

110TH CONGRESS
2^D SESSION

H. R. 6800

To amend title XVIII of the Social Security Act to replace the Medicare prescription drug benefit adopted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 with a revised and simplified prescription benefit program for all Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 1, 2008

Mr. KUCINICH (for himself, Mr. DEFAZIO, Ms. LEE, Mr. CONYERS, Mr. DAVIS of Illinois, Mr. ABERCROMBIE, Mr. JEFFERSON, Ms. WOOLSEY, Mr. FILNER, Mr. HINCHEY, Mr. JACKSON of Illinois, Mr. ELLISON, Ms. KAPTUR, Mr. GRIJALVA, Ms. HIRONO, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. CUMMINGS, Ms. JACKSON-LEE of Texas, Mr. NADLER, and Mr. CARSON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

A BILL

To amend title XVIII of the Social Security Act to replace the Medicare prescription drug benefit adopted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 with a revised and simplified prescription benefit program for all Medicare beneficiaries.

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

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Medicare Drugs for Seniors (MEDS) Act of 2008”.

4 (b) TABLE OF CONTENTS.—The table of contents for
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Repeal and transition.
- Sec. 4. Prescription medicine benefit program.

“PART D—PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND
DISABLED

- “Sec. 1860D–1. Establishment of prescription medicine benefit program for the aged and disabled.
- “Sec. 1860D–2. Scope of benefits.
- “Sec. 1860D–3. Payment of benefits.
- “Sec. 1860D–4. Eligibility and enrollment.
- “Sec. 1860D–5. No premium.
- “Sec. 1860D–6. Prescription Medicine Insurance Account.
- “Sec. 1860D–7. Administration of benefits.
- “Sec. 1860D–8. Promotion of pharmaceutical research on break-through medicines while providing program cost containment.
- “Sec. 1860D–9. Appropriations to cover Government contributions.
- “Sec. 1860D–10. Prescription medicine defined.
- Sec. 5. Substantial reductions in the price of prescription drugs for medicare beneficiaries.
- Sec. 6. Importation of certain prescription drugs.
- Sec. 7. Reasonable price agreement for federally funded research.
- Sec. 8. GAO ongoing studies and reports on program; miscellaneous reports.
- Sec. 9. Medigap transition provisions.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) The amendments made by title I of the
9 Medicare Prescription Drug, Improvement, and
10 Modernization Act of 2003 (Public Law 108–173)
11 do not ensure the long-term financial viability of the
12 Medicare prescription drug benefit enacted by such
13 title through cost-containment measures, and con-

1 tains a provision that explicitly prohibits Medicare
2 from negotiating for lower prescription drug prices,
3 which is a practice of the Department of Veterans
4 Affairs (VA).

5 (2) Medicare Part D pays on average 30 per-
6 cent more for drugs than does its federally adminis-
7 tered counterpart in Medicaid. That amounted to a
8 windfall worth over \$3.7 billion for drug manufac-
9 turers in the first two years of the Medicare Part D
10 program.

11 (3) Since the inception of privatized Part D, av-
12 erage premiums have increased from \$25.93 in 2006
13 to \$27.39 in 2007. In 2008 the average premium
14 could increase by 17 percent to \$31.99 if enrollees
15 stay in their current plan, which is the norm.

16 (4) Only 8 percent of enrollees are in a Part D
17 plan that provides any coverage in the “doughnut
18 hole,” a period in which there is no coverage of drug
19 costs, which exemplifies the ways in which insurance
20 plans cause significant financial vulnerability for en-
21 rollees by providing partial coverage for prescription
22 drugs.

23 (5) All Medicare beneficiaries should have ac-
24 cess to a voluntary, reliable, affordable, and defined
25 outpatient medicine benefit that is part of the Medi-

1 care program and that assists with the high cost of
2 prescription medicines and protects such bene-
3 ficiaries from excessive out-of-pocket costs.

4 (6) Americans unjustly pay up to 5 times more
5 to fill their prescriptions than consumers in other
6 countries.

7 (7) The United States is the largest market for
8 pharmaceuticals in the world, yet American con-
9 sumers pay the highest prices for brand pharma-
10 ceuticals in the world.

11 (8) A prescription drug is neither safe nor ef-
12 fective to an individual who cannot afford it.

13 (9) Allowing and structuring the importation of
14 prescription drugs to ensure access to safe and af-
15 fordable drugs approved by the Food and Drug Ad-
16 ministration will provide a level of safety to Amer-
17 ican consumers that they do not currently enjoy.

18 (10) Allowing open pharmaceutical markets
19 could save American consumers well over
20 \$38,000,000,000 each year

21 **SEC. 3. REPEAL AND TRANSITION.**

22 (a) REPEAL OF MEDICARE PART D BENEFIT AND
23 TRANSITION TO NEW MEDICARE PRESCRIPTION MEDI-
24 CINE BENEFIT PROGRAM.—The amendments made by
25 title I of the Medicare Prescription Drug, Improvement,

1 and Modernization Act of 2003 (Public Law 108–173) are
2 repealed as of December 31, 2009, and the provisions of
3 law amended by such title shall read as if such title had
4 not been enacted.

5 (b) TRANSITION.—The Secretary of Health and
6 Human Services shall provide for an appropriate transi-
7 tion from administering the Social Security Act in accord-
8 ance with the amendments made by title I of the Medicare
9 Prescription Drug, Improvement, and Modernization Act
10 of 2003 (Public Law 108–173) to administering such Act
11 in accordance with the amendments made by section 4 of
12 this Act.

13 **SEC. 4. PRESCRIPTION MEDICINE BENEFIT PROGRAM.**

14 (a) IN GENERAL.—Title XVIII of the Social Security
15 Act (42 U.S.C. 1395 et seq.), as in effect before the inser-
16 tion of part D under title I of the Medicare Prescription
17 Drug, Improvement, and Modernization Act of 2003, is
18 amended—

19 (1) by redesignating part D as part E; and

20 (2) by inserting after part C the following new
21 part:

1 “PART D—PRESCRIPTION MEDICINE BENEFIT FOR THE
2 AGED AND DISABLED

3 “ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT
4 PROGRAM FOR THE AGED AND DISABLED

5 “SEC. 1860D–1. There is established a voluntary in-
6 surance program to provide prescription medicine benefits,
7 including pharmacy services, in accordance with the provi-
8 sions of this part for individuals who are aged or disabled
9 or have end-stage renal disease and who elect to enroll
10 under such program, to be financed from premium pay-
11 ments by enrollees together with contributions from funds
12 appropriated by the Federal Government.

13 “SCOPE OF BENEFITS

14 “SEC. 1860D–2. (a) IN GENERAL.—The benefits
15 provided to an individual enrolled in the insurance pro-
16 gram under this part shall consist of—

17 “(1) payments made, in accordance with the
18 provisions of this part, for covered prescription
19 medicines (as specified in subsection (b)) dispensed
20 by any pharmacy participating in the program under
21 this part (and, in circumstances designated by the
22 Secretary, by a nonparticipating pharmacy), includ-
23 ing any specifically named medicine prescribed for
24 the individual by a qualified health care professional
25 regardless of whether the medicine is included in any
26 formulary established under this part if such medi-

1 cine is certified as medically necessary by such
2 health care professional (except that the Secretary
3 shall encourage to the maximum extent possible the
4 substitution and use of lower-cost generics), up to
5 the benefit limits specified in section 1860D–3; and

6 “(2) charging by pharmacies of the negotiated
7 price—

8 “(A) for all covered prescription medicines,
9 without regard to such benefit limit; and

10 “(B) established with respect to any drugs
11 or classes of drugs described in subparagraphs
12 (A), (B), (D), (E), or (F) of section 1927(d)(2)
13 that are available to individuals receiving bene-
14 fits under this title.

15 “(b) COVERED PRESCRIPTION MEDICINES.—

16 “(1) IN GENERAL.—Covered prescription medi-
17 cines, for purposes of this part, include all prescrip-
18 tion medicines (as defined in section 1860D–10(1)),
19 including smoking cessation agents, except as other-
20 wise provided in this subsection.

21 “(2) EXCLUSIONS FROM COVERAGE.—Covered
22 prescription medicines shall not include drugs or
23 classes of drugs described in subparagraphs (A)
24 through (D) and (F) through (H) of section
25 1927(d)(2) unless—

1 “(A) specifically provided otherwise by the
2 Secretary with respect to a drug in any of such
3 classes; or

4 “(B) a drug in any of such classes is cer-
5 tified to be medically necessary by a health care
6 professional.

7 “(3) EXCLUSION OF PRESCRIPTION MEDICINES
8 TO THE EXTENT COVERED UNDER PART A OR B.—
9 A medicine prescribed for an individual that would
10 otherwise be a covered prescription medicine under
11 this part shall not be so considered to the extent
12 that payment for such medicine is available under
13 part A or B, including all injectable drugs and
14 biologicals for which payment was made or should
15 have been made by a carrier under section
16 1861(s)(2) (A) or (B) as of the date of enactment
17 of the Medicare Drugs for Seniors (MEDS) Act of
18 2008. Medicines otherwise covered under part A or
19 B shall be covered under this part to the extent that
20 benefits under part A or B are exhausted.

21 “(4) STUDY ON INCLUSION OF HOME INFUSION
22 THERAPY SERVICES.—Not later than one year after
23 the date of the enactment of the Medicare Drugs for
24 Seniors (MEDS) Act of 2008, the Secretary shall
25 submit to Congress a legislative proposal for the de-

1 livery of home infusion therapy services under this
2 title and for a system of payment for such a benefit
3 that coordinates items and services furnished under
4 part B and under this part.

5 “PAYMENT OF BENEFITS

6 “SEC. 1860D–3.

7 “There shall be paid from the Prescription Medicine
8 Insurance Account within the Supplementary Medical In-
9 surance Trust Fund, in the case of each individual who
10 is enrolled in the insurance program under this part and
11 who purchases covered prescription medicines in a cal-
12 endar year, 100 percent of the negotiated price for each
13 such covered prescription medicine.

14 “ELIGIBILITY AND ENROLLMENT

15 “SEC. 1860D–4. (a) ELIGIBILITY.—Every individual
16 who, during or after 2009, is entitled to hospital insurance
17 benefits under part A or enrolled in the medical insurance
18 program under part B, whether or not the individual is
19 enrolled in a Medicare Advantage plan under part C, is
20 eligible to enroll, in accordance with the provisions of this
21 section, in the insurance program under this part, during
22 an enrollment period under this section, in such manner
23 and form specified by the Secretary in regulations.

24 “(b) ENROLLMENT.—

25 “(1) IN GENERAL.—Each individual who satis-
26 fies subsection (a) shall be enrolled (or eligible to en-

1 roll) in the program under this part in accordance
2 with the provisions of section 1837, as if that section
3 applied to this part, except as otherwise explicitly
4 provided in this part.

5 “(2) SINGLE ENROLLMENT PERIOD.—Except as
6 provided in section 1837(i) (as such section applies
7 to this part) or 1860D–8(e), or as otherwise explic-
8 itly provided, no individual shall be entitled to enroll
9 in the program under this part at any time after the
10 initial enrollment period without penalty, and in the
11 case of all other late enrollments, the Secretary shall
12 develop a late enrollment penalty for the individual
13 that fully recovers the additional actuarial risk in-
14 volved providing coverage for the individual.

15 “(3) SPECIAL ENROLLMENT PERIOD FOR
16 2009.—

17 “(A) IN GENERAL.—An individual who
18 first satisfies subsection (a) in 2009 may on or
19 after the date on which they first become eligi-
20 ble and at any time on or before December 31,
21 2009—

22 “(i) enroll in the program under this
23 part; and

1 “(ii) enroll or reenroll in such pro-
2 gram after having previously declined or
3 terminated enrollment in such program.

4 “(B) EFFECTIVE DATE OF COVERAGE.—

5 An individual who enrolls under the program
6 under this part pursuant to subparagraph (A)
7 shall be entitled to benefits under this part be-
8 ginning on the first day of the month following
9 the month in which such enrollment occurs, but
10 in no case earlier than January 1, 2010.

11 “(c) PERIOD OF COVERAGE.—

12 “(1) IN GENERAL.—Except as otherwise pro-
13 vided in this part, an individual’s coverage under the
14 program under this part shall be effective for the pe-
15 riod provided in section 1838, as if that section ap-
16 plied to the program under this part.

17 “(2) PART D COVERAGE TERMINATED BY TER-
18 MINATION OF COVERAGE UNDER PARTS A AND B.—

19 In addition to the causes of termination specified in
20 section 1838, an individual’s coverage under this
21 part shall be terminated if the individual retains cov-
22 erage under neither the program under part A nor
23 the program under part B, effective on the effective
24 date of termination of coverage under part A or (if
25 later) under part B.

1 “NO PREMIUM

2 “SEC. 1860D–5. There is no premium for enrollment
3 under this part.

4 “PRESCRIPTION MEDICINE INSURANCE ACCOUNT

5 “SEC. 1860D–6. (a) ESTABLISHMENT.—There is
6 created within the Federal Supplemental Medical Insur-
7 ance Trust Fund established by section 1841 an account
8 to be known as the ‘Prescription Medicine Insurance Ac-
9 count’ (in this section referred to as the ‘Account’).

10 “(b) AMOUNTS IN ACCOUNT.—

11 “(1) IN GENERAL.—The Account shall consist
12 of—

13 “(A) such amounts as may be deposited in,
14 or appropriated to, such fund as provided in
15 this part; and

16 “(B) such gifts and bequests as may be
17 made as provided in section 201(i)(1).

18 “(2) SEPARATION OF FUNDS.—Funds provided
19 under this part to the Account shall be kept sepa-
20 rate from all other funds within the Federal Supple-
21 mental Medical Insurance Trust Fund.

22 “(c) PAYMENTS FROM ACCOUNT.—The Managing
23 Trustee shall pay from time to time from the Account such
24 amounts as the Secretary certifies are necessary to make
25 the payments provided for by this part, and the payments

1 with respect to administrative expenses in accordance with
2 section 201(g).

3 “ADMINISTRATION OF BENEFITS

4 “SEC. 1860D-7. (a) THROUGH CMS.—The Sec-
5 retary shall provide for administration of the benefits
6 under this part through the Centers for Medicare & Med-
7 icaid Services in accordance with the provisions of this sec-
8 tion. The Administrator of such Centers may enter into
9 contracts with carriers to administer this part in the same
10 manner as the Administrator enters into such contracts
11 to administer part B. Any such contract shall be separate
12 from any contract under section 1842.

13 “(b) ADMINISTRATION FUNCTIONS.—In carrying out
14 this part, the Administrator (or a carrier under a contract
15 with the Administrator) shall (or in the case of the func-
16 tion described in paragraph (9), may) perform the fol-
17 lowing functions:

18 “(1) PARTICIPATION AGREEMENTS, PRICES,
19 AND FEES.—

20 “(A) NEGOTIATED PRICES.—Establish,
21 through negotiations with medicine manufactur-
22 ers and wholesalers and pharmacies, a schedule
23 of prices for covered prescription medicines.

24 “(B) AGREEMENTS WITH PHARMACIES.—
25 Enter into participation agreements under sub-

1 section (c) with pharmacies, that include terms
2 that—

3 “(i) secure the participation of suffi-
4 cient numbers of pharmacies to ensure
5 convenient access (including adequate
6 emergency access);

7 “(ii) permit the participation of any
8 pharmacy in the service area that meets
9 the participation requirements described in
10 subsection (c); and

11 “(iii) allow for reasonable dispensing
12 and consultation fees for pharmacies.

13 “(C) LISTS OF PRICES AND PARTICIPATING
14 PHARMACIES.—Ensure that the negotiated
15 prices established under subparagraph (A) and
16 the list of pharmacies with agreements under
17 subsection (c) are regularly updated and readily
18 available to health care professionals authorized
19 to prescribe medicines, participating phar-
20 macies, and enrolled individuals.

21 “(2) TRACKING OF COVERED ENROLLED INDI-
22 VIDUALS.—Maintain accurate, updated records of all
23 enrolled individuals (other than individuals enrolled
24 in a plan under part C).

1 “(3) PAYMENT AND COORDINATION OF BENE-
2 FITS.—

3 “(A) PAYMENT.—

4 “(i) Administer claims for payment of
5 benefits under this part and encourage, to
6 the maximum extent possible, use of elec-
7 tronic means for the submissions of claims.

8 “(ii) Determine amounts of benefit
9 payments to be made.

10 “(iii) Receive, disburse, and account
11 for funds used in making such payments,
12 including through the activities specified in
13 the provisions of this paragraph.

14 “(B) COORDINATION.—Coordinate with
15 other private benefit providers, pharmacies, and
16 other relevant entities as necessary to ensure
17 appropriate coordination of benefits with re-
18 spect to enrolled individuals, including coordina-
19 tion of access to and payment for covered pre-
20 scription medicines according to an individual’s
21 in-service area plan provisions, when such indi-
22 vidual is traveling outside the home service
23 area, and under such other circumstances as
24 the Secretary may specify.

1 “(C) EXPLANATION OF BENEFITS.—Fur-
2 nish to enrolled individuals an explanation of
3 benefits in accordance with section 1806(a),
4 and a notice of the balance of benefits remain-
5 ing for the current year, whenever prescription
6 medicine benefits are provided under this part
7 (except that such notice need not be provided
8 more often than monthly).

9 “(4) RULES RELATING TO PROVISION OF BENE-
10 FITS.—

11 “(A) IN GENERAL.—In providing benefits
12 under this part, the Secretary (directly or
13 through contracts) shall employ mechanisms to
14 provide benefits economically, including the use
15 of—

16 “(i) formularies (consistent with sub-
17 paragraph (B));

18 “(ii) automatic generic medicine sub-
19 stitution (unless the physician specifies
20 otherwise, in which case a 30-day prescrip-
21 tion may be dispensed pending a consulta-
22 tion with the physician on whether a ge-
23 neric substitute can be dispensed in the fu-
24 ture); and

25 “(iii) therapeutic interchange.

1 “(B) REQUIREMENTS WITH RESPECT TO
2 FORMULARIES.—If a formulary is used to con-
3 tain costs under this part—

4 “(i) use an advisory committee (or a
5 therapeutics committee) comprised of li-
6 censed practicing physicians, pharmacists,
7 and other health care practitioners to de-
8 velop and manage the formulary;

9 “(ii) include in the formulary at least
10 one medicine from each therapeutic class
11 and, if available, a generic equivalent
12 thereof; and

13 “(iii) disclose to current and prospec-
14 tive enrollees and to participating providers
15 and pharmacies, the nature of the for-
16 mulary restrictions, including information
17 regarding the medicines included in the
18 formulary.

19 “(C) CONSTRUCTION.—Nothing in this
20 subsection shall be construed to prevent the
21 Secretary (directly or through contracts) from
22 using incentives to encourage enrollees to select
23 generic or other cost-effective medicines, so long
24 as—

1 “(i) such incentives are designed not
2 to result in any increase in the aggregate
3 expenditures under the Federal Medicare
4 Prescription Medicine Trust Fund; and

5 “(ii) the reimbursement for a pre-
6 scribed nonformulary medicine without a
7 restrictive prescription in no case shall be
8 more than the lowest reimbursement for a
9 formulary medicine in the therapeutic class
10 of the prescribed medicine.

11 “(D) RESTRICTIVE PRESCRIPTION.—For
12 purposes of this section:

13 “(i) WRITTEN PRESCRIPTIONS.—In
14 the case of a written prescription for a
15 medicine, it is a restrictive prescription
16 only if the prescription indicates, in the
17 writing of the physician or other qualified
18 person prescribing the medicine and with
19 an appropriate phrase (such as ‘brand
20 medically necessary’) recognized by the
21 Secretary, that a particular medicine prod-
22 uct must be dispensed based upon a belief
23 by the physician or person prescribing the
24 medicine that the particular medicine will
25 provide even marginally superior thera-

1 peutic benefits to the individual for whom
2 the medicine is prescribed or would have
3 marginally fewer adverse reactions with re-
4 spect to such individual.

5 “(ii) TELEPHONE PRESCRIPTIONS.—

6 In the case of a prescription issued by tele-
7 phone for a medicine, it is a restrictive
8 prescription only if the prescription cannot
9 be longer than 30 days and the physician
10 or other qualified person prescribing the
11 medicine (through use of such an appro-
12 priate phrase) states that a particular
13 medicine product must be dispensed, and
14 the physician or other qualified person sub-
15 mits to the pharmacy involved, within 30
16 days after the date of the telephone pre-
17 scription, a written confirmation from the
18 physician or other qualified person pre-
19 scribing the medicine and which indicates
20 with such appropriate phrase that the par-
21 ticular medicine product was required to
22 have been dispensed based upon a belief by
23 the physician or person prescribing the
24 medicine that the particular medicine will
25 provide even marginally superior thera-

1 peutic benefits to the individual for whom
2 the medicine is prescribed or would have
3 marginally fewer adverse reactions with re-
4 spect to such individual. Such written con-
5 firmation is required to refill the prescrip-
6 tion.

7 “(iii) REVIEW OF RESTRICTIVE PRE-
8 SCRIPTIONS.—The advisory committee (es-
9 tablished under subparagraph (B)(i)) may
10 decide to review a restrictive prescription
11 and, if so, it may approve or disapprove
12 such restrictive prescription. It may not
13 disapprove such restrictive prescription un-
14 less it finds that there is no literature ap-
15 proved by the Food and Drug Administra-
16 tion that supports a determination that the
17 particular medicine provides even margin-
18 ally superior therapeutic benefits to the in-
19 dividual for whom the medicine is pre-
20 scribed or would have marginally fewer ad-
21 verse reactions with respect to such indi-
22 vidual. If it disapproves, upon request of
23 the prescribing physician or the enrollee,
24 the committee must provide for a review by
25 an independent contractor of such decision

1 within 48 hours of the time of submission
2 of the prescription, to determine whether
3 the prescription is an eligible benefit under
4 this part. The Secretary shall ensure that
5 independent contractors so used are com-
6 pletely independent of the contractor or its
7 advisory committee.

8 “(5) COST AND UTILIZATION MANAGEMENT;
9 QUALITY ASSURANCE.—Have in place effective cost
10 and utilization management, drug utilization review,
11 quality assurance measures, and systems to reduce
12 medical errors, including at least the following, to-
13 gether with such additional measures as the Admin-
14 istrator may specify:

15 “(A) DRUG UTILIZATION REVIEW.—A drug
16 utilization review program conforming to the
17 standards provided in section 1927(g)(2) (with
18 such modifications as the Administrator finds
19 appropriate).

20 “(B) FRAUD AND ABUSE CONTROL.—Ac-
21 tivities to control fraud, abuse, and waste, in-
22 cluding prevention of diversion of pharma-
23 ceuticals to the illegal market.

24 “(C) MEDICATION THERAPY MANAGE-
25 MENT.—

1 “(i) IN GENERAL.—A program of
2 medicine therapy management and medica-
3 tion administration that is designed to as-
4 sure that covered outpatient medicines are
5 appropriately used to achieve therapeutic
6 goals and reduce the risk of adverse
7 events, including adverse drug interactions.

8 “(ii) ELEMENTS.—Such program may
9 include—

10 “(I) enhanced beneficiary under-
11 standing of such appropriate use
12 through beneficiary education, coun-
13 seling, and other appropriate means;
14 and

15 “(II) increased beneficiary adher-
16 ence with prescription medication
17 regimens through medication refill re-
18 minders, special packaging, and other
19 appropriate means.

20 “(iii) DEVELOPMENT OF PROGRAM IN
21 COOPERATION WITH LICENSED PHAR-
22 MACISTS.—The program shall be developed
23 in cooperation with licensed pharmacists
24 and physicians.

1 “(iv) CONSIDERATIONS IN PHARMACY
2 FEES.—There shall be taken into account,
3 in establishing fees for pharmacists and
4 others providing services under the medica-
5 tion therapy management program, the re-
6 sources and time used in implementing the
7 program.

8 “(6) EDUCATION AND INFORMATION ACTIVI-
9 TIES.—Have in place mechanisms for disseminating
10 educational and informational materials to enrolled
11 individuals and health care providers designed to en-
12 courage effective and cost-effective use of prescrip-
13 tion medicine benefits and to ensure that enrolled in-
14 dividuals understand their rights and obligations
15 under the program.

16 “(7) BENEFICIARY PROTECTIONS.—

17 “(A) CONFIDENTIALITY OF HEALTH IN-
18 FORMATION.—Have in effect systems to safe-
19 guard the confidentiality of health care infor-
20 mation on enrolled individuals, which comply
21 with section 1106 and with section 552a of title
22 5, United States Code, and meet such addi-
23 tional standards as the Administrator may pre-
24 scribe.

1 “(B) GRIEVANCE AND APPEAL PROCE-
2 DURES.—Have in place such procedures as the
3 Administrator may specify for hearing and re-
4 solving grievances and appeals, including expe-
5 dited appeals, brought by enrolled individuals
6 against the Administrator or a pharmacy con-
7 cerning benefits under this part, which shall in-
8 clude procedures equivalent to those specified in
9 subsections (f) and (g) of section 1852.

10 “(8) RECORDS, REPORTS, AND AUDITS.—

11 “(A) RECORDS AND AUDITS.—Maintain
12 adequate records, and afford the Administrator
13 access to such records (including for audit pur-
14 poses).

15 “(B) REPORTS.—Make such reports and
16 submissions of financial and utilization data as
17 the Administrator may require taking into ac-
18 count standard commercial practices.

19 “(9) PROPOSAL FOR ALTERNATIVE COINSUR-
20 ANCE AMOUNT.—

21 “(A) SUBMISSION.—The Administrator
22 may provide for increased Government cost-
23 sharing for generic prescription medicines, pre-
24 scription medicines on a formulary, or prescrip-

1 tion medicines obtained through mail order
2 pharmacies.

3 “(B) CONTENTS.—The proposal submitted
4 under subparagraph (A) shall contain evidence
5 that such increased cost-sharing would not re-
6 sult in an increase in aggregate costs to the Ac-
7 count, including an analysis of differences in
8 projected drug utilization patterns by bene-
9 ficiaries whose cost-sharing would be reduced
10 under the proposal and those making the cost-
11 sharing payments that would otherwise apply.

12 “(10) OTHER REQUIREMENTS.—Meet such
13 other requirements as the Secretary may specify.

14 The Administrator shall negotiate a schedule of prices
15 under paragraph (1)(A), except that nothing in this sen-
16 tence shall prevent a carrier under a contract with the Ad-
17 ministrators from negotiating a lower schedule of prices for
18 covered prescription medicines.

19 “(c) PHARMACY PARTICIPATION AGREEMENTS.—

20 “(1) IN GENERAL.—A pharmacy that meets the
21 requirements of this subsection shall be eligible to
22 enter an agreement with the Administrator to fur-
23 nish covered prescription medicines and pharmacists’
24 services to enrolled individuals.

1 “(2) TERMS OF AGREEMENT.—An agreement
2 under this subsection shall include the following
3 terms and requirements:

4 “(A) LICENSING.—The pharmacy and
5 pharmacists shall meet (and throughout the
6 contract period will continue to meet) all appli-
7 cable State and local licensing requirements.

8 “(B) LIMITATION ON CHARGES.—Phar-
9 macies participating under this part shall not
10 charge an enrolled individual more than the ne-
11 gotiated price for an individual medicine as es-
12 tablished under subsection (b)(1), regardless of
13 whether such individual has attained the benefit
14 limit under section 1860D–3(b), and shall not
15 charge an enrolled individual more than the in-
16 dividual’s share of the negotiated price as deter-
17 mined under the provisions of this part.

18 “(C) PERFORMANCE STANDARDS.—The
19 pharmacy and the pharmacist shall comply with
20 performance standards relating to—

21 “(i) measures for quality assurance,
22 reduction of medical errors, and participa-
23 tion in the drug utilization review program
24 described in subsection (b)(3)(A);

1 “(ii) systems to ensure compliance
2 with the confidentiality standards applica-
3 ble under subsection (b)(5)(A); and

4 “(iii) other requirements as the Sec-
5 retary may impose to ensure integrity, effi-
6 ciency, and the quality of the program.

7 “(D) DISCLOSURE OF PRICE OF GENERIC
8 MEDICINE.—A pharmacy participating under
9 this part shall inform an enrollee of the dif-
10 ference in price between generic and non-ge-
11 neric equivalents.

12 “(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-
13 SERVE AREAS.—

14 “(1) IN GENERAL.—The Secretary shall ensure
15 that all beneficiaries have access to the full range of
16 pharmaceuticals under this part, and shall give spe-
17 cial attention to access, pharmacist counseling, and
18 delivery in rural and hard-to-serve areas (as the Sec-
19 retary may define by regulation).

20 “(2) SPECIAL ATTENTION DEFINED.—For pur-
21 poses of paragraph (1), the term ‘special attention’
22 may include bonus payments to retail pharmacists in
23 rural areas and any other actions the Secretary de-
24 termines are necessary to ensure full access to rural
25 and hard-to-serve beneficiaries.

1 “(3) GAO REPORT.—Not later than two years
2 after the implementation of this part the Comp-
3 troller General of the United States shall submit to
4 Congress a report on the access of medicare bene-
5 ficiaries to pharmaceuticals and pharmacists’ serv-
6 ices in rural and hard-to-serve areas under this part
7 together with any recommendations of the Comp-
8 troller General regarding any additional steps the
9 Secretary may need to take to ensure the access of
10 medicare beneficiaries to pharmaceuticals and phar-
11 macists’ services in such areas under this part.

12 “(e) INCENTIVES FOR COST AND UTILIZATION MAN-
13 AGEMENT AND QUALITY IMPROVEMENT.—The Secretary
14 is authorized to include in a contract awarded under sub-
15 section (b) with a carrier such incentives for cost and utili-
16 zation management and quality improvement as the Sec-
17 retary may deem appropriate, including—

18 “(1) bonus and penalty incentives to encourage
19 administrative efficiency;

20 “(2) incentives under which carriers share in
21 any benefit savings achieved;

22 “(3) risk-sharing arrangements related to ini-
23 tiatives to encourage savings in benefit payments;

24 “(4) financial incentives under which savings
25 derived from the substitution of generic medicines in

1 lieu of non-generic medicines are made available to
2 carriers, pharmacies, and the Prescription Medicine
3 Insurance Account; and

4 “(5) any other incentive that the Secretary
5 deems appropriate and likely to be effective in man-
6 aging costs or utilization.

7 “PROMOTION OF PHARMACEUTICAL RESEARCH ON
8 BREAK-THROUGH MEDICINES WHILE PROVIDING
9 PROGRAM COST CONTAINMENT

10 “SEC. 1860D–8. (a) MONITORING EXPENDI-
11 TURES.—The Secretary shall monitor expenditures under
12 this part. On October 1, 2009, the Secretary shall esti-
13 mate total expenditures under this part for 2010.

14 “(b) ESTABLISHMENT OF SUSTAINABLE GROWTH
15 RATE.—

16 “(1) IN GENERAL.—The Secretary shall estab-
17 lish a sustainable growth rate prescription medicine
18 target system for expenditures under this part for
19 each year after 2010.

20 “(2) INITIAL COMPUTATION.—Such target shall
21 equal the amount of total expenditures estimated for
22 2010 adjusted by the Secretary’s estimate of a sus-
23 tainable growth rate (in this section referred to as
24 an ‘SGR’) percentage between 2010 and 2011. Such
25 SGR shall be estimated based on the following:

1 “(A) Reasonable changes in the cost of
2 production or price of covered pharmaceuticals,
3 but in no event more than the rate of increase
4 in the consumer price index for all urban con-
5 sumers for the period involved.

6 “(B) Population enrolled in this part, both
7 in numbers and in average age and severity of
8 chronic and acute illnesses.

9 “(C) Appropriate changes in utilization of
10 pharmaceuticals, as determined by the Drug
11 Review Board (established under subsection
12 (c)(3)) and based on best estimates of utiliza-
13 tion change if there were no direct-to-consumer
14 advertising or promotions to providers.

15 “(D) Productivity index of manufacturers
16 and distributors.

17 “(E) Percentage of products with patent
18 and market exclusivity protection versus prod-
19 ucts without patent protection and changes in
20 the availability of generic substitutes.

21 “(F) Such other factors as the Secretary
22 may determine are appropriate.

23 In no event may the sustainable growth rate exceed
24 120 percent of the estimated per capita growth in
25 total spending under this title.

1 “(3) COMPUTATION FOR SUBSEQUENT
2 YEARS.—In October of 2011 and each year there-
3 after, for purposes of setting the SGRs for the suc-
4 ceeding year, the Secretary shall adjust each current
5 year’s estimated expenditures by the estimated SGR
6 for the succeeding year, further adjusted for correc-
7 tions in earlier estimates and the receipt of addi-
8 tional data on previous years spending as follows:

9 “(A) ERROR ESTIMATES.—An adjustment
10 (up or down) for errors in the estimate of total
11 expenditures under this part for the previous
12 year.

13 “(B) COSTS.—An adjustment (up or
14 down) for corrections in the cost of production
15 of prescriptions covered under this part between
16 the current calendar year and the previous year.

17 “(C) TARGET.—An adjustment for any
18 amount (over or under) that expenditures in the
19 current year under this part are estimated to
20 differ from the target amount set for the year.
21 If expenditures in the current year are esti-
22 mated to be—

23 “(i) less than the target amount, fu-
24 ture target amounts will be adjusted down-
25 ward; or

1 “(ii) more than the target amount,
2 the Secretary shall notify all pharma-
3 ceutical manufacturers with sales of phar-
4 maceutical prescription medicine products
5 to medicare beneficiaries under this part,
6 of a rebate requirement (except as pro-
7 vided in this subparagraph) to be deposited
8 in the Federal Medicare Prescription Medi-
9 cine Trust Fund.

10 “(D) REBATE DETERMINATION.—The
11 amount of the rebate described in subparagraph
12 (C)(ii) may vary among manufacturers and
13 shall be based on the manufacturer’s estimated
14 contribution to the expenditure above the target
15 amount, taking into consideration such factors
16 as—

17 “(i) above average increases in the
18 cost of the manufacturer’s product;

19 “(ii) increases in utilization due to
20 promotion activities of the manufacturer,
21 wholesaler, or retailer;

22 “(iii) launch prices of new drugs at
23 the same or higher prices as similar drugs
24 already in the marketplace (so-called ‘me
25 too’ or ‘copy-cat’ drugs);

1 “(iv) the role of the manufacturer in
2 delaying the entry of generic products into
3 the market; and

4 “(v) such other actions by the manu-
5 facturer that the Secretary may determine
6 has contributed to the failure to meet the
7 SGR target.

8 The rebates shall be established under such
9 subparagraph so that the total amount of the
10 rebates is estimated to ensure that the amount
11 the target for the current year is estimated to
12 be exceeded is recovered in lower spending in
13 the subsequent year; except that, no rebate
14 shall be made in any manufacturer’s product
15 which the Food and Drug Administration has
16 determined is a breakthrough medicine (as de-
17 termined under subsection (c)) or an orphan
18 medicine.

19 “(c) BREAKTHROUGH MEDICINES.—

20 “(1) DETERMINATION.—For purposes of this
21 section, a medicine is a ‘breakthrough medicine’ if
22 the Drug Review Board (established under para-
23 graph (3)) determines—

24 “(A) it is a new product that will make a
25 significant and major improvement by reducing

1 physical or mental illness, reducing mortality,
2 or reducing disability; and

3 “(B) that no other product is available to
4 beneficiaries that achieves similar results for
5 the same condition at a lower cost.

6 “(2) CONDITION.—An exemption from rebates
7 under subsection (b)(3) for a breakthrough medicine
8 shall continue as long as the medicine is certified as
9 a breakthrough medicine but shall be limited to
10 seven calendar years from 2007 or seven calendar
11 years from the date of the initial determination
12 under paragraph (1), whichever is later.

13 “(3) DRUG REVIEW BOARD.—The Drug Review
14 Board under this paragraph shall consist of the
15 Commissioner of Food and Drugs, the Directors of
16 the National Institutes of Health, the Director of
17 the National Science Foundation, and 10 experts in
18 pharmaceuticals, medical research, and clinical care,
19 selected by the Commissioner of Food and Drugs
20 from the faculty of academic medical centers, except
21 that no person who has (or who has an immediate
22 family member that has) any conflict of interest with
23 any pharmaceutical manufacturer shall serve on the
24 Board.

1 “(d) NO REVIEW.—The Secretary’s determination of
2 the rebate amounts under this section, and the Drug Re-
3 view Board’s determination of what is a breakthrough
4 drug, are not subject to administrative or judicial review.

5 “APPROPRIATIONS TO COVER GOVERNMENT

6 CONTRIBUTIONS

7 “SEC. 1860D–9.

8 “There are authorized to be appropriated from time
9 to time, out of any moneys in the Treasury not otherwise
10 appropriated, to the Prescription Medicine Insurance Ac-
11 count, a Government contribution equal to the aggregate
12 costs payable under this part.

13 “PRESCRIPTION MEDICINE DEFINED

14 “SEC. 1860D–10. As used in this part, the term ‘pre-
15 scription medicine’ means—

16 “(1) a drug that may be dispensed only upon
17 a prescription, and that is described in subpara-
18 graph (A)(i), (A)(ii), or (B) of section 1927(k)(2);
19 and

20 “(2) insulin certified under section 506 of the
21 Federal Food, Drug, and Cosmetic Act, and needles,
22 syringes, and disposable pumps for the administra-
23 tion of such insulin.”.

24 (b) CONFORMING AMENDMENTS.—

25 (1) AMENDMENTS TO FEDERAL SUPPLE-
26 MENTARY HEALTH INSURANCE TRUST FUND.—Sec-

1 tion 1841 of the Social Security Act (42 U.S.C.
2 1395t) is amended—

3 (A) in the last sentence of subsection (a)—

4 (i) by striking “and” after “section
5 201(i)(1)”; and

6 (ii) by inserting before the period the
7 following: “, and such amounts as may be
8 deposited in, or appropriated to, the Pre-
9 scription Medicine Insurance Account es-
10 tablished by section 1860D–6”;

11 (B) in subsection (g), by inserting after
12 “by this part,” the following: “the payments
13 provided for under part D (in which case the
14 payments shall come from the Prescription
15 Medicine Insurance Account in the Supple-
16 mentary Medical Insurance Trust Fund),”;

17 (C) in the first sentence of subsection (h),
18 by inserting before the period the following:
19 “and section 1860D–5(b)(4) (in which case the
20 payments shall come from the Prescription
21 Medicine Insurance Account in the Supple-
22 mentary Medical Insurance Trust Fund)”;

23 (D) in the first sentence of subsection
24 (i)—

1 (i) by striking “and” after “section
2 1840(b)(1)”; and

3 (ii) by inserting before the period the
4 following: “, section 1860D–5(b)(2) (in
5 which case the payments shall come from
6 the Prescription Medicine Insurance Ac-
7 count in the Supplementary Medical Insur-
8 ance Trust Fund)”.

9 (2) NO PART D PRESCRIPTION MEDICINE COV-
10 ERAGE UNDER MA PLANS.—Section 1852(a)(1)(A)
11 of the Social Security Act (42 U.S.C. 1395w–
12 22(a)(1)(A)) is amended by adding at the end the
13 following: “No Medicare Advantage plan shall pro-
14 vide benefits for coverage provided under part D.”

15 (3) EXCLUSIONS FROM COVERAGE.—

16 (A) APPLICATION TO PART D.—Section
17 1862(a) of the Social Security Act (42 U.S.C.
18 1395y(a)) is amended in the matter preceding
19 paragraph (1) by striking “part A or part B”
20 and inserting “part A, B, or D”.

21 (B) PRESCRIPTION MEDICINES NOT EX-
22 CLUDED FROM COVERAGE IF APPROPRIATELY
23 PRESCRIBED.—Section 1862(a)(1) of such Act
24 (42 U.S.C. 1395y(a)(1)) is amended—

1 (i) in subparagraph (N), by striking
2 “and” at the end;

3 (ii) in subparagraph (O), by striking
4 the semicolon at the end and inserting “,
5 and”; and

6 (iii) by adding at the end the fol-
7 lowing new subparagraph:

8 “(P) in the case of prescription medicines
9 covered under part D, which are not prescribed
10 in accordance with such part;”.

11 (c) EFFECTIVE DATE.—The amendments made by
12 this section shall take effect on January 1, 2010, and the
13 Secretary of Health and Human Services shall administer
14 the Social Security Act in accordance with such amend-
15 ments on and after such date.

16 **SEC. 5. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRE-**
17 **SCRIPTION DRUGS FOR MEDICARE BENE-**
18 **FICIARIES.**

19 (a) PARTICIPATING MANUFACTURERS.—

20 (1) IN GENERAL.—Each participating manufac-
21 turer of a covered outpatient drug shall make avail-
22 able for purchase by each pharmacy such covered
23 outpatient drug in the amount described in para-
24 graph (2) at the price described in paragraph (3).

1 (2) DESCRIPTION OF AMOUNT OF DRUGS.—The
2 amount of a covered outpatient drug that a partici-
3 pating manufacturer shall make available for pur-
4 chase by a pharmacy is an amount equal to the ag-
5 gregate amount of the covered outpatient drug sold
6 or distributed by the pharmacy to medicare bene-
7 ficiaries.

8 (3) DESCRIPTION OF PRICE.—The price at
9 which a participating manufacturer shall make a
10 covered outpatient drug available for purchase by a
11 pharmacy is the price equal to the lowest of the fol-
12 lowing:

13 (A) The lowest price paid for the covered
14 outpatient drug by any agency or department of
15 the United States.

16 (B) The manufacturer's best price for the
17 covered outpatient drug, as defined in section
18 1927(c)(1)(C) of the Social Security Act (42
19 U.S.C. 1396r-8(c)(1)(C)).

20 (C) The lowest price at which the drug is
21 available (as determined by the Secretary)
22 through importation consistent with the provi-
23 sions of section 804 of the Federal Food, Drug,
24 and Cosmetic Act.

1 (b) SPECIAL PROVISION WITH RESPECT TO HOSPICE
2 PROGRAMS.—For purposes of determining the amount of
3 a covered outpatient drug that a participating manufac-
4 turer shall make available for purchase by a pharmacy
5 under subsection (a), there shall be included in the cal-
6 culation of such amount the amount of the covered out-
7 patient drug sold or distributed by a pharmacy to a hos-
8 pice program. In calculating such amount, only amounts
9 of the covered outpatient drug furnished to a medicare
10 beneficiary enrolled in the hospice program shall be in-
11 cluded.

12 (c) ADMINISTRATION.—The Secretary shall issue
13 such regulations as may be necessary to implement this
14 section.

15 (d) REPORTS TO CONGRESS REGARDING EFFECTIVE-
16 NESS OF SECTION.—

17 (1) IN GENERAL.—Not later than two years
18 after the date of the enactment of this Act, and an-
19 nually thereafter, the Secretary shall report to Con-
20 gress regarding the effectiveness of this section in—

21 (A) protecting medicare beneficiaries from
22 discriminatory pricing by drug manufacturers;
23 and

1 (B) making prescription drugs available to
2 medicare beneficiaries at substantially reduced
3 prices.

4 (2) CONSULTATION.—In preparing such re-
5 ports, the Secretary shall consult with public health
6 experts, affected industries, organizations rep-
7 resenting consumers and older Americans, and other
8 interested persons.

9 (3) RECOMMENDATIONS.—The Secretary shall
10 include in such reports any recommendations they
11 consider appropriate for changes in this section to
12 further reduce the cost of covered outpatient drugs
13 to medicare beneficiaries.

14 (e) DEFINITIONS.—For purposes of this section:

15 (1) PARTICIPATING MANUFACTURER.—The
16 term “participating manufacturer” means any man-
17 ufacturer of drugs or biologicals that, on or after the
18 date of the enactment of this Act, enters into a con-
19 tract or agreement with the United States for the
20 sale or distribution of covered outpatient drugs to
21 the United States.

22 (2) COVERED OUTPATIENT DRUG.—The term
23 “covered outpatient drug” has the meaning given
24 that term in section 1927(k)(2) of the Social Secu-
25 rity Act (42 U.S.C. 1396r–8(k)(2)).

1 (3) MEDICARE BENEFICIARY.—The term
2 “medicare beneficiary” means an individual entitled
3 to benefits under part A of title XVIII of the Social
4 Security Act or enrolled under part B of such title,
5 or both.

6 (4) HOSPICE PROGRAM.—The term “hospice
7 program” has the meaning given that term under
8 section 1861(dd)(2) of the Social Security Act (42
9 U.S.C. 1395x(dd)(2)).

10 (5) SECRETARY.—The term “Secretary” means
11 the Secretary of Health and Human Services.

12 (f) EFFECTIVE DATE.—This section shall take effect
13 on January 1, 2010, and the Secretary shall implement
14 this section in a manner consistent with the obligations
15 of the United States.

16 **SEC. 6. IMPORTATION OF CERTAIN PRESCRIPTION DRUGS.**

17 (a) REPEAL OF CERTAIN SECTION REGARDING IM-
18 PORTATION OF PRESCRIPTION DRUGS.—Chapter VIII of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381
20 et seq.) is amended by striking section 804.

21 (b) IMPORTATION OF PRESCRIPTION DRUGS; WAIVER
22 OF CERTAIN IMPORT RESTRICTIONS.—

23 (1) IN GENERAL.—Chapter VIII of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et

1 seq.), as amended by section 3, is further amended
2 by inserting after section 803 the following:

3 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
4 **PRESCRIPTION DRUGS.**

5 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

6 “(1) IN GENERAL.—In the case of qualifying
7 drugs imported or offered for import into the United
8 States from registered exporters or by registered im-
9 porters—

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

12 “(B) the standards referred to in section
13 801(a) regarding admission of the drugs are
14 subject to subsection (g) of this section (includ-
15 ing with respect to qualifying drugs to which
16 section 801(d)(1) does not apply).

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

19 “(A) the drug is imported by a pharmacy,
20 group of pharmacies, or a wholesaler that is a
21 registered importer; or

22 “(B) the drug is imported by an individual
23 for personal use or for the use of a family mem-
24 ber of the individual (not for resale) from a reg-
25 istered exporter.

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

5 “(A) by a registered importer; or

6 “(B) from a registered exporter to an indi-
7 vidual.

8 “(4) DEFINITIONS.—

9 “(A) REGISTERED EXPORTER; REG-
10 ISTERED IMPORTER.—For purposes of this sec-
11 tion:

12 “(i) The term ‘registered exporter’
13 means an exporter for which a registration
14 under subsection (b) has been approved
15 and is in effect.

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

21 “(iii) The term ‘registration condition’
22 means a condition that must exist for a
23 registration under subsection (b) to be ap-
24 proved.

1 “(B) QUALIFYING DRUG.—For purposes
2 of this section, the term ‘qualifying drug’ means
3 a drug for which there is a corresponding U.S.
4 label drug.

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

8 “(i) with respect to a qualifying drug,
9 has the same active ingredient or ingredi-
10 ents, route of administration, dosage form,
11 and strength as the qualifying drug;

12 “(ii) with respect to the qualifying
13 drug, is manufactured by or for the person
14 that manufactures the qualifying drug;

15 “(iii) is approved under section
16 505(c); and

17 “(iv) is not—

18 “(I) a controlled substance, as
19 defined in section 102 of the Con-
20 trolled Substances Act (21 U.S.C.
21 802);

22 “(II) a biological product, as de-
23 fined in section 351 of the Public
24 Health Service Act (42 U.S.C. 262),
25 including—

1 “(aa) a therapeutic DNA
2 plasmid product;

3 “(bb) a therapeutic synthetic
4 peptide product;

5 “(cc) a monoclonal antibody
6 product for in vivo use; and

7 “(dd) a therapeutic recom-
8 binant DNA-derived product;

9 “(III) an infused drug, including
10 a peritoneal dialysis solution;

11 “(IV) an injected drug;

12 “(V) a drug that is inhaled dur-
13 ing surgery; or

14 “(VI) a drug that is the listed
15 drug referred to in 2 or more abbrev-
16 viated new drug applications under
17 which the drug is commercially mar-
18 keted.

19 “(D) OTHER DEFINITIONS.—For purposes
20 of this section:

21 “(i)(I) The term ‘exporter’ means a
22 person that is in the business of exporting
23 a drug to individuals in the United States
24 from Canada or from a permitted country
25 designated by the Secretary under sub-

1 clause (II), or that, pursuant to submitting
2 a registration under subsection (b), seeks
3 to be in such business.

4 “(II) The Secretary shall designate a
5 permitted country under subparagraph (E)
6 (other than Canada) as a country from
7 which an exporter may export a drug to in-
8 dividuals in the United States if the Sec-
9 retary determines that—

10 “(aa) the country has statutory
11 or regulatory standards that are
12 equivalent to the standards in the
13 United States and Canada with re-
14 spect to—

15 “(AA) the training of phar-
16 macists;

17 “(BB) the practice of phar-
18 macy; and

19 “(CC) the protection of the
20 privacy of personal medical infor-
21 mation; and

22 “(bb) the importation of drugs to
23 individuals in the United States from
24 the country will not adversely affect
25 public health.

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

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

12 “(iv) The term ‘pharmacy’ means a
13 person that—

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

17 “(II) employs 1 or more phar-
18 macists.

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

21 “(vi) The term ‘wholesaler’—

22 “(I) means a person licensed as a whole-
23 saler or distributor of prescription drugs in the
24 United States under section 503(e)(2)(A); and

1 “(II) does not include a person authorized
2 to import drugs under section 801(d)(1).

3 “(E) PERMITTED COUNTRY.—The term ‘permitted
4 country’ means—

5 “(i) Australia;

6 “(ii) Canada;

7 “(iii) a member country of the European
8 Union, but does not include a member country with
9 respect to which—

10 “(I) the country’s Annex to the Treaty of
11 Accession to the European Union 2003 includes
12 a transitional measure for the regulation of
13 human pharmaceutical products that has not
14 expired; or

15 “(II) the Secretary determines that the re-
16 quirements described in subclauses (I) and (II)
17 of clause (vii) will not be met by the date on
18 which such transitional measure for the regula-
19 tion of human pharmaceutical products expires;

20 “(iv) Japan;

21 “(v) New Zealand;

22 “(vi) Switzerland; and

23 “(vii) a country in which the Secretary deter-
24 mines the following requirements are met:

1 “(I) The country has statutory or regu-
2 latory requirements—

3 “(aa) that require the review of drugs
4 for safety and effectiveness by an entity of
5 the government of the country;

6 “(bb) that authorize the approval of
7 only those drugs that have been deter-
8 mined to be safe and effective by experts
9 employed by or acting on behalf of such
10 entity and qualified by scientific training
11 and experience to evaluate the safety and
12 effectiveness of drugs on the basis of ade-
13 quate and well-controlled investigations, in-
14 cluding clinical investigations, conducted
15 by experts qualified by scientific training
16 and experience to evaluate the safety and
17 effectiveness of drugs;

18 “(cc) that require the methods used
19 in, and the facilities and controls used for
20 the manufacture, processing, and packing
21 of drugs in the country to be adequate to
22 preserve their identity, quality, purity, and
23 strength;

24 “(dd) for the reporting of adverse re-
25 actions to drugs and procedures to with-

1 draw approval and remove drugs found not
2 to be safe or effective; and

3 “(ee) that require the labeling and
4 promotion of drugs to be in accordance
5 with the approval of the drug.

6 “(II) The valid marketing authorization
7 system in the country is equivalent to the sys-
8 tems in the countries described in clauses (i)
9 through (vi).

10 “(III) The importation of drugs to the
11 United States from the country will not ad-
12 versely affect public health.

13 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
14 ERS.—

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

20 “(A)(i) In the case of an exporter, the
21 name of the exporter and an identification of all
22 places of business of the exporter that relate to
23 qualifying drugs, including each warehouse or
24 other facility owned or controlled by, or oper-
25 ated for, the exporter.

1 “(ii) In the case of an importer, the name
2 of the importer and an identification of the
3 places of business of the importer at which the
4 importer initially receives a qualifying drug
5 after importation (which shall not exceed 3
6 places of business except by permission of the
7 Secretary).

8 “(B) Such information as the Secretary
9 determines to be necessary to demonstrate that
10 the registrant is in compliance with registration
11 conditions under—

12 “(i) in the case of an importer, sub-
13 sections (c), (d), (e), (g), and (j) (relating
14 to the sources of imported qualifying
15 drugs; the inspection of facilities of the im-
16 porter; the payment of fees; compliance
17 with the standards referred to in section
18 801(a); and maintenance of records and
19 samples); or

20 “(ii) in the case of an exporter, sub-
21 sections (c), (d), (f), (g), (h), (i), and (j)
22 (relating to the sources of exported quali-
23 fying drugs; the inspection of facilities of
24 the exporter and the marking of compliant
25 shipments; the payment of fees; and com-

1 pliance with the standards referred to in
2 section 801(a); being licensed as a phar-
3 macist; conditions for individual importa-
4 tion; and maintenance of records and sam-
5 ples).

6 “(C) An agreement by the registrant that
7 the registrant will not under subsection (a) im-
8 port or export any drug that is not a qualifying
9 drug.

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

11 “(i) notify the Secretary of a recall or
12 withdrawal of a qualifying drug distributed
13 in a permitted country that the registrant
14 has exported or imported, or intends to ex-
15 port or import, to the United States under
16 subsection (a);

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

19 “(iii) cease, or not begin, the expor-
20 tation or importation of such drug unless
21 the Secretary has notified the registrant
22 that exportation or importation of such
23 drug may proceed.

24 “(E) An agreement by the registrant to
25 ensure and monitor compliance with each reg-

1 istration condition, to promptly correct any
2 noncompliance with such a condition, and to
3 promptly report to the Secretary any such non-
4 compliance.

5 “(F) A plan describing the manner in
6 which the registrant will comply with the agree-
7 ment under subparagraph (E).

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

14 “(H) An agreement by the registrant to
15 notify the Secretary not more than 30 days be-
16 fore the registrant intends to make the change,
17 of—

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

21 “(ii) any change that the registrant
22 intends to make in the compliance plan
23 under subparagraph (F).

24 “(I) In the case of an exporter—

1 “(i) An agreement by the exporter
2 that a qualifying drug will not under sub-
3 section (a) be exported to any individual
4 not authorized pursuant to subsection
5 (a)(2)(B) to be an importer of such drug.

6 “(ii) An agreement to post a bond,
7 payable to the Treasury of the United
8 States that is equal in value to the lesser
9 of—

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

14 “(II) \$1,000,000;

15 “(iii) An agreement by the exporter to
16 comply with applicable provisions of Cana-
17 dian law, or the law of the permitted coun-
18 try designated under subsection
19 (a)(4)(D)(i)(II) in which the exporter is lo-
20 cated, that protect the privacy of personal
21 information with respect to each individual
22 importing a prescription drug from the ex-
23 porter under subsection (a)(2)(B).

24 “(iv) An agreement by the exporter to
25 report to the Secretary—

1 “(I) not later than August 1 of
2 each fiscal year, the total price and
3 the total volume of drugs exported to
4 the United States by the exporter dur-
5 ing the 6-month period from January
6 1 through June 30 of that year; and

7 “(II) not later than January 1 of
8 each fiscal year, the total price and
9 the total volume of drugs exported to
10 the United States by the exporter dur-
11 ing the previous fiscal year.

12 “(J) In the case of an importer, an agree-
13 ment by the importer to report to the Sec-
14 retary—

15 “(i) not later than August 1 of each
16 fiscal year, the total price and the total
17 volume of drugs imported to the United
18 States by the importer during the 6-month
19 period from January 1 through June 30 of
20 that fiscal year; and

21 “(ii) not later than January 1 of each
22 fiscal year, the total price and the total
23 volume of drugs imported to the United
24 States by the importer during the previous
25 fiscal year.

1 “(K) Such other provisions as the Sec-
2 retary may require by regulation to protect the
3 public health while permitting—

4 “(i) the importation by pharmacies,
5 groups of pharmacies, and wholesalers as
6 registered importers of qualifying drugs
7 under subsection (a); and

8 “(ii) importation by individuals of
9 qualifying drugs under subsection (a).

10 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
11 TION.—

12 “(A) IN GENERAL.—Not later than 90
13 days after the date on which a registrant sub-
14 mits to the Secretary a registration under para-
15 graph (1), the Secretary shall notify the reg-
16 istrant whether the registration is approved or
17 is disapproved. The Secretary shall disapprove
18 a registration if there is reason to believe that
19 the registrant is not in compliance with one or
20 more registration conditions, and shall notify
21 the registrant of such reason. In the case of a
22 disapproved registration, the Secretary shall
23 subsequently notify the registrant that the reg-
24 istration is approved if the Secretary deter-

1 mines that the registrant is in compliance with
2 such conditions.

3 “(B) CHANGES IN REGISTRATION INFOR-
4 MATION.—Not later than 30 days after receiv-
5 ing a notice under paragraph (1)(H) from a
6 registrant, the Secretary shall determine wheth-
7 er the change involved affects the approval of
8 the registration of the registrant under para-
9 graph (1), and shall inform the registrant of
10 the determination.

11 “(3) PUBLICATION OF CONTACT INFORMATION
12 FOR REGISTERED EXPORTERS.—Through the Inter-
13 net website of the Food and Drug Administration
14 and a toll-free telephone number, the Secretary shall
15 make readily available to the public a list of reg-
16 istered exporters, including contact information for
17 the exporters. Promptly after the approval of a reg-
18 istration submitted under paragraph (1), the Sec-
19 retary shall update the Internet website and the in-
20 formation provided through the toll-free telephone
21 number accordingly.

22 “(4) SUSPENSION AND TERMINATION.—

23 “(A) SUSPENSION.—With respect to the
24 effectiveness of a registration submitted under
25 paragraph (1):

1 “(i) Subject to clause (ii), the Sec-
2 retary may suspend the registration if the
3 Secretary determines, after notice and op-
4 portunity for a hearing, that the registrant
5 has failed to maintain substantial compli-
6 ance with a registration condition.

7 “(ii) If the Secretary determines that,
8 under color of the registration, the ex-
9 porter has exported a drug or the importer
10 has imported a drug that is not a quali-
11 fying drug, or a drug that does not comply
12 with subsection (g)(2)(A) or (g)(4), or has
13 exported a qualifying drug to an individual
14 in violation of subsection (i)(2)(F), the
15 Secretary shall immediately suspend the
16 registration. A suspension under the pre-
17 ceding sentence is not subject to the provi-
18 sion by the Secretary of prior notice, and
19 the Secretary shall provide to the reg-
20 istrant an opportunity for a hearing not
21 later than 10 days after the date on which
22 the registration is suspended.

23 “(iii) The Secretary may reinstate the
24 registration, whether suspended under
25 clause (i) or (ii), if the Secretary deter-

1 mines that the registrant has demonstrated
2 that further violations of registration con-
3 ditions will not occur.

4 “(B) TERMINATION.—The Secretary, after
5 notice and opportunity for a hearing, may ter-
6 minate the registration under paragraph (1) of
7 a registrant if the Secretary determines that
8 the registrant has engaged in a pattern or prac-
9 tice of violating 1 or more registration condi-
10 tions, or if on 1 or more occasions the Secretary
11 has under subparagraph (A)(ii) suspended the
12 registration of the registrant. The Secretary
13 may make the termination permanent, or for a
14 fixed period of not less than 1 year. During the
15 period in which the registration is terminated,
16 any registration submitted under paragraph (1)
17 by the registrant, or a person that is a partner
18 in the export or import enterprise, or a prin-
19 cipal officer in such enterprise, and any reg-
20 istration prepared with the assistance of the
21 registrant or such a person, has no legal effect
22 under this section.

23 “(5) DEFAULT OF BOND.—A bond required to
24 be posted by an exporter under paragraph (1)(I)(ii)
25 shall be defaulted and paid to the Treasury of the

1 United States if, after opportunity for an informal
2 hearing, the Secretary determines that the exporter
3 has—

4 “(A) exported a drug to the United States
5 that is not a qualifying drug or that is not in
6 compliance with subsection (g)(2)(A), (g)(4), or
7 (i); or

8 “(B) failed to permit the Secretary to con-
9 duct an inspection described under subsection
10 (d).

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

16 “(1) The drug was manufactured in an estab-
17 lishment—

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

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

21 “(ii) for which the Secretary has elected to
22 rely on a satisfactory report of a good manufac-
23 turing practice inspection of the establishment
24 from a permitted country whose regulatory sys-
25 tem the Secretary recognizes as equivalent

1 under a mutual recognition agreement, as pro-
2 vided for under section 510(i)(3), section 803,
3 or part 26 of title 21, Code of Federal Regula-
4 tions (or any corresponding successor rule or
5 regulation).

6 “(2) The establishment is located in any coun-
7 try, and the establishment manufactured the drug
8 for distribution in the United States or for distribu-
9 tion in 1 or more of the permitted countries (without
10 regard to whether in addition the drug is manufac-
11 tured for distribution in a foreign country that is
12 not a permitted country).

13 “(3) The exporter or importer obtained the
14 drug—

15 “(A) directly from the establishment; or

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

18 “(i) provides to the exporter or im-
19 porter a statement (in such form and con-
20 taining such information as the Secretary
21 may require) that, for the chain of custody
22 from the establishment, identifies each
23 prior sale, purchase, or trade of the drug
24 (including the date of the transaction and

1 the names and addresses of all parties to
2 the transaction);

3 “(ii) agrees to permit the Secretary to
4 inspect such statements and related
5 records to determine their accuracy;

6 “(iii) agrees, with respect to the quali-
7 fying drugs involved, to permit the Sec-
8 retary to inspect warehouses and other fa-
9 cilities, including records, of the entity for
10 purposes of determining whether the facili-
11 ties are in compliance with any standards
12 under this Act that are applicable to facili-
13 ties of that type in the United States; and

14 “(iv) has ensured, through such con-
15 tractual relationships as may be necessary,
16 that the Secretary has the same authority
17 regarding other parties in the chain of cus-
18 tody from the establishment that the Sec-
19 retary has under clauses (ii) and (iii) re-
20 garding such entity.

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

1 “(B) The foreign country from which the ex-
2 porter will export the drug is the permitted country
3 in which the exporter is located.

4 “(5) During any period in which the drug was
5 not in the control of the manufacturer of the drug,
6 the drug did not enter any country that is not a per-
7 mitted country.

8 “(6) The exporter or importer retains a sample
9 of each lot of the drug sufficient for testing by the
10 Secretary.

11 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
12 MENTS.—

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

18 “(A) the exporter agrees to permit the Sec-
19 retary—

20 “(i) to conduct onsite inspections, in-
21 cluding monitoring on a day-to-day basis,
22 of places of business of the exporter that
23 relate to qualifying drugs, including each
24 warehouse or other facility owned or con-
25 trolled by, or operated for, the exporter;

1 “(ii) to have access, including on a
2 day-to-day basis, to—

3 “(I) records of the exporter that
4 relate to the export of such drugs, in-
5 cluding financial records; and

6 “(II) samples of such drugs;

7 “(iii) to carry out the duties described
8 in paragraph (3); and

9 “(iv) to carry out any other functions
10 determined by the Secretary to be nec-
11 essary regarding the compliance of the ex-
12 porter; and

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

21 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
22 registration condition is that the exporter involved
23 agrees to affix to each shipping container of quali-
24 fying drugs exported under subsection (a) such
25 markings as the Secretary determines to be nec-

1 essary to identify the shipment as being in compli-
2 ance with all registration conditions. Markings under
3 the preceding sentence shall—

4 “(A) be designed to prevent affixation of
5 the markings to any shipping container that is
6 not authorized to bear the markings; and

7 “(B) include anticounterfeiting or track-
8 and-trace technologies, taking into account the
9 economic and technical feasibility of those tech-
10 nologies.

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

14 “(A) Inspecting, randomly, but not less
15 than 12 times annually, the places of business
16 of the exporter at which qualifying drugs are
17 stored and from which qualifying drugs are
18 shipped.

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 exporter, 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 ex-
6 porter.

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

15 “(D) Monitoring the affixing of markings
16 under paragraph (2).

17 “(E) Inspecting as the Secretary deter-
18 mines is necessary the warehouses and other fa-
19 cilities, including records, of other parties in the
20 chain of custody of qualifying drugs.

21 “(F) Determining whether the exporter is
22 in compliance with all other registration condi-
23 tions.

24 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-
25 istration condition is that, not less than 8 hours and

1 not more than 5 days in advance of the time of the
2 importation of a shipment of qualifying drugs, the
3 importer involved agrees to submit to the Secretary
4 a notice with respect to the shipment of drugs to be
5 imported or offered for import into the United
6 States under subsection (a). A notice under the pre-
7 ceding sentence shall include—

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

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

12 “(C) the identity of the drug, including the
13 established name of the drug, the quantity of
14 the drug, and the lot number assigned by the
15 manufacturer;

16 “(D) the identity of the manufacturer of
17 the drug, including the identity of the establish-
18 ment at which the drug was manufactured;

19 “(E) the country from which the drug is
20 shipped;

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

23 “(G) anticipated arrival information, in-
24 cluding the port of arrival and crossing location
25 within that port, and the date and time;

1 “(H) a summary of the chain of custody of
2 the drug from the establishment in which the
3 drug was manufactured to the importer;

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

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

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

24 “(A) be designed to prevent affixation of
25 the markings or other technology to any con-

1 tainer that is not authorized to bear the mark-
2 ings; and

3 “(B) shall include anticounterfeiting or
4 track-and-trace technologies, taking into ac-
5 count the economic and technical feasibility of
6 such technologies.

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

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

14 “(B) During the inspections under sub-
15 paragraph (A), verifying the chain of custody of
16 a statistically significant sample of qualifying
17 drugs from the establishment in which the drug
18 was manufactured to the importer, which shall
19 be accomplished or supplemented by the use of
20 anticounterfeiting or track-and-trace tech-
21 nologies, taking into account the economic and
22 technical feasibility of those technologies, except
23 that a drug that lacks such technologies from
24 the point of manufacture shall not for that rea-

1 son be excluded from importation by an im-
2 porter.

3 “(C) Reviewing notices under paragraph
4 (4).

5 “(D) Inspecting as the Secretary deter-
6 mines is necessary the warehouses and other fa-
7 cilities, including records of other parties in the
8 chain of custody of qualifying drugs.

9 “(E) Determining whether the importer is
10 in compliance with all other registration condi-
11 tions.

12 “(e) IMPORTER FEES.—

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

18 “(2) INSPECTION FEE.—A registration condi-
19 tion is that the importer involved pays a fee to the
20 Secretary in accordance with this subsection. Such
21 fee shall be paid not later than October 1 and April
22 1 of each fiscal year in the amount provided for
23 under paragraph (3).

24 “(3) AMOUNT OF INSPECTION FEE.—

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

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

16 “(ii) developing, implementing, and
17 operating under such subsection an elec-
18 tronic system for submission and review of
19 the notices required under subsection
20 (d)(4) with respect to shipments of quali-
21 fying drugs under subsection (a) to assess
22 compliance with all registration conditions
23 when such shipments are offered for im-
24 port into the United States; and

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

6 “(B) LIMITATION.—Subject to subpara-
7 graph (C), the aggregate total of fees collected
8 under paragraph (2) for a fiscal year shall not
9 exceed 1 percent of the total price of qualifying
10 drugs imported during that fiscal year into the
11 United States by registered importers under
12 subsection (a).

13 “(C) TOTAL PRICE OF DRUGS.—

14 “(i) ESTIMATE.—For the purposes of
15 complying with the limitation described in
16 subparagraph (B) when establishing under
17 subparagraph (A) the aggregate total of
18 fees to be collected under paragraph (2)
19 for a fiscal year, the Secretary shall esti-
20 mate the total price of qualifying drugs im-
21 ported into the United States by registered
22 importers during that fiscal year by adding
23 the total price of qualifying drugs imported
24 by each registered importer during the 6-
25 month period from January 1 through

1 June 30 of the previous fiscal year, as re-
2 ported to the Secretary by each registered
3 importer under subsection (b)(1)(J).

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

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

1 sequent fiscal year so that the limitation
2 described in subparagraph (B) is observed.

3 “(D) INDIVIDUAL IMPORTER 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 importer shall be
7 an amount that is proportional to a reasonable
8 estimate by the Secretary of the semiannual
9 share of the importer of the volume of quali-
10 fying drugs imported by importers 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 “(f) EXPORTER FEES.—

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

20 “(2) INSPECTION FEE.—A registration condi-
21 tion is that the exporter involved pays a fee to the
22 Secretary in accordance with this subsection. Such
23 fee shall be paid not later than October 1 and April
24 1 of each fiscal year in the amount provided for
25 under paragraph (3).

1 “(3) AMOUNT OF INSPECTION FEE.—

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

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

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

24 “(iii) screening such markings, and
25 inspecting such shipments as necessary,

1 when offered for import into the United
2 States to determine if such a shipment
3 should be refused admission under sub-
4 section (g)(5).

5 “(B) LIMITATION.—Subject to subpara-
6 graph (C), the aggregate total of fees collected
7 under paragraph (2) for a fiscal year shall not
8 exceed 1 percent of the total price of qualifying
9 drugs imported during that fiscal year into the
10 United States by registered exporters under
11 subsection (a).

12 “(C) TOTAL PRICE OF DRUGS.—

13 “(i) ESTIMATE.—For the purposes of
14 complying with the limitation described in
15 subparagraph (B) when establishing under
16 subparagraph (A) the aggregate total of
17 fees to be collected under paragraph (2)
18 for a fiscal year, the Secretary shall esti-
19 mate the total price of qualifying drugs im-
20 ported into the United States by registered
21 exporters during that fiscal year by adding
22 the total price of qualifying drugs exported
23 by each registered exporter during the 6-
24 month period from January 1 through
25 June 30 of the previous fiscal year, as re-

1 ported to the Secretary by each registered
2 exporter under subsection (b)(1)(I)(iv).

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

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

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

10 “(4) USE OF FEES.—

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

24 “(B) SOLE PURPOSE.—Fees collected by
25 the Secretary under paragraphs (1) and (2) are

1 only available to the Secretary and, if trans-
2 ferred, to the Secretary of Homeland Security,
3 and are for the sole purpose of paying the costs
4 referred to in paragraph (3)(A).

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

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

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

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

22 “(A) IN GENERAL.—A qualifying drug that
23 is imported or offered for import under sub-
24 section (a) shall comply with the conditions es-
25 tablished in the approved application under sec-

1 tion 505(b) for the U.S. label drug as described
2 under this subsection.

3 “(B) NOTICE BY MANUFACTURER; GEN-
4 ERAL PROVISIONS.—

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

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

15 “(aa) the variations provided
16 for in the application; and

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

20 “(II) states that there is no dif-
21 ference in the qualifying drug from a
22 condition established in the approved
23 application for the U.S. label drug be-
24 yond—

1 “(aa) the variations provided
2 for in the application; and

3 “(bb) any difference in label-
4 ing (except ingredient labeling).

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

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

21 “(II) Information demonstrating
22 that the person submitting the notice
23 has also notified the government of
24 the permitted country in writing that
25 the person is submitting to the Sec-

1 retary a notice under clause (i)(I),
2 which notice describes the difference
3 in the qualifying drug from a condi-
4 tion established in the approved appli-
5 cation for the U.S. label drug.

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

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

22 “(I) the information provided in
23 the notice is complete and true; and

24 “(II) a copy of the notice has
25 been provided to the Federal Trade

1 Commission and to the State attor-
2 neys general.

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

18 “(v) TIMING OF SUBMISSION OF NO-
19 TICES.—

20 “(I) PRIOR APPROVAL NO-
21 TICES.—A notice under clause (i) to
22 which subparagraph (C) applies shall
23 be submitted to the Secretary not
24 later than 120 days before the quali-
25 fying drug with the difference is intro-

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

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

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

22 “(vi) REVIEW BY SECRETARY.—

23 “(I) IN GENERAL.—In this para-
24 graph, the difference in a qualifying
25 drug that is submitted in a notice

1 under clause (i) from the U.S. label
2 drug shall be treated by the Secretary
3 as if it were a manufacturing change
4 to the U.S. label drug under section
5 506A.

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

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

24 “(aa) include in the labeling
25 provided under paragraph (3) a

1 prominent advisory that the
2 qualifying drug is safe and effec-
3 tive but is not bioequivalent to
4 the U.S. label drug if the Sec-
5 retary determines that such an
6 advisory is necessary for health
7 care practitioners and patients to
8 use the qualifying drug safely
9 and effectively; or

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

16 “(IV) REVIEW BY THE SEC-
17 RETARY.—The Secretary shall review
18 and approve or disapprove the dif-
19 ference in a notice submitted under
20 clause (i), if required under section
21 506A, not later than 120 days after
22 the date on which the notice is sub-
23 mitted.

24 “(V) ESTABLISHMENT INSPEC-
25 TION.—If review of such difference

1 would require an inspection of the es-
2 tablishment in which the qualifying
3 drug is manufactured—

4 “(aa) such inspection by the
5 Secretary shall be authorized;
6 and

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

20 “(vii) PUBLICATION OF INFORMATION
21 ON NOTICES.—

22 “(I) IN GENERAL.—Through the
23 Internet website of the Food and
24 Drug Administration and a toll-free
25 telephone number, the Secretary shall

1 readily make available to the public a
2 list of notices submitted under clause
3 (i).

4 “(II) CONTENTS.—The list under
5 subclause (I) shall include the date on
6 which a notice is submitted and
7 whether—

8 “(aa) a notice is under re-
9 view;

10 “(bb) the Secretary has or-
11 dered that importation of the
12 qualifying drug from a permitted
13 country cease; or

14 “(cc) the importation of the
15 drug is permitted under sub-
16 section (a).

17 “(III) UPDATE.—The Secretary
18 shall promptly update the Internet
19 website with any changes to the list.

20 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
21 ING PRIOR APPROVAL.—In the case of a notice
22 under subparagraph (B)(i) that includes a dif-
23 ference that would, under section 506A(c) or
24 (d)(3)(B)(i), require the approval of a supple-
25 mental application before the difference could

1 be made to the U.S. label drug the following
2 shall occur:

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

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

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country not begin until the
21 Secretary completes review of the no-
22 tice; and

23 “(II) promptly notify registered
24 exporters, registered importers, the

1 Federal Trade Commission, and the
2 State attorneys general of the order.

3 “(iii) If the Secretary determines that
4 such a supplemental application regarding
5 the U.S. label drug would not be approved,
6 the Secretary shall—

7 “(I) order that the importation of
8 the qualifying drug involved from the
9 permitted country cease, or provide
10 that an order under clause (ii), if any,
11 remains in effect;

12 “(II) notify the permitted coun-
13 try that approved the qualifying drug
14 for commercial distribution of the de-
15 termination; and

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

21 “(iv) If the Secretary determines that
22 such a supplemental application regarding
23 the U.S. label drug would be approved, the
24 Secretary shall—

1 “(I) vacate the order under
2 clause (ii), if any;

3 “(II) consider the difference to
4 be a variation provided for in the ap-
5 proved application for the U.S. label
6 drug;

7 “(III) permit importation of the
8 qualifying drug under subsection (a);
9 and

10 “(IV) promptly notify registered
11 exporters, registered importers, the
12 Federal Trade Commission, and the
13 State attorneys general of the deter-
14 mination.

15 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
16 QUIRING PRIOR APPROVAL.—In the case of a
17 notice under subparagraph (B)(i) that includes
18 a difference that would, under section
19 506A(d)(3)(B)(ii), not require the approval of a
20 supplemental application before the difference
21 could be made to the U.S. label drug the fol-
22 lowing shall occur:

23 “(i) During the period in which the
24 notice is being reviewed by the Secretary,
25 the authority under this subsection to im-

1 port the qualifying drug involved continues
2 in effect.

3 “(ii) If the Secretary determines that
4 such a supplemental application regarding
5 the U.S. label drug would not be approved,
6 the Secretary shall—

7 “(I) order that the importation of
8 the qualifying drug involved from the
9 permitted country cease;

10 “(II) notify the permitted coun-
11 try that approved the qualifying drug
12 for commercial distribution of the de-
13 termination; and

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

19 “(iii) If the Secretary determines that
20 such a supplemental application regarding
21 the U.S. label drug would be approved, the
22 difference shall be considered to be a vari-
23 ation provided for in the approved applica-
24 tion for the U.S. label drug.

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

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

12 “(ii) may not order that the importa-
13 tion of the qualifying drug involved cease;
14 and

15 “(iii) shall promptly notify registered
16 exporters and registered importers.

17 “(F) DIFFERENCES IN ACTIVE INGRE-
18 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
19 FORM, OR STRENGTH.—

20 “(i) IN GENERAL.—A person who
21 manufactures a drug approved under sec-
22 tion 505(b) shall submit an application
23 under section 505(b) for approval of an-
24 other drug that is manufactured for dis-
25 tribution in a permitted country by or for

1 the person that manufactures the drug ap-
2 proved under section 505(b) if—

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

13 “(II) each active ingredient of
14 the other drug is related to an active
15 ingredient of the drug approved under
16 section 505(b), as defined in clause
17 (v).

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

21 “(I) request approval of the other
22 drug for the indication or indications
23 for which the drug approved under
24 section 505(b) is labeled;

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

13 “(III) include a right of reference
14 to the application for the drug ap-
15 proved under section 505(b); and

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

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

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

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

12 “(I) the same; or

13 “(II) different salts, esters, or
14 complexes of the same moiety.

15 “(3) SECTION 502; LABELING.—

16 “(A) IMPORTATION BY REGISTERED IM-
17 PORTER.—

18 “(i) IN GENERAL.—In the case of a
19 qualifying drug that is imported or offered
20 for import by a registered importer, such
21 drug shall be considered to be in compli-
22 ance with section 502 and the labeling re-
23 quirements under the approved application
24 for the U.S. label drug if the qualifying
25 drug bears—

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

6 “(II) the name of the manufac-
7 turer and location of the manufac-
8 turer;

9 “(III) the lot number assigned by
10 the manufacturer;

11 “(IV) the name, location, and
12 registration number of the importer;
13 and

14 “(V) the National Drug Code
15 number assigned to the qualifying
16 drug by the Secretary.

17 “(ii) REQUEST FOR COPY OF THE LA-
18 BELING.—The Secretary shall provide such
19 copy to the registered importer involved,
20 upon request of the importer.

21 “(iii) REQUESTED LABELING.—The
22 labeling provided by the Secretary under
23 clause (ii) shall—

24 “(I) include the established
25 name, as defined in section 502(e)(3),

1 for each active ingredient in the quali-
2 fying drug;

3 “(II) not include the proprietary
4 name of the U.S. label drug or any
5 active ingredient thereof;

6 “(III) if required under para-
7 graph (2)(B)(vi)(III), a prominent ad-
8 visory that the qualifying drug is safe
9 and effective but not bioequivalent to
10 the U.S. label drug; and

11 “(IV) if the inactive ingredients
12 of the qualifying drug are different
13 from the inactive ingredients for the
14 U.S. label drug, include—

15 “(aa) a prominent notice
16 that the ingredients of the quali-
17 fying drug differ from the ingre-
18 dients of the U.S. label drug and
19 that the qualifying drug must be
20 dispensed with an advisory to
21 people with allergies about this
22 difference and a list of ingredi-
23 ents; and

24 “(bb) a list of the ingredi-
25 ents of the qualifying drug as

1 would be required under section
2 502(e).

3 “(B) IMPORTATION BY INDIVIDUAL.—

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

17 “(I) directions for use by the
18 consumer;

19 “(II) the lot number assigned by
20 the manufacturer;

21 “(III) the name and registration
22 number of the exporter;

23 “(IV) if required under para-
24 graph (2)(B)(vi)(III), a prominent ad-
25 visory that the drug is safe and effec-

1 tive but not bioequivalent to the U.S.
2 label drug;

3 “(V) if the inactive ingredients of
4 the drug are different from the inac-
5 tive ingredients for the U.S. label
6 drug—

7 “(aa) a prominent advisory
8 that persons with an allergy
9 should check the ingredient list
10 of the drug because the ingredi-
11 ents of the drug differ from the
12 ingredients of the U.S. label
13 drug; and

14 “(bb) a list of the ingredi-
15 ents of the drug as would be re-
16 quired under section 502(e); and

17 “(VI) a copy of any special label-
18 ing that would be required by the Sec-
19 retary had the U.S. label drug been
20 dispensed by a pharmacist in the
21 United States, without regard to
22 whether the special labeling bears any
23 trademark involved.

24 “(ii) REQUEST FOR COPY OF SPECIAL
25 LABELING AND INGREDIENT LIST.—The

1 Secretary shall provide to the registered
2 exporter involved a copy of the special la-
3 beling, the advisory, and the ingredient list
4 of the drug, upon request of the exporter.

5 “(iii) REQUESTED LABELING AND IN-
6 GREDIENT LIST.—The labeling and ingre-
7 dient list provided by the Secretary under
8 clause (ii) 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) LICENSING AS PHARMACIST.—A registration
20 condition is that the exporter involved agrees that a quali-
21 fying drug will be exported to an individual only if the
22 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 less 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 “(l) DRUG LABELING.—When a qualifying drug that
13 is imported into the United States by an importer under
14 subsection (a) is dispensed by a pharmacist to an indi-
15 vidual, the pharmacist shall provide that the packaging
16 and labeling of the drug complies with all applicable regu-
17 lations promulgated under sections 3 and 4 of the Poison
18 Prevention Packaging Act of 1970 (15 U.S.C. 1471 et
19 seq.) and include with any other labeling provided to the
20 individual the following:

21 “(1) The lot number assigned by the manufac-
22 turer.

23 “(2) The name and registration number of the
24 importer.

1 “(3) If the inactive ingredients of the drug are
2 different from the inactive ingredients for the U.S.
3 label drug—

4 “(A) a prominent advisory that persons
5 with allergies should check the ingredient list of
6 the drug because the ingredients of the drug
7 differ from the ingredients of the U.S. label
8 drug; and

9 “(B) a list of the ingredients of the drug
10 as would be required under section 502(e).

11 “(4) If required under paragraph
12 (2)(B)(vi)(III) of subsection (g), a prominent advi-
13 sory that the drug is safe and effective but not bio-
14 equivalent to the U.S. label drug.

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

23 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
24 TICES.—

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

5 “(A) discriminate by charging a higher
6 price for a prescription drug sold to a registered
7 exporter or other person in a permitted country
8 that exports a qualifying drug to the United
9 States under this section than the price that is
10 charged, inclusive of rebates or other incentives
11 to the permitted country or other person, to an-
12 other person that is in the same country and
13 that does not export a qualifying drug into the
14 United States under this section;

15 “(B) discriminate by charging a higher
16 price for a prescription drug sold to a registered
17 importer or other person that distributes, sells,
18 or uses a qualifying drug imported into the
19 United States under this section than the price
20 that is charged to another person in the United
21 States that does not import a qualifying drug
22 under this section, or that does not distribute,
23 sell, or use such a drug;

24 “(C) discriminate by denying, restricting,
25 or delaying supplies of a prescription drug to a

1 registered exporter or other person in a per-
2 mitted country that exports a qualifying drug to
3 the United States under this section or to a
4 registered importer or other person that distrib-
5 utes, sells, or uses a qualifying drug imported
6 into the United States under this section;

7 “(D) discriminate by publicly, privately, or
8 otherwise refusing to do business with a reg-
9 istered exporter or other person in a permitted
10 country that exports a qualifying drug to the
11 United States under this section or with a reg-
12 istered importer or other person that distrib-
13 utes, sells, or uses a qualifying drug imported
14 into the United States under this section;

15 “(E) knowingly fail to submit a notice
16 under subsection (g)(2)(B)(i), knowingly fail to
17 submit such a notice on or before the date spec-
18 ified in subsection (g)(2)(B)(v) or as otherwise
19 required under subsection (e) (3), (4), and (5)
20 of section 4 of the Pharmaceutical Market Ac-
21 cess and Drug Safety Act of 2005, knowingly
22 submit such a notice that makes a materially
23 false, fictitious, or fraudulent statement, or
24 knowingly fail to provide promptly any informa-

1 tion requested by the Secretary to review such
2 a notice;

3 “(F) knowingly fail to submit an applica-
4 tion required under subsection (g)(2)(F), know-
5 ingly fail to submit such an application on or
6 before the date specified in subsection
7 (g)(2)(F)(ii), knowingly submit such an applica-
8 tion that makes a materially false, fictitious, or
9 fraudulent statement, or knowingly fail to pro-
10 vide promptly any information requested by the
11 Secretary to review such an application;

12 “(G) cause there to be a difference (includ-
13 ing a difference in active ingredient, route of
14 administration, dosage form, strength, formula-
15 tion, manufacturing establishment, manufac-
16 turing process, or person that manufactures the
17 drug) between a prescription drug for distribu-
18 tion in the United States and the drug for dis-
19 tribution in a permitted country;

20 “(H) refuse to allow an inspection author-
21 ized under this section of an establishment that
22 manufactures a qualifying drug that is, or will
23 be, introduced for commercial distribution in a
24 permitted country;

1 “(I) fail to conform to the methods used
2 in, or the facilities used for, the manufacturing,
3 processing, packing, or holding of a qualifying
4 drug that is, or will be, introduced for commer-
5 cial distribution in a permitted country to good
6 manufacturing practice under this Act;

7 “(J) become a party to a licensing agree-
8 ment or other agreement related to a qualifying
9 drug that fails to provide for compliance with
10 all requirements of this section with respect to
11 such drug;

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

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

18 “(M) engage in any other action that the
19 Federal Trade Commission determines to dis-
20 criminate against a person that engages or at-
21 tempts to engage in the importation of a quali-
22 fying drug under this section.

23 “(2) AFFIRMATIVE DEFENSE.—

24 “(A) DISCRIMINATION.—It shall be an af-
25 firmative defense to a charge that a manufac-

1 turer has discriminated under subparagraph
2 (A), (B), (C), (D), or (M) of paragraph (1) that
3 the higher price charged for a prescription drug
4 sold to a person, the denial, restriction, or delay
5 of supplies of a prescription drug to a person,
6 the refusal to do business with a person, or
7 other discriminatory activity against a person,
8 is not based, in whole or in part, on—

9 “(i) the person exporting or importing
10 a qualifying drug into the United States
11 under this section; or

12 “(ii) the person distributing, selling,
13 or using a qualifying drug imported into
14 the United States under this section.

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

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

22 “(ii) the Secretary has determined
23 that the difference was necessary to im-
24 prove the safety or effectiveness of the
25 drug;

1 “(iii) the person manufacturing the
2 drug for distribution in the United States
3 has given notice to the Secretary under
4 subsection (g)(2)(B)(i) that the drug for
5 distribution in the United States is not dif-
6 ferent from a drug for distribution in per-
7 mitted countries whose combined popu-
8 lation represents at least 50 percent of the
9 total population of all permitted countries;
10 or

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

15 “(3) EFFECT OF SUBSECTION.—

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

24 “(B) DISCOUNTS TO INSURERS, HEALTH
25 PLANS, PHARMACY BENEFIT MANAGERS, AND

1 COVERED ENTITIES.—Nothing in this sub-
2 section shall be construed to—

3 “(i) prevent or restrict a manufac-
4 turer of a prescription drug from providing
5 discounts to an insurer, health plan, phar-
6 macy benefit manager in the United
7 States, or covered entity in the drug dis-
8 count program under section 340B of the
9 Public Health Service Act (42 U.S.C.
10 256b) in return for inclusion of the drug
11 on a formulary;

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

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

19 “(C) CHARITABLE CONTRIBUTIONS.—
20 Nothing in this subsection shall be construed
21 to—

22 “(i) prevent a manufacturer from do-
23 nating a prescription drug, or supplying a
24 prescription drug at nominal cost, to a
25 charitable or humanitarian organization,

1 including the United Nations and affili-
2 ates, or to a government of a foreign coun-
3 try; or

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

6 “(4) ENFORCEMENT.—

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

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

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

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

1 Trade Commission under the Federal
2 Trade Commission Act (15 U.S.C. 41 et
3 seq.).

4 “(5) ACTIONS BY STATES.—

5 “(A) IN GENERAL.—

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

17 “(I) enjoin that practice;

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

20 “(III) obtain damages, restitu-
21 tion, or other compensation on behalf
22 of residents of the State and persons
23 doing business in the State, including
24 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 “(6) 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 “(7) 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 (2) PROHIBITED ACTS.—The Federal Food,
18 Drug, and Cosmetic Act is amended—

19 (A) in section 301 (21 U.S.C. 331), by
20 striking paragraph (aa) and inserting the fol-
21 lowing:

22 “(aa)(1) The sale or trade by a pharmacist, or by
23 a business organization of which the pharmacist is a part,
24 of a qualifying drug that under section 804(a)(2)(A) was
25 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 (B) in section 303(a) (21 U.S.C. 333(a)),
23 by striking paragraph (6) and inserting the fol-
24 lowing:

1 “(6) Notwithstanding subsection (a), any person that
2 knowingly violates section 301(i) (2) or (3) or section
3 301(aa)(4) shall be imprisoned not more than 10 years,
4 or fined in accordance with title 18, United States Code,
5 or both.”.

6 (3) AMENDMENT OF CERTAIN PROVISIONS.—

7 (A) IN GENERAL.—Section 801 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 381) is amended by striking subsection (g) and
10 inserting the following:

11 “(g) With respect to a prescription drug that is im-
12 ported or offered for import into the United States by an
13 individual who is not in the business of such importation,
14 that is not shipped by a registered exporter under section
15 804, and that is refused admission under subsection (a),
16 the Secretary shall notify the individual that—

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

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

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

1 “(4) the individual can find information about
2 such importation, including a list of registered ex-
3 porters, on the Internet website of the Food and
4 Drug Administration or through a toll-free telephone
5 number required under section 804.”.

6 (B) ESTABLISHMENT REGISTRATION.—

7 Section 510(i) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 360(i)) is amended in
9 paragraph (1) by inserting after “import into
10 the United States” the following: “, including a
11 drug that is, or may be, imported or offered for
12 import into the United States under section
13 804,”.

14 (C) EFFECTIVE DATE.—The amendments

15 made by this subsection shall take effect on the
16 date that is 90 days after the date of enactment
17 of this Act.

18 (4) EXHAUSTION.—

19 (A) IN GENERAL.—Section 271 of title 35,
20 United States Code, is amended—

21 (i) by redesignating subsections (h)
22 and (i) as (i) and (j), respectively; and

23 (ii) by inserting after subsection (g)
24 the following:

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

7 (B) RULE OF CONSTRUCTION.—Nothing in
8 the amendment made by paragraph (1) shall be
9 construed to affect the ability of a patent owner
10 or licensee to enforce their patent, subject to
11 such amendment.

12 (5) EFFECT OF SECTION 804.—

13 (A) IN GENERAL.—Section 804 of the Fed-
14 eral Food, Drug, and Cosmetic Act, as added
15 by subsection (a), shall permit the importation
16 of qualifying drugs (as defined in such section
17 804) into the United States without regard to
18 the status of the issuance of implementing reg-
19 ulations—

20 (i) from exporters registered under
21 such section 804 on the date that is 90
22 days after the date of enactment of this
23 Act; and

24 (ii) from permitted countries, as de-
25 fined in such section 804, by importers

1 registered under such section 804 on the
2 date that is 1 year after the date of enact-
3 ment of this Act.

4 (B) REVIEW OF REGISTRATION BY CER-
5 TAIN EXPORTERS.—

6 (i) REVIEW PRIORITY.—In the review
7 of registrations submitted under subsection
8 (b) of such section 804, registrations sub-
9 mitted by entities in Canada that are sig-
10 nificant exporters of prescription drugs to
11 individuals in the United States as of the
12 date of enactment of this Act will have pri-
13 ority during the 90-day period that begins
14 on such date of enactment.

15 (ii) PERIOD FOR REVIEW.—During
16 such 90-day period, the reference in sub-
17 section (b)(2)(A) of such section 804 to 90
18 days (relating to approval or disapproval of
19 registrations) is, as applied to such enti-
20 ties, deemed to be 30 days.

21 (iii) LIMITATION.—That an exporter
22 in Canada exports, or has exported, pre-
23 scription drugs to individuals in the United
24 States on or before the date that is 90
25 days after the date of enactment of this

1 Act shall not serve as a basis, in whole or
2 in part, for disapproving a registration
3 under such section 804 from the exporter.

4 (iv) FIRST YEAR LIMIT ON NUMBER
5 OF EXPORTERS.—During the 1-year period
6 beginning on the date of enactment of this
7 Act, the Secretary of Health and Human
8 Services (referred to in this section as the
9 “Secretary”) may limit the number of reg-
10 istered exporters under such section 804 to
11 not less than 50, so long as the Secretary
12 gives priority to those exporters with dem-
13 onstrated ability to process a high volume
14 of shipments of drugs to individuals in the
15 United States.

16 (v) SECOND YEAR LIMIT ON NUMBER
17 OF EXPORTERS.—During the 1-year period
18 beginning on the date that is 1 year after
19 the date of enactment of this Act, the Sec-
20 retary may limit the number of registered
21 exporters under such section 804 to not
22 less than 100, so long as the Secretary
23 gives priority to those exporters with dem-
24 onstrated ability to process a high volume

1 of shipments of drugs to individuals in the
2 United States.

3 (vi) FURTHER LIMIT ON NUMBER OF
4 EXPORTERS.—The Secretary shall report
5 to Congress to request the authority to im-
6 pose a limitation on the number of reg-
7 istered exporters under such section 804
8 during any period beginning on a date that
9 is not less than 2 years after the date of
10 enactment of this Act if the Secretary de-
11 termines that—

12 (I) a limitation on the number of
13 registered exporters is necessary for
14 the effective and efficient enforcement
15 of the requirements of such section
16 804 with respect to such exporters;
17 and

18 (II) such limitation will not re-
19 strict the ability of individuals to im-
20 port prescription drugs for personal
21 use from registered exporters under
22 such section 804.

23 (C) LIMITS ON NUMBER OF IMPORTERS.—

24 (i) FIRST YEAR LIMIT ON NUMBER OF
25 IMPORTERS.—During the 1-year period be-

1 ginning on the date that is 1 year after the
2 date of enactment of this Act, the Sec-
3 retary may limit the number of registered
4 importers under such section 804 to not
5 less than 100 (of which at least a signifi-
6 cant number shall be groups of phar-
7 macies, to the extent feasible given the ap-
8 plications submitted by such groups), so
9 long as the Secretary gives priority to
10 those importers with demonstrated ability
11 to process a high volume of shipments of
12 drugs imported into the United States.

13 (ii) SECOND YEAR LIMIT ON NUMBER
14 OF IMPORTERS.—During the 1-year period
15 beginning on the date that is 2 years after
16 the date of enactment of this Act, the Sec-
17 retary may limit the number of registered
18 importers under such section 804 to not
19 less than 200 (of which at least a signifi-
20 cant number shall be groups of phar-
21 macies, to the extent feasible given the ap-
22 plications submitted by such groups), so
23 long as the Secretary gives priority to
24 those importers with demonstrated ability

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

3 (iii) FURTHER LIMIT ON NUMBER OF
4 IMPORTERS.—The Secretary shall report to
5 Congress to request the authority to im-
6 pose a limitation on the number of reg-
7 istered importers under such section 804
8 during any period beginning on a date that
9 is not less than 3 years after the date of
10 enactment of this Act if the Secretary de-
11 termines that—

12 (I) a limitation on the number of
13 registered importers is necessary for
14 the effective and efficient enforcement
15 of the requirements of such section
16 804 with respect to such importers;
17 and

18 (II) such limitation will not re-
19 strict the ability of individuals to pur-
20 chase qualifying drugs imported under
21 such section 804 or savings available
22 to individuals by purchasing such
23 qualifying drugs.

24 (D) NOTICES FOR DRUGS FOR IMPORT
25 FROM CANADA.—The notice with respect to a

1 qualifying drug introduced for commercial dis-
2 tribution in Canada as of the date of enactment
3 of this Act that is required under subsection
4 (g)(2)(B)(i) of such section 804 shall be sub-
5 mitted to the Secretary not later than 30 days
6 after the date of enactment of this Act if—

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

14 (ii) the notice is a notice under sub-
15 section (g)(2)(B)(i)(II) of such section
16 804.

17 (E) NOTICE FOR DRUGS FOR IMPORT
18 FROM OTHER COUNTRIES.—The notice with re-
19 spect to a qualifying drug introduced for com-
20 mercial distribution in a permitted country
21 other than Canada as of the date of enactment
22 of this Act that is required under subsection
23 (g)(2)(B)(i) of such section 804 shall be sub-
24 mitted to the Secretary not later than 180 days
25 after the date of enactment of this Act if—

1 (i) the U.S. label drug for the quali-
2 fying drug is 1 of the 100 prescription
3 drugs with the highest dollar volume of
4 sales in the United States based on the 12
5 calendar month period that is first com-
6 pleted on the date that is 120 days after
7 the date of enactment of this Act; or

8 (ii) the notice is a notice under sub-
9 section (g)(2)(B)(i)(II) of such section
10 804.

11 (F) NOTICE FOR OTHER DRUGS FOR IM-
12 PORT.—

13 (i) GUIDANCE ON SUBMISSION
14 DATES.—The Secretary shall by guidance
15 establish a series of submission dates for
16 the notices under subsection (g)(2)(B)(i) of
17 such section 804 with respect to qualifying
18 drugs introduced for commercial distribu-
19 tion as of the date of enactment of this Act
20 and that are not required to be submitted
21 under subparagraph (D) or (E).

22 (ii) CONSISTENT AND EFFICIENT USE
23 OF RESOURCES.—The Secretary shall es-
24 tablish the dates described under clause (i)
25 so that such notices described under such

1 clause are submitted and reviewed at a
2 rate that allows consistent and efficient
3 use of the resources and staff available to
4 the Secretary for such reviews. Review of
5 all such notices shall be completed not
6 later than 5 years after the date of enact-
7 ment of this Act.

8 (iii) PRIORITY FOR DRUGS WITH
9 HIGHER SALES.—The Secretary shall es-
10 tablish the dates described under clause (i)
11 so that the Secretary reviews the notices
12 described under such clause with respect to
13 qualifying drugs with higher dollar volume
14 of sales in the United States before the no-
15 tices with respect to drugs with lower sales
16 in the United States.

17 (G) NOTICES FOR DRUGS APPROVED
18 AFTER EFFECTIVE DATE.—The notice required
19 under subsection (g)(2)(B)(i) of such section
20 804 for a qualifying drug first introduced for
21 commercial distribution in a permitted country
22 (as defined in such section 804) after the date
23 of enactment of this Act shall be submitted to
24 and reviewed by the Secretary as provided
25 under subsection (g)(2)(B) of such section 804,

1 without regard to subparagraph (D), (E), or
2 (F).

3 (H) REPORT.—Beginning with fiscal year
4 2009, not later than 90 days after the end of
5 each fiscal year during which the Secretary re-
6 views a notice referred to in subparagraph (D),
7 (E), or (F), the Secretary shall submit a report
8 to Congress concerning the progress of the
9 Food and Drug Administration in reviewing the
10 notices referred to in subparagraphs (D), (E),
11 and (F).

12 (I) USER FEES.—

13 (i) EXPORTERS.—When establishing
14 an aggregate total of fees to be collected
15 from exporters under subsection (f)(2) of
16 such section 804, the Secretary shall,
17 under subsection (f)(3)(C)(i) of such sec-
18 tion 804, estimate the total price of drugs
19 imported under subsection (a) of such sec-
20 tion 804 into the United States by reg-
21 istered exporters during fiscal year 2009 to
22 be \$1,000,000,000.

23 (ii) IMPORTERS.—When establishing
24 an aggregate total of fees to be collected
25 from importers under subsection (e)(2) of

1 such section 804, the Secretary shall,
2 under subsection (e)(3)(C)(i) of such sec-
3 tion 804, estimate the total price of drugs
4 imported under subsection (a) of such sec-
5 tion 804 into the United States by reg-
6 istered importers during—

7 (I) fiscal year 2009 to be
8 \$1,000,000,000; and

9 (II) fiscal year 2010 to be
10 \$10,000,000,000.

11 (iii) FISCAL YEAR 2010 ADJUST-
12 MENT.—

13 (I) REPORTS.—Not later than
14 February 20, 2010, registered import-
15 ers shall report to the Secretary the
16 total price and the total volume of
17 drugs imported to the United States
18 by the importer during the 4-month
19 period from October 1, 2009, through
20 January 31, 2010.

21 (II) REESTIMATE.—Notwith-
22 standing subsection (e)(3)(C)(ii) of
23 such section 804 or clause (ii), the
24 Secretary shall reestimate the total
25 price of qualifying drugs imported

1 under subsection (a) of such section
2 804 into the United States by reg-
3 istered importers during fiscal year
4 2010. Such reestimate shall be equal
5 to—

6 (aa) the total price of quali-
7 fying drugs imported by each im-
8 porter as reported under sub-
9 clause (I); multiplied by

10 (bb) 3.

11 (III) ADJUSTMENT.—The Sec-
12 retary shall adjust the fee due on
13 April 1, 2010, from each importer so
14 that the aggregate total of fees col-
15 lected under paragraph (5)(B) for fis-
16 cal year 2010 does not exceed the
17 total price of qualifying drugs im-
18 ported under subsection (a) of such
19 section 804 into the United States by
20 registered importers during fiscal year
21 2008 as reestimated under subclause
22 (II).

23 (iv) ANNUAL REPORT.—

24 (I) FOOD AND DRUG ADMINIS-
25 TRATION.—Beginning with fiscal year

1 2009, not later than 180 days after
2 the end of each fiscal year during
3 which fees are collected under sub-
4 section (e), (f), or (g)(2)(B)(iv) of
5 such section 804, the Secretary shall
6 prepare and submit to the House of
7 Representatives and the Senate a re-
8 port on the implementation of the au-
9 thority for such fees during such fis-
10 cal year and the use, by the Food and
11 Drug Administration, of the fees col-
12 lected for the fiscal year for which the
13 report is made and credited to the
14 Food and Drug Administration.

15 (II) CUSTOMS AND BORDER CON-
16 TROL.—Beginning with fiscal year
17 2007, not later than 180 days after
18 the end of each fiscal year during
19 which fees are collected under sub-
20 section (e) or (f) of such section 804,
21 the Secretary of Homeland Security,
22 in consultation with the Secretary of
23 the Treasury, shall prepare and sub-
24 mit to the House of Representatives
25 and the Senate a report on the use,

1 by the Bureau of Customs and Border
2 Protection, of the fees, if any, trans-
3 ferred by the Secretary to the Bureau
4 of Customs and Border Protection for
5 the fiscal year for which the report is
6 made.

7 (6) IMPLEMENTATION OF SECTION 804.—

8 (A) INTERIM RULE.—The Secretary may
9 promulgate an interim rule for implementing
10 section 804 of the Federal Food, Drug, and
11 Cosmetic Act, as added by subsection (a) of this
12 section.

13 (B) NO NOTICE OF PROPOSED RULE-
14 MAKING.—The interim rule described under
15 subparagraph (A) may be developed and pro-
16 mulgated by the Secretary without providing
17 general notice of proposed rulemaking.

18 (C) FINAL RULE.—Not later than 1 year
19 after the date on which the Secretary promul-
20 gates an interim rule under subparagraph (A),
21 the Secretary shall, in accordance with proce-
22 dures under section 553 of title 5, United
23 States Code, promulgate a final rule for imple-
24 menting such section 804, which may incor-
25 porate by reference provisions of the interim

1 rule provided for under subparagraph (A), to
2 the extent that such provisions are not modi-
3 fied.

4 (7) CONSUMER EDUCATION.—The Secretary
5 shall carry out activities that educate consumers—

6 (A) with regard to the availability of quali-
7 fying drugs for import for personal use from an
8 exporter registered with and approved by the
9 Food and Drug Administration under section
10 804 of the Federal Food, Drug, and Cosmetic
11 Act, as added by this section, including infor-
12 mation on how to verify whether an exporter is
13 registered and approved by use of the Internet
14 website of the Food and Drug Administration
15 and the toll-free telephone number required by
16 this Act;

17 (B) that drugs that consumers attempt to
18 import from an exporter that is not registered
19 with and approved by the Food and Drug Ad-
20 ministration can be seized by the United States
21 Customs Service and destroyed, and that such
22 drugs may be counterfeit, unapproved, unsafe,
23 or ineffective; and

24 (C) with regard to the availability at do-
25 mestic retail pharmacies of qualifying drugs im-

1 ported under such section 804 by domestic
2 wholesalers and pharmacies registered with and
3 approved by the Food and Drug Administra-
4 tion.

5 (8) EFFECT ON ADMINISTRATION PRACTICES.—

6 Notwithstanding any provision of this Act (and the
7 amendments made by this Act), nothing in this Act
8 (or the amendments made by this Act) shall be con-
9 strued to change, limit, or restrict the practices of
10 the Food and Drug Administration or the Bureau of
11 Customs and Border Protection in effect on January
12 1, 2008, with respect to the importation of prescrip-
13 tion drugs into the United States by an individual,
14 on the person of such individual, for personal use.

15 (c) DISPOSITION OF CERTAIN DRUGS DENIED AD-

16 MISSION INTO UNITED STATES.—

17 (1) IN GENERAL.—Chapter VIII of the Federal

18 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et
19 seq.), as amended by this section, is further amend-
20 ed by adding at the end the following section:

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

23 “(a) IN GENERAL.—The Secretary of Homeland Se-
24 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 (2) PROCEDURES.—Procedures for carrying out
4 section 805 of the Federal Food, Drug, and Cos-
5 metic Act, as added by this subsection, shall be es-
6 tablished not later than 90 days after the date of the
7 enactment of this Act.

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

11 (d) CIVIL ACTIONS REGARDING PROPERTY.—

12 (1) IN GENERAL.—Section 303 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is
14 amended by adding at the end the following sub-
15 section:

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

21 “(A) to enjoin such alienation or disposition of
22 property; or

23 “(B) for a restraining order to—

24 “(i) prohibit any person from withdrawing,
25 transferring, removing, dissipating, or disposing

1 of any such property or property of equivalent
2 value; and

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

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

8 (2) EFFECTIVE DATE.—The amendment made
9 by this subsection shall take effect on the day that
10 is 90 days after the date of enactment of this Act.

11 (e) WHOLESALE DISTRIBUTION OF DRUGS; STATE-
12 MENTS REGARDING PRIOR SALE, PURCHASE, OR
13 TRADE.—

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

18 (A) in paragraph (1)—

19 (i) by striking “and who is not the
20 manufacturer or an authorized distributor
21 of record of such drug”;

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

24 (iii) by striking subparagraph (B) and
25 inserting 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 (B) in paragraph (2)(A), by adding at the
6 end the following: “The preceding sentence may
7 not be construed as having any applicability
8 with respect to a registered exporter under sec-
9 tion 804.”; and

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

17 (2) CONFORMING AMENDMENT.—Section
18 503(d) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 353(d)) is amended by adding at the
20 end the following:

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

24 “(5) For purposes of this subsection, the term ‘au-
25 thorized distributors of record’ means those distributors

1 with whom a manufacturer has established an ongoing re-
2 lationship to distribute such manufacturer's products.”.

3 (3) EFFECTIVE DATE.—

4 (A) IN GENERAL.—The amendments made
5 by subparagraphs (A) and (C) of paragraph (1)
6 and by paragraph (2) shall take effect on Janu-
7 ary 1, 2013.

8 (B) DRUGS IMPORTED BY REGISTERED IM-
9 PORTERS UNDER SECTION 804.—Notwith-
10 standing subparagraph (A), the amendments
11 made by subparagraphs (A) and (C) of para-
12 graph (1) and by paragraph (2) shall take ef-
13 fect on the date that is 90 days after the date
14 of enactment of this Act with respect to quali-
15 fying drugs imported under section 804 of the
16 Federal Food, Drug, and Cosmetic Act, as
17 added by this section.

18 (C) HIGH-RISK DRUGS.—

19 (i) IN GENERAL.—Notwithstanding
20 subparagraph (A), the Secretary of Health
21 and Human Services (referred to in this
22 section as the “Secretary”) may apply the
23 amendments made by subparagraphs (A)
24 and (C) of paragraph (1) and by para-
25 graph (2) before January 1, 2013, with re-

1 spect to a prescription drug if the Sec-
2 retary—

3 (I) determines that the drug is at
4 high risk for being counterfeited; and

5 (II) publishes the determination
6 and the basis for the determination in
7 the Federal Register.

8 (ii) PEDIGREE NOT REQUIRED.—Not-
9 withstanding a determination under clause
10 (i) with respect to a prescription drug, the
11 amendments described in such clause shall
12 not apply with respect to a wholesale dis-
13 tribution of such drug if the drug is dis-
14 tributed by the manufacturer of the drug
15 to a person that distributes the drug to a
16 retail pharmacy for distribution to the con-
17 sumer or patient, with no other intervening
18 transactions.

19 (iii) LIMITATION.—The Secretary may
20 make the determination under clause (i)
21 with respect to not more than 50 drugs be-
22 fore January 1, 2013.

23 (D) EFFECT WITH RESPECT TO REG-
24 ISTERED EXPORTERS.—The amendment made
25 by paragraph (1)(B) shall take effect on the

1 date that is 90 days after the date of enactment
2 of this Act.

3 (E) ALTERNATIVE REQUIREMENTS.—The
4 Secretary shall issue regulations to establish the
5 alternative requirements, referred to in the
6 amendment made by paragraph (1)(A), that
7 take effect not later than—

8 (i) January 1, 2011, with respect to a
9 prescription drug determined under sub-
10 paragraph (C)(i) to be at high risk for
11 being counterfeited; and

12 (ii) January 1, 2013, with respect to
13 all other prescription drugs.

14 (F) INTERMEDIATE REQUIREMENTS.—
15 With respect to the prescription drugs described
16 under subparagraph (E)(ii), the Secretary shall
17 by regulation require the use of standardized
18 anti-counterfeiting or track-and-trace tech-
19 nologies on such prescription drugs at the case
20 and pallet level effective not later than January
21 1, 2012.

22 (f) INTERNET SALES OF PRESCRIPTION DRUGS.—

23 (1) IN GENERAL.—Chapter V of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et

1 seq.) is amended by inserting after section 503A the
2 following:

3 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

4 “(a) REQUIREMENTS REGARDING INFORMATION ON
5 INTERNET SITE.—

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

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

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

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

21 “(i) are not intended to be accessed
22 by purchasers or prospective purchasers; or

23 “(ii) provide an Internet information
24 location tool within the meaning of section

1 231(e)(5) of the Communications Act of
2 1934 (47 U.S.C. 231(e)(5)).

3 “(2) REQUIREMENTS.—With respect to an
4 Internet site, the requirements referred to in sub-
5 paragraph (C) of paragraph (1) for a person to
6 whom such paragraph applies are as follows:

7 “(A) Each page of the site shall include ei-
8 ther the following information or a link to a
9 page that provides the following information:

10 “(i) The name of such person.

11 “(ii) Each State in which the person
12 is authorized by law to dispense prescrip-
13 tion drugs.

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

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

1 “(v) If the person provides for medical
2 consultations through the site for purposes
3 of providing prescriptions, the name of
4 each individual who provides such con-
5 sultations; each State in which the indi-
6 vidual is licensed or otherwise authorized
7 by law to provide such consultations or
8 practice medicine; and the type or types of
9 health professions for which the individual
10 holds such licenses or other authorizations.

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

16 “(b) INTERNET SALES WITHOUT APPROPRIATE
17 MEDICAL RELATIONSHIPS.—

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

21 “(A) for purposes of such dispensing or
22 sale, the purchaser communicated with the per-
23 son through the Internet;

24 “(B) the patient for whom the drug was
25 dispensed or purchased did not, when such

1 communications began, have a prescription for
2 the drug that is valid in the United States;

3 “(C) pursuant to such communications, the
4 person provided for the involvement of a practi-
5 tioner, or an individual represented by the per-
6 son as a practitioner, and the practitioner or
7 such individual issued a prescription for the
8 drug that was purchased;

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

14 “(E) the person received payment for the
15 dispensing or sale of the drug.

16 For purposes of subparagraph (E), payment is re-
17 ceived if money or other other valuable consideration
18 is received.

19 “(2) EXCEPTIONS.—Paragraph (1) does not
20 apply to—

21 “(A) the dispensing or selling of a pre-
22 scription drug pursuant to telemedicine prac-
23 tices sponsored by—

24 “(i) a hospital that has in effect a
25 provider agreement under title XVIII of

1 the Social Security Act (relating to the
2 Medicare program); or

3 “(ii) a group practice that has not
4 fewer than 100 physicians who have in ef-
5 fect provider agreements under such title;
6 or

7 “(B) the dispensing or selling of a pre-
8 scription drug pursuant to practices that pro-
9 mote the public health, as determined by the
10 Secretary by regulation.

11 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

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

17 “(i) at least one in-person medical
18 evaluation of the patient has been con-
19 ducted by the practitioner; or

20 “(ii) the practitioner conducts a med-
21 ical evaluation of the patient as a covering
22 practitioner.

23 “(B) IN-PERSON MEDICAL EVALUATION.—
24 A medical evaluation by a practitioner is an in-
25 person medical evaluation for purposes of this

1 section if the practitioner is in the physical
2 presence of the patient as part of conducting
3 the evaluation, without regard to whether por-
4 tions of the evaluation are conducted by other
5 health professionals.

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

18 “(4) RULES OF CONSTRUCTION.—

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

24 “(B) STANDARD PRACTICE OF PHAR-
25 MACY.—Paragraph (1) may not be construed as

1 prohibiting any conduct that is a standard prac-
2 tice in the practice of pharmacy.

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

9 “(c) ACTIONS BY STATES.—

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

1 “(2) NOTICE.—The State shall serve prior writ-
2 ten notice of any civil action under paragraph (1) or
3 (5)(B) upon the Secretary and provide the Secretary
4 with a copy of its complaint, except that if it is not
5 feasible for the State to provide such prior notice,
6 the State shall serve such notice immediately upon
7 instituting such action. Upon receiving a notice re-
8 specting a civil action, the Secretary shall have the
9 right—

10 “(A) to intervene in such action;

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

13 “(C) to file petitions for appeal.

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

22 “(4) VENUE; SERVICE OF PROCESS.—Any civil
23 action brought under paragraph (1) in a district
24 court of the United States may be brought in the
25 district in which the defendant is found, is an inhab-

1 itant, or transacts business or wherever venue is
2 proper under section 1391 of title 28, United States
3 Code. Process in such an action may be served in
4 any district in which the defendant is an inhabitant
5 or in which the defendant may be found.

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

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

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

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

21 “(e) GENERAL DEFINITIONS.—For purposes of this
22 section:

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

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

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

6 “(f) INTERNET-RELATED DEFINITIONS.—

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

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

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

1 “(i) to move from viewing one portion
2 of a page on such site to another portion
3 of the page;

4 “(ii) to move from viewing one page
5 on such site to another page on such site;
6 or

7 “(iii) to move from viewing a page on
8 one Internet site to a page on another
9 Internet site.

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

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

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

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

4 “(2) AUTHORITY OF SECRETARY.—The Sec-
5 retary may by regulation modify any definition
6 under paragraph (1) to take into account changes in
7 technology.

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

18 (2) INCLUSION AS PROHIBITED ACT.—Section
19 301 of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 331) is amended by inserting after sub-
21 section (k) the following:

22 “(l) The dispensing or selling of a prescription drug
23 in violation of section 503B.”.

24 (3) INTERNET SALES OF PRESCRIPTION DRUGS;
25 CONSIDERATION BY SECRETARY OF PRACTICES AND

1 PROCEDURES FOR CERTIFICATION OF LEGITIMATE
2 BUSINESSES.—In carrying out section 503B of the
3 Federal Food, Drug, and Cosmetic Act (as added by
4 this section), the Secretary of Health and Human
5 Services shall take into consideration the practices
6 and procedures of public or private entities that cer-
7 tify that businesses selling prescription drugs
8 through Internet sites are legitimate businesses, in-
9 cluding practices and procedures regarding disclo-
10 sure formats and verification programs.

11 (4) REPORTS REGARDING INTERNET-RELATED
12 VIOLATIONS OF FEDERAL AND STATE LAWS ON DIS-
13 PENSING OF DRUGS.—

14 (A) IN GENERAL.—The Secretary of
15 Health and Human Services (referred to in this
16 paragraph as the “Secretary”) shall, pursuant
17 to the submission of an application meeting the
18 criteria of the Secretary, make an award of a
19 grant or contract to the National Clearinghouse
20 on Internet Prescribing (operated by the Fed-
21 eration of State Medical Boards) for the pur-
22 pose of—

23 (i) identifying Internet sites that ap-
24 pear to be in violation of Federal or State
25 laws concerning the dispensing of drugs;

1 (ii) reporting such sites to State med-
2 ical licensing boards and State pharmacy
3 licensing boards, and to the Attorney Gen-
4 eral and the Secretary, for further inves-
5 tigation; and

6 (iii) submitting, for each fiscal year
7 for which the award under this subsection
8 is made, a report to the Secretary describ-
9 ing investigations undertaken with respect
10 to violations described in clause (i).

11 (B) AUTHORIZATION OF APPROPRIA-
12 TIONS.—For the purpose of carrying out sub-
13 paragraph (A), there is authorized to be appro-
14 priated \$100,000 for each of the fiscal years
15 2009 through 2011.

16 (5) EFFECTIVE DATE.—The amendments made
17 by paragraphs (1) and (2) take effect 90 days after
18 the date of enactment of this Act, without regard to
19 whether a final rule to implement such amendments
20 has been promulgated by the Secretary of Health
21 and Human Services under section 701(a) of the
22 Federal Food, Drug, and Cosmetic Act. The pre-
23 ceding sentence may not be construed as affecting
24 the authority of such Secretary to promulgate such
25 a final rule.

1 (g) IMPORTATION EXEMPTION UNDER CONTROLLED
2 SUBSTANCES IMPORT AND EXPORT ACT.—Section
3 1006(a)(2) of the Controlled Substances Import and Ex-
4 port Act (21 U.S.C. 956(a)(2)) is amended by striking
5 “not import the controlled substance into the United
6 States in an amount that exceeds 50 dosage units of the
7 controlled substance.” and inserting “import into the
8 United States not more than 10 dosage units combined
9 of all such controlled substances.”.

10 **SEC. 7. REASONABLE PRICE AGREEMENT FOR FEDERALLY**
11 **FUNDED RESEARCH.**

12 (a) IN GENERAL.—If any Federal agency or any non-
13 profit entity undertakes federally funded health care re-
14 search and development and is to convey or provide a pat-
15 ent or other exclusive right to use such research and devel-
16 opment for a drug or other health care technology, such
17 agency or entity shall not make such conveyance or pro-
18 vide such patent or other right until the person who will
19 receive such conveyance or patent or other right first
20 agrees to a reasonable pricing agreement with the Sec-
21 retary of Health and Human Services or the Secretary
22 makes a determination that the public interest is served
23 by a waiver of the reasonable pricing agreement provided
24 in accordance with subsection (c).

1 (b) CONSIDERATION OF COMPETITIVE BIDDING.—In
2 cases where the Federal Government conveys or licenses
3 exclusive rights to federally funded research under sub-
4 section (a), consideration shall be given to mechanisms for
5 determining reasonable prices which are based upon a
6 competitive bidding process. When appropriate, the mech-
7 anisms should be considered where—

8 (1) qualified bidders compete on the basis of
9 the lowest prices that will be charged to consumers;

10 (2) qualified bidders compete on the basis of
11 the least sales revenues before prices are adjusted in
12 accordance with a cost based reasonable pricing for-
13 mula;

14 (3) qualified bidders compete on the basis of
15 the least period of time before prices are adjusted in
16 accordance with a cost based reasonable pricing for-
17 mula;

18 (4) qualified bidders compete on the basis of
19 the shortest period of exclusivity; or

20 (5) qualified bidders compete under other com-
21 petitive bidding systems.

22 Such competitive bidding process may incorporate require-
23 ments for minimum levels of expenditures on research,
24 marketing, maximum price, or other factors.

1 (c) WAIVER.—No waiver shall take effect under sub-
2 section (a) before the public is given notice of the proposed
3 waiver and provided a reasonable opportunity to comment
4 on the proposed waiver. A decision to grant a waiver shall
5 set out the Secretary’s finding that such a waiver is in
6 the public interest.

7 **SEC. 8. GAO ONGOING STUDIES AND REPORTS ON PRO-**
8 **GRAM; MISCELLANEOUS REPORTS.**

9 (a) ONGOING STUDY.—The Comptroller General of
10 the United States shall conduct an ongoing study and
11 analysis of the prescription medicine benefit program
12 under part D of the medicare program under title XVIII
13 of the Social Security Act (as added by section 4 of this
14 Act), including an analysis of each of the following:

15 (1) The extent to which the administering enti-
16 ties have achieved volume-based discounts similar to
17 the favored price paid by other large purchasers.

18 (2) Whether access to the benefits under such
19 program are in fact available to all beneficiaries,
20 with special attention given to access for bene-
21 ficiaries living in rural and hard-to-serve areas.

22 (3) The success of such program in reducing
23 medication error and adverse medicine reactions and
24 improving quality of care, and whether it is probable
25 that the program has resulted in savings through re-

1 duced hospitalizations and morbidity due to medica-
2 tion errors and adverse medicine reactions.

3 (4) Whether patient medical record confiden-
4 tiality is being maintained and safe-guarded.

5 (5) Such other issues as the Comptroller Gen-
6 eral may consider.

7 (b) REPORTS.—The Comptroller General shall issue
8 such reports on the results of the ongoing study described
9 in (a) as the Comptroller General shall deem appropriate
10 and shall notify Congress on a timely basis of significant
11 problems in the operation of the part D prescription medi-
12 cine program and the need for legislative adjustments and
13 improvements.

14 (c) MISCELLANEOUS STUDIES AND REPORTS.—

15 (1) STUDY ON METHODS TO ENCOURAGE ADDI-
16 TIONAL RESEARCH ON BREAKTHROUGH PHARMA-
17 CEUTICALS.—

18 (A) IN GENERAL.—The Secretary of
19 Health and Human Services shall seek the ad-
20 vice of the Secretary of the Treasury on pos-
21 sible tax and trade law changes to encourage
22 increased original research on new pharma-
23 ceutical breakthrough products designed to ad-
24 dress disease and illness.

1 (B) REPORT.—Not later than January 1,
2 2009, the Secretary shall submit to Congress a
3 report on such study. The report shall include
4 recommended methods to encourage the phar-
5 maceutical industry to devote more resources to
6 research and development of new covered prod-
7 ucts than it devotes to overhead expenses.

8 (2) STUDY ON PHARMACEUTICAL SALES PRAC-
9 TICES AND IMPACT ON COSTS AND QUALITY OF
10 CARE.—

11 (A) IN GENERAL.—The Secretary of
12 Health and Human Services shall conduct a
13 study on the methods used by the pharma-
14 ceutical industry to advertise and sell to con-
15 sumers and educate and sell to providers.

16 (B) REPORT.—Not later than January 1,
17 2009, the Secretary shall submit to Congress a
18 report on such study. The report shall include
19 the estimated direct and indirect costs of the
20 sales methods used, the quality of the informa-
21 tion conveyed, and whether such sales efforts
22 leads (or could lead) to inappropriate pre-
23 scribing. Such report may include legislative
24 and regulatory recommendations to encourage

1 more appropriate education and prescribing
2 practices.

3 (3) STUDY ON COST OF PHARMACEUTICAL RE-
4 SEARCH.—

5 (A) IN GENERAL.—The Secretary of
6 Health and Human Services shall conduct a
7 study on the costs of, and needs for, the phar-
8 maceutical research and the role that the tax-
9 payer provides in encouraging such research.

10 (B) REPORT.—Not later than January 1,
11 2009, the Secretary shall submit to Congress a
12 report on such study. The report shall include
13 a description of the full-range of taxpayer-as-
14 sisted programs impacting pharmaceutical re-
15 search, including tax, trade, government re-
16 search, and regulatory assistance. The report
17 may also include legislative and regulatory rec-
18 ommendations that are designed to ensure that
19 the taxpayer's investment in pharmaceutical re-
20 search results in the availability of pharma-
21 ceuticals at reasonable prices.

22 (4) REPORT ON PHARMACEUTICAL PRICES IN
23 MAJOR FOREIGN NATIONS.—Not later than January
24 1, 2009, the Secretary of Health and Human Serv-
25 ices shall submit to Congress a report on the retail

1 price of major pharmaceutical products in various
2 developed nations, compared to prices for the same
3 or similar products in the United States. The report
4 shall include a description of the principal reasons
5 for any price differences that may exist.

6 **SEC. 9. MEDIGAP TRANSITION PROVISIONS.**

7 (a) IN GENERAL.—Notwithstanding any other provi-
8 sion of law, no new medicare supplemental policy that pro-
9 vides coverage of expenses for prescription drugs may be
10 issued under section 1882 of the Social Security Act on
11 or after January 1, 2010, to an individual unless it re-
12 places a medicare supplemental policy that was issued to
13 that individual and that provided some coverage of ex-
14 penses for prescription drugs.

15 (b) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN
16 PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE.—

17 (1) IN GENERAL.—The issuer of a medicare
18 supplemental policy—

19 (A) may not deny or condition the issuance
20 or effectiveness of a medicare supplemental pol-
21 icy that has a benefit package classified as “A”,
22 “B”, “C”, “D”, “E”, “F”, or “G” (under the
23 standards established under subsection (p)(2) of
24 section 1882 of the Social Security Act, 42
25 U.S.C. 1395ss) and that is offered and is avail-

1 able for issuance to new enrollees by such
2 issuer;

3 (B) may not discriminate in the pricing of
4 such policy, because of health status, claims ex-
5 perience, receipt of health care, or medical con-
6 dition; and

7 (C) may not impose an exclusion of bene-
8 fits based on a pre-existing condition under
9 such policy,

10 in the case of an individual described in paragraph
11 (2) who seeks to enroll under the policy not later
12 than 63 days after the date of the termination of en-
13 rollment described in such paragraph and who sub-
14 mits evidence of the date of termination or
15 disenrollment along with the application for such
16 medicare supplemental policy.

17 (2) INDIVIDUAL COVERED.—An individual de-
18 scribed in this paragraph is an individual who—

19 (A) enrolls under part D of title XVIII of
20 the Social Security Act; and

21 (B) at the time of such enrollment was en-
22 rolled and terminates enrollment in a medicare
23 supplemental policy which has a benefit pack-
24 age classified as “H”, “I”, or “J” under the
25 standards referred to in paragraph (1)(A) or

1 terminates enrollment in a policy to which such
2 standards do not apply but which provides ben-
3 efits for prescription drugs.

4 (3) ENFORCEMENT.—The provisions of para-
5 graph (1) shall be enforced as though they were in-
6 cluded in section 1882(s) of the Social Security Act
7 (42 U.S.C. 1395ss(s)) on and after January 1,
8 2010.

9 (4) DEFINITIONS.—For purposes of this sub-
10 section, the term “medicare supplemental policy”
11 has the meaning given such term in section 1882(g)
12 of the Social Security Act (42 U.S.C. 1395ss(g)).

○