;

4 “(H) the name, address, telephone num-
5 ber, and professional license number of the
6 drug importation facility located in Canada or
7 a permitted country; and

8 “(I) certification from the drug importa-
9 tion facility located in a foreign country or from
10 the manufacturer of the prescription drug that
11 the prescription drug—

12 “(i) is approved for marketing in the
13 United States and is not adulterated or
14 misbranded; and

15 “(ii) meets all labeling requirements
16 under this Act.

17 “(2) REFUSAL OF ADMISSION.—A prescription
18 drug imported or offered for importation without
19 submission of a notice under paragraph (1) shall be
20 refused admission into the United States.

21 “(3) PERIOD OF ADVANCE NOTICE.—The pe-
22 riod in which the notice under paragraph (1) is re-
23 quired to be made in advance of the time of the im-
24 portation of a prescription drug or the offering of a

1 prescription drug for importation shall be not less
2 than 24 hours and not more than 5 days.

3 “(4) FAILURE TO PROVIDE NOTICE.—

4 “(A) IN GENERAL.—If a prescription drug
5 is being imported or offered for importation
6 into the United States and notice is not pro-
7 vided in advance in accordance with paragraph
8 (1), the prescription drug shall be held at the
9 port of entry for the prescription drug, and may
10 not be delivered to the importer, owner, or con-
11 signee of the prescription drug, until the notice
12 is submitted to the Secretary and the Secretary
13 examines the notice and determines that the no-
14 tice is in accordance with the requirements
15 under paragraph (1).

16 “(5) EFFECT OF BONDING PROVISION.—Sub-
17 section (b) does not authorize the delivery of a pre-
18 scription drug pursuant to the execution of a bond
19 while the prescription drug is held under this sub-
20 section.

21 “(6) REMOVAL.—A prescription drug held
22 under this subsection shall be removed to a secure
23 facility, as appropriate.

24 “(7) NO TRANSFER.—During a period in which
25 a prescription drug is held under this subsection, the

1 prescription drug shall not be transferred by any
2 person from the port of entry into the United States
3 for the article or from the secure facility to which
4 the prescription drug has been removed.

5 “(8) EFFECT OF SUBSECTION.—

6 “(A) AUTHORITY.—This subsection does
7 not limit the authority of the Secretary to ob-
8 tain information under any other provision of
9 this Act.

10 “(B) IMPORTATION BY INDIVIDUALS.—
11 Nothing in this subsection applies to a prescrip-
12 tion drug imported by an individual under sec-
13 tion 812 or to a commercial transaction con-
14 ducted between an Internet pharmacy and an
15 individual.”.

16 (b) PROHIBITED ACT.—Section 301 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as
18 amended by section 8(c)) is amended by adding at the end
19 the following:

20 “(pp) The failure to submit prior notice of the impor-
21 tation of a prescription drug in violation of section
22 801(s).”.

1 **SEC. 11. AUTHORITY TO MARK PRESCRIPTION DRUGS RE-**
2 **FUSED ADMISSION INTO THE UNITED**
3 **STATES.**

4 (a) IN GENERAL.—Section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by
6 section 10(a)) is amended by adding at the end the fol-
7 lowing:

8 “(v) PRESCRIPTION DRUGS REFUSED ADMISSION.—

9 “(1) IN GENERAL.—If a prescription drug has
10 been refused admission under subsection (a), other
11 than such a prescription drug that is required to be
12 destroyed, the Secretary may require the owner or
13 consignee of the prescription drug to affix to the
14 container of the prescription drug a label that clear-
15 ly and conspicuously bears the statement: ‘UNITED
16 STATES: REFUSED ENTRY’.

17 “(2) EXPENSES.—All expenses in connection
18 with affixing a label under paragraph (1)—

19 “(A) shall be paid by the owner or con-
20 signee of the prescription drug; and

21 “(B) in default of such payment, shall con-
22 stitute a lien against future importations made
23 by the owner or consignee.

24 “(3) EFFECTIVE PERIOD.—A requirement
25 under paragraph (1) with respect to a prescription
26 drug remains in effect until the Secretary deter-

1 mines that the prescription drug has been brought
2 into compliance with this Act.

3 “(4) EFFECT OF SUBSECTION.—Nothing in this
4 subsection applies to a prescription drug imported
5 by an individual under section 812 or to a commer-
6 cial transaction conducted between an Internet phar-
7 macy and an individual.”.

8 (b) MISBRANDED PRESCRIPTION DRUGS.—Section
9 502 of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 352) is amended by adding at the end the fol-
11 lowing:

12 “(w) If—

13 “(1) it is a prescription drug refused admission
14 into the United States that fails to bear a label re-
15 quired by the Secretary under section 801(v);

16 “(2) the Secretary finds that the prescription
17 drug presents a risk to the public health; and

18 “(3) on or after notifying the owner or con-
19 signee of the prescription drug that the label is re-
20 quired under section 801(v), the Secretary informs
21 the owner or consignee that the prescription drug
22 presents such a risk.”.

23 (c) RULE OF CONSTRUCTION.—With respect to a
24 prescription drug that is imported or offered for importa-
25 tion into the United States, nothing in this section limits

1 the authority of the Secretary of Health and Human Serv-
2 ices or the Secretary of the Treasury to require the mark-
3 ing of prescription drugs refused admission under any
4 other provision of law.

5 **SEC. 12. PROHIBITION OF PORT SHOPPING.**

6 Section 502 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 352) (as amended by section 11(b)) is
8 amended by adding at the end the following:

9 “(x) PORT SHOPPING.—

10 “(1) IN GENERAL.—If—

11 “(A) it is a prescription drug imported or
12 offered for importation into the United States;
13 and

14 “(B) the prescription drug has previously
15 been refused admission under section 801(a);
16 unless the person reoffering the prescription drug af-
17 firmatively establishes, at the expense of the owner
18 or consignee of the prescription drug, that the pre-
19 scription drug complies with the applicable require-
20 ments of this Act, as determined by the Secretary.

21 “(2) EFFECT OF PARAGRAPH.—Nothing in this
22 paragraph applies to importation of a prescription
23 drug under section 812 or to a commercial trans-
24 action conducted between an Internet pharmacy and
25 an individual.”.

1 **SEC. 13. AUTHORITY TO COMMISSION OTHER FEDERAL**
2 **AND STATE OFFICIALS TO CONDUCT INSPEC-**
3 **TIONS.**

4 Section 702(a) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 372(a)) is amended—

6 (1) by redesignating paragraphs (3) and (4) as
7 paragraphs (5) and (6), respectively; and

8 (2) inserting after paragraph (2) the following:

9 “(3)(A) The Secretary, pursuant to a memo-
10 randum of understanding between the Secretary and
11 the head of another Federal agency, may conduct
12 examinations and investigations for the purposes of
13 enforcing compliance with the amendments made by
14 the Safe IMPORT Act of 2004 through the officers
15 and employees of the other agency.

16 “(B) A memorandum of understanding under
17 subparagraph (A) shall include—

18 “(i) provisions to ensure adequate training
19 of officers and employees to conduct the exami-
20 nations and investigations; and

21 “(ii) provisions regarding reimbursement
22 that may, in the discretion of the head of the
23 other agency, require reimbursement, in whole
24 or in part, from the Secretary for the examina-
25 tions or investigations performed under this

1 paragraph by the officers or employees of the
2 other agency.

3 “(C) A memorandum of understanding under
4 subparagraph (A) shall be effective only with respect
5 to examinations or inspections at facilities or other
6 locations that are jointly regulated by the Secretary
7 and the other agency.

8 “(D) Not later than 60 days after the end of
9 each fiscal year in which the head a Federal agency
10 carries out 1 or more examinations or inspections
11 under a memorandum of understanding under sub-
12 paragraph (A), the Secretary and the agency head
13 shall submit to the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate and to
15 the Committee on Energy and Commerce of the
16 House of Representatives, a report that discloses,
17 for that year—

18 “(i) the number of officers or employees
19 that carried out 1 or more programs, projects,
20 or activities under the memorandum of under-
21 standing;

22 “(ii) the number of additional articles that
23 were inspected or examined as a result of the
24 memorandum of understanding; and

1 “(iii) the number of additional examina-
2 tions or investigations that were carried out
3 pursuant to the memorandum of understanding.

4 “(4)(A) The Secretary may enter into a con-
5 tract with a State to use the State Board of Phar-
6 macy personnel of the State to conduct examinations
7 and inspection for the purpose of carrying out the
8 amendments made by the Safe IMPORT Act of
9 2004.

10 “(B) A contract entered into under subpara-
11 graph (A) shall—

12 “(i) ensure adequate training of officers
13 and employees to conduct the examinations and
14 investigations; and

15 “(ii) be effective only with respect to ex-
16 aminations or inspections of drug importation
17 facilities, pharmacies, Internet pharmacies, and
18 wholesalers located in the State.”.

19 **SEC. 14. USER FEES RELATING TO PRESCRIPTION DRUG**
20 **IMPORTATION.**

21 Subchapter C of chapter VII of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 397f et seq.) is
23 amended by adding at the end the following:

1 **“PART 5—FEES RELATING TO PRESCRIPTION**

2 **DRUG IMPORTATION**

3 **“SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IM-**

4 **PORTATION.**

5 “(a) REGISTRATION FEE.—The Secretary shall es-
6 tablish a user fee program under which a drug importation
7 facility, pharmacy, Internet pharmacy, or wholesaler reg-
8 istering with the Secretary under section 814 shall be re-
9 quired to pay a fee to the Secretary.

10 “(b) COLLECTION.—

11 “(1) COLLECTION ON INITIAL REGISTRATION.—

12 A fee under this section shall be payable for the fis-
13 cal year in which the drug importation facility, phar-
14 macy, Internet pharmacy, or wholesaler first reg-
15 isters under section 814 (or reregisters under that
16 section if that person has withdrawn its registration
17 and subsequently reregisters).

18 “(2) COLLECTION IN SUBSEQUENT YEARS.—

19 After the fee is paid for that fiscal year, the fee shall
20 be payable on or before October 1 of each year.

21 “(3) ONE FEE PER FACILITY.—The fee shall be

22 paid only once for each drug importation facility,
23 pharmacy, Internet pharmacy, or wholesaler reg-
24 istered for a fiscal year in which the fee is payable.

25 “(c) FEE AMOUNT.—The amount of the fee shall be
26 determined each year by the Secretary and shall be based

1 on the anticipated costs to the Secretary of enforcing the
2 amendments made by the Safe IMPORT Act of 2004 in
3 the subsequent fiscal year.

4 “(d) USE OF FEES.—The fees collected under this
5 section shall be used, without further appropriation, to en-
6 force the amendments made by the Safe IMPORT Act of
7 2004.

8 “(e) ANNUAL FEE SETTING.—The Secretary shall
9 establish, 60 days before the beginning of each fiscal year
10 beginning after September 30, 2004, for that fiscal year,
11 registration fees.

12 “(f) EFFECT OF FAILURE TO PAY FEES.—

13 “(1) DUE DATE.—A fee payable under this sec-
14 tion shall be paid by the date that is 30 days after
15 the date on which the fee is due.

16 “(2) FAILURE TO PAY.—If a registered drug
17 importation facility, pharmacy, Internet pharmacy,
18 or wholesaler subject to a fee under this section fails
19 to pay the fee, the Secretary shall not permit the
20 drug importation facility pharmacy, Internet phar-
21 macy, or wholesaler to engage in importation or of-
22 fering for importation prescription drugs under this
23 Act until all such fees owed by that person are paid.

24 “(g) REPORTS.—

1 “(1) FEE ESTABLISHMENT.—Not later than 60
2 days before each fiscal year, the Secretary shall—

3 “(A) publish user fees under this section
4 for that fiscal year;

5 “(B) hold a meeting at which the public
6 may comment on the recommendations; and

7 “(C) provide for a period of 30 days for
8 the public to provide written comments on the
9 recommendations.

10 “(2) PERFORMANCE AND FISCAL REPORT.—Be-
11 ginning with fiscal year 2005, not later than 60 days
12 after the end of each fiscal year during which fees
13 are collected under this section, the Secretary shall
14 submit to the Committee on Health, Education,
15 Labor, and Pensions of the Senate and the Com-
16 mittee on Energy and Commerce of the House of
17 Representatives a report that describes—

18 “(A) implementation of the user fee au-
19 thority during the fiscal year; and

20 “(B) the use by the Secretary of the fees
21 collected during the fiscal year for which the re-
22 port is made.”.

23 **SEC. 15. ANTICOUNTERFEITING PROVISIONS.**

24 (a) REQUIRED RECORDS.—Section 503(e) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))

1 is amended by striking paragraph (1) and inserting the
2 following: “(1) A distributor of record that is engaged in
3 the wholesale distribution of a drug subject to subsection
4 (b), shall—

5 “(A) before each wholesale distribution of the
6 drug—

7 “(i) with respect to each wholesale dis-
8 tribution of a drug subject to subsection (b),
9 provide the person that receives the drug a
10 statement that identifies the immediately pre-
11 vious distributor of record from which the drug
12 was purchased; and

13 “(ii) with respect to a drug subject to sub-
14 section (b) that is imported to the United
15 States, provide the person that receives the
16 drug a statement (in such form and containing
17 such information as the Secretary may require)
18 identifying each prior sale, purchase, or trade of
19 the drug (including the date of transmission
20 and the names and addresses of all parties to
21 the transaction); and

22 “(B) create, maintain for 2 years, and make
23 available to the Secretary for inspection at reason-
24 able time, records that—

1 “(i) with respect to each wholesale dis-
2 tribution of a drug subject to subsection (b),
3 identifies—

4 “(I) the immediately previous dis-
5 tributor of record from which the drug was
6 purchased; and

7 “(II) the immediately subsequent dis-
8 tributor of record to which the drug was
9 sold or otherwise transferred; and

10 “(ii) with respect to a drug subject to sub-
11 section (b) that is imported to the United
12 States, identifies—

13 “(I) each previous distributor of
14 record from which the drug was purchased
15 or otherwise transferred; and

16 “(II) each subsequent distributor of
17 record to which the drug was sold or other-
18 wise transferred, to the extent feasible.”.

19 (b) ELECTRONIC TRACK AND TRACE TECH-
20 NOLOGY.—Not later than December 31, 2007, the Sec-
21 retary of Health and Human Services shall require the
22 adoption and use of electronic track and trace technology
23 for a prescription drug at the case and pallet level that
24 will identify each sale, purchase, or trade of that case or

1 pallet (including the date of transmission and the names
2 and addresses of all parties to the transaction) .

3 (c) DISTRIBUTORS OF RECORD.—Section 503(e) of
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 353(e)) is amended by striking paragraph (3) and insert-
6 ing the following:

7 “(3) For the purposes of this subsection and sub-
8 section (d)—

9 “(A) the term ‘distributor of record’—

10 “(i) means a person that takes title to or
11 possession of a drug subject to subsection (b)
12 from manufacture to retail sale;

13 “(ii) includes a person that manufacturers,
14 processes, packs, distributes, receives, holds,
15 imports, or offers for importation a drug sub-
16 ject to subsection (b); and

17 “(iii) does not include a transporter;

18 “(B) the term ‘transporter’ means the United
19 States Postal Service, or equivalent governmental
20 service of a foreign country, or a private carrier en-
21 gaged in the business of transporting packages for
22 hire; and

23 “(C) the term ‘wholesale distribution’ means
24 the distribution of a drug subject to subsection (b)
25 to other than the consumer or patient but not in-

1 including an intracompany sale or distribution of a
2 drug described in subsection (c)(3)(B).”.

3 (d) ANTICOUNTERFEITING PROGRAMS.—Section
4 503(e) of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 353(e)) is amended by adding at the end the fol-
6 lowing:

7 “(4) The Secretary shall—

8 “(A) establish a network to be known as the
9 ‘Counterfeit Alert Network’ for the purpose of pro-
10 viding prompt notification to health professionals
11 and the public of counterfeit drugs subject to sub-
12 section (b);

13 “(B)(i) develop and publish an Internet acces-
14 sible-reference document to facilitate the positive
15 identification by health professionals and regulatory
16 agency personnel of prescription drugs marketed in
17 the United States and Canada; and

18 “(ii) update the materials described under
19 clause (i) quarterly and when a new permitted coun-
20 try is designated by the Secretary;

21 “(C) develop and publish educational materials
22 to health professionals and consumers identify and
23 report cases of counterfeit drugs subject to sub-
24 section (b);

1 “(D) develop and publish secure business prac-
2 tice guidelines for the sale and distribution of such
3 drugs in cooperation with members of a drug supply
4 chain; and

5 “(E) in cooperation with the National Associa-
6 tion of Boards of Pharmacy, develop and publish re-
7 vised model rules for licensure of drug wholesalers
8 for adoption by the States.”.

9 **SEC. 16. CONFORMING AMENDMENTS.**

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

12 (b) The Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 301 et seq.) is amended—

14 (1) in section 301(aa)—

15 (A) by striking “section 804” and insert-
16 ing “subchapter B of chapter VIII”; and

17 (B) by striking “such section” each place
18 it appears and inserting “that subchapter”;

19 (2) in section 801(d)(1), by striking “section
20 804” and inserting “subchapter B”; and

21 (3) by striking section 804.

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