

111<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4813

To provide for insurance reform (including health insurance reform), amend title XVIII of the Social Security Act to reform Medicare Advantage and reduce disparities in the Medicare Program, regulate the importation of prescription drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 2010

Mr. BERRY introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Oversight and Government Reform, Ways and Means, and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for insurance reform (including health insurance reform), amend title XVIII of the Social Security Act to reform Medicare Advantage and reduce disparities in the Medicare Program, regulate the importation of prescription drugs, and for other purposes.

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

3 **SECTION 1. TABLE OF CONTENTS.**

4 The table of contents of this Act is as follows:

Sec. 1. Table of contents.

Sec. 2. Definitions.

## TITLE I—INSURANCE REFORM

- Sec. 101. Restoring application of antitrust laws to insurers.
- Sec. 102. Premiums and prohibitions on exclusions.
- Sec. 103. Guaranteed coverage availability and continuation.
- Sec. 104. Increasing the medical loss ratio.
- Sec. 105. Limitation of abortion funding.
- Sec. 106. Access limited to lawful residents.
- Sec. 107. Enforcement and treatment of Medicare, Medicaid, CHIP, and Tricare.

## TITLE II—MEDICARE AND MEDICAID REFORM

- Sec. 201. Medicare Advantage reforms.
- Sec. 202. Medicare disparities.
- Sec. 203. Establishment of Medicare operated prescription drug plan option.
- Sec. 204. Application to pharmacies and pharmacists of the eligible professional exemption from certain Medicare accreditation requirements.
- Sec. 205. Providing adequate pharmacy reimbursement.

## TITLE III—PRESCRIPTION DRUG IMPORTATION

- Sec. 301. Repeal of certain section regarding importation of prescription drugs.
- Sec. 302. Importation of prescription drugs; waiver of certain import restrictions.
- Sec. 303. Disposition of certain drugs denied admission into United States.
- Sec. 304. Wholesale distribution of drugs; statements regarding prior sale, purchase, or trade.
- Sec. 305. Internet sales of prescription drugs.
- Sec. 306. Prohibiting payments to unregistered foreign pharmacies.
- Sec. 307. Importation exemption under Controlled Substances Import and Export Act.
- Sec. 308. Severability.

## TITLE IV—ADDITIONAL PRESCRIPTION DRUGS PROVISIONS

- Sec. 401. Disallowance of deduction for advertising and promotional expenses for prescription pharmaceuticals.
- Sec. 402. Integrity for Pharmacy benefit managers.
- Sec. 403. Price information under Medicaid.

1 **SEC. 2. DEFINITIONS.**

2 For purposes of titles I and IV:

- 3 (1) **HEALTH BENEFITS PLAN.**—The term
- 4 “health benefits plan” means health insurance cov-
- 5 erage and an employment-based health plan and in-
- 6 cludes the public health insurance option.

1           (2) HEALTH BENEFITS PLAN OFFERING ENTI-  
2           TY.—The term “health benefits plan offering entity”  
3           means, with respect to a health benefits plan that  
4           is—

5                   (A) a group health plan, the plan sponsor  
6                   in relation to such group health plan, except  
7                   that, in the case of a plan maintained jointly by  
8                   1 or more employers and 1 or more employee  
9                   organizations and with respect to which an em-  
10                  ployer is the primary source of financing, such  
11                  term means such employer;

12                  (B) health insurance coverage, the health  
13                  insurance issuer offering the coverage;

14                  (C) a non-Federal governmental plan, the  
15                  State or political subdivision of a State (or  
16                  agency or instrumentality of such State or sub-  
17                  division) which establishes or maintains such  
18                  plan; or

19                  (D) a Federal governmental plan, the ap-  
20                  propriate Federal official.

21           (3) TERMS FROM ERISA.—The terms “em-  
22           ployer”, “employer”, “participant”, “beneficiary”,  
23           “person”, “plan sponsor”, and “governmental plan”  
24           have the meaning given such terms in section 3 of

1 the Employee Retirement Income Security Act of  
2 1974.

3 (4) TERMS FROM PHSA.—The terms “group  
4 health plan”, “health insurance coverage”, “health  
5 insurance issuer”, “group health insurance cov-  
6 erage”, “applicable State authority”, “Federal gov-  
7 ernmental plan”, “non-Federal governmental plan”,  
8 “State”, “individual market”, “large group market”,  
9 and “small group market” have the meaning given  
10 such terms in section 2971 of the Public Health  
11 Service Act.

12 (5) ADDITIONAL TERMS.—

13 (A) FAMILY.—The term “family” means  
14 an individual and includes the individual’s de-  
15 pendents

16 (B) SECRETARY.—The term “Secretary”  
17 means the Secretary of Health and Human  
18 Services.

19 (C) DEPENDENT.—The term “dependent”  
20 has the meaning given such term by the Sec-  
21 retary and includes a spouse.

22 (D) PLAN YEAR.—The term “plan year”  
23 means—

1 (i) with respect to an employment-  
2 based health plan, a plan year as specified  
3 under such plan; or

4 (ii) with respect to a health benefits  
5 plan other than an employment-based  
6 health plan, a 12-month period as specified  
7 by the Secretary.

## 8 **TITLE I—INSURANCE REFORM**

### 9 **SEC. 101. RESTORING APPLICATION OF ANTITRUST LAWS** 10 **TO INSURERS.**

11 (a) IN GENERAL.—Section 3 of the Act of March 9,  
12 1945 (15 U.S.C. 1013), commonly known as the  
13 McCarran-Ferguson Act, is amended by adding at the end  
14 the following:

15 “(c)(1) Nothing contained in this Act shall modify,  
16 impair, or supersede the operation of any of the antitrust  
17 laws with respect to price fixing, market allocation, or mo-  
18 nopolization (or attempting to monopolize) by a person en-  
19 gaged in the business of insurance.

20 “(2) For purposes of this subsection the term ‘anti-  
21 trust laws’ has the meaning given it in subsection (a) of  
22 the 1st section of the Clayton Act, except that such term  
23 includes section 5 of the Federal Trade Commission Act  
24 to the extent that such section 5 applies to unfair methods  
25 of competition.”.

1 (b) RELATED PROVISION.—For purposes of section  
2 5 of the Federal Trade Commission Act (15 U.S.C. 45)  
3 to the extent such section applies to unfair methods of  
4 competition, section 3(c) of the McCarran-Ferguson Act  
5 shall apply with respect to the business of insurance with-  
6 out regard to whether such business is carried on for prof-  
7 it, notwithstanding the definition of “Corporation” con-  
8 tained in section 4 of the Federal Trade Commission Act.

9 (c) RELATED PRESERVATION OF ANTITRUST  
10 LAWS.—Except as provided in subsections (a) and (b),  
11 nothing in this Act, or in the amendments made by this  
12 Act, shall be construed to modify, impair, or supersede  
13 the operation of any of the antitrust laws. For purposes  
14 of the preceding sentence, the term “antitrust laws” has  
15 the meaning given it in subsection (a) of the 1st section  
16 of the Clayton Act, except that it includes section 5 of  
17 the Federal Trade commission Act to the extent that such  
18 section 5 applies to unfair methods of competition.

19 **SEC. 102. PREMIUMS AND PROHIBITIONS ON EXCLUSIONS.**

20 (a) PREMIUM RATE VARIATION.—The premium rate  
21 charged for a health benefits plan may not vary except  
22 as follows:

23 (1) By geographic premium rating area (as per-  
24 mitted by State insurance regulators).



1           (A) RESTRICTION.—A health benefits plan  
2 issuer described in paragraph (1) may restrict  
3 enrollment in coverage described in such sub-  
4 section to open or special enrollment periods.

5           (B) ESTABLISHMENT.—A health benefits  
6 plan issuer described in paragraph (1) shall, in  
7 accordance with the regulations promulgated  
8 under subparagraph (C), establish special en-  
9 rollment periods for qualifying events (under  
10 section 603 of the Employee Retirement Income  
11 Security Act of 1974).

12           (C) REGULATIONS.—The Secretary shall  
13 promulgate regulations with respect to enroll-  
14 ment periods under subparagraphs (A) and (B).

15       (b) GUARANTEED RENEWABILITY OF COVERAGE.—  
16 If a health benefits plan issuer offers health insurance cov-  
17 erage in the individual or group market, the issuer must  
18 renew or continue in force such coverage at the option of  
19 the plan sponsor or the individual, as applicable.

20       (c) PROHIBITION OF RESCISSION.—Rescissions of  
21 health insurance coverage offered by a health benefits plan  
22 issuer shall be prohibited except in cases of fraud as de-  
23 fined in section 2712(b)(2) of the Public Health Service  
24 Act.



1 **SEC. 104. INCREASING THE MEDICAL LOSS RATIO.**

2 Each health benefits plan issuer that offers health in-  
3 surance coverage in the small or large group market shall  
4 provide that for any plan year in which the coverage has  
5 a medical loss ratio below 92 percent, the issuer shall pro-  
6 vide for rebates to enrollees of the amount by which the  
7 issuer's medical loss ratio is less than the level so speci-  
8 fied.

9 **SEC. 105. LIMITATION OF ABORTION FUNDING.**

10 (a) IN GENERAL.—No Federal funds may be used  
11 to pay for any abortion or to cover any part of the costs  
12 of any health plan that includes coverage of abortion, ex-  
13 cept in the case where a woman suffers from a physical  
14 disorder, physical injury, or physical illness that would, as  
15 certified by a physician, place the woman in danger of  
16 death unless an abortion is performed, including a life-  
17 endangering physical condition caused by or arising from  
18 the pregnancy itself, or unless the pregnancy is the result  
19 of an act of rape or incest.

20 (b) OPTION TO PURCHASE SEPARATE SUPPLE-  
21 MENTAL COVERAGE OR PLAN.—Nothing in this section  
22 shall be construed as prohibiting any nonfederal entity (in-  
23 cluding an individual, a State government, and a local gov-  
24 ernment) from purchasing separate supplemental coverage  
25 for abortions for which funding is prohibited under this

1 section, or a plan that includes such abortions, so long  
2 as—

3 (1) such coverage or plan is paid for entirely  
4 using only nonfederal funds; and

5 (2) such coverage or plan is not purchased  
6 using nonfederal funds that are required to receive  
7 a federal payment, including a State's or locality's  
8 contribution of Medicaid matching funds.

9 (c) **OPTION TO OFFER SEPARATE SUPPLEMENTAL**  
10 **COVERAGE OR PLAN.**—Nothing in this section shall re-  
11 strict any nonfederal health benefits plan offering entity  
12 from offering separate supplemental coverage for abor-  
13 tions for which funding is prohibited under this section,  
14 or a plan that includes such abortions, so long as—

15 (1) premiums for such separate supplemental  
16 coverage or plan are paid for entirely with non-  
17 federal funds; and

18 (2) administrative costs and all services offered  
19 through such supplemental coverage or plan are paid  
20 for using only premiums collected for such coverage  
21 or plan.

22 **SEC. 106. ACCESS LIMITED TO LAWFUL RESIDENTS.**

23 (a) **SALE OF INSURANCE.**—A health benefits plan  
24 issuer may not sell health insurance coverage under a  
25 health benefits plan, if, at the time of such sale, a partici-

1 pant or beneficiary of such plan is not, or is not reasonably  
2 expected to be for the entire period for which enrollment  
3 is sought, a citizen or national of the United States or  
4 an alien lawfully present in the United States.

5 (b) ENROLLMENT.—A health benefits plan issuer  
6 may not enroll a participant or beneficiary in a health ben-  
7 efits plan, if, at the time of such enrollment, such partici-  
8 pant or beneficiary is not, or is not reasonably expected  
9 to be for the entire period for which enrollment is sought,  
10 a citizen or national of the United States or an alien law-  
11 fully present in the United States.

12 **SEC. 107. ENFORCEMENT AND TREATMENT OF MEDICARE,**  
13 **MEDICAID, CHIP, AND TRICARE.**

14 (a) ENFORCEMENT.—For purposes of enforcement,  
15 the provisions of this title shall be treated as if included  
16 such provisions were included in title XXVII of the Public  
17 Health Service Act, title VII of the Employee Retirement  
18 Income Security Act of 1974, and chapter 89 of title 5,  
19 United States Code.

20 (b) TREATMENT OF MEDICARE, MEDICAID, CHIP,  
21 AND TRICARE.—The provisions of sections 102, 103, and  
22 104 shall not apply to the Medicare, Medicaid, and CHIP  
23 programs under titles XVIII, XIX, and XXI of the Social  
24 Security Act, respectively, or to Tricare.

1                   **TITLE II—MEDICARE AND**  
2                   **MEDICAID REFORM**

3   **SEC. 201. MEDICARE ADVANTAGE REFORMS.**

4           (a) PHASE-IN OF PAYMENT BASED ON FEE-FOR-  
5   SERVICE COSTS.—Section 1853 of the Social Security Act  
6   (42 U.S.C. 1395w–23) is amended—

7                   (1) in subsection (j)(1)(A)—

8                           (A) by striking “beginning with 2007” and  
9                           inserting “for 2007, 2008, 2009, and 2010”;  
10                           and—

11                           (B) by inserting after “(k)(1)” the fol-  
12                           lowing: “, or, beginning with 2011,  $\frac{1}{12}$  of the  
13                           blended benchmark amount determined under  
14                           subsection (n)(1)”;

15                   (2) by adding at the end the following new sub-  
16   section:

17           “(n) DETERMINATION OF BLENDED BENCHMARK  
18   AMOUNT.—

19                   “(1) IN GENERAL.—For purposes of subsection  
20   (j), subject to paragraphs (3) and (4), the term  
21   ‘blended benchmark amount’ means for an area—

22                           “(A) for 2011 the sum of—

23                                   “(i)  $\frac{2}{3}$  of the applicable amount (as  
24                                   defined in subsection (k)) for the area and  
25                                   year; and

1           “(ii)  $\frac{1}{3}$  of the amount specified in  
2           paragraph (2) for the area and year;

3           “(B) for 2012 the sum of—

4           “(i)  $\frac{1}{3}$  of the applicable amount for  
5           the area and year; and

6           “(ii)  $\frac{2}{3}$  of the amount specified in  
7           paragraph (2) for the area and year; and

8           “(C) for a subsequent year the amount  
9           specified in paragraph (2) for the area and  
10          year.

11          “(2) SPECIFIED AMOUNT.—The amount speci-  
12          fied in this paragraph for an area and year is the  
13          amount specified in subsection (c)(1)(D)(i) for the  
14          area and year adjusted (in a manner specified by the  
15          Secretary) to take into account the phase-out in the  
16          indirect costs of medical education from capitation  
17          rates described in subsection (k)(4).

18          “(3) FEE-FOR-SERVICE PAYMENT FLOOR.—In  
19          no case shall the blended benchmark amount for an  
20          area and year be less than the amount specified in  
21          paragraph (2).

22          “(4) EXCEPTION FOR PACE PLANS.—This sub-  
23          section shall not apply to payments to a PACE pro-  
24          gram under section 1894.”.

1 (b) ELIMINATION OF MEDICARE ADVANTAGE RE-  
2 GIONAL STABILIZATION PLAN.—

3 (1) IN GENERAL.—Section 1858 of the Social  
4 Security Act (42 U.S.C. 1395w–27a) is amended by  
5 striking subsection (e).

6 (2) TRANSITION.—Any amount contained in the  
7 MA Regional Plan Stabilization Fund as of the date  
8 of the enactment of this Act shall be transferred to  
9 the Federal Supplementary Medical Insurance Trust  
10 Fund.

11 **SEC. 202. MEDICARE DISPARITIES.**

12 (a) FLOOR ON THE MEDICARE HOSPITAL AREA  
13 WAGE INDEX.—

14 (1) IN GENERAL.—Section 1886(d)(3)(E) of  
15 the Social Security Act (42 U.S.C.  
16 1395ww(d)(3)(E)) is amended—

17 (A) in clause (i), by striking “clause (ii)”  
18 and inserting “clause (ii) or (iii)”; and—

19 (B) by adding at the end of the following  
20 new clause:

21 “(iii) FLOOR ON AREA WAGE  
22 INDEX.—For discharges occurring on or  
23 after October 1, 2010, the area wage index  
24 applicable under this subparagraph to any  
25 hospital may not be less than 1.00.”.

1 (b) INCREASE THE PHYSICIAN FEE SCHEDULE  
 2 PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT.—Sec-  
 3 tion 1848(e)(1) is amended by adding after subparagraph  
 4 (E) the following new subparagraph:

5 “(F) FLOOR FOR PRACTICE EXPENSE GEO-  
 6 GRAPHIC INDEX.—After calculating the practice  
 7 expense geographic index in subparagraph  
 8 (A)(i), for purposes of payment for services fur-  
 9 nished on or after October 1, 2010, the Sec-  
 10 retary shall increase the practice expense geo-  
 11 graphic index to 1.00 for any locality for which  
 12 such practice expense geographic index is less  
 13 than 1.00.”.

14 **SEC. 203. ESTABLISHMENT OF MEDICARE OPERATED PRE-**  
 15 **SCRIPTION DRUG PLAN OPTION.**

16 (a) IN GENERAL.—Subpart 2 of part D of the Social  
 17 Security Act is amended by inserting after section 1860D-  
 18 11 (42 U.S.C. 1395w-111) the following new section:

19 “MEDICARE OPERATED PRESCRIPTION DRUG PLAN  
 20 OPTION

21 “SEC. 1860D-11A. (a) IN GENERAL.—Notwith-  
 22 standing any other provision of this part, for each year  
 23 (beginning with 2011), in addition to any plans offered  
 24 under section 1860D-11, the Secretary—

25 “(1) shall offer one or more Medicare operated  
 26 prescription drug plans (as defined in subsection (c))

1 with a service area that consists of the entire United  
2 States; and

3 “(2) shall enter into negotiations, in accordance  
4 with subsection (b), with pharmaceutical manufac-  
5 turers to reduce the purchase cost of covered part D  
6 drugs for eligible part D individuals who enroll in  
7 such a plan.

8 “(b) NEGOTIATIONS.—Notwithstanding section  
9 1860D–11(i), for purposes of offering a medicare operated  
10 prescription drug plan under this section, the Secretary  
11 shall negotiate with pharmaceutical manufacturers with  
12 respect to the purchase price of covered part D drugs for  
13 a Medicare operated prescription drug plan and shall en-  
14 courage the use of more affordable therapeutic equivalents  
15 to the extent such practices do not override medical neces-  
16 sity as determined by the prescribing physician. To the  
17 extent practicable and consistent with the previous sen-  
18 tence, the Secretary shall implement strategies similar to  
19 those used by other Federal purchasers of prescription  
20 drugs, and other strategies, including the use of a for-  
21 mulary and formulary incentives in subsection (e), to re-  
22 duce the purchase cost of covered part D drugs.

23 “(c) MEDICARE OPERATED PRESCRIPTION DRUG  
24 PLAN DEFINED.—For purposes of this part, the term  
25 ‘medicare operated prescription drug plan’ means a pre-



1 prescription drug plan that offers qualified prescription drug  
2 coverage and access to negotiated prices described in sec-  
3 tion 1860D–2(a)(1)(A). Such a plan may offer supple-  
4 mental prescription drug coverage in the same manner as  
5 other qualified prescription drug coverage offered by other  
6 prescription drug plans.

7 “(d) MONTHLY BENEFICIARY PREMIUM.—

8 “(1) QUALIFIED PRESCRIPTION DRUG COV-  
9 ERAGE.—The monthly beneficiary premium for  
10 qualified prescription drug coverage and access to  
11 negotiated prices described in section 1860D–  
12 2(a)(1)(A) to be charged under a medicare operated  
13 prescription drug plan shall be uniform nationally.  
14 Such premium for months in 2010 and each suc-  
15 ceeding year shall be based on the average monthly  
16 per capita actuarial cost of offering the medicare op-  
17 erated prescription drug plan for the year involved,  
18 including administrative expenses.

19 “(2) SUPPLEMENTAL PRESCRIPTION DRUG COV-  
20 ERAGE.—Insofar as a medicare operated prescrip-  
21 tion drug plan offers supplemental prescription drug  
22 coverage, the Secretary may adjust the amount of  
23 the premium charged under paragraph (1).

24 “(e) USE OF A FORMULARY AND FORMULARY INCEN-  
25 TIVES.—

1           “(1) IN GENERAL.—With respect to the oper-  
2           ation of a medicare operated prescription drug plan,  
3           the Secretary shall establish and apply a formulary  
4           (and may include formulary incentives described in  
5           paragraph (2)(C)(ii)) in accordance with this sub-  
6           section in order to—

7                   “(A) increase patient safety;

8                   “(B) increase appropriate use and reduce  
9           inappropriate use of drugs; and

10                   “(C) reward value.

11           “(2) DEVELOPMENT OF INITIAL FORMULARY.—

12                   “(A) IN GENERAL.—In selecting covered  
13           part D drugs for inclusion in a formulary, the  
14           Secretary shall consider clinical benefit and  
15           price of such drug.

16                   “(B) ROLE OF AHRQ.—The Director of the  
17           Agency for Healthcare Research and Quality  
18           shall be responsible for assessing the clinical  
19           benefit of covered part D drugs and making  
20           recommendations to the Secretary regarding  
21           which drugs should be included in the for-  
22           mulary. In conducting such assessments and  
23           making such recommendations, the Director  
24           shall—

1 “(i) consider safety concerns, includ-  
2 ing those identified by the Federal Food  
3 and Drug Administration;

4 “(ii) use available data and evalua-  
5 tions, with priority given to randomized  
6 controlled trials, to examine clinical effec-  
7 tiveness, comparative effectiveness, safety,  
8 and enhanced compliance with a drug regi-  
9 men;

10 “(iii) use the same classes of drugs  
11 developed by United States Pharmacopeia  
12 for this part;

13 “(iv) consider evaluations made by—  
14 “(I) the Director under section  
15 1013 of Medicare Prescription Drug,  
16 Improvement, and Modernization Act  
17 of 2003;

18 “(II) other Federal entities, such  
19 as the Secretary of Veterans Affairs;  
20 and

21 “(III) other private and public  
22 entities, such as the Drug Effective-  
23 ness Review Project and Medicaid  
24 programs; and

25 “(v) recommend to the Secretary—

1           “(I) those drugs in a class that  
2           provide a greater clinical benefit, in-  
3           cluding fewer safety concerns or less  
4           risk of side-effects, than another drug  
5           in the same class that should be in-  
6           cluded in the formulary;

7           “(II) those drugs in a class that  
8           provide less clinical benefit, including  
9           greater safety concerns or a greater  
10          risk of side-effects, than another drug  
11          in the same class that should be ex-  
12          cluded from the formulary; and

13          “(III) drugs in a class with same  
14          or similar clinical benefit for which it  
15          would be appropriate for the Sec-  
16          retary to competitively bid (or nego-  
17          tiate) for placement on the formulary.

18          “(C) CONSIDERATION OF AHRQ REC-  
19          COMMENDATIONS.—

20                 “(i) IN GENERAL.—The Secretary,  
21                 after taking into consideration the rec-  
22                 ommendations under subparagraph (B)(v),  
23                 shall establish a formulary, and formulary  
24                 incentives, to encourage use of covered  
25                 part D drugs that—

1           “(I) have a lower cost and pro-  
2           vide a greater clinical benefit than  
3           other drugs;

4           “(II) have a lower cost than  
5           other drugs with same or similar clin-  
6           ical benefit; and

7           “(III) drugs that have the same  
8           cost but provide greater clinical ben-  
9           efit than other drugs.

10          “(ii) FORMULARY INCENTIVES.—The  
11          formulary incentives under clause (i) may  
12          be in the form of one or more of the fol-  
13          lowing:

14                 “(I) Tiered copayments.

15                 “(II) Reference pricing.

16                 “(III) Prior authorization.

17                 “(IV) Step therapy.

18                 “(V) Medication therapy manage-  
19                 ment.

20                 “(VI) Generic drug substitution.

21          “(iii) FLEXIBILITY.—In applying such  
22          formulary incentives the Secretary may de-  
23          cide not to impose any cost-sharing for a  
24          covered part D drug for which—

1                   “(I) the elimination of cost shar-  
2                   ing would be expected to increase  
3                   compliance with a drug regimen; and

4                   “(II) compliance would be ex-  
5                   pected to produce savings under part  
6                   A or B or both.

7                   “(3) LIMITATIONS ON FORMULARY.—In any  
8                   formulary established under this subsection, the for-  
9                   mulary may not be changed during a year, except—

10                   “(A) to add a generic version of a covered  
11                   part D drug that entered the market;

12                   “(B) to remove a drug for which a safety  
13                   problem is found; and

14                   “(C) to add a drug that the Secretary  
15                   identifies as a drug which treats a condition for  
16                   which there has not previously been a treatment  
17                   option or for which a clear and significant ben-  
18                   efit has been demonstrated over other covered  
19                   part D drugs.

20                   “(4) ADDING DRUGS TO THE INITIAL FOR-  
21                   MULARY.—

22                   “(A) USE OF ADVISORY COMMITTEE.—The  
23                   Secretary shall establish and appoint an advi-  
24                   sory committee (in this paragraph referred to  
25                   as the ‘advisory committee’)—

1           “(i) to review petitions from drug  
2           manufacturers, health care provider orga-  
3           nizations, patient groups, and other enti-  
4           ties for inclusion of a drug in, or other  
5           changes to, such formulary; and

6           “(ii) to recommend any changes to the  
7           formulary established under this sub-  
8           section.

9           “(B) COMPOSITION.—The advisory com-  
10          mittee shall be composed of 9 members and  
11          shall include representatives of physicians,  
12          pharmacists, and consumers and others with ex-  
13          pertise in evaluating prescription drugs. The  
14          Secretary shall select members based on their  
15          knowledge of pharmaceuticals and the Medicare  
16          population. Members shall be deemed to be spe-  
17          cial Government employees for purposes of ap-  
18          plying the conflict of interest provisions under  
19          section 208 of title 18, United States Code, and  
20          no waiver of such provisions for such a member  
21          shall be permitted.

22          “(C) CONSULTATION.—The advisory com-  
23          mittee shall consult, as necessary, with physi-  
24          cians who are specialists in treating the disease  
25          for which a drug is being considered.

1           “(D) REQUEST FOR STUDIES.—The advi-  
2 sory committee may request the Agency for  
3 Healthcare Research and Quality or an aca-  
4 demic or research institution to study and make  
5 a report on a petition described in subpara-  
6 graph (A)(ii) in order to assess—

7                   “(i) clinical effectiveness;

8                   “(ii) comparative effectiveness;

9                   “(iii) safety; and

10                   “(iv) enhanced compliance with a  
11 drug regimen.

12           “(E) RECOMMENDATIONS.—The advisory  
13 committee shall make recommendations to the  
14 Secretary regarding—

15                   “(i) whether a covered part D drug is  
16 found to provide a greater clinical benefit,  
17 including fewer safety concerns or less risk  
18 of side-effects, than another drug in the  
19 same class that is currently included in the  
20 formulary and should be included in the  
21 formulary;

22                   “(ii) whether a covered part D drug is  
23 found to provide less clinical benefit, in-  
24 cluding greater safety concerns or a great-  
25 er risk of side-effects, than another drug in



1 the same class that is currently included in  
2 the formulary and should not be included  
3 in the formulary; and

4 “(iii) whether a covered part D drug  
5 has the same or similar clinical benefit to  
6 a drug in the same class that is currently  
7 included in the formulary and whether the  
8 drug should be included in the formulary.

9 “(F) LIMITATIONS ON REVIEW OF MANU-  
10 FACTURER PETITIONS.—The advisory com-  
11 mittee shall not review a petition of a drug  
12 manufacturer under subparagraph (A)(ii) with  
13 respect to a covered part D drug unless the pe-  
14 tition is accompanied by the following:

15 “(i) Raw data from clinical trials on  
16 the safety and effectiveness of the drug.

17 “(ii) Any data from clinical trials con-  
18 ducted using active controls on the drug or  
19 drugs that are the current standard of  
20 care.

21 “(iii) Any available data on compara-  
22 tive effectiveness of the drug.

23 “(iv) Any other information the Sec-  
24 retary requires for the advisory committee  
25 to complete its review.

1           “(G) RESPONSE TO RECOMMENDATIONS.—

2           The Secretary shall review the recommenda-  
3           tions of the advisory committee and if the Sec-  
4           retary accepts such recommendations the Sec-  
5           retary shall modify the formulary established  
6           under this subsection accordingly. Nothing in  
7           this section shall preclude the Secretary from  
8           adding to the formulary a drug for which the  
9           Director of the Agency for Healthcare Research  
10          and Quality or the advisory committee has not  
11          made a recommendation.

12          “(H) NOTICE OF CHANGES.—The Sec-  
13          retary shall provide timely notice to bene-  
14          ficiaries and health professionals about changes  
15          to the formulary or formulary incentives.

16          “(f) INFORMING BENEFICIARIES.—The Secretary  
17          shall take steps to inform beneficiaries about the avail-  
18          ability of a Medicare operated drug plan or plans including  
19          providing information in the annual handbook distributed  
20          to all beneficiaries and adding information to the official  
21          public Medicare website related to prescription drug cov-  
22          erage available through this part.

23          “(g) APPLICATION OF ALL OTHER REQUIREMENTS  
24          FOR PRESCRIPTION DRUG PLANS.—Except as specifically  
25          provided in this section, any Medicare operated drug plan

1 shall meet the same requirements as apply to any other  
2 prescription drug plan, including the requirements of sec-  
3 tion 1860D–4(b)(1) relating to assuring pharmacy ac-  
4 cess).”.

5 (b) CONFORMING AMENDMENTS.—

6 (1) Section 1860D–3(a) of the Social Security  
7 Act (42 U.S.C. 1395w–103(a)) is amended by add-  
8 ing at the end the following new paragraph:

9 “(4) AVAILABILITY OF THE MEDICARE OPER-  
10 ATED PRESCRIPTION DRUG PLAN.—A medicare oper-  
11 ated prescription drug plan (as defined in section  
12 1860D–11A(c)) shall be offered nationally in accord-  
13 ance with section 1860D–11A.”.

14 (2)(A) Section 1860D–3 of the Social Security  
15 Act (42 U.S.C. 1395w–103) is amended by adding  
16 at the end the following new subsection:

17 “(c) PROVISIONS ONLY APPLICABLE IN 2006, 2007,  
18 2008, AND 2009.—The provisions of this section shall only  
19 apply with respect to 2006, 2007, 2008, and 2009.”.

20 (B) Section 1860D–11(g) of such Act (42  
21 U.S.C. 1395w–111(g)) is amended by adding at the  
22 end the following new paragraph:

23 “(8) NO AUTHORITY FOR FALLBACK PLANS  
24 AFTER 2009.—A fallback prescription drug plan shall  
25 not be available after December 31, 2009.”.

1           (3) Section 1860D–13(c)(3) of such Act (42  
2 U.S.C. 1395w–113(c)(3)) is amended—

3           (A) in the heading, by inserting “AND  
4 MEDICARE OPERATED PRESCRIPTION DRUG  
5 PLANS” after “FALLBACK PLANS”; and

6           (B) by inserting “or a medicare operated  
7 prescription drug plan” after “a fallback pre-  
8 scription drug plan”.

9           (4) Section 1860D–16(b)(1) of such Act (42  
10 U.S.C.1395w–116(b)(1)) is amended—

11           (A) in subparagraph (C), by striking  
12 “and” after the semicolon at the end;

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

15           (C) by adding at the end the following new  
16 subparagraph:

17           “(E) payments for expenses incurred with  
18 respect to the operation of medicare operated  
19 prescription drug plans under section 1860D–  
20 11A.”.

21           (5) Section 1860D–41(a) of such Act (42  
22 U.S.C. 1395w–151(a)) is amended by adding at the  
23 end the following new paragraph:

24           “(19) MEDICARE OPERATED PRESCRIPTION  
25 DRUG PLAN.—The term ‘medicare operated prescrip-

1       tion drug plan’ has the meaning given such term in  
2       section 1860D–11A(c).”.

3       (c) IMPROVED APPEALS PROCESS UNDER THE MEDI-  
4 CARE OPERATED PRESCRIPTION DRUG PLAN.—Section  
5 1860D–4(h) of the Social Security Act (42 U.S.C. 1305w–  
6 104(h)) is amended by adding at the end the following  
7 new paragraph:

8               “(4) APPEALS PROCESS FOR MEDICARE OPER-  
9       ATED PRESCRIPTION DRUG PLAN.—

10               “(A) IN GENERAL.—The Secretary shall  
11       develop a well-defined process for appeals for  
12       denials of benefits under this part under the  
13       Medicare operated prescription drug plan. Such  
14       process shall be efficient, impose minimal ad-  
15       ministrative burdens, and ensure the timely  
16       procurement of non-formulary drugs or exemp-  
17       tion from formulary incentives when medically  
18       necessary. Medical necessity shall be based on  
19       professional medical judgment, the medical con-  
20       dition of the beneficiary, and other medical evi-  
21       dence. Such appeals process shall include—

22               “(i) an initial review and determina-  
23       tion made by the Secretary; and

24               “(ii) for appeals denied during the ini-  
25       tial review and determination, the option of

1 an external review and determination by  
2 an independent entity selected by the Sec-  
3 retary.

4 “(B) CONSULTATION IN DEVELOPMENT OF  
5 PROCESS.—In developing the appeals process  
6 under subparagraph (A), the Secretary shall  
7 consult with consumer and patient groups, as  
8 well as other key stakeholders to ensure the  
9 goals described in subparagraph (A) are  
10 achieved.”.

11 (d) EFFECTIVE DATE.—The amendments made by  
12 this section shall take effect on January 1, 2011.

13 **SEC. 204. APPLICATION TO PHARMACIES AND PHAR-**  
14 **MACISTS OF THE ELIGIBLE PROFESSIONAL**  
15 **EXEMPTION FROM CERTAIN MEDICARE AC-**  
16 **CREDITATION REQUIREMENTS.**

17 Section 1834(a)(20)(F)(ii) of the Social Security Act  
18 (42 U.S.C. 1395m(a)(20)(F)(ii)) is amended—

19 (1) by inserting “pharmacies, and phar-  
20 macists,” after “eligible professionals (as defined in  
21 section 1848(k)(3)(B)),”; and

22 (2) by inserting “, pharmacies, pharmacists,”  
23 after “such professionals” each place it appears.

1 **SEC. 205. PROVIDING ADEQUATE PHARMACY REIMBURSE-**  
2 **MENT.**

3 (a) PHARMACY REIMBURSEMENT LIMITS.—

4 (1) IN GENERAL.—Section 1927(e) of the So-  
5 cial Security Act (42 U.S.C. 1396r-8(e)) is amend-  
6 ed—

7 (A) in paragraph (4), by striking “(or, ef-  
8 fective January 1, 2007, two or more)”; and

9 (B) by striking paragraph (5) and insert-  
10 ing the following:

11 “(5) USE OF AMP IN UPPER PAYMENT LIM-  
12 ITS.—The Secretary shall calculate the Federal  
13 upper reimbursement limit established under para-  
14 graph (4) as no less than 300 percent of the weight-  
15 ed average (determined on the basis of utilization) of  
16 the most recently reported monthly average manu-  
17 facturer prices for pharmaceutically and therapeuti-  
18 cally equivalent multiple source drug products that  
19 are available for purchase by retail community phar-  
20 macies on a nationwide basis. The Secretary shall  
21 implement a process using rolling averages to cal-  
22 culate average manufacturer prices. Such process  
23 shall be similar to the process used in determining  
24 the average sales price of a drug or biological under  
25 section 1847A(c)(5)(A).”.

1           (2) DEFINITION OF AMP.—Section 1927(k)(1)  
2 of such Act (42 U.S.C. 1396r–8(k)(1)) is amend-  
3 ed—

4           (A) in subparagraph (A), by striking “by”  
5 and all that follows through the period and in-  
6 serting “by—”

7           “(i) wholesalers for drugs distributed  
8 to retail community pharmacies; and

9           “(ii) retail community pharmacies  
10 that purchase drugs directly from the man-  
11 ufacturer.”;

12          (B) by striking subparagraph (B) and in-  
13 serting the following:

14          “(B) EXCLUSION OF CUSTOMARY PROMPT  
15 PAY DISCOUNTS AND OTHER PAYMENTS.—

16           “(i) IN GENERAL.—The average man-  
17 ufacturer price for a covered outpatient  
18 drug shall exclude—

19           “(I) customary prompt pay dis-  
20 counts extended to wholesalers;

21           “(II) bona fide service fees paid  
22 by manufacturers to wholesalers or re-  
23 tail community pharmacies, including  
24 (but not limited to) distribution serv-  
25 ice fees, inventory management fees,



1 product stocking allowances, and fees  
2 associated with administrative services  
3 agreements and patient care programs  
4 (such as medication compliance pro-  
5 grams and patient education pro-  
6 grams);

7 “(III) reimbursement by manu-  
8 facturers for recalled, damaged, ex-  
9 pired, or otherwise unsalable returned  
10 goods, including (but not limited to)  
11 reimbursement for the cost of the  
12 goods and any reimbursement of costs  
13 associated with return goods handling  
14 and processing, reverse logistics, and  
15 drug destruction; and

16 “(IV) payments received from,  
17 and rebates or discounts provided to,  
18 pharmacy benefit managers, managed  
19 care organizations, health mainte-  
20 nance organizations, insurers, hos-  
21 pitals, clinics, mail order pharmacies,  
22 long term care providers, manufactur-  
23 ers, or any other entity that does not  
24 conduct business as a wholesaler or a  
25 retail community pharmacy.

1                   “(ii) INCLUSION OF OTHER DIS-  
2                   COUNTS AND PAYMENTS.—Notwith-  
3                   standing clause (i), any other discounts,  
4                   rebates, payments, or other financial trans-  
5                   actions that are received by, paid by, or  
6                   passed through to, retail community phar-  
7                   macies shall be included in the average  
8                   manufacturer price for a covered out-  
9                   patient drug.”; and

10                   (C) in subparagraph (C), by striking “the  
11                   retail pharmacy class of trade” and inserting  
12                   “retail community pharmacies”.

13                   (3) DEFINITION OF A MULTIPLE SOURCE  
14                   DRUG.—Section 1927(k)(7) of such Act (42 U.S.C.  
15                   1396r–8(k)(7)) is amended—

16                   (A) in subparagraph (A)(i)(III), by strik-  
17                   ing “the State” and inserting “the United  
18                   States”; and

19                   (B) in subparagraph (C)—

20                   (i) in clause (i), by inserting “and”  
21                   after the semicolon;

22                   (ii) in clause (ii), by striking “; and”  
23                   and inserting a period; and

24                   (iii) by striking clause (iii).

1           (4) DEFINITION OF RETAIL COMMUNITY PHAR-  
2           MACY.—Section 1927(k) of such Act (42 U.S.C.  
3           1396r–8(k)) is amended by adding at the end the  
4           following new paragraphs:

5           “(10) RETAIL COMMUNITY PHARMACY.—The  
6           term ‘retail community pharmacy’ means an inde-  
7           pendent pharmacy, a chain pharmacy, a super-  
8           market pharmacy, or a mass merchandiser phar-  
9           macy that is licensed as a pharmacy by the State  
10          and that dispenses medications to the general public  
11          at retail prices. Such term does not include a phar-  
12          macy that dispenses prescription medications to pa-  
13          tients primarily through the mail, nursing home  
14          pharmacies, long-term care facility pharmacies, hos-  
15          pital pharmacies, clinics, charitable or not-for-profit  
16          pharmacies, government pharmacies, or pharmacy  
17          benefit managers.

18          “(11) WHOLESALER.—The term ‘wholesaler’  
19          means a drug wholesaler that is engaged in whole-  
20          sale distribution of prescription drugs to retail com-  
21          munity pharmacies, including (but not limited to)  
22          manufacturers, repackers, distributors, own-label  
23          distributors, private-label distributors, jobbers, bro-  
24          kers, warehouses (including manufacturer’s and dis-  
25          tributor’s warehouses, chain drug warehouses, and



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

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

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

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

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

19                   “(A) by a registered importer; or

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

22           “(4) DEFINITIONS.—

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

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

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

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

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

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

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

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

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

6           “(iv) is not—

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

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

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

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

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

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

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

25           “(IV) an injected drug;

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

15           “(vi) The term ‘wholesaler’—

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

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

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

25                   “(i) Australia;

1 “(ii) Canada;

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

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

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

18 “(iv) Japan;

19 “(v) New Zealand;

20 “(vi) Switzerland; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

9 “(I) In the case of an exporter:

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

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

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

23 “(II) \$1,000,000.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5               “(4) SUSPENSION AND TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23           “(A) directly from the establishment; or

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(II) samples of such drugs;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

16 “(e) IMPORTER FEES.—

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

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

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

3 “(3) AMOUNT OF INSPECTION FEE.—

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

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

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

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

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

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

15          “(C) TOTAL PRICE OF DRUGS.—

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

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

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

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

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

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

13 “(4) USE OF FEES.—

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

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

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

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

16 “(f) EXPORTER FEES.—

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

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

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

3 “(3) AMOUNT OF INSPECTION FEE.—

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

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

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

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

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

14          “(C) TOTAL PRICE OF DRUGS.—

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



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

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

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

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

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

12          “(4) USE OF FEES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(vi) REVIEW BY SECRETARY.—



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 “(I) the same; or

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

19 “(3) SECTION 502; LABELING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(B) IMPORTATION BY INDIVIDUAL.—

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13          “(F) The Secretary becomes aware that—

14               “(i) the drug may be counterfeit;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11       “(k) DRUG RECALLS.—

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

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

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

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

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

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



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

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

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

12          “(1) DRUG LABELING AND PACKAGING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(3) AFFIRMATIVE DEFENSE.—

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

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

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

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

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

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

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

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



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

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

12 “(4) EFFECT OF SUBSECTION.—

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

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

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

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

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

17           “(C) CHARITABLE CONTRIBUTIONS.—

18           Nothing in this subsection shall be construed  
19           to—

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

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

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

5           “(5) ENFORCEMENT.—

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

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

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

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

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

3 “(6) ACTIONS BY STATES.—

4 “(A) IN GENERAL.—

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

16 “(I) enjoin that practice;

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

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

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

4           “(ii) NOTICE.—

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

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

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

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

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

3                   “(B) INTERVENTION.—

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

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

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

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

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

23                         “(i) conduct investigations;

24                         “(ii) administer oaths or affirmations;

25                         or

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

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

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

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

21                  “(i) is an inhabitant; or

22                  “(ii) may be found.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

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

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

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

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

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

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

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

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

14 (d) EXHAUSTION.—

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

17 (A) by redesignating subsections (h) and

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

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

20 following:

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

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

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

8 (e) EFFECT OF SECTION 804.—

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

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

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

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

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

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

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

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

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

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

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

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

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

4           (3) LIMITS ON NUMBER OF IMPORTERS.—

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

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



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

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

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

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

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

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

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

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

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

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

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

6 (A) GUIDANCE ON SUBMISSION DATES.—

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

14 (B) CONSISTENT AND EFFICIENT USE OF

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

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

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

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

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

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

5 (9) USER FEES.—

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

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

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

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

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

11 (C) SECOND YEAR ADJUSTMENT.—

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

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

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

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

8 (II) 3.

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

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

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

4 (E) ANNUAL REPORT.—

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

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



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

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

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

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

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

1 Canada described under such subpara-  
2 graph; and

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

6 (f) IMPLEMENTATION OF SECTION 804.—

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

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

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

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

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

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

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

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

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

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

16 **SEC. 303. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**  
17 **SION INTO UNITED STATES.**

18 (a) IN GENERAL.—Chapter VIII of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),  
20 as amended by section 302, is further amended by adding  
21 at the end the following section:

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

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

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

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

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

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

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

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

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

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

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

3 “(d) CERTAIN PROCEDURES.—

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

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

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

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

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

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

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

10 **SEC. 304. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
11 **MENTS REGARDING PRIOR SALE, PURCHASE,**  
12 **OR TRADE.**

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

17 (1) in paragraph (1)—

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

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

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

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

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

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



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

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

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

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

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

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

25 (c) EFFECTIVE DATE.—

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

4           (2) DRUGS IMPORTED BY REGISTERED IMPORT-  
5 ERS UNDER SECTION 804.—Notwithstanding para-  
6 graph (1), the amendments made by paragraphs (1)  
7 and (3) of subsection (a) and by subsection (b) shall  
8 take effect on the date that is 90 days after the date  
9 of enactment of this Act with respect to qualifying  
10 drugs imported under section 804 of the Federal  
11 Food, Drug, and Cosmetic Act, as added by section  
12 303.

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

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

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

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

3 (6) ADDITIONAL REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

22 **SEC. 305. INTERNET SALES OF PRESCRIPTION DRUGS.**

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

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

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

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

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

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

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

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

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

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

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

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

6 “(i) The name of such person.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



1           fect provider agreements under such title;  
2           or

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

7           “(3) QUALIFYING MEDICAL RELATIONSHIP.—

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

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

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

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

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

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

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

15 “(4) RULES OF CONSTRUCTION.—

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

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

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

7           “(c) ACTIONS BY STATES.—

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

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

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

7 “(A) to intervene in such action;

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

10 “(C) to file petitions for appeal.

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

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

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

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

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

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

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

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

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

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

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

4           “(f) INTERNET-RELATED DEFINITIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

18 **SEC. 306. PROHIBITING PAYMENTS TO UNREGISTERED**  
19 **FOREIGN PHARMACIES.**

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

23 “(h) RESTRICTED TRANSACTIONS.—

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

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

3 “(2) PAYMENT SYSTEM.—

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

11 “(i) a credit card system;

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

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

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

24 “(i) a creditor;

25 “(ii) a credit card issuer;

1                   “(iii) a financial institution;

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

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

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

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

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

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

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

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

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

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

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

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

3 “(6) OTHER DEFINITIONS.—

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

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

9 “(B) ACCESS DEVICE; ELECTRONIC FUND

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

12 “(i) have the meaning given the term

13 in section 903 of the Electronic Fund  
14 Transfer Act (15 U.S.C. 1693a); and

15 “(ii) the term ‘electronic fund trans-

16 fer’ also includes any fund transfer covered  
17 under Article 4A of the Uniform Commer-  
18 cial Code, as in effect in any State.

19 “(C) FINANCIAL INSTITUTION.—The term

20 ‘financial institution’—

21 “(i) has the meaning given the term

22 in section 903 of the Electronic Transfer  
23 Fund Act (15 U.S.C. 1693a); and

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

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

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

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

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

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

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

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

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

7 “(iv) any other person described in  
8 paragraph (2)(B) and specified by the  
9 Board in such regulations,

10 to establish policies and procedures that are  
11 reasonably designed to prevent the introduction  
12 of a restricted transaction into a payment sys-  
13 tem or the completion of a restricted trans-  
14 action using a payment system.

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

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



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

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

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

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

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

7 “(D) ENFORCEMENT.—

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

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

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

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

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

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

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



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

4 **SEC. 308. SEVERABILITY.**

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

11 **TITLE IV—ADDITIONAL PRE-**  
 12 **SCRIPTION DRUGS PROVI-**  
 13 **SIONS**

14 **SEC. 401. DISALLOWANCE OF DEDUCTION FOR ADVER-**  
 15 **TISING AND PROMOTIONAL EXPENSES FOR**  
 16 **PRESCRIPTION PHARMACEUTICALS.**

17 (a) IN GENERAL.—Part IX of subchapter B of chap-  
 18 ter 1 of the Internal Revenue Code of 1986 (relating to  
 19 items not deductible) is amended by adding at the end  
 20 the following new section:

21 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR PRESCRIP-**  
 22 **TION PHARMACEUTICALS ADVERTISING AND**  
 23 **PROMOTIONAL EXPENSES.**

24 “(a) IN GENERAL.—No deduction shall be allowed  
 25 under this chapter for expenses relating to advertising or

1 promoting the sale and use of prescription pharma-  
2 ceuticals for any taxable year.

3 “(b) ADVERTISING OR PROMOTING.—For purposes of  
4 this section, the term ‘advertising or promoting’ includes  
5 direct to consumer advertising in any media and any activ-  
6 ity designed to promote the use of a prescription pharma-  
7 ceutical directed to providers or others who may make de-  
8 cisions about the use of prescription pharmaceuticals (in-  
9 cluding the provision of product samples, free trials, and  
10 starter kits).”.

11 (b) CONFORMING AMENDMENT.—The table of sec-  
12 tions for such part IX is amended by adding after the  
13 item relating to section 280H the following new item:

“Sec. 280I. Disallowance of deduction for prescription pharmaceuticals adver-  
tising and promotional expenses.”.

14 (c) EFFECTIVE DATE.—The amendments made by  
15 this section shall apply to amounts paid or incurred after  
16 the date of the enactment of this Act, in taxable years  
17 ending after such date.

18 **SEC. 402. INTEGRITY FOR PHARMACY BENEFIT MANAGERS.**

19 (a) STANDARDS.—A pharmacy benefit manager with  
20 a contract with a health benefits plan (as such term is  
21 defined in section 101) shall, with respect to such plan,  
22 comply with fiduciary standards established, by regulation,  
23 by the Secretary of Health and Human Services, that are  
24 consistent with the provisions of this section.

1 (b) DISCLOSURE.—Under such standards, a phar-  
2 macy benefit manager shall, upon request by the health  
3 benefits plan—

4 (1) provide all available financial information to  
5 such plan regarding its enrollees; and

6 (2) disclose to the sponsor of such plan all the  
7 rebates and other discounts that the pharmacy ben-  
8 efit manager receives from drug manufacturers, with  
9 respect to drugs dispensed to enrollees of such plan.

10 (c) NON-DISCLOSURE.—A pharmacy benefit manager  
11 that is owned by, owns, or is otherwise affiliated with a  
12 retail pharmacy may not share with such affiliated retail  
13 pharmacy data on plan enrollees or other individuals that  
14 is obtained from claims submitted by other pharmacies.

15 (d) NOTICE OF DRUG INTERCHANGES.—

16 (1) IN GENERAL.—Under the standards under  
17 subsection (a), pharmacy benefit manager shall pro-  
18 vide notice to a plan enrollee if the pharmacy benefit  
19 manager is switching the enrollee from a lower cost  
20 drug to a higher cost drug.

21 (2) CONTENTS.—Such notice shall contain—

22 (A) an explanation of the reason for the  
23 switch;

24 (B) the difference in cost between the 2  
25 drugs; and

1                   (C) whether a lower cost generic is avail-  
2                   able.

3           (e) ADDITIONAL DISCLOSURES.—Under the stand-  
4           ards under subsection (a), a pharmacy benefit manager  
5           shall disclose to the health benefits plan the actual reim-  
6           bursement amount that is paid to the pharmacy for a pre-  
7           scription or service by the pharmacy benefit manager that  
8           is covered under such plan.

9           (f) EQUAL REIMBURSEMENTS FOR MAIL ORDER AND  
10          RETAIL.—Under the standards under subsection (a), a  
11          pharmacy benefit manager shall reimburse mail order and  
12          retail pharmacies at the same rates—

13                   (1) for identical prescription drugs; and

14                   (2) for identical services.

15          (g) ELIMINATION OF SPREAD PRICING.—Under the  
16          standards under subsection (a), with respect to a prescrip-  
17          tion drug that is covered by a health benefits plan and  
18          dispensed to a plan participant or beneficiary, a pharmacy  
19          benefit manager may not pay such pharmacy an amount  
20          that is less than the amount that is paid to the pharmacy  
21          benefit manager by such plan for such drug and any re-  
22          lated dispensing fee.

23          (h) EQUAL COPAYS.—Under the standards under  
24          subsection (a), a pharmacy benefit manager may not re-  
25          quire that a participant or beneficiary of a health benefits



1 plan pay a different co-payment amount for a drug dis-  
2 pensed at a retail pharmacy, compared to the co-payment  
3 amount that would be charged to such participant or bene-  
4 ficiary for the same amount of that drug at a mail order  
5 pharmacy.

6 (i) COMPUTATION OF CO-PAYMENT AMOUNTS.—

7 Under the standards under subsection (a), a pharmacy  
8 benefit manager shall determine the co-payment amount  
9 charged a participant or beneficiary of a health benefits  
10 plan for a drug covered by the plan based on the amount  
11 that the plan or pharmacy benefit manager reimburses the  
12 pharmacy for such drug (including any applicable dis-  
13 pensing fee). Such co-payment amount may not be deter-  
14 mined based on the amount that the plan pays to the  
15 pharmacy benefit manager for such drug.

16 (j) ENFORCEMENT.—In the regulations issued under

17 subsection (a), the Secretary shall specify the sanctions  
18 which shall apply to health benefits plans and issuers of  
19 health insurance coverage under such plans that contract  
20 with pharmacy benefit managers that fail to comply with  
21 the standards under subsection (a). Such sanctions shall  
22 include the following:

23 (1) RESTRICTION ON FEDERAL CON-

24 TRACTING.—The health benefits plan issuer shall

25 not be eligible to contract with a Federal program,

1 including Medicare under title XVIII of the Social  
2 Security Act and the Federal Employees Health  
3 Benefits Plan under chapter 89 of title 5, United  
4 States Code.

5 (2) CIVIL MONETARY PENALTIES.—A health  
6 benefits plan or an issuer of such plan may be sub-  
7 ject to a civil monetary penalty not to exceed  
8 \$1,000.00 for each day that the pharmacy benefit  
9 manager is in an contract with the health benefits  
10 plan or issuer and such pharmacy benefit manager  
11 fails to comply with the standards under subsection  
12 (a).

13 (k) PHARMACY BENEFIT MANAGER DEFINED.—The  
14 term “pharmacy benefit manager” means any entity that  
15 provides pharmacy benefit management services on behalf  
16 of a health benefits plan.

17 (l) EFFECTIVE DATE.—This section shall take effect  
18 on January 1, 2011.

19 **SEC. 403. PRICE INFORMATION UNDER MEDICAID.**

20 (a) DISCLOSURE OF INFORMATION TO THE SEC-  
21 RETARY.—Section 1927(b)(3) of such Act (42 U.S.C.  
22 1396r–8(b)(3)) is amended—

23 (1) in subparagraph (A)—

24 (A) in the first sentence, by inserting after  
25 clause (iii) the following clause:

1           “(iv) not later than 30 days after the  
2           last day of each month of a rebate period  
3           under the agreement, on the manufactur-  
4           er’s total number of units that are used to  
5           calculate the monthly average manufac-  
6           turer price for each covered outpatient  
7           drug;” and

8           (B) in the second sentence, by inserting  
9           “(relating to the weighted average of the most  
10          recently reported monthly average manufacturer  
11          prices)” after “(D)(v)”; and

12          (2) in subparagraph (D)(v), by striking “aver-  
13          age manufacturer prices” and inserting “the weight-  
14          ed average of the most recently reported monthly av-  
15          erage manufacturer prices and the average retail  
16          survey price determined for each multiple source  
17          drug in accordance with subsection (f)”.

18          (b) CLARIFICATION OF APPLICATION OF SURVEY OF  
19          RETAIL PRICES.—Section 1927(f)(1) of such Act (4222  
20          U.S.C. 1396r–8(b)(1)) is amended—

21                 (1) in subparagraph (A)(i), by inserting “with  
22                 respect to a retail community pharmacy,” before  
23                 “the determination”; and

1           (2) in subparagraph (C)(ii), by striking “retail  
2           pharmacies” and inserting “retail community phar-  
3           macies”.

4           (c) EFFECTIVE DATE.—The amendments made by  
5 this section shall take effect on the first day of the first  
6 calendar year quarter that begins at least 180 days after  
7 the date of enactment of this Act, without regard to  
8 whether or not final regulations to carry out such amend-  
9 ments have been promulgated by such date.

○