

108TH CONGRESS
2D SESSION

H. R. 4923

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 HOUSE OF REPRESENTATIVES

JULY 22, 2004

Mr. BRADLEY of New Hampshire introduced the following bill; which was referred to the Committee on Energy and Commerce

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 Prescription**
 12 **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 scription 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 avoid, reduce, or mitigate such in-
11 creased 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 WHOLESALER 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

24 “(ii) includes any fund transfer cov-
25 ered under Article 4A of the Uniform

1 Commercial Code, as in effect in any
2 State.

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

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

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

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

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

20 “(c) LICENSING OF INTERNET PHARMACIES.—

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

23 “(A) have its principal place of business in
24 the United States, Canada, or a permitted
25 country; and

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

4 “(2) CONDITIONS FOR LICENSING.—

5 “(A) APPLICATION REQUIREMENTS.—An
6 Internet pharmacy shall submit to the Sec-
7 retary an application that includes—

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

17 “(aa) the practice of pharmacy,
18 including licensing laws and inspec-
19 tion requirements; and

20 “(bb) the manufacturing and dis-
21 tribution of controlled substances, in-
22 cluding with respect to mailing or
23 shipping controlled substances to con-
24 sumers; or

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

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

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

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

23 “(iii) verification from the person that
24 owns the Internet pharmacy that the per-
25 son will permit inspection of the facilities

1 and business practices of the Internet
2 pharmacy by the Secretary to the extent
3 necessary to determine whether the Inter-
4 net pharmacy is in compliance with this
5 subsection; and

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

14 “(B) IDENTIFICATION REQUIREMENTS.—

15 An Internet pharmacy shall provide to any per-
16 son that accesses the Internet pharmacy
17 website, on each page of the website of the
18 Internet pharmacy or by a link to a separate
19 page, the following information:

20 “(i) The street address, city, ZIP
21 Code or comparable mail code, State (or
22 comparable entity), country, and telephone
23 number of—

24 “(I) each place of business of the
25 Internet pharmacy; and

1 “(II) the name of the supervising
2 pharmacist of the Internet pharmacy
3 and each individual who serves as a
4 pharmacist for purposes of the Inter-
5 net pharmacy website.

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

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

17 “(I) the name, street address,
18 city, ZIP Code or comparable mail
19 code, State, and telephone number of
20 the practitioner or group; and

21 “(II) the name of each State in
22 which each practitioner is licensed or
23 otherwise authorized to prescribe
24 drugs.

1 “(iv) A statement that the Internet
2 pharmacy will dispense prescription drugs
3 only after receipt of a valid prescription.

4 “(C) PROFESSIONAL SERVICES REQUIRE-
5 MENTS.—An Internet pharmacy shall carry out
6 the following:

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

12 “(ii) Conduct prospective drug use re-
13 views before dispensing medications or
14 medical devices.

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

22 “(iv) Offer interactive and meaningful
23 consultation by a licensed pharmacist to
24 the caregiver or patient prior to and subse-

1 quent to the time at which the Internet
2 pharmacy dispenses the drug.

3 “(v)(I) Establish a mechanism for pa-
4 tients to report errors and suspected ad-
5 verse drug reactions.

6 “(II) Document in the reporting
7 mechanism the response of the Internet
8 pharmacy to those reports.

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

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

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

19 “(ix)(I) Verify the validity of the pre-
20 scription of an individual by using 1 of the
21 following methods:

22 “(aa) Receiving from the indi-
23 vidual or treating provider of the indi-
24 vidual the prescription of the indi-
25 vidual by mail (including a private

1 carrier), or receiving from the treating
2 provider of the individual the prescrip-
3 tion of the individual by electronic
4 mail.

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

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

16 “(aa) The full name and address
17 of the individual.

18 “(bb) Identification of the pre-
19 scription drug.

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

22 “(dd) The date on which the in-
23 dividual presented the prescription to
24 the Internet pharmacy.

1 “(ee) The date and time of the
2 verification request.

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

8 “(III) A prescription is verified under
9 subclause (I)(bb) only if 1 of the following
10 occurs:

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

15 “(bb) The treating provider in-
16 forms the Internet pharmacy that the
17 prescription is inaccurate and provides
18 the accurate prescription.

19 “(IV) An Internet pharmacy shall not
20 fill a prescription if—

21 “(aa) a treating provider informs
22 the Internet pharmacy within 72
23 hours after receipt of a communica-
24 tion under subclause (I)(bb) that the

1 prescription is inaccurate or expired;
2 or

3 “(bb) the treating provider does
4 not respond within that time.

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

11 “(3) LICENSURE PROCEDURE.—

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

15 “(i) assign an identification number
16 to each Internet pharmacy;

17 “(ii) notify the applicant of the receipt
18 of the licensure application; and

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

24 “(B) ELECTRONIC FILING.—

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

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

16 “(4) LIST.—

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

20 “(B) AVAILABILITY.—The Secretary shall
21 make the list described under subparagraph (A)
22 and information submitted by the licensee
23 under paragraph (2)(B) available to the public
24 on an Internet website and through a toll-free
25 telephone number.

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

5 “(A) COLLECTION.—

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

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

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

20 “(B) FEE AMOUNT.—The amount of the
21 licensing fee shall be determined each year by
22 the Secretary based on the anticipated costs to
23 the Secretary of enforcing the requirements of
24 this section in the subsequent fiscal year.

25 “(C) ANNUAL FEE DETERMINATION.—

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

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

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

17 “(E) FAILURE TO PAY FEE.—

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

22 “(ii) FAILURE TO PAY.—If an Inter-
23 net pharmacy subject to a fee under this
24 section fails to pay the fee by the date
25 specified under clause (i), the Secretary

1 shall not permit the Internet pharmacy to
2 engage in the dispensing of drugs as de-
3 scribed under this section until all such
4 fees owed by the Internet pharmacy are
5 paid.

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

15 “(i) implementation of the licensing
16 fee authority during the fiscal year; and

17 “(ii) the use by the Secretary of the
18 licensing fees collected during the fiscal
19 year for which the report is made.

20 “(6) TERMINATION OF LICENSE.—The Sec-
21 retary, upon the initiative of the Secretary, may ter-
22 minate a license issued under subsection (c), after
23 notice to the Internet pharmacy and an opportunity
24 for a hearing, and if the Secretary determines that
25 an Internet pharmacy—

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

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

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

8 “(7) RENEWAL EVALUATION.—

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

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

23 “(8) CONTRACT FOR OPERATION OF PRO-
24 GRAM.—

1 “(A) IN GENERAL.—The Secretary may
2 award a contract under this subsection for the
3 operation of the licensing program.

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

7 “(C) PERFORMANCE REVIEW.—The Sec-
8 retary shall annually review performance under
9 a contract under subparagraph (A).

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

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

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

1 “(e) POLICIES AND PROCEDURES REQUIRED TO
2 PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHAR-
3 MACY REQUESTS.—

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

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

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

19 “(B) prevent the acceptance of the prod-
20 ucts or services of the payment system in con-
21 nection with a restricted transaction.

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

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

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

10 “(ii) denying authorization of a credit
11 card transaction in response to an author-
12 ization message; and

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

20 “(3) COMPLIANCE WITH PAYMENT SYSTEM
21 POLICIES AND PROCEDURES.—A person described in
22 subsection (a)(2)(B) meets the requirement of para-
23 graph (1) if—

24 “(A) the person relies on and complies
25 with the policies and procedures of a designated

1 payment system of which the person is a mem-
2 ber or in which the person is a participant, to—

3 “(i) identify and block restricted
4 transactions; or

5 “(ii) otherwise prevent the acceptance
6 of the products or services of the payment
7 system, member, or participant in connec-
8 tion with restricted transactions; and

9 “(B) such policies and procedures of the
10 designated payment system comply with the re-
11 quirements of regulations promulgated under
12 paragraph (1).

13 “(4) NO LIABILITY FOR BLOCKING OR REFUS-
14 ING TO HONOR RESTRICTED TRANSACTION.—A per-
15 son that is subject to a regulation or an order issued
16 under this section and blocks or otherwise refuses to
17 honor a restricted transaction (or a transaction that
18 such person reasonably believes to be a restricted
19 transaction) or as a member of a designated pay-
20 ment system, relies on the policies and procedures of
21 the payment system in an effort to comply with reg-
22 ulations promulgated under this section, shall not be
23 liable to any party for such action.

24 “(5) ENFORCEMENT.—

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

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

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

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

22 “(iii) The extent to which the person
23 has established and is maintaining policies
24 and procedures in compliance with regula-
25 tions prescribed under this subsection.

1 “(iv) The feasibility that any specific
2 remedy prescribed can be implemented by
3 the person without substantial deviation
4 from normal business practice.

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

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

14 “(1) identifying Internet pharmacy websites
15 that are not licensed or that appear to be operating
16 in violation of Federal or State laws concerning the
17 dispensing of drugs;

18 “(2) reporting such Internet pharmacy websites
19 to State medical licensing boards and State phar-
20 macy licensing boards, and to the Attorney General
21 and the Secretary, for further investigation; and

22 “(3) submitting, for each fiscal year for which
23 the award under this subsection is made, a report to
24 the Secretary describing investigations undertaken

1 with respect to violations described in paragraph
2 (1).”.

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

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

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

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

21 (c) LINKS TO ILLEGAL INTERNET PHARMACIES.—
22 Section 302 of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 332) is amended by adding at the end the fol-
24 lowing:

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

8 “(2) Relief under paragraph (1)—

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

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

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

17 (d) REGULATIONS.—

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

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

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

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

20 “(q) LICENSED INTERNET PHARMACY.—If a ship-
21 ment of a prescription drug from an Internet pharmacy
22 licensed by the Secretary in accordance with section 511
23 to an individual is refused admission into the United
24 States, the Secretary shall—

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

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

9 **SEC. 5. ADMINISTRATIVE DETENTION AND TEMPORARY**
10 **HOLD.**

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

14 **“SEC. 816. ADMINISTRATIVE DETENTION.**

15 “(a) ADMINISTRATIVE DETENTION OF PRESCRIP-
16 TION DRUGS.—

17 “(1) DETENTION AUTHORITY.—

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

1 formation indicating that the prescription drug
2 presents a risk to the public health.

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

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

13 “(3) SECURITY OF DETAINED ARTICLE.—

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

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

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

21 “(B) NO TRANSFER.—A prescription drug
22 subject to an order under paragraph (1) shall
23 not be transferred by any person from the place
24 at which the prescription drug is ordered de-
25 tained or from the place to which the prescrip-

1 tion drug is removed, until released by the Sec-
2 retary or until the expiration of the detention
3 period applicable under the order, whichever oc-
4 curs first.

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

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

15 “(4) APPEAL OF DETENTION ORDER.—

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

22 “(B) ACTION BY THE SECRETARY.—Not
23 later than 5 days after an appeal is filed, the
24 Secretary, after providing opportunity for an in-
25 formal hearing, shall confirm or terminate the

1 order, and confirmation by the Secretary shall
2 be considered to be a final agency action for
3 purposes of section 702 of title 5, United States
4 Code.

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

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

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

21 (b) TEMPORARY HOLD AT PORT OF ENTRY.—Sec-
22 tion 801 of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 381) (as amended by section 4(e)) is amended
24 by adding at the end the following:

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

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

15 “(2) APPROVAL.—

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

21 “(B) DESIGNEES.—An official may not be
22 designated under subparagraph (A) unless the
23 official is the director of the district under this
24 Act in which the prescription drug is located, or
25 is an official senior to that director.

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

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

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

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

23 “(7) EFFECT OF SUBSECTION.—Nothing in this
24 subsection applies to a prescription drug imported
25 by an individual under section 812 or to a commer-

1 cial transaction conducted between an Internet phar-
2 macy and an individual.”.

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

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

11 **SEC. 6. SUSPENSION.**

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

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

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

23 “(b) SUSPENSION.—If the Secretary determines that
24 a drug importation facility, pharmacy, Internet pharmacy,
25 or wholesaler is engaged in a pattern of importing or offer-

1 ing for importation a prescription drug into the United
2 States in violation of any of the requirements of this Act,
3 the Secretary may immediately order the suspension of
4 that person from engaging in the importation or offering
5 for importation of prescription drugs into the United
6 States.

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

16 “(d) APPEAL OF SUSPENSION ORDER.—

17 “(1) IN GENERAL.—

18 “(A) PRESCRIPTION DRUGS.—With respect
19 to the importation of a prescription drug, the
20 importation of which is suspended under sub-
21 section (a), any person that would be entitled to
22 be a claimant for the prescription drug may ap-
23 peal the suspension order to the Secretary.

24 “(B) SUSPENDED PERSONS.—With respect
25 to a drug importation facility, pharmacy, Inter-

1 net pharmacy, or wholesaler subject to a sus-
2 pension order under subsection (b) or (c), the
3 drug importation facility, pharmacy, Internet
4 pharmacy or wholesaler may appeal the suspen-
5 sion order to the Secretary.

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

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

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

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

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

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

4 **SEC. 7. DEBARMENT FOR REPEATED OR SERIOUS PRE-**
5 **SCRIPTION DRUG IMPORTATION VIOLA-**
6 **TIONS.**

7 (a) DEBARMENT AUTHORITY.—

8 (1) PERMISSIVE DEBARMENT.—Section
9 306(b)(1) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 335a(b)(1)) is amended—

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

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

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

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

19 (2) AMENDMENT REGARDING DEBARMENT
20 GROUNDS.—Section 306(b) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is
22 amended—

23 (A) by redesignating paragraph (4) as
24 paragraph (5); and

1 (B) by inserting after paragraph (3) the
2 following:

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

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

7 “(i) the person has been convicted of
8 a felony for conduct relating to the impor-
9 tation into the United States of any pre-
10 scription drug; or

11 “(ii) the person has engaged in a pat-
12 tern of importing or offering for import a
13 prescription drug that presents a risk to
14 the public health.

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

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

23 (1) in subsection (b), by striking the subsection
24 heading and inserting the following:

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

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

7 (3) in subsection (d)(3)—

8 (A) in subparagraph (A)(i), by striking “or
9 paragraph (2)(A) or (3) of subsection (b)” and
10 inserting “paragraph (2)(A), (3), or (4) of sub-
11 section (b)”;

12 (B) in clauses (i) and (ii) of subparagraph
13 (B), by striking “or subsection (b)(3)” and in-
14 serting “paragraph (3) or (4) of subsection
15 (b)”;

16 (C) in subparagraph (B)(ii), by striking
17 “or the food importation process, as the case
18 may be” and inserting “, or the food or pre-
19 scription drug importation process, as the case
20 may be”.

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

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

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

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

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

14 (e) IMPORTATION BY DEBARRED PERSONS.—Section
15 801 of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 381) (as amended by section 5(b)) is amended by
17 adding at the end the following:

18 “(s) IMPORTATION OF PRESCRIPTION DRUGS BY
19 DEBARRED PERSONS.—

20 “(1) IN GENERAL.—If a prescription drug is
21 imported or offered for importation into the United
22 States, and the importer, owner, or consignee of the
23 prescription drug is a person that has been debarred
24 under section 306(b)(4), the prescription drug—

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

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

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

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

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

18 “(5) PERMISSIBLE DELIVERY.—A prescription
19 drug held under this subsection may be delivered to
20 a person that is not a debarred person under section
21 306(b)(4) if the person affirmatively establishes, at
22 the expense of the person, that the prescription drug
23 complies with the requirements of this Act, as deter-
24 mined by the Secretary.”.

1 **SEC. 8. REGISTRATION OF PRESCRIPTION DRUG IMPORTA-**
2 **TION FACILITIES.**

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

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

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

14 “(b) REGISTRATION.—

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

20 “(A) the name and address of each drug
21 importation facility, pharmacy, Internet phar-
22 macy, or wholesaler at which, and all trade
23 names under which, the registrant conducts
24 business;

25 “(B) the name of each prescription drug to
26 be imported into the United States by each

1 drug importation facility, pharmacy, Internet
2 pharmacy, or wholesaler; and

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

5 “(2) CHANGE IN INFORMATION.—The reg-
6 istrant shall notify the Secretary in a timely manner
7 of any change in the information provided under
8 paragraph (1).

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

12 “(A) assign a registration number to each
13 registered drug importation facility, pharmacy,
14 Internet pharmacy, and wholesaler; and

15 “(B) notify the registrant of the receipt of
16 the registration.

17 “(4) LIST.—

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

21 “(B) AVAILABILITY.—The Secretary shall
22 make the list described under subparagraph (A)
23 and information submitted by a registrant
24 under paragraph (1) available to the public on

1 an Internet website and through a toll-free tele-
2 phone number.

3 “(c) ELECTRONIC FILING.—

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

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

16 “(d) EFFECT OF SECTION.—

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

21 “(2) IMPORTATION BY INDIVIDUALS.—
22 Nothing in this section applies to a prescription
23 drug imported by an individual under section
24 812 or to a commercial transaction conducted

1 between an Internet pharmacy and an indi-
2 vidual.”.

3 (b) REGULATIONS.—

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

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

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

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

20 (c) IMPORTATION; FAILURE TO REGISTER.—Section
21 801 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 381) (as amended by section 7(e)) is amended by
23 adding at the end the following:

24 “(t) FAILURE TO REGISTER.—

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

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

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

20 “(4) NO TRANSFER.—During the period in
21 which a prescription drug is held under this sub-
22 section, the prescription drug shall not be trans-
23 ferred by any person from the port of entry into the
24 United States for the prescription drug or from the

1 secure facility to which the prescription drug has
2 been removed.”.

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

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

12 **SEC. 9. MAINTENANCE AND INSPECTION OF RECORDS FOR**
13 **PRESCRIPTION DRUGS.**

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

17 **“SEC. 815. MAINTENANCE AND INSPECTION OF RECORDS**
18 **FOR PRESCRIPTION DRUGS.**

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

22 “(1) a drug importation facility, pharmacy,
23 Internet pharmacy, or wholesaler engaged in the im-
24 portation of prescription drugs into the United
25 States, or in the dispensing of such drugs; and

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

4 “(b) INSPECTION.—

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

22 “(2) APPLICABILITY.—Paragraph (1) applies to
23 all records maintained by or on behalf of the drug
24 importation facility, pharmacy, Internet pharmacy,
25 or wholesaler or such other person in any format

1 (including paper and electronic formats) and at any
2 location.

3 “(c) PROTECTION OF SENSITIVE INFORMATION.—

4 The Secretary shall take appropriate measures to ensure
5 that there are in effect effective procedures to prevent the
6 unauthorized disclosure of any trade secret or confidential
7 information that is obtained by the Secretary under this
8 section or any commercial or financial information that
9 is privileged or confidential.

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

14 **SEC. 10. ADVANCE NOTICE OF IMPORTED PRESCRIPTION**
15 **DRUG SHIPMENTS.**

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

19 “(u) ADVANCE NOTICE OF IMPORTED PRESCRIPTION
20 DRUG SHIPMENTS.—

21 “(1) IN GENERAL.—For purposes of enabling
22 the Secretary to inspect at ports of entry a prescrip-
23 tion drug that is being imported or offered for im-
24 portation into the United States, the person import-
25 ing or offering for importation the prescription drug

1 shall, in advance, provide to the Secretary a notice
2 that includes—

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

6 “(B) the name of the shipper of the pre-
7 scription drug;

8 “(C) the name of the country from which
9 the prescription drug originates;

10 “(D) the country from which the prescrip-
11 tion drug is shipped;

12 “(E) the name of the port of entry of the
13 prescription drug;

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

17 “(i) the original source of the pre-
18 scription drug; and

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

22 “(G) the lot or control number assigned to
23 the prescription drug by the manufacturer of
24 the prescription drug;

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

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

9 “(i) is approved for marketing in the
10 United States and is not adulterated or
11 misbranded; and

12 “(ii) meets all labeling requirements
13 under this Act.

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

18 “(3) PERIOD OF ADVANCE NOTICE.—The pe-
19 riod in which the notice under paragraph (1) is re-
20 quired to be made in advance of the time of the im-
21 portation of a prescription drug or the offering of a
22 prescription drug for importation shall be not less
23 than 24 hours and not more than 5 days.

24 “(4) FAILURE TO PROVIDE NOTICE.—

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

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

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

21 “(7) NO TRANSFER.—During a period in which
22 a prescription drug is held under this subsection, the
23 prescription drug shall not be transferred by any
24 person from the port of entry into the United States

1 for the article or from the secure facility to which
2 the prescription drug has been removed.

3 “(8) EFFECT OF SUBSECTION.—

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

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

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

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

21 **SEC. 11. AUTHORITY TO MARK PRESCRIPTION DRUGS RE-**
22 **FUSED ADMISSION INTO THE UNITED**
23 **STATES.**

24 (a) IN GENERAL.—Section 801 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by

1 section 10(a)) is amended by adding at the end the fol-
2 lowing:

3 “(v) PRESCRIPTION DRUGS REFUSED ADMISSION.—

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

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

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

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

19 “(3) EFFECTIVE PERIOD.—A requirement
20 under paragraph (1) with respect to a prescription
21 drug remains in effect until the Secretary deter-
22 mines that the prescription drug has been brought
23 into compliance with this Act.

24 “(4) EFFECT OF SUBSECTION.—Nothing in this
25 subsection applies to a prescription drug imported

1 by an individual under section 812 or to a commer-
2 cial transaction conducted between an Internet phar-
3 macy and an individual.”.

4 (b) MISBRANDED PRESCRIPTION DRUGS.—Section
5 502 of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 352) is amended by adding at the end the fol-
7 lowing:

8 “(w) If—

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

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

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

19 (c) RULE OF CONSTRUCTION.—With respect to a
20 prescription drug that is imported or offered for importa-
21 tion into the United States, nothing in this section limits
22 the authority of the Secretary of Health and Human Serv-
23 ices or the Secretary of the Treasury to require the mark-
24 ing of prescription drugs refused admission under any
25 other provision of law.

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

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

5 “(x) PORT SHOPPING.—

6 “(1) IN GENERAL.—If—

7 “(A) it is a prescription drug imported or
8 offered for importation into the United States;
9 and

10 “(B) the prescription drug has previously
11 been refused admission under section 801(a);

12 unless the person reoffering the prescription drug af-
13 firmatively establishes, at the expense of the owner
14 or consignee of the prescription drug, that the pre-
15 scription drug complies with the applicable require-
16 ments of this Act, as determined by the Secretary.

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

22 **SEC. 13. AUTHORITY TO COMMISSION OTHER FEDERAL**
23 **AND STATE OFFICIALS TO CONDUCT INSPEC-**
24 **TIONS.**

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

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

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

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

11 “(B) A memorandum of understanding under
12 subparagraph (A) shall include—

13 “(i) provisions to ensure adequate training
14 of officers and employees to conduct the exami-
15 nations and investigations; and

16 “(ii) provisions regarding reimbursement
17 that may, in the discretion of the head of the
18 other agency, require reimbursement, in whole
19 or in part, from the Secretary for the examina-
20 tions or investigations performed under this
21 paragraph by the officers or employees of the
22 other agency.

23 “(C) A memorandum of understanding under
24 subparagraph (A) shall be effective only with respect
25 to examinations or inspections at facilities or other

1 locations that are jointly regulated by the Secretary
2 and the other agency.

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

13 “(i) the number of officers or employees
14 that carried out 1 or more programs, projects,
15 or activities under the memorandum of under-
16 standing;

17 “(ii) the number of additional articles that
18 were inspected or examined as a result of the
19 memorandum of understanding; and

20 “(iii) the number of additional examina-
21 tions or investigations that were carried out
22 pursuant to the memorandum of understanding.

23 “(4)(A) The Secretary may enter into a con-
24 tract with a State to use the State Board of Phar-
25 macy personnel of the State to conduct examinations

1 and inspection for the purpose of carrying out the
2 amendments made by the Safe IMPORT Act of
3 2004.

4 “(B) A contract entered into under subpara-
5 graph (A) shall—

6 “(i) ensure adequate training of officers
7 and employees to conduct the examinations and
8 investigations; and

9 “(ii) be effective only with respect to ex-
10 aminations or inspections of drug importation
11 facilities, pharmacies, Internet pharmacies, and
12 wholesalers located in the State.”.

13 **SEC. 14. USER FEES RELATING TO PRESCRIPTION DRUG**
14 **IMPORTATION.**

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

18 **“PART 5—FEES RELATING TO PRESCRIPTION**
19 **DRUG IMPORTATION**

20 **“SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IM-**
21 **PORTATION.**

22 “(a) REGISTRATION FEE.—The Secretary shall es-
23 tablish a user fee program under which a drug importation
24 facility, pharmacy, Internet pharmacy, or wholesaler reg-

1 istering with the Secretary under section 814 shall be re-
2 quired to pay a fee to the Secretary.

3 “(b) COLLECTION.—

4 “(1) COLLECTION ON INITIAL REGISTRATION.—

5 A fee under this section shall be payable for the fis-
6 cal year in which the drug importation facility, phar-
7 macy, Internet pharmacy, or wholesaler first reg-
8 isters under section 814 (or reregisters under that
9 section if that person has withdrawn its registration
10 and subsequently reregisters).

11 “(2) COLLECTION IN SUBSEQUENT YEARS.—

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

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

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

18 “(c) FEE AMOUNT.—The amount of the fee shall be

19 determined each year by the Secretary and shall be based
20 on the anticipated costs to the Secretary of enforcing the
21 amendments made by the Safe IMPORT Act of 2004 in
22 the subsequent fiscal year.

23 “(d) USE OF FEES.—The fees collected under this

24 section shall be used, without further appropriation, to en-

1 force the amendments made by the Safe IMPORT Act of
2 2004.

3 “(e) ANNUAL FEE SETTING.—The Secretary shall
4 establish, 60 days before the beginning of each fiscal year
5 beginning after September 30, 2004, for that fiscal year,
6 registration fees.

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

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

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

19 “(g) REPORTS.—

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

22 “(A) publish user fees under this section
23 for that fiscal year;

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

1 “(C) provide for a period of 30 days for
2 the public to provide written comments on the
3 recommendations.

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

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

14 “(B) the use by the Secretary of the fees
15 collected during the fiscal year for which the re-
16 port is made.”.

17 **SEC. 15. ANTICOUNTERFEITING PROVISIONS.**

18 (a) **REQUIRED RECORDS.**—Section 503(e) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))
20 is amended by striking paragraph (1) and inserting the
21 following:

22 “(1) A distributor of record that is engaged in
23 the wholesale distribution of a drug subject to sub-
24 section (b), shall—

1 “(A) before each wholesale distribution of the
2 drug—

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

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

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

21 “(i) with respect to each wholesale dis-
22 tribution of a drug subject to subsection (b),
23 identifies—

1 “(I) the immediately previous dis-
2 tributor of record from which the drug was
3 purchased; and

4 “(II) the immediately subsequent dis-
5 tributor of record to which the drug was
6 sold or otherwise transferred; and

7 “(ii) with respect to a drug subject to sub-
8 section (b) that is imported to the United
9 States, identifies—

10 “(I) each previous distributor of
11 record from which the drug was purchased
12 or otherwise transferred; and

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

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

24 (c) DISTRIBUTORS OF RECORD.—Section 503(e) of
25 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 353(e)) is amended by striking paragraph (3) and insert-
2 ing the following:

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

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

6 “(i) means a person that takes title to or
7 possession of a drug subject to subsection (b)
8 from manufacture to retail sale;

9 “(ii) includes a person that manufacturers,
10 processes, packs, distributes, receives, holds,
11 imports, or offers for importation a drug sub-
12 ject to subsection (b); and

13 “(iii) does not include a transporter;

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

19 “(C) the term ‘wholesale distribution’ means
20 the distribution of a drug subject to subsection (b)
21 to other than the consumer or patient but not in-
22 cluding an intracompany sale or distribution of a
23 drug described in subsection (c)(3)(B).”.

24 (d) ANTICOUNTERFEITING PROGRAMS.—Section
25 503(e) of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 353(e) is amended by adding at the end the fol-
2 lowing:

3 “(4) The Secretary shall—

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

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

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

17 “(C) develop and publish educational materials
18 to help health professionals and consumers identify
19 and report cases of counterfeit drugs subject to sub-
20 section (b);

21 “(D) develop and publish secure business prac-
22 tice guidelines for the sale and distribution of such
23 drugs in cooperation with members of a drug supply
24 chain; and

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

5 **SEC. 16. CONFORMING AMENDMENTS.**

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

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

10 (1) in section 301(aa)—

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

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

15 (2) in section 801(d)(1), by striking “section
16 804” and inserting “subchapter B”; and

17 (3) by striking section 804.

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