

109TH CONGRESS
2^D SESSION

H. R. 4697

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

FEBRUARY 1, 2006

Mr. SANDERS (for himself, Mr. KUCINICH, Mr. DEFazio, Mr. OWENS, Ms. LEE, Mr. HINCHEY, Mr. PAYNE, Mr. GRIJALVA, Mr. OLVER, Mr. STARK, Ms. WOOLSEY, Mr. NADLER, Mr. MCGOVERN, Ms. KAPTUR, Mr. CONYERS, Ms. CORRINE BROWN of Florida, Mrs. EMERSON, and Mr. TIERNEY) 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 2006”.

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. 1860. Establishment of prescription medicine benefit program for
the aged and disabled

“Sec. 1860A. Scope of benefits

“Sec. 1860B. Payment of benefits; benefit limits

“Sec. 1860C. Eligibility and enrollment

“Sec. 1860D. Premiums

“Sec. 1860E. Special eligibility, enrollment, and copayment rules for low-
income individuals

“Sec. 1860F. Prescription Medicine Insurance Account

“Sec. 1860G. Administration of benefits

“Sec. 1860H. Employer Incentive Program for employment-based retiree
medicine coverage

“Sec. 1860I. Promotion of pharmaceutical research on break-through
medicines while providing program cost containment

“Sec. 1860J. Appropriations to cover Government contributions

“Sec. 1860K. Prescription medicine defined

Sec. 5. Substantial reductions in the price of prescription drugs for medicare
beneficiaries

Sec. 6. Importation of certain prescription drugs

“Sec. 804. Commercial and personal importation of prescription drugs

“Sec. 805. Disposition of certain drugs denied admission

“Sec. 503B. Internet sales of 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 first month of implementation of the
9 Medicare prescription drug benefit enacted by the
10 amendments made by title I of the Medicare Pre-

1 scription Drug, Improvement, and Modernization
2 Act of 2003 (Public Law 108–173) revealed inherent
3 problems with the structure of the benefit and dem-
4 onstrated that the benefit is complicated and con-
5 fusing to individuals eligible for the benefit.

6 (2) During such first month, hundreds of thou-
7 sands of low-income Medicare beneficiaries had dif-
8 ficulty obtaining their covered prescription drugs;
9 many were turned away from the pharmacies with-
10 out their covered prescription drugs and many oth-
11 ers were overcharged for their covered prescription
12 drugs.

13 (3) Since implementation of such prescription
14 drug benefit 26 states needed to intervene to ensure
15 that their low-income Medicare beneficiaries ob-
16 tained their covered prescription drugs and many
17 States have been forced to declare public health
18 emergencies.

19 (4) The amendments made by title I of the
20 Medicare Prescription Drug, Improvement, and
21 Modernization Act of 2003 do not ensure the long-
22 term financial viability of the Medicare prescription
23 drug benefit enacted by such title through cost-con-
24 tainment measures, and contains a provision that ex-
25 plicitly prohibits Medicare from negotiating for lower

1 prescription drug prices, which is a practice of the
2 Department of Veterans Affairs (VA).

3 (5) All Medicare beneficiaries should have ac-
4 cess to a voluntary, reliable, affordable, and defined
5 outpatient medicine benefit that is part of the Medi-
6 care program and that assists with the high cost of
7 prescription medicines and protects such bene-
8 ficiaries from excessive out-of-pocket costs.

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

12 (7) The United States is the largest market for
13 pharmaceuticals in the world, yet American con-
14 sumers pay the highest prices for brand pharma-
15 ceuticals in the world.

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

18 (9) Allowing and structuring the importation of
19 prescription drugs to ensure access to safe and af-
20 fordable drugs approved by the Food and Drug Ad-
21 ministration will provide a level of safety to Amer-
22 ican consumers that they do not currently enjoy.

23 (10) American seniors will spend
24 \$1,800,000,000,000 on pharmaceuticals over the
25 next 10 years.

1 (11) Allowing open pharmaceutical markets
2 could save American consumers at least
3 \$38,000,000,000 each year.

4 **SEC. 3. REPEAL AND TRANSITION.**

5 (a) REPEAL OF MEDICARE PART D BENEFIT AND
6 TRANSITION TO NEW MEDICARE PRESCRIPTION MEDI-
7 CINE BENEFIT PROGRAM.—The amendments made by
8 title I of the Medicare Prescription Drug, Improvement,
9 and Modernization Act of 2003 (Public Law 108–173) are
10 repealed as of December 31, 2006, and the provisions of
11 law amended by such title shall read as if such title had
12 not been enacted.

13 (b) TRANSITION.—The Secretary of Health and
14 Human Services shall provide for an appropriate transi-
15 tion from administering the Social Security Act in accord-
16 ance with the amendments made by title I of the Medicare
17 Prescription Drug, Improvement, and Modernization Act
18 of 2003 (Public Law 108–173) to administering such Act
19 in accordance with the amendments made by section 4 of
20 this Act.

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

22 (a) IN GENERAL.—Title XVIII of the Social Security
23 Act (42 U.S.C. 1395 et seq.) is amended—

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

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

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

5 “ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT
6 PROGRAM FOR THE AGED AND DISABLED

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

15 “SCOPE OF BENEFITS

16 “SEC. 1860A. (a) IN GENERAL.—The benefits pro-
17 vided to an individual enrolled in the insurance program
18 under this part shall consist of—

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

1 regardless of whether the medicine is included in any
2 formulary established under this part if such medi-
3 cine is certified as medically necessary by such
4 health care professional (except that the Secretary
5 shall encourage to the maximum extent possible the
6 substitution and use of lower-cost generics), up to
7 the benefit limits specified in section 1860B; and

8 “(2) charging by pharmacies of the negotiated
9 price—

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

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

17 “(b) COVERED PRESCRIPTION MEDICINES.—

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

23 “(2) EXCLUSIONS FROM COVERAGE.—Covered
24 prescription medicines shall not include drugs or
25 classes of drugs described in subparagraphs (A)

1 through (D) and (F) through (H) of section
2 1927(d)(2) unless—

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

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

9 “(3) EXCLUSION OF PRESCRIPTION MEDICINES
10 TO THE EXTENT COVERED UNDER PART A OR B.—
11 A medicine prescribed for an individual that would
12 otherwise be a covered prescription medicine under
13 this part shall not be so considered to the extent
14 that payment for such medicine is available under
15 part A or B, including all injectable drugs and
16 biologicals for which payment was made or should
17 have been made by a carrier under section
18 1861(s)(2) (A) or (B) as of the date of enactment
19 of the Medicare Drugs for Seniors (MEDS) Act of
20 2006. Medicines otherwise covered under part A or
21 B shall be covered under this part to the extent that
22 benefits under part A or B are exhausted.

23 “(4) STUDY ON INCLUSION OF HOME INFUSION
24 THERAPY SERVICES.—Not later than one year after
25 the date of the enactment of the Medicare Drugs for

1 Seniors (MEDS) Act of 2006, the Secretary shall
2 submit to Congress a legislative proposal for the de-
3 livery of home infusion therapy services under this
4 title and for a system of payment for such a benefit
5 that coordinates items and services furnished under
6 part B and under this part.

7 “PAYMENT OF BENEFITS; BENEFIT LIMITS

8 “SEC. 1860B. (a) PAYMENT OF BENEFITS.—

9 “(1) IN GENERAL.—There shall be paid from
10 the Prescription Medicine Insurance Account within
11 the Supplementary Medical Insurance Trust Fund,
12 in the case of each individual who is enrolled in the
13 insurance program under this part and who pur-
14 chases covered prescription medicines in a calendar
15 year—

16 “(A) with respect to costs incurred for cov-
17 ered prescription medicine furnished during a
18 year, before the individual has incurred out-of-
19 pocket expenses under this subsection equal to
20 the catastrophic out-of-pocket limit specified in
21 subsection (b), an amount equal to the applica-
22 ble percentage (specified in paragraph (2)) of
23 the negotiated price for each such covered pre-
24 scription medicine or such higher percentage as
25 is proposed under section 1860G(b)(7); and

1 “(B) with respect to costs incurred for cov-
2 ered prescription medicine furnished during a
3 year, after the individual has incurred out-of-
4 pocket expenses under this subsection equal to
5 the catastrophic out-of-pocket limit specified in
6 subsection (b), an amount equal to 100 percent
7 of the negotiated price for each such covered
8 prescription medicine.

9 “(2) APPLICABLE PERCENTAGE.—The applica-
10 ble percentage specified in this paragraph is 80 per-
11 cent or such higher percentage as is proposed under
12 section 1860G(b)(7), if the Secretary finds that such
13 higher percentage will not increase aggregate costs
14 to the Prescription Medicine Insurance Account.

15 “(b) CATASTROPHIC LIMIT ON OUT-OF-POCKET EX-
16 PENSES.—

17 “(1) IN GENERAL.—The catastrophic limit on
18 out-of-pocket expenses specified in this subsection—

19 “(A) for each of calendar years 2007 and
20 2008, \$2,000; and

21 “(B) subject to paragraph (2), for calendar
22 year 2009 and each subsequent calendar year is
23 equal to the limit for the preceding year under
24 this paragraph adjusted by the sustainable

1 growth rate percentage (determined under sec-
2 tion 1860I(b)) for the year involved.

3 “(2) ROUNDING.—Any amount determined
4 under paragraph (1)(B) that is not a multiple of
5 \$10 shall be rounded to the nearest multiple of \$10.

6 “ELIGIBILITY AND ENROLLMENT

7 “SEC. 1860C. (a) ELIGIBILITY.—Every individual
8 who, during or after 2007, is entitled to hospital insurance
9 benefits under part A or enrolled in the medical insurance
10 program under part B is eligible to enroll, in accordance
11 with the provisions of this section, in the insurance pro-
12 gram under this part, during an enrollment period under
13 this section, in such manner and form specified by the Sec-
14 retary in regulations.

15 “(b) ENROLLMENT.—

16 “(1) IN GENERAL.—Each individual who satis-
17 fies subsection (a) shall be enrolled (or eligible to en-
18 roll) in the program under this part in accordance
19 with the provisions of section 1837, as if that section
20 applied to this part, except as otherwise explicitly
21 provided in this part.

22 “(2) SINGLE ENROLLMENT PERIOD.—Except as
23 provided in section 1837(i) (as such section applies
24 to this part), 1860E, or 1860H(e), or as otherwise
25 explicitly provided, no individual shall be entitled to
26 enroll in the program under this part at any time

1 after the initial enrollment period without penalty,
2 and in the case of all other late enrollments, the Sec-
3 retary shall develop a late enrollment penalty for the
4 individual that fully recovers the additional actuarial
5 risk involved providing coverage for the individual.

6 “(3) SPECIAL ENROLLMENT PERIOD FOR
7 2007.—

8 “(A) IN GENERAL.—An individual who
9 first satisfies subsection (a) in 2007 may on or
10 after the date on which they first become eligi-
11 ble and at any time on or before December 31,
12 2007—

13 “(i) enroll in the program under this
14 part; and

15 “(ii) enroll or reenroll in such pro-
16 gram after having previously declined or
17 terminated enrollment in such program.

18 “(B) EFFECTIVE DATE OF COVERAGE.—
19 An individual who enrolls under the program
20 under this part pursuant to subparagraph (A)
21 shall be entitled to benefits under this part be-
22 ginning on the first day of the month following
23 the month in which such enrollment occurs.

24 “(c) PERIOD OF COVERAGE.—

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

6 “(2) PART D COVERAGE TERMINATED BY TER-
7 MINATION OF COVERAGE UNDER PARTS A AND B.—
8 In addition to the causes of termination specified in
9 section 1838, an individual’s coverage under this
10 part shall be terminated if the individual retains cov-
11 erage under neither the program under part A nor
12 the program under part B, effective on the effective
13 date of termination of coverage under part A or (if
14 later) under part B.

15 “PREMIUMS

16 “SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF
17 MONTHLY PREMIUM RATES.—

18 “(1) IN GENERAL.—The Secretary shall, during
19 September of 2006 and of each succeeding year, de-
20 termine and promulgate a monthly premium rate for
21 the succeeding year in accordance with the provi-
22 sions of this subsection.

23 “(2) INITIAL PREMIUMS.—For months in 2007,
24 the monthly premium rate under this subsection
25 shall be—

1 “(A) \$25, in the case of premiums paid by
2 an individual enrolled in the program under this
3 part; and

4 “(B) \$32, in the case of premiums paid for
5 such an individual by a former employer (as de-
6 fined in section 1860H(f)(2)).

7 “(3) SUBSEQUENT YEARS.—

8 “(A) IN GENERAL.—For months in a year
9 after 2007, the monthly premium under this
10 subsection shall be (subject to subparagraph
11 (B)) the monthly premium (computed under
12 this subsection without regard to subparagraph
13 (B)) for the previous year increased by the an-
14 nual percentage increase in average per capita
15 aggregate expenditures for covered outpatient
16 medicines in the United States for medicare
17 beneficiaries, as estimated and published by the
18 Secretary in September before the year and for
19 the year involved.

20 “(B) ROUNDING.—The monthly premium
21 determined under subparagraph (A) shall be
22 rounded to the nearest multiple of 10 cents if
23 it is not a multiple of 10 cents.

24 “(C) PUBLICATION OF ASSUMPTIONS.—
25 The Secretary shall publish, together with the

1 promulgation of the monthly premium rates
2 under this paragraph, a statement setting forth
3 the actuarial assumptions and bases employed
4 in arriving at the monthly premium under sub-
5 paragraph (A).

6 “(b) PAYMENT OF PREMIUMS.—

7 “(1) PAYMENTS BY DEDUCTION FROM SOCIAL
8 SECURITY, RAILROAD RETIREMENT BENEFITS, OR
9 BENEFITS ADMINISTERED BY OPM.—

10 “(A) DEDUCTION FROM BENEFITS.—In
11 the case of an individual who is entitled to or
12 receiving benefits as described in subsection (a),
13 (b), or (d) of section 1840, premiums payable
14 under this part shall be collected by deduction
15 from such benefits at the same time and in the
16 same manner as premiums payable under part
17 B are collected pursuant to section 1840.

18 “(B) TRANSFERS TO PRESCRIPTION MEDI-
19 CINE INSURANCE ACCOUNT.—The Secretary of
20 the Treasury shall, from time to time, but not
21 less often than quarterly, transfer premiums
22 collected pursuant to subparagraph (A) to the
23 Prescription Medicine Insurance Account from
24 the appropriate funds and accounts described in
25 subsections (a)(2), (b)(2), and (d)(2) of section

1 1840, on the basis of the certifications de-
2 scribed in such subsections. The amounts of
3 such transfers shall be appropriately adjusted
4 to the extent that prior transfers were too great
5 or too small.

6 “(2) DIRECT PAYMENTS TO SECRETARY.—

7 “(A) ADDITIONAL PAYMENT BY EN-
8 ROLLEE.—An individual to whom paragraph
9 (1) applies (other than an individual receiving
10 benefits as described in section 1840(d)) and
11 who estimates that the amount that will be
12 available for deduction under such paragraph
13 for any premium payment period will be less
14 than the amount of the monthly premiums for
15 such period may (under regulations) pay to the
16 Secretary the estimated balance, or such great-
17 er portion of the monthly premium as the indi-
18 vidual chooses.

19 “(B) PAYMENTS BY OTHER ENROLLEES.—
20 An individual enrolled in the insurance program
21 under this part with respect to whom none of
22 the preceding provisions of this subsection ap-
23 plies (or to whom section 1840(c) applies) shall
24 pay premiums to the Secretary at such times

1 and in such manner as the Secretary shall by
2 regulations prescribe.

3 “(C) DEPOSIT OF PREMIUMS.—Amounts
4 paid to the Secretary under this paragraph
5 shall be deposited in the Treasury to the credit
6 of the Prescription Medicine Insurance Account
7 in the Supplementary Medical Insurance Trust
8 Fund.

9 “(c) CERTAIN LOW-INCOME INDIVIDUALS.—For
10 rules concerning premiums for certain low-income individ-
11 uals, see section 1860E.

12 “SPECIAL ELIGIBILITY, ENROLLMENT, AND COPAYMENT
13 RULES FOR LOW-INCOME INDIVIDUALS

14 “SEC. 1860E. (a) STATE AGREEMENTS FOR COV-
15 ERAGE.—

16 “(1) IN GENERAL.—The Secretary shall, at the
17 request of a State, enter into an agreement with the
18 State under which all individuals described in para-
19 graph (2) are enrolled in the program under this
20 part, without regard to whether any such individual
21 has previously declined the opportunity to enroll in
22 such program.

23 “(2) ELIGIBILITY GROUPS.—The individuals de-
24 scribed in this paragraph, for purposes of paragraph
25 (1), are individuals who satisfy section 1860C(a)
26 and who are—

1 “(A)(i) eligible individuals within the
2 meaning of section 1843; and

3 “(ii) in a coverage group or groups per-
4 mitted under section 1843 (as selected by the
5 State and specified in the agreement); or

6 “(B) qualified medicare medicine bene-
7 ficiaries (as defined in subsection (e)(1)).

8 “(3) COVERAGE PERIOD.—The period of cov-
9 erage under this part of an individual enrolled under
10 an agreement under this subsection shall be as fol-
11 lows:

12 “(A) INDIVIDUALS ELIGIBLE (AT STATE
13 OPTION) FOR PART B BUY-IN.—In the case of
14 an individual described in subsection (a)(2)(A),
15 the coverage period shall be the same period
16 that applies (or would apply) pursuant to sec-
17 tion 1843(d).

18 “(B) QUALIFIED MEDICARE MEDICINE
19 BENEFICIARIES.—In the case of an individual
20 described in subsection (a)(2)(B)—

21 “(i) the coverage period shall begin on
22 the latest of—

23 “(I) January 1, 2007;

24 “(II) the first day of the third
25 month following the month in which

1 the State agreement is entered into;
2 or

3 “(III) the first day of the first
4 month following the month in which
5 the individual satisfies section
6 1860C(a); and

7 “(ii) the coverage period shall end on
8 the last day of the month in which the in-
9 dividual is determined by the State to have
10 become ineligible for medicare medicine
11 cost-sharing.

12 “(4) ALTERNATIVE ENROLLMENT METHODS.—
13 In the process of enrolling low-income individuals
14 under this part, the Secretary shall use the system
15 provided under section 154 of the Social Security
16 Act Amendments of 1994 for newly eligible medicare
17 beneficiaries and shall apply a similar system for
18 other medicare beneficiaries. Such system shall use
19 existing Federal government databases to identify
20 eligibility. Such system shall not require that bene-
21 ficiaries apply for, or enroll through, State medicaid
22 systems in order to obtain low-income assistance de-
23 scribed in this section.

1 “(b) SPECIAL PART D ENROLLMENT OPPORTUNITY
2 FOR INDIVIDUALS LOSING MEDICAID ELIGIBILITY.—In
3 the case of an individual who—

4 “(1) satisfies section 1860C(a); and

5 “(2) loses eligibility for benefits under the State
6 plan under title XIX after having been enrolled
7 under such plan or having been determined eligible
8 for such benefits;

9 the Secretary shall provide an opportunity for enrollment
10 under the program under this part during the period that
11 begins on the date that such individual loses such eligi-
12 bility and ends on the date specified by the Secretary.

13 “(c) STATE OPTION TO BUY-IN DUALY ELIGIBLE
14 INDIVIDUALS.—

15 “(1) COVERAGE OF PREMIUMS AS MEDICAL AS-
16 SISTANCE.—For purposes of applying the second
17 sentence of section 1905(a), any reference to pre-
18 miums under part B shall be considered to include
19 a reference to premiums under this part.

20 “(2) STATE COMMITMENT TO CONTINUE PAR-
21 TICIPATION IN PART D AFTER BENEFIT LIMIT
22 REACHED.—As a condition of additional funding to
23 a State under subsection (d), the State, in its State
24 plan under title XIX, shall provide that in the case
25 of any individual whose eligibility for medical assist-

1 ance under title XIX is not limited to medicare cost-
2 sharing and for whom the State elects to pay pre-
3 miums under this part pursuant to this section, the
4 State will purchase all prescription medicines for
5 such individual in accordance with the provisions of
6 this part without regard to whether the benefit limit
7 for such individual under section 1860B(b) has been
8 reached.

9 “(3) MEDICARE COST-SHARING REQUIRED FOR
10 QUALIFIED MEDICARE BENEFICIARIES.—In applying
11 title XIX, the term ‘medicare cost-sharing’ (as de-
12 fined in section 1905(p)(3)) is deemed to include—

13 “(A) premiums under section 1860D; and

14 “(B) the difference between the amount
15 that is paid under section 1860B and the
16 amount that would be paid under such section
17 if any reference to ‘80 percent’ in subsection
18 (a)(2) of such section were deemed a reference
19 to ‘100 percent’ (or, if the Secretary approves
20 a higher percentage under such section, if such
21 percentage were deemed to be 100 percent).

22 “(d) PAYMENT TO STATES FOR COVERAGE OF CER-
23 TAIN MEDICARE COST-SHARING.—

1 “(1) IN GENERAL.—The Secretary shall provide
2 for payment under this subsection to each State that
3 provides for—

4 “(A) medicare cost-sharing described in
5 section 1905(p)(3)(A)(ii) for individuals who
6 would be qualified medicare beneficiaries de-
7 scribed in section 1905(p)(1) but for the fact
8 that their income exceeds the income level es-
9 tablished by the State under section 1905(p)(2)
10 and is at least 120 percent, but less than 135
11 percent, of the official poverty line (referred to
12 in such section) for a family of the size involved
13 and who are not otherwise eligible for medical
14 assistance under the State plan; and

15 “(B) medicare medicine cost-sharing (as
16 defined in subsection (e)(2)) for qualified medi-
17 care medicine beneficiaries described in sub-
18 section (e)(1).

19 “(2) AMOUNT OF PAYMENT.—The amount of
20 payment under paragraph (1) shall equal 100 per-
21 cent of the cost-sharing described in such paragraph,
22 except that, in the case of an individual whose eligi-
23 bility for medical assistance under title XIX is not
24 limited to medicare cost-sharing or medicare medi-
25 cine cost-sharing, the amount of payment under

1 paragraph (1)(B) shall be equal to the Federal med-
2 ical assistance percentage described in section
3 1905(b)) of amounts as expended for such cost-shar-
4 ing.

5 “(3) METHOD OF PAYMENT; RELATION TO
6 OTHER PAYMENTS.—Amounts shall be paid to
7 States under this subsection in a manner similar to
8 that provided under section 1903(d). Payments
9 under this subsection shall be made in lieu of any
10 payments that otherwise may be made for medical
11 assistance provided under section
12 1902(a)(10)(E)(iv).

13 “(4) TREATMENT OF TERRITORIES.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), this subsection shall not apply to
16 States other than the 50 States and the Dis-
17 trict of Columbia.

18 “(B) PAYMENTS.—In the case of a State
19 (other than the 50 States and the District of
20 Columbia) that develops and implements a plan
21 of assistance for pharmaceuticals provided to
22 low-income medicare beneficiaries, the Secretary
23 shall provide for payment to the State in an
24 amount that is reasonable in relation to the

1 payment levels provided to other States under
2 paragraph (2).

3 “(e) DEFINITIONS; SPECIAL RULES.—For purposes
4 of this section:

5 “(1) QUALIFIED MEDICARE MEDICINE BENE-
6 FICIARY.—The term ‘qualified medicare medicine
7 beneficiary’ means an individual—

8 “(A) who is entitled to hospital insurance
9 benefits under part A (including an individual
10 entitled to such benefits pursuant to an enroll-
11 ment under section 1818, but not including an
12 individual entitled to such benefits only pursu-
13 ant to an enrollment under section 1818A);

14 “(B) whose income (as determined under
15 section 1612 for purposes of the supplemental
16 security income program, except as provided in
17 section 1905(p)(2)(D)) is above 100 percent
18 but below 150 percent of the official poverty
19 line (as defined by the Office of Management
20 and Budget, and revised annually in accordance
21 with section 673(2) of the Omnibus Budget
22 Reconciliation Act of 1981) applicable to a fam-
23 ily of the size involved; and

24 “(C) whose resources (as determined under
25 section 1613 for purposes of the supplemental

1 security income program) do not exceed twice
2 the maximum amount of resources that an indi-
3 vidual may have and obtain benefits under that
4 program.

5 “(2) MEDICARE MEDICINE COST-SHARING.—
6 The term ‘medicare medicine cost-sharing’ means
7 the following costs incurred with respect to a quali-
8 fied medicare medicine beneficiary, without regard to
9 whether the costs incurred were for items and serv-
10 ices for which medical assistance is otherwise avail-
11 able under a State plan under title XIX:

12 “(A) In the case of a qualified medicare
13 medicine beneficiary whose income (as deter-
14 mined under paragraph (1)) is less than 135
15 percent of the official poverty line—

16 “(i) premiums under section 1860D;
17 and

18 “(ii) the difference between the
19 amount that is paid under section 1860B
20 and the amount that would be paid under
21 such section if any reference to ‘50 per-
22 cent’ therein were deemed a reference to
23 ‘100 percent’ (or, if the Secretary approves
24 a higher percentage under such section, if

1 such percentage were deemed to be 100
2 percent).

3 “(B) In the case of a qualified medicare
4 medicine beneficiary whose income (as deter-
5 mined under paragraph (1)) is at least 135 per-
6 cent but less than 150 percent of the official
7 poverty line, a percentage of premiums under
8 section 1860D, determined on a linear sliding
9 scale ranging from 100 percent for individuals
10 with incomes at 135 percent of such line to 0
11 percent for individuals with incomes at 150 per-
12 cent of such line.

13 “(3) STATE.—The term ‘State’ has the mean-
14 ing given such term under section 1101(a) for pur-
15 poses of title XIX.

16 “(4) TREATMENT OF DRUGS PURCHASED.—The
17 provisions of section 1927 shall not apply to pre-
18 scription drugs purchased under this part pursuant
19 to an agreement with the Secretary under this sec-
20 tion (including any drugs so purchased after the
21 limit under section 1860B(b) has been exceeded).

22 “PRESCRIPTION MEDICINE INSURANCE ACCOUNT

23 “SEC. 1860F. (a) ESTABLISHMENT.—There is cre-
24 ated within the Federal Supplemental Medical Insurance
25 Trust Fund established by section 1841 an account to be

1 known as the ‘Prescription Medicine Insurance Account’
2 (in this section referred to as the ‘Account’).

3 “(b) AMOUNTS IN ACCOUNT.—

4 “(1) IN GENERAL.—The Account shall consist
5 of—

6 “(A) such amounts as may be deposited in,
7 or appropriated to, such fund as provided in
8 this part; and

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

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

15 “(c) PAYMENTS FROM ACCOUNT.—The Managing
16 Trustee shall pay from time to time from the Account such
17 amounts as the Secretary certifies are necessary to make
18 the payments provided for by this part, and the payments
19 with respect to administrative expenses in accordance with
20 section 201(g).

21 “ADMINISTRATION OF BENEFITS

22 “SEC. 1860G. (a) THROUGH CMS.—The Secretary
23 shall provide for administration of the benefits under this
24 part through the Centers for Medicare & Medicaid Serv-
25 ices in accordance with the provisions of this section. The
26 Administrator of such Centers may enter into contracts

1 with carriers to administer this part in the same manner
2 as the Administrator enters into such contracts to admin-
3 ister part B. Any such contract shall be separate from any
4 contract under section 1842.

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

10 “(1) PARTICIPATION AGREEMENTS, PRICES,
11 AND FEES.—

12 “(A) NEGOTIATED PRICES.—Establish,
13 through negotiations with medicine manufactur-
14 ers and wholesalers and pharmacies, a schedule
15 of prices for covered prescription medicines.

16 “(B) AGREEMENTS WITH PHARMACIES.—
17 Enter into participation agreements under sub-
18 section (c) with pharmacies, that include terms
19 that—

20 “(i) secure the participation of suffi-
21 cient numbers of pharmacies to ensure
22 convenient access (including adequate
23 emergency access);

24 “(ii) permit the participation of any
25 pharmacy in the service area that meets

1 the participation requirements described in
2 subsection (c); and

3 “(iii) allow for reasonable dispensing
4 and consultation fees for pharmacies.

5 “(C) LISTS OF PRICES AND PARTICIPATING
6 PHARMACIES.—Ensure that the negotiated
7 prices established under subparagraph (A) and
8 the list of pharmacies with agreements under
9 subsection (c) are regularly updated and readily
10 available to health care professionals authorized
11 to prescribe medicines, participating phar-
12 macies, and enrolled individuals.

13 “(2) TRACKING OF COVERED ENROLLED INDI-
14 VIDUALS.—Maintain accurate, updated records of all
15 enrolled individuals (other than individuals enrolled
16 in a plan under part C).

17 “(3) PAYMENT AND COORDINATION OF BENE-
18 FITS.—

19 “(A) PAYMENT.—

20 “(i) Administer claims for payment of
21 benefits under this part and encourage, to
22 the maximum extent possible, use of elec-
23 tronic means for the submissions of claims.

24 “(ii) Determine amounts of benefit
25 payments to be made.

1 “(iii) Receive, disburse, and account
2 for funds used in making such payments,
3 including through the activities specified in
4 the provisions of this paragraph.

5 “(B) COORDINATION.—Coordinate with
6 other private benefit providers, pharmacies, and
7 other relevant entities as necessary to ensure
8 appropriate coordination of benefits with re-
9 spect to enrolled individuals, including coordina-
10 tion of access to and payment for covered pre-
11 scription medicines according to an individual’s
12 in-service area plan provisions, when such indi-
13 vidual is traveling outside the home service
14 area, and under such other circumstances as
15 the Secretary may specify.

16 “(C) EXPLANATION OF BENEFITS.—Fur-
17 nish to enrolled individuals an explanation of
18 benefits in accordance with section 1806(a),
19 and a notice of the balance of benefits remain-
20 ing for the current year, whenever prescription
21 medicine benefits are provided under this part
22 (except that such notice need not be provided
23 more often than monthly).

24 “(4) RULES RELATING TO PROVISION OF BENE-
25 FITS.—

1 “(A) IN GENERAL.—In providing benefits
2 under this part, the Secretary (directly or
3 through contracts) shall employ mechanisms to
4 provide benefits economically, including the use
5 of—

6 “(i) formularies (consistent with sub-
7 paragraph (B));

8 “(ii) automatic generic medicine sub-
9 stitution (unless the physician specifies
10 otherwise, in which case a 30-day prescrip-
11 tion may be dispensed pending a consulta-
12 tion with the physician on whether a ge-
13 neric substitute can be dispensed in the fu-
14 ture);

15 “(iii) tiered copayments (which may
16 include copayments at a rate lower than 20
17 percent) to encourage the use of the lowest
18 cost, on-formulary product in cases where
19 there is no restrictive prescription (de-
20 scribed in subparagraph (D)(i)); and

21 “(iv) therapeutic interchange.

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

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

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

10 “(iii) disclose to current and prospec-
11 tive enrollees and to participating providers
12 and pharmacies, the nature of the for-
13 mulary restrictions, including information
14 regarding the medicines included in the
15 formulary and any difference in cost-shar-
16 ing amounts.

17 “(C) CONSTRUCTION.—Nothing in this
18 subsection shall be construed to prevent the
19 Secretary (directly or through contracts) from
20 using incentives (including a lower beneficiary
21 coinsurance) to encourage enrollees to select ge-
22 neric or other cost-effective medicines, so long
23 as—

24 “(i) such incentives are designed not
25 to result in any increase in the aggregate

1 expenditures under the Federal Medicare
2 Prescription Medicine Trust Fund;

3 “(ii) the average coinsurance charged
4 to all beneficiaries by the Secretary (di-
5 rectly or through contractors) shall seek to
6 approximate (but in no case exceed) 20
7 percent for on-formulary medicines;

8 “(iii) a beneficiary’s coinsurance shall
9 be no greater than 20 percent if the pre-
10 scription is a restrictive prescription; and

11 “(iv) the reimbursement for a pre-
12 scribed nonformulary medicine without a
13 restrictive prescription in no case shall be
14 more than the lowest reimbursement for a
15 formulary medicine in the therapeutic class
16 of the prescribed medicine.

17 “(D) RESTRICTIVE PRESCRIPTION.—For
18 purposes of this section:

19 “(i) WRITTEN PRESCRIPTIONS.—In
20 the case of a written prescription for a
21 medicine, it is a restrictive prescription
22 only if the prescription indicates, in the
23 writing of the physician or other qualified
24 person prescribing the medicine and with
25 an appropriate phrase (such as ‘brand

1 medically necessary') recognized by the
2 Secretary, that a particular medicine prod-
3 uct must be dispensed based upon a belief
4 by the physician or person prescribing the
5 medicine that the particular medicine will
6 provide even marginally superior thera-
7 peutic benefits to the individual for whom
8 the medicine is prescribed or would have
9 marginally fewer adverse reactions with re-
10 spect to such individual.

11 “(ii) TELEPHONE PRESCRIPTIONS.—
12 In the case of a prescription issued by tele-
13 phone for a medicine, it is a restrictive
14 prescription only if the prescription cannot
15 be longer than 30 days and the physician
16 or other qualified person prescribing the
17 medicine (through use of such an appro-
18 priate phrase) states that a particular
19 medicine product must be dispensed, and
20 the physician or other qualified person sub-
21 mits to the pharmacy involved, within 30
22 days after the date of the telephone pre-
23 scription, a written confirmation from the
24 physician or other qualified person pre-
25 scribing the medicine and which indicates

1 with such appropriate phrase that the par-
2 ticular medicine product was required to
3 have been dispensed based upon a belief by
4 the physician or person prescribing the
5 medicine that the particular medicine will
6 provide even marginally superior thera-
7 peutic benefits to the individual for whom
8 the medicine is prescribed or would have
9 marginally fewer adverse reactions with re-
10 spect to such individual. Such written con-
11 firmation is required to refill the prescrip-
12 tion.

13 “(iii) REVIEW OF RESTRICTIVE PRE-
14 SCRIPTIONS.—The advisory committee (es-
15 tablished under subparagraph (B)(i)) may
16 decide to review a restrictive prescription
17 and, if so, it may approve or disapprove
18 such restrictive prescription. It may not
19 disapprove such restrictive prescription un-
20 less it finds that there is no literature ap-
21 proved by the Food and Drug Administra-
22 tion that supports a determination that the
23 particular medicine provides even margin-
24 ally superior therapeutic benefits to the in-
25 dividual for whom the medicine is pre-

1 scribed or would have marginally fewer ad-
2 verse reactions with respect to such indi-
3 vidual. If it disapproves, upon request of
4 the prescribing physician or the enrollee,
5 the committee must provide for a review by
6 an independent contractor of such decision
7 within 48 hours of the time of submission
8 of the prescription, to determine whether
9 the prescription is an eligible benefit under
10 this part. The Secretary shall ensure that
11 independent contractors so used are com-
12 pletely independent of the contractor or its
13 advisory committee.

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

21 “(A) DRUG UTILIZATION REVIEW.—A drug
22 utilization review program conforming to the
23 standards provided in section 1927(g)(2) (with
24 such modifications as the Administrator finds
25 appropriate).

1 “(B) FRAUD AND ABUSE CONTROL.—Ac-
2 tivities to control fraud, abuse, and waste, in-
3 cluding prevention of diversion of pharma-
4 ceuticals to the illegal market.

5 “(C) MEDICATION THERAPY MANAGE-
6 MENT.—

7 “(i) IN GENERAL.—A program of
8 medicine therapy management and medica-
9 tion administration that is designed to as-
10 sure that covered outpatient medicines are
11 appropriately used to achieve therapeutic
12 goals and reduce the risk of adverse
13 events, including adverse drug interactions.

14 “(ii) ELEMENTS.—Such program may
15 include—

16 “(I) enhanced beneficiary under-
17 standing of such appropriate use
18 through beneficiary education, coun-
19 seling, and other appropriate means;
20 and

21 “(II) increased beneficiary adher-
22 ence with prescription medication
23 regimens through medication refill re-
24 minders, special packaging, and other
25 appropriate means.

1 “(iii) DEVELOPMENT OF PROGRAM IN
2 COOPERATION WITH LICENSED PHAR-
3 MACISTS.—The program shall be developed
4 in cooperation with licensed pharmacists
5 and physicians.

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

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

21 “(7) BENEFICIARY PROTECTIONS.—

22 “(A) CONFIDENTIALITY OF HEALTH IN-
23 FORMATION.—Have in effect systems to safe-
24 guard the confidentiality of health care infor-
25 mation on enrolled individuals, which comply

1 with section 1106 and with section 552a of title
2 5, United States Code, and meet such addi-
3 tional standards as the Administrator may pre-
4 scribe.

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

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

15 “(A) RECORDS AND AUDITS.—Maintain
16 adequate records, and afford the Administrator
17 access to such records (including for audit pur-
18 poses).

19 “(B) REPORTS.—Make such reports and
20 submissions of financial and utilization data as
21 the Administrator may require taking into ac-
22 count standard commercial practices.

23 “(9) PROPOSAL FOR ALTERNATIVE COINSUR-
24 ANCE AMOUNT.—

1 “(A) SUBMISSION.—The Administrator
2 may provide for increased Government cost-
3 sharing for generic prescription medicines, pre-
4 scription medicines on a formulary, or prescrip-
5 tion medicines obtained through mail order
6 pharmacies.

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

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

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

23 “(c) PHARMACY PARTICIPATION AGREEMENTS.—

24 “(1) IN GENERAL.—A pharmacy that meets the
25 requirements of this subsection shall be eligible to

1 enter an agreement with the Administrator to fur-
2 nish covered prescription medicines and pharmacists'
3 services to enrolled individuals.

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

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

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

21 “(C) PERFORMANCE STANDARDS.—The
22 pharmacy and the pharmacist shall comply with
23 performance standards relating to—

24 “(i) measures for quality assurance,
25 reduction of medical errors, and participa-

1 tion in the drug utilization review program
2 described in subsection (b)(3)(A);

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

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

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

14 “(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-
15 SERVE AREAS.—

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

22 “(2) SPECIAL ATTENTION DEFINED.—For pur-
23 poses of paragraph (1), the term ‘special attention’
24 may include bonus payments to retail pharmacists in
25 rural areas and any other actions the Secretary de-

1 termines are necessary to ensure full access to rural
2 and hard-to-serve beneficiaries.

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

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

20 “(1) bonus and penalty incentives to encourage
21 administrative efficiency;

22 “(2) incentives under which carriers share in
23 any benefit savings achieved;

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

1 “(4) financial incentives under which savings
 2 derived from the substitution of generic medicines in
 3 lieu of non-generic medicines are made available to
 4 carriers, pharmacies, and the Prescription Medicine
 5 Insurance Account; and

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

9 “EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-
 10 BASED RETIREE MEDICINE COVERAGE

11 “SEC. 1860H. (a) PROGRAM AUTHORITY.—The Sec-
 12 retary shall develop and implement a program under this
 13 section called the ‘Employer Incentive Program’ that en-
 14 courages employers and other sponsors of employment-
 15 based health care coverage to provide adequate prescrip-
 16 tion medicine benefits to retired individuals and to main-
 17 tain such existing benefit programs, by subsidizing, in
 18 part, the sponsor’s cost of providing coverage under quali-
 19 fying plans.

20 “(b) SPONSOR REQUIREMENTS.—In order to be eligi-
 21 ble to receive an incentive payment under this section with
 22 respect to coverage of an individual under a qualified re-
 23 tiree prescription medicine plan (as defined in subsection
 24 (f)(3)), a sponsor shall meet the following requirements:

25 “(1) ASSURANCES.—The sponsor shall—

1 “(A) annually attest, and provide such as-
2 surances as the Secretary may require, that the
3 coverage offered by the sponsor is a qualified
4 retiree prescription medicine plan, and will re-
5 main such a plan for the duration of the spon-
6 sor’s participation in the program under this
7 section; and

8 “(B) guarantee that it will give notice to
9 the Secretary and covered retirees—

10 “(i) at least 120 days before termi-
11 nating its plan; and

12 “(ii) immediately upon determining
13 that the actuarial value of the prescription
14 medicine benefit under the plan falls below
15 the actuarial value of the insurance benefit
16 under this part.

17 “(2) OTHER REQUIREMENTS.—The sponsor
18 shall provide such information, and comply with
19 such requirements, including information require-
20 ments to ensure the integrity of the program, as the
21 Secretary may find necessary to administer the pro-
22 gram under this section.

23 “(c) INCENTIVE PAYMENT.—

24 “(1) IN GENERAL.—A sponsor that meets the
25 requirements of subsection (b) with respect to a

1 quarter in a calendar year shall have payment made
2 by the Secretary on a quarterly basis (to the sponsor
3 or, at the sponsor’s direction, to the appropriate em-
4 ployment-based health plan) of an incentive pay-
5 ment, in the amount determined as described in
6 paragraph (2), for each retired individual (or
7 spouse) who—

8 “(A) was covered under the sponsor’s
9 qualified retiree prescription medicine plan dur-
10 ing such quarter; and

11 “(B) was eligible for but was not enrolled
12 in the insurance program under this part.

13 “(2) AMOUNT OF INCENTIVE.—The payment
14 under this section with respect to each individual de-
15 scribed in paragraph (1) for a month shall be equal
16 to $\frac{2}{3}$ of the monthly premium amount payable from
17 the Prescription Medicine Insurance Account for an
18 enrolled individual, as set for the calendar year pur-
19 suant to section 1860D(a)(2).

20 “(3) PAYMENT DATE.—The incentive under
21 this section with respect to a calendar quarter shall
22 be payable as of the end of the next succeeding cal-
23 endar quarter.

24 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
25 plan, or other entity that the Secretary determines has,

1 directly or through its agent, provided information in con-
2 nection with a request for an incentive payment under this
3 section that the entity knew or should have known to be
4 false shall be subject to a civil monetary penalty in an
5 amount equal to \$2,000 for each false representation plus
6 an amount not to exceed three times the total incentive
7 amounts under subsection (c) that were paid (or would
8 have been payable) on the basis of such information.

9 “(e) PART D ENROLLMENT FOR CERTAIN INDIVID-
10 UALS COVERED BY EMPLOYMENT-BASED RETIREE
11 HEALTH COVERAGE PLANS.—

12 “(1) ELIGIBLE INDIVIDUALS.—An individual
13 shall be given the opportunity to enroll in the pro-
14 gram under this part during the period specified in
15 paragraph (2) if—

16 “(A) the individual declined enrollment in
17 the program under this part at the time the in-
18 dividual first satisfied section 1860C(a);

19 “(B) at that time, the individual was cov-
20 ered under a qualified retiree prescription medi-
21 cine plan for which an incentive payment was
22 paid under this section; and

23 “(C)(i) the sponsor subsequently ceased to
24 offer such plan; or

1 “(ii) the value of prescription medicine cov-
2 erage under such plan is reduced below the
3 value of the coverage provided at the time the
4 individual first became eligible to participate in
5 the program under this part.

6 “(2) SPECIAL ENROLLMENT PERIOD.—An indi-
7 vidual described in paragraph (1) shall be eligible to
8 enroll in the program under this part during the six-
9 month period beginning on the first day of the
10 month in which—

11 “(A) the individual receives a notice that
12 coverage under such plan has terminated (in
13 the circumstance described in paragraph
14 (1)(C)(i)) or notice that a claim has been de-
15 nied because of such a termination; or

16 “(B) the individual received notice of the
17 change in benefits (in the circumstance de-
18 scribed in paragraph (1)(C)(ii)).

19 “(f) DEFINITIONS.—In this section:

20 “(1) EMPLOYMENT-BASED RETIREE HEALTH
21 COVERAGE.—The term ‘employment-based retiree
22 health coverage’ means health insurance or other
23 coverage of health care costs for retired individuals
24 (or for such individuals and their spouses and de-

1 pendents) based on their status as former employees
2 or labor union members.

3 “(2) EMPLOYER.—The term ‘employer’ has the
4 meaning given to such term by section 3(5) of the
5 Employee Retirement Income Security Act of 1974
6 (except that such term shall include only employers
7 of two or more employees).

8 “(3) QUALIFIED RETIREE PRESCRIPTION MEDI-
9 CINE PLAN.—The term ‘qualified retiree prescription
10 medicine plan’ means health insurance coverage in-
11 cluded in employment-based retiree health coverage
12 that—

13 “(A) provides coverage of the cost of pre-
14 scription medicines whose actuarial value to
15 each retired beneficiary equals or exceeds the
16 actuarial value of the benefits provided to an in-
17 dividual enrolled in the program under this
18 part; and

19 “(B) does not deny, limit, or condition the
20 coverage or provision of prescription medicine
21 benefits for retired individuals based on age or
22 any health status-related factor described in
23 section 2702(a)(1) of the Public Health Service
24 Act.

1 “(4) SPONSOR.—The term ‘sponsor’ has the
2 meaning given the term ‘plan sponsor’ by section
3 3(16)(B) of the Employee Retirement Income Secu-
4 rity Act of 1974.

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

8 “SEC. 1860I. (a) MONITORING EXPENDITURES.—
9 The Secretary shall monitor expenditures under this part.
10 On October 1, 2007, the Secretary shall estimate total ex-
11 penditures under this part for 2007.

12 “(b) ESTABLISHMENT OF SUSTAINABLE GROWTH
13 RATE.—

14 “(1) IN GENERAL.—The Secretary shall estab-
15 lish a sustainable growth rate prescription medicine
16 target system for expenditures under this part for
17 each year after 2007.

18 “(2) INITIAL COMPUTATION.—Such target shall
19 equal the amount of total expenditures estimated for
20 2007 adjusted by the Secretary’s estimate of a sus-
21 tainable growth rate (in this section referred to as
22 an ‘SGR’) percentage between 2007 and 2008. Such
23 SGR shall be estimated based on the following:

24 “(A) Reasonable changes in the cost of
25 production or price of covered pharmaceuticals,
26 but in no event more than the rate of increase

1 in the consumer price index for all urban con-
2 sumers for the period involved.

3 “(B) Population enrolled in this part, both
4 in numbers and in average age and severity of
5 chronic and acute illnesses.

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

12 “(D) Productivity index of manufacturers
13 and distributors.

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

18 “(F) Such other factors as the Secretary
19 may determine are appropriate.

20 In no event may the sustainable growth rate exceed
21 120 percent of the estimated per capita growth in
22 total spending under this title.

23 “(3) COMPUTATION FOR SUBSEQUENT
24 YEARS.—In October of 2008 and each year there-
25 after, for purposes of setting the SGRs for the suc-

1 ceeding year, the Secretary shall adjust each current
2 year's estimated expenditures by the estimated SGR
3 for the succeeding year, further adjusted for correc-
4 tions in earlier estimates and the receipt of addi-
5 tional data on previous years spending as follows:

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

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

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

20 “(i) less than the target amount, fu-
21 ture target amounts will be adjusted down-
22 ward; or

23 “(ii) more than the target amount,
24 the Secretary shall notify all pharma-
25 ceutical manufacturers with sales of phar-

1 maceutical prescription medicine products
2 to medicare beneficiaries under this part,
3 of a rebate requirement (except as pro-
4 vided in this subparagraph) to be deposited
5 in the Federal Medicare Prescription Medi-
6 cine Trust Fund.

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

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

16 “(ii) increases in utilization due to
17 promotion activities of the manufacturer,
18 wholesaler, or retailer;

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

23 “(iv) the role of the manufacturer in
24 delaying the entry of generic products into
25 the market; and

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

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

16 “(c) BREAKTHROUGH MEDICINES.—

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

21 “(A) it is a new product that will make a
22 significant and major improvement by reducing
23 physical or mental illness, reducing mortality,
24 or reducing disability; and

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

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

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

23 “(d) NO REVIEW.—The Secretary’s determination of
24 the rebate amounts under this section, and the Drug Re-

1 view Board’s determination of what is a breakthrough
2 drug, are not subject to administrative or judicial review.

3 “APPROPRIATIONS TO COVER GOVERNMENT

4 CONTRIBUTIONS

5 “SEC. 1860J. (a) IN GENERAL.—There are author-
6 ized to be appropriated from time to time, out of any mon-
7 eys in the Treasury not otherwise appropriated, to the
8 Prescription Medicine Insurance Account, a Government
9 contribution equal to—

10 “(1) the aggregate premiums payable for a
11 month pursuant to section 1860D(a)(2) by individ-
12 uals enrolled in the program under this part; plus

13 “(2) one-half the aggregate premiums payable
14 for a month pursuant to such section for such indi-
15 viduals by former employers; plus

16 “(3) the benefits payable by reason of the appli-
17 cation of paragraph (2) of section 1860B(a) (relat-
18 ing to catastrophic benefits).

19 “(b) APPROPRIATIONS TO COVER INCENTIVES FOR
20 EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE.—

21 There are authorized to be appropriated to the Prescrip-
22 tion Medicine Insurance Account from time to time, out
23 of any moneys in the Treasury not otherwise appropriated
24 such sums as may be necessary for payment of incentive
25 payments under section 1860H(c).

1 “PRESCRIPTION MEDICINE DEFINED

2 “SEC. 1860K.

3 As used in this part, the term ‘prescription medicine’
4 means—

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

9 “(2) insulin certified under section 506 of the
10 Federal Food, Drug, and Cosmetic Act, and needles,
11 syringes, and disposable pumps for the administra-
12 tion of such insulin.”.

13 (b) CONFORMING AMENDMENTS.—

14 (1) AMENDMENTS TO FEDERAL SUPPLE-
15 MENTARY HEALTH INSURANCE TRUST FUND.—Sec-
16 tion 1841 of the Social Security Act (42 U.S.C.
17 1395t) is amended—

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

19 (i) by striking “and” after “section
20 201(i)(1)”; and

21 (ii) by inserting before the period the
22 following: “, and such amounts as may be
23 deposited in, or appropriated to, the Pre-
24 scription Medicine Insurance Account es-
25 tablished by section 1860F”;

1 (B) in subsection (g), by inserting after
2 “by this part,” the following: “the payments
3 provided for under part D (in which case the
4 payments shall come from the Prescription
5 Medicine Insurance Account in the Supple-
6 mentary Medical Insurance Trust Fund),”;

7 (C) in the first sentence of subsection (h),
8 by inserting before the period the following:
9 “and section 1860D(b)(4) (in which case the
10 payments shall come from the Prescription
11 Medicine Insurance Account in the Supple-
12 mentary Medical Insurance Trust Fund)”;

13 (D) in the first sentence of subsection
14 (i)—

15 (i) by striking “and” after “section
16 1840(b)(1)”;

17 (ii) by inserting before the period the
18 following: “, section 1860D(b)(2) (in which
19 case the payments shall come from the
20 Prescription Medicine Insurance Account
21 in the Supplementary Medical Insurance
22 Trust Fund)”.

23 (2) PRESCRIPTION MEDICINE OPTION UNDER
24 MA PLANS.—

1 (A) ELIGIBILITY, ELECTION, AND ENROLL-
2 MENT.—Section 1851 of the Social Security Act
3 (42 U.S.C. 1395w–21) is amended—

4 (i) in subsection (a)(1)(A), by striking
5 “parts A and B” and inserting “parts A,
6 B, and D”; and

7 (ii) in subsection (i)(1), by striking
8 “parts A and B” and inserting “parts A,
9 B, and D”.

10 (B) VOLUNTARY BENEFICIARY ENROLL-
11 MENT FOR MEDICINE COVERAGE.—Section
12 1852(a)(1)(A) of such Act (42 U.S.C. 1395w–
13 22(a)(1)(A)) is amended by inserting “(and
14 under part D to individuals also enrolled under
15 that part)” after “parts A and B”.

16 (C) ACCESS TO SERVICES.—Section
17 1852(d)(1) of such Act (42 U.S.C. 1395w–
18 22(d)(1)) is amended—

19 (i) in subparagraph (D), by striking
20 “and” at the end;

21 (ii) in subparagraph (E), by striking
22 the period at the end and inserting “;
23 and”; and

24 (iii) by adding at the end the fol-
25 lowing new subparagraph:

1 “(F) the plan for prescription medicine
2 benefits under part D guarantees coverage of
3 any specifically named covered prescription
4 medicine for an enrollee, when prescribed by a
5 physician in accordance with the provisions of
6 such part, regardless of whether such medicine
7 would otherwise be covered under an applicable
8 formulary or discount arrangement.”.

9 (D) PAYMENTS TO ORGANIZATIONS.—Sec-
10 tion 1853(a)(1)(A) of such Act (42 U.S.C.
11 1395w-23(a)(1)(A)) is amended—

12 (i) by inserting “determined sepa-
13 rately for benefits under parts A and B
14 and under part D (for individuals enrolled
15 under that part)” after “as calculated
16 under subsection (c)”;

17 (ii) by striking “that area, adjusted
18 for such risk factors” and inserting “that
19 area. In the case of payment for benefits
20 under parts A and B, such payment shall
21 be adjusted for such risk factors as”;

22 (iii) by inserting before the last sen-
23 tence the following: “In the case of the
24 payments for benefits under part D, such
25 payment shall initially be adjusted for the

1 risk factors of each enrollee as the Sec-
2 retary determines to be feasible and appro-
3 priate. By 2010, the adjustments would be
4 for the same risk factors applicable for
5 benefits under parts A and B.”.

6 (E) CALCULATION OF ANNUAL MA CAPITA-
7 TION RATES.—Section 1853(c) of such Act (42
8 U.S.C. 1395w–23(c)) is amended—

9 (i) in paragraph (1), in the matter
10 preceding subparagraph (A), by inserting
11 “for benefits under parts A and B” after
12 “capitation rate”;

13 (ii) in paragraph (6)(A), by striking
14 “rate of growth in expenditures under this
15 title” and inserting “rate of growth in ex-
16 penditures for benefits available under
17 parts A and B”; and

18 (iii) by adding at the end the fol-
19 lowing new paragraph:

20 “(8) PAYMENT FOR PRESCRIPTION MEDI-
21 CINES.—The Secretary shall determine a capitation
22 rate for prescription medicines—

23 “(A) dispensed in 2007, which is based on
24 the projected national per capita costs for pre-
25 scription medicine benefits under part D and

1 associated claims processing costs for bene-
2 ficiaries under the original medicare fee-for-
3 service program; and

4 “(B) dispensed in each subsequent year,
5 which shall be equal to the rate for the previous
6 year updated by the Secretary’s estimate of the
7 projected per capita rate of growth in expendi-
8 tures under this title for an individual enrolled
9 under part D.”.

10 (F) LIMITATION ON ENROLLEE LIABIL-
11 ITY.—Section 1854(e) of such Act (42 U.S.C.
12 1395w–24(e)) is amended by adding at the end
13 the following new paragraph:

14 “(5) SPECIAL RULE FOR PROVISION OF PART D
15 BENEFITS.—In no event may a Medicare Advantage
16 organization include as part of a plan for prescrip-
17 tion medicine benefits under part D a requirement
18 that an enrollee pay a deductible, or a coinsurance
19 percentage that exceeds 20 percent.”.

20 (G) REQUIREMENT FOR ADDITIONAL BEN-
21 EFITS.—Section 1854(f)(1) of such Act (42
22 U.S.C. 1395w–24(f)(1)) is amended by adding
23 at the end the following new sentence: “Such
24 determination shall be made separately for ben-

1 efits under parts A and B and for prescription
2 medicine benefits under part D.”.

3 (3) EXCLUSIONS FROM COVERAGE.—

4 (A) APPLICATION TO PART D.—Section
5 1862(a) of the Social Security Act (42 U.S.C.
6 1395y(a)) is amended in the matter preceding
7 paragraph (1) by striking “part A or part B”
8 and inserting “part A, B, or D”.

9 (B) PRESCRIPTION MEDICINES NOT EX-
10 CLUDED FROM COVERAGE IF APPROPRIATELY
11 PRESCRIBED.—Section 1862(a)(1) of such Act
12 (42 U.S.C. 1395y(a)(1)) is amended—

13 (i) in subparagraph (H), by striking
14 “and” at the end;

15 (ii) in subparagraph (I), by striking
16 the semicolon at the end and inserting “,
17 and”; and

18 (iii) by adding at the end the fol-
19 lowing new subparagraph:

20 “(J) in the case of prescription medicines
21 covered under part D, which are not prescribed
22 in accordance with such part;”.

23 (c) EFFECTIVE DATE.—The amendments made by
24 this section shall take effect on January 1, 2007, and the
25 Secretary of Health and Human Services shall administer

1 the Social Security Act in accordance with such amend-
2 ments on and after such date.

3 **SEC. 5. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRE-**
4 **SCRIPTION DRUGS FOR MEDICARE BENE-**
5 **FICIARIES.**

6 (a) PARTICIPATING MANUFACTURERS.—

7 (1) IN GENERAL.—Each participating manufac-
8 turer of a covered outpatient drug shall make avail-
9 able for purchase by each pharmacy such covered
10 outpatient drug in the amount described in para-
11 graph (2) at the price described in paragraph (3).

12 (2) DESCRIPTION OF AMOUNT OF DRUGS.—The
13 amount of a covered outpatient drug that a partici-
14 pating manufacturer shall make available for pur-
15 chase by a pharmacy is an amount equal to the ag-
16 gregate amount of the covered outpatient drug sold
17 or distributed by the pharmacy to medicare bene-
18 ficiaries.

19 (3) DESCRIPTION OF PRICE.—The price at
20 which a participating manufacturer shall make a
21 covered outpatient drug available for purchase by a
22 pharmacy is the price equal to the lowest of the fol-
23 lowing:

1 (A) The lowest price paid for the covered
2 outpatient drug by any agency or department of
3 the United States.

4 (B) The manufacturer's best price for the
5 covered outpatient drug, as defined in section
6 1927(c)(1)(C) of the Social Security Act (42
7 U.S.C. 1396r-8(c)(1)(C)).

8 (C) The lowest price at which the drug is
9 available (as determined by the Secretary)
10 through importation consistent with the provi-
11 sions of section 804 of the Federal Food, Drug,
12 and Cosmetic Act.

13 (b) SPECIAL PROVISION WITH RESPECT TO HOSPICE
14 PROGRAMS.—For purposes of determining the amount of
15 a covered outpatient drug that a participating manufac-
16 turer shall make available for purchase by a pharmacy
17 under subsection (a), there shall be included in the cal-
18 culation of such amount the amount of the covered out-
19 patient drug sold or distributed by a pharmacy to a hos-
20 pice program. In calculating such amount, only amounts
21 of the covered outpatient drug furnished to a medicare
22 beneficiary enrolled in the hospice program shall be in-
23 cluded.

1 (c) ADMINISTRATION.—The Secretary shall issue
2 such regulations as may be necessary to implement this
3 section.

4 (d) REPORTS TO CONGRESS REGARDING EFFECTIVE-
5 NESS OF SECTION.—

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

10 (A) protecting medicare beneficiaries from
11 discriminatory pricing by drug manufacturers;
12 and

13 (B) making prescription drugs available to
14 medicare beneficiaries at substantially reduced
15 prices.

16 (2) CONSULTATION.—In preparing such re-
17 ports, the Secretary shall consult with public health
18 experts, affected industries, organizations rep-
19 resenting consumers and older Americans, and other
20 interested persons.

21 (3) RECOMMENDATIONS.—The Secretary shall
22 include in such reports any recommendations they
23 consider appropriate for changes in this section to
24 further reduce the cost of covered outpatient drugs
25 to medicare beneficiaries.

1 (f) DEFINITIONS.—For purposes of this section:

2 (1) PARTICIPATING MANUFACTURER.—The
3 term “participating manufacturer” means any man-
4 ufacturer of drugs or biologicals that, on or after the
5 date of the enactment of this Act, enters into a con-
6 tract or agreement with the United States for the
7 sale or distribution of covered outpatient drugs to
8 the United States.

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

13 (3) MEDICARE BENEFICIARY.—The term
14 “medicare beneficiary” means an individual entitled
15 to benefits under part A of title XVIII of the Social
16 Security Act or enrolled under part B of such title,
17 or both.

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

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

24 (f) EFFECTIVE DATE.—This section shall take effect
25 on January 1, 2007, and the Secretary shall implement

1 this section in a manner consistent with the obligations
2 of the United States.

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

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

8 (b) IMPORTATION OF PRESCRIPTION DRUGS; WAIVER
9 OF CERTAIN IMPORT RESTRICTIONS.—

10 (1) IN GENERAL.—Chapter VIII of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et
12 seq.), as amended by section 3, is further amended
13 by inserting after section 803 the following:

14 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
15 **PRESCRIPTION DRUGS.**

16 **“(a) IMPORTATION OF PRESCRIPTION DRUGS.—**

17 **“(1) IN GENERAL.—**In the case of qualifying
18 drugs imported or offered for import into the United
19 States from registered exporters or by registered im-
20 porters—

21 **“(A)** the limitation on importation that is
22 established in section 801(d)(1) is waived; and

23 **“(B)** the standards referred to in section
24 801(a) regarding admission of the drugs are
25 subject to subsection (g) of this section (includ-

1 ing with respect to qualifying drugs to which
2 section 801(d)(1) does not apply).

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

5 “(A) the drug is imported by a pharmacy,
6 group of pharmacies, or a wholesaler that is a
7 registered importer; or

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

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

16 “(A) by a registered importer; or

17 “(B) from a registered exporter to an indi-
18 vidual.

19 “(4) DEFINITIONS.—

20 “(A) REGISTERED EXPORTER; REG-
21 ISTERED IMPORTER.—For purposes of this sec-
22 tion:

23 “(i) The term ‘registered exporter’
24 means an exporter for which a registration

1 under subsection (b) has been approved
2 and is in effect.

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

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

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

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

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

23 “(ii) with respect to the qualifying
24 drug, is manufactured by or for the person
25 that manufactures the qualifying drug;

1 “(iii) is approved under section
2 505(e); and

3 “(iv) is not—

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

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

12 “(aa) a therapeutic DNA
13 plasmid product;

14 “(bb) a therapeutic synthetic
15 peptide product;

16 “(cc) a monoclonal antibody
17 product for in vivo use; and

18 “(dd) a therapeutic recom-
19 binant DNA-derived product;

20 “(III) an infused drug, including
21 a peritoneal dialysis solution;

22 “(IV) an injected drug;

23 “(V) a drug that is inhaled dur-
24 ing surgery; or

1 “(VI) a drug that is the listed
2 drug referred to in 2 or more abbrevi-
3 ated new drug applications under
4 which the drug is commercially mar-
5 keted.

6 “(D) OTHER DEFINITIONS.—For purposes
7 of this section:

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

16 “(II) The Secretary shall designate a
17 permitted country under subparagraph (E)
18 (other than Canada) as a country from
19 which an exporter may export a drug to in-
20 dividuals in the United States if the Sec-
21 retary determines that—

22 “(aa) the country has statutory
23 or regulatory standards that are
24 equivalent to the standards in the

1 United States and Canada with re-
2 spect to—

3 “(AA) the training of phar-
4 macists;

5 “(BB) the practice of phar-
6 macy; and

7 “(CC) the protection of the
8 privacy of personal medical infor-
9 mation; and

10 “(bb) the importation of drugs to
11 individuals in the United States from
12 the country will not adversely affect
13 public health.

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

21 “(iii) The term ‘pharmacist’ means a
22 person licensed by a State to practice
23 pharmacy, including the dispensing and
24 selling of prescription drugs.

1 “(iv) The term ‘pharmacy’ means a
2 person that—

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

6 “(II) employs 1 or more phar-
7 macists.

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

10 “(vi) The term ‘wholesaler’—

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

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

16 “(E) PERMITTED COUNTRY.—The term ‘permitted
17 country’ means—

18 “(i) Australia;

19 “(ii) Canada;

20 “(iii) a member country of the European
21 Union, but does not include a member country with
22 respect to which—

23 “(I) the country’s Annex to the Treaty of
24 Accession to the European Union 2003 includes
25 a transitional measure for the regulation of

1 human pharmaceutical products that has not
2 expired; or

3 “(II) the Secretary determines that the re-
4 quirements described in subclauses (I) and (II)
5 of clause (vii) will not be met by the date on
6 which such transitional measure for the regula-
7 tion of human pharmaceutical products expires;

8 “(iv) Japan;

9 “(v) New Zealand;

10 “(vi) Switzerland; and

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

13 “(I) The country has statutory or regu-
14 latory requirements—

15 “(aa) that require the review of drugs
16 for safety and effectiveness by an entity of
17 the government of the country;

18 “(bb) that authorize the approval of
19 only those drugs that have been deter-
20 mined to be safe and effective by experts
21 employed by or acting on behalf of such
22 entity and qualified by scientific training
23 and experience to evaluate the safety and
24 effectiveness of drugs on the basis of ade-
25 quate and well-controlled investigations, in-

1 including clinical investigations, conducted
2 by experts qualified by scientific training
3 and experience to evaluate the safety and
4 effectiveness of drugs;

5 “(cc) that require the methods used
6 in, and the facilities and controls used for
7 the manufacture, processing, and packing
8 of drugs in the country to be adequate to
9 preserve their identity, quality, purity, and
10 strength;

11 “(dd) for the reporting of adverse re-
12 actions to drugs and procedures to with-
13 draw approval and remove drugs found not
14 to be safe or effective; and

15 “(ee) that require the labeling and
16 promotion of drugs to be in accordance
17 with the approval of the drug.

18 “(II) The valid marketing authorization
19 system in the country is equivalent to the sys-
20 tems in the countries described in clauses (i)
21 through (vi).

22 “(III) The importation of drugs to the
23 United States from the country will not ad-
24 versely affect public health.

1 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
2 ERS.—

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

8 “(A)(i) In the case of an exporter, the
9 name of the exporter and an identification of all
10 places of business of the exporter that relate to
11 qualifying drugs, including each warehouse or
12 other facility owned or controlled by, or oper-
13 ated for, the exporter.

14 “(ii) In the case of an importer, the name
15 of the importer and an identification of the
16 places of business of the importer at which the
17 importer initially receives a qualifying drug
18 after importation (which shall not exceed 3
19 places of business except by permission of the
20 Secretary).

21 “(B) Such information as the Secretary
22 determines to be necessary to demonstrate that
23 the registrant is in compliance with registration
24 conditions under—

1 “(i) in the case of an importer, sub-
2 sections (c), (d), (e), (g), and (j) (relating
3 to the sources of imported qualifying
4 drugs; the inspection of facilities of the im-
5 porter; the payment of fees; compliance
6 with the standards referred to in section
7 801(a); and maintenance of records and
8 samples); or

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

20 “(C) An agreement by the registrant that
21 the registrant will not under subsection (a) im-
22 port or export any drug that is not a qualifying
23 drug.

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

1 “(i) notify the Secretary of a recall or
2 withdrawal of a qualifying drug distributed
3 in a permitted country that the registrant
4 has exported or imported, or intends to ex-
5 port or import, to the United States under
6 subsection (a);

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

9 “(iii) cease, or not begin, the expor-
10 tation or importation of such drug unless
11 the Secretary has notified the registrant
12 that exportation or importation of such
13 drug may proceed.

14 “(E) An agreement by the registrant to
15 ensure and monitor compliance with each reg-
16 istration condition, to promptly correct any
17 noncompliance with such a condition, and to
18 promptly report to the Secretary any such non-
19 compliance.

20 “(F) A plan describing the manner in
21 which the registrant will comply with the agree-
22 ment under subparagraph (E).

23 “(G) An agreement by the registrant to
24 enforce a contract under subsection (c)(3)(B)
25 against a party in the chain of custody of a

1 qualifying drug with respect to the authority of
2 the Secretary under clauses (ii) and (iii) of that
3 subsection.

4 “(H) An agreement by the registrant to
5 notify the Secretary not more than 30 days be-
6 fore the registrant intends to make the change,
7 of—

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

11 “(ii) any change that the registrant
12 intends to make in the compliance plan
13 under subparagraph (F).

14 “(I) In the case of an exporter—

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

20 “(ii) An agreement to post a bond,
21 payable to the Treasury of the United
22 States that is equal in value to the lesser
23 of—

24 “(I) the value of drugs exported
25 by the exporter to the United States

1 in a typical 4-week period over the
2 course of a year under this section; or

3 “(II) \$1,000,000;

4 “(iii) An agreement by the exporter to
5 comply with applicable provisions of Cana-
6 dian law, or the law of the permitted coun-
7 try designated under subsection
8 (a)(4)(D)(i)(II) in which the exporter is lo-
9 cated, that protect the privacy of personal
10 information with respect to each individual
11 importing a prescription drug from the ex-
12 porter under subsection (a)(2)(B).

13 “(iv) An agreement by the exporter to
14 report to the Secretary—

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

21 “(II) not later than January 1 of
22 each fiscal year, the total price and
23 the total volume of drugs exported to
24 the United States by the exporter dur-
25 ing the previous fiscal year.

1 “(J) In the case of an importer, an agree-
2 ment by the importer to report to the Sec-
3 retary—

4 “(i) not later than August 1 of each
5 fiscal year, the total price and the total
6 volume of drugs imported to the United
7 States by the importer during the 6-month
8 period from January 1 through June 30 of
9 that fiscal year; and

10 “(ii) not later than January 1 of each
11 fiscal year, the total price and the total
12 volume of drugs imported to the United
13 States by the importer during the previous
14 fiscal year.

15 “(K) Such other provisions as the Sec-
16 retary may require by regulation to protect the
17 public health while permitting—

18 “(i) the importation by pharmacies,
19 groups of pharmacies, and wholesalers as
20 registered importers of qualifying drugs
21 under subsection (a); and

22 “(ii) importation by individuals of
23 qualifying drugs under subsection (a).

24 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
25 TION.—

1 “(A) IN GENERAL.—Not later than 90
2 days after the date on which a registrant sub-
3 mits to the Secretary a registration under para-
4 graph (1), the Secretary shall notify the reg-
5 istrant whether the registration is approved or
6 is disapproved. The Secretary shall disapprove
7 a registration if there is reason to believe that
8 the registrant is not in compliance with one or
9 more registration conditions, and shall notify
10 the registrant of such reason. In the case of a
11 disapproved registration, the Secretary shall
12 subsequently notify the registrant that the reg-
13 istration is approved if the Secretary deter-
14 mines that the registrant is in compliance with
15 such conditions.

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

24 “(3) PUBLICATION OF CONTACT INFORMATION
25 FOR REGISTERED EXPORTERS.—Through the Inter-

1 net website of the Food and Drug Administration
2 and a toll-free telephone number, the Secretary shall
3 make readily available to the public a list of reg-
4 istered exporters, including contact information for
5 the exporters. Promptly after the approval of a reg-
6 istration submitted under paragraph (1), the Sec-
7 retary shall update the Internet website and the in-
8 formation provided through the toll-free telephone
9 number accordingly.

10 “(4) SUSPENSION AND TERMINATION.—

11 “(A) SUSPENSION.—With respect to the
12 effectiveness of a registration submitted under
13 paragraph (1):

14 “(i) Subject to clause (ii), the Sec-
15 retary may suspend the registration if the
16 Secretary determines, after notice and op-
17 portunity for a hearing, that the registrant
18 has failed to maintain substantial compli-
19 ance with a registration condition.

20 “(ii) If the Secretary determines that,
21 under color of the registration, the ex-
22 porter has exported a drug or the importer
23 has imported a drug that is not a quali-
24 fying drug, or a drug that does not comply
25 with subsection (g)(2)(A) or (g)(4), or has

1 exported a qualifying drug to an individual
2 in violation of subsection (i)(2)(F), the
3 Secretary shall immediately suspend the
4 registration. A suspension under the pre-
5 ceding sentence is not subject to the provi-
6 sion by the Secretary of prior notice, and
7 the Secretary shall provide to the reg-
8 istrant an opportunity for a hearing not
9 later than 10 days after the date on which
10 the registration is suspended.

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

17 “(B) TERMINATION.—The Secretary, after
18 notice and opportunity for a hearing, may ter-
19 minate the registration under paragraph (1) of
20 a registrant if the Secretary determines that
21 the registrant has engaged in a pattern or prac-
22 tice of violating 1 or more registration condi-
23 tions, or if on 1 or more occasions the Secretary
24 has under subparagraph (A)(ii) suspended the
25 registration of the registrant. The Secretary

1 may make the termination permanent, or for a
2 fixed period of not less than 1 year. During the
3 period in which the registration is terminated,
4 any registration submitted under paragraph (1)
5 by the registrant, or a person that is a partner
6 in the export or import enterprise, or a prin-
7 cipal officer in such enterprise, and any reg-
8 istration prepared with the assistance of the
9 registrant or such a person, has no legal effect
10 under this section.

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

17 “(A) exported a drug to the United States
18 that is not a qualifying drug or that is not in
19 compliance with subsection (g)(2)(A), (g)(4), or
20 (i); or

21 “(B) failed to permit the Secretary to con-
22 duct an inspection described under subsection
23 (d).

24 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
25 tion condition is that the exporter or importer involved

1 agrees that a qualifying drug will under subsection (a) be
2 exported or imported into the United States only if there
3 is compliance with the following:

4 “(1) The drug was manufactured in an estab-
5 lishment—

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

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

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

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

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

3 “(A) directly from the establishment; or

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

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

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

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

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

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

11 “(B) The foreign country from which the ex-
12 porter will export the drug is the permitted country
13 in which the exporter is located.

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

18 “(6) The exporter or importer retains a sample
19 of each lot of the drug sufficient for testing by the
20 Secretary.

21 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
22 MENTS.—

23 “(1) INSPECTION OF FACILITIES.—A registra-
24 tion condition is that, for the purpose of assisting
25 the Secretary in determining whether the exporter

1 involved is in compliance with all other registration
2 conditions—

3 “(A) the exporter agrees to permit the Sec-
4 retary—

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

11 “(ii) to have access, including on a
12 day-to-day basis, to—

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

16 “(II) samples of such drugs;

17 “(iii) to carry out the duties described
18 in paragraph (3); and

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

23 “(B) the Secretary has assigned 1 or more
24 employees of the Secretary to carry out the
25 functions described in this subsection for the

1 Secretary randomly, but not less than 12 times
2 annually, on the premises of places of busi-
3 nesses referred to in subparagraph (A)(i), and
4 such an assignment remains in effect on a con-
5 tinuous basis.

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

14 “(A) be designed to prevent affixation of
15 the markings to any shipping container that is
16 not authorized to bear the markings; and

17 “(B) include anticounterfeiting or track-
18 and-trace technologies, taking into account the
19 economic and technical feasibility of those tech-
20 nologies.

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

24 “(A) Inspecting, randomly, but not less
25 than 12 times annually, the places of business

1 of the exporter at which qualifying drugs are
2 stored and from which qualifying drugs are
3 shipped.

4 “(B) During the inspections under sub-
5 paragraph (A), verifying the chain of custody of
6 a statistically significant sample of qualifying
7 drugs from the establishment in which the drug
8 was manufactured to the exporter, which shall
9 be accomplished or supplemented by the use of
10 anticounterfeiting or track-and-trace tech-
11 nologies, taking into account the economic and
12 technical feasibility of those technologies, except
13 that a drug that lacks such technologies from
14 the point of manufacture shall not for that rea-
15 son be excluded from importation by an ex-
16 porter.

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

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

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

7 “(F) Determining whether the exporter is
8 in compliance with all other registration condi-
9 tions.

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

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

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

23 “(C) the identity of the drug, including the
24 established name of the drug, the quantity of

1 the drug, and the lot number assigned by the
2 manufacturer;

3 “(D) the identity of the manufacturer of
4 the drug, including the identity of the establish-
5 ment at which the drug was manufactured;

6 “(E) the country from which the drug is
7 shipped;

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

10 “(G) anticipated arrival information, in-
11 cluding the port of arrival and crossing location
12 within that port, and the date and time;

13 “(H) a summary of the chain of custody of
14 the drug from the establishment in which the
15 drug was manufactured to the importer;

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

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

22 “(5) MARKING OF COMPLIANT SHIPMENTS.—A
23 registration condition is that the importer involved
24 agrees, before wholesale distribution (as defined in
25 section 503(e)) of a qualifying drug that has been

1 imported under subsection (a), to affix to each con-
2 tainer of such drug such markings or other tech-
3 nology as the Secretary determines necessary to
4 identify the shipment as being in compliance with all
5 registration conditions, except that the markings or
6 other technology shall not be required on a drug
7 that bears comparable, compatible markings or tech-
8 nology from the manufacturer of the drug. Markings
9 or other technology under the preceding sentence
10 shall—

11 “(A) be designed to prevent affixation of
12 the markings or other technology to any con-
13 tainer that is not authorized to bear the mark-
14 ings; and

15 “(B) shall include anticounterfeiting or
16 track-and-trace technologies, taking into ac-
17 count the economic and technical feasibility of
18 such technologies.

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

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

1 “(B) During the inspections under sub-
2 paragraph (A), verifying the chain of custody of
3 a statistically significant sample of qualifying
4 drugs from the establishment in which the drug
5 was manufactured to the importer, which shall
6 be accomplished or supplemented by the use of
7 anticounterfeiting or track-and-trace tech-
8 nologies, taking into account the economic and
9 technical feasibility of those technologies, except
10 that a drug that lacks such technologies from
11 the point of manufacture shall not for that rea-
12 son be excluded from importation by an im-
13 porter.

14 “(C) Reviewing notices under paragraph
15 (4).

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

20 “(E) Determining whether the importer is
21 in compliance with all other registration condi-
22 tions.

23 “(e) IMPORTER FEES.—

24 “(1) REGISTRATION FEE.—A registration con-
25 dition is that the importer involved pays to the Sec-

1 retary a fee of \$10,000 due on the date on which
2 the importer first submits the registration to the
3 Secretary under subsection (b).

4 “(2) INSPECTION FEE.—A registration condi-
5 tion is that the importer involved pays a fee to the
6 Secretary in accordance with this subsection. Such
7 fee shall be paid not later than October 1 and April
8 1 of each fiscal year in the amount provided for
9 under paragraph (3).

10 “(3) AMOUNT OF INSPECTION FEE.—

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

22 “(i) inspecting the facilities of reg-
23 istered importers, and of other entities in
24 the chain of custody of a qualifying drug
25 as necessary, under subsection (d)(6);

1 “(ii) developing, implementing, and
2 operating under such subsection an elec-
3 tronic system for submission and review of
4 the notices required under subsection
5 (d)(4) with respect to shipments of quali-
6 fying drugs under subsection (a) to assess
7 compliance with all registration conditions
8 when such shipments are offered for im-
9 port into the United States; and

10 “(iii) inspecting such shipments as
11 necessary, when offered for import into the
12 United States to determine if such a ship-
13 ment should be refused admission under
14 subsection (g)(5).

15 “(B) LIMITATION.—Subject to subpara-
16 graph (C), the aggregate total of fees collected
17 under paragraph (2) for a fiscal year shall not
18 exceed 1 percent of the total price of qualifying
19 drugs imported during that fiscal year into the
20 United States by registered importers under
21 subsection (a).

22 “(C) TOTAL PRICE OF DRUGS.—

23 “(i) ESTIMATE.—For the purposes of
24 complying with the limitation described in
25 subparagraph (B) when establishing under

1 subparagraph (A) the aggregate total of
2 fees to be collected under paragraph (2)
3 for a fiscal year, the Secretary shall esti-
4 mate the total price of qualifying drugs im-
5 ported into the United States by registered
6 importers during that fiscal year by adding
7 the total price of qualifying drugs imported
8 by each registered importer during the 6-
9 month period from January 1 through
10 June 30 of the previous fiscal year, as re-
11 ported to the Secretary by each registered
12 importer under subsection (b)(1)(J).

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

1 “(iii) ADJUSTMENT.—If the total
2 price of qualifying drugs imported into the
3 United States by registered importers dur-
4 ing a fiscal year as calculated under clause
5 (ii) is less than the aggregate total of fees
6 collected under paragraph (2) for that fis-
7 cal year, the Secretary shall provide for a
8 pro-rata reduction in the fee due from each
9 registered importer on April 1 of the sub-
10 sequent fiscal year so that the limitation
11 described in subparagraph (B) is observed.

12 “(D) INDIVIDUAL IMPORTER FEE.—Sub-
13 ject to the limitation described in subparagraph
14 (B), the fee under paragraph (2) to be paid on
15 October 1 and April 1 by an importer shall be
16 an amount that is proportional to a reasonable
17 estimate by the Secretary of the semiannual
18 share of the importer of the volume of quali-
19 fying drugs imported by importers under sub-
20 section (a).

21 “(4) USE OF FEES.—

22 “(A) IN GENERAL.—Subject to appropria-
23 tions Acts, fees collected by the Secretary under
24 paragraphs (1) and (2) shall be credited to the
25 appropriation account for salaries and expenses

1 of the Food and Drug Administration until ex-
2 pended (without fiscal year limitation), and the
3 Secretary may, in consultation with the Sec-
4 retary of Homeland Security and the Secretary
5 of the Treasury, transfer some proportion of
6 such fees to the appropriation account for sala-
7 ries and expenses of the Bureau of Customs
8 and Border Protection until expended (without
9 fiscal year limitation).

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

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

23 “(f) EXPORTER FEES.—

24 “(1) REGISTRATION FEE.—A registration con-
25 dition is that the exporter involved pays to the Sec-

1 retary a fee of \$10,000 due on the date on which
2 the exporter first submits that registration to the
3 Secretary under subsection (b).

4 “(2) INSPECTION FEE.—A registration condi-
5 tion is that the exporter involved pays a fee to the
6 Secretary in accordance with this subsection. Such
7 fee shall be paid not later than October 1 and April
8 1 of each fiscal year in the amount provided for
9 under paragraph (3).

10 “(3) AMOUNT OF INSPECTION FEE.—

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

22 “(i) inspecting the facilities of reg-
23 istered exporters, and of other entities in
24 the chain of custody of a qualifying drug
25 as necessary, under subsection (d)(3);

1 “(ii) developing, implementing, and
2 operating under such subsection a system
3 to screen marks on shipments of qualifying
4 drugs under subsection (a) that indicate
5 compliance with all registration conditions,
6 when such shipments are offered for im-
7 port into the United States; and

8 “(iii) screening such markings, and
9 inspecting such shipments as necessary,
10 when offered for import into the United
11 States to determine if such a shipment
12 should be refused admission under sub-
13 section (g)(5).

14 “(B) LIMITATION.—Subject to subpara-
15 graph (C), the aggregate total of fees collected
16 under paragraph (2) for a fiscal year shall not
17 exceed 1 percent of the total price of qualifying
18 drugs imported during that fiscal year into the
19 United States by registered exporters under
20 subsection (a).

21 “(C) TOTAL PRICE OF DRUGS.—

22 “(i) ESTIMATE.—For the purposes of
23 complying with the limitation described in
24 subparagraph (B) when establishing under
25 subparagraph (A) the aggregate total of

1 fees to be collected under paragraph (2)
2 for a fiscal year, the Secretary shall esti-
3 mate the total price of qualifying drugs im-
4 ported into the United States by registered
5 exporters during that fiscal year by adding
6 the total price of qualifying drugs exported
7 by each registered exporter during the 6-
8 month period from January 1 through
9 June 30 of the previous fiscal year, as re-
10 ported to the Secretary by each registered
11 exporter under subsection (b)(1)(I)(iv).

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

24 “(iii) ADJUSTMENT.—If the total
25 price of qualifying drugs imported into the

1 United States by registered exporters dur-
2 ing a fiscal year as calculated under clause
3 (ii) is less than the aggregate total of fees
4 collected under paragraph (2) for that fis-
5 cal year, the Secretary shall provide for a
6 pro-rata reduction in the fee due from each
7 registered exporter on April 1 of the subse-
8 quent fiscal year so that the limitation de-
9 scribed in subparagraph (B) is observed.

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

19 “(4) USE OF FEES.—

20 “(A) IN GENERAL.—Subject to appropria-
21 tions Acts, fees collected by the Secretary under
22 paragraphs (1) and (2) shall be credited to the
23 appropriation account for salaries and expenses
24 of the Food and Drug Administration until ex-
25 pended (without fiscal year limitation), and the

1 Secretary may, in consultation with the Sec-
2 retary of Homeland Security and the Secretary
3 of the Treasury, transfer some proportion of
4 such fees to the appropriation account for sala-
5 ries and expenses of the Bureau of Customs
6 and Border Protection until expended (without
7 fiscal year limitation).

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

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

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

22 “(1) IN GENERAL.—A registration condition is
23 that each qualifying drug exported under subsection
24 (a) by the registered exporter involved or imported
25 under subsection (a) by the registered importer in-

1 volved is in compliance with the standards referred
2 to in section 801(a) regarding admission of the drug
3 into the United States, subject to paragraphs (2),
4 (3), and (4).

5 “(2) SECTION 505; APPROVAL STATUS.—

6 “(A) IN GENERAL.—A qualifying drug that
7 is imported or offered for import under sub-
8 section (a) shall comply with the conditions es-
9 tablished in the approved application under sec-
10 tion 505(b) for the U.S. label drug as described
11 under this subsection.

12 “(B) NOTICE BY MANUFACTURER; GEN-
13 ERAL PROVISIONS.—

14 “(i) IN GENERAL.—The person that
15 manufactures a qualifying drug that is, or
16 will be, introduced for commercial distribu-
17 tion in a permitted country shall in accord-
18 ance with this paragraph submit to the
19 Secretary a notice that—

20 “(I) includes each difference in
21 the qualifying drug from a condition
22 established in the approved applica-
23 tion for the U.S. label drug beyond—

24 “(aa) the variations provided
25 for in the application; and

1 “(bb) any difference in label-
2 ing (except ingredient labeling);

3 or

4 “(II) states that there is no dif-
5 ference in the qualifying drug from a
6 condition established in the approved
7 application for the U.S. label drug be-
8 yond—

9 “(aa) the variations provided
10 for in the application; and

11 “(bb) any difference in label-
12 ing (except ingredient labeling).

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

1 “(I) The date on which the quali-
2 fying drug with such difference was,
3 or will be, introduced for commercial
4 distribution in the permitted country.

5 “(II) Information demonstrating
6 that the person submitting the notice
7 has also notified the government of
8 the permitted country in writing that
9 the person is submitting to the Sec-
10 retary a notice under clause (i)(I),
11 which notice describes the difference
12 in the qualifying drug from a condi-
13 tion established in the approved appli-
14 cation for the U.S. label drug.

15 “(III) The information that the
16 person submitted or will submit to the
17 government of the permitted country
18 for purposes of obtaining approval for
19 commercial distribution of the drug in
20 the country which, if in a language
21 other than English, shall be accom-
22 panied by an English translation
23 verified to be complete and accurate,
24 with the name, address, and a brief

1 statement of the qualifications of the
2 person that made the translation.

3 “(iii) CERTIFICATIONS.—The chief ex-
4 ecutive officer and the chief medical officer
5 of the manufacturer involved shall each
6 certify in the notice under clause (i) that—

7 “(I) the information provided in
8 the notice is complete and true; and

9 “(II) a copy of the notice has
10 been provided to the Federal Trade
11 Commission and to the State attor-
12 neys general.

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

1 of paying the costs of reviewing notices
2 submitted under clause (i).

3 “(v) TIMING OF SUBMISSION OF NO-
4 TICES.—

5 “(I) PRIOR APPROVAL NO-
6 TICES.—A notice under clause (i) to
7 which subparagraph (C) applies shall
8 be submitted to the Secretary not
9 later than 120 days before the quali-
10 fying drug with the difference is intro-
11 duced for commercial distribution in a
12 permitted country, unless the country
13 requires that distribution of the quali-
14 fying drug with the difference begin
15 less than 120 days after the country
16 requires the difference.

17 “(II) OTHER APPROVAL NO-
18 TICES.—A notice under clause (i) to
19 which subparagraph (D) applies shall
20 be submitted to the Secretary not
21 later than the day on which the quali-
22 fying drug with the difference is intro-
23 duced for commercial distribution in a
24 permitted country.

1 “(III) OTHER NOTICES.—A no-
2 tice under clause (i) to which subpara-
3 graph (E) applies shall be submitted
4 to the Secretary on the date that the
5 qualifying drug is first introduced for
6 commercial distribution in a permitted
7 country and annually thereafter.

8 “(vi) REVIEW BY SECRETARY.—

9 “(I) IN GENERAL.—In this para-
10 graph, the difference in a qualifying
11 drug that is submitted in a notice
12 under clause (i) from the U.S. label
13 drug shall be treated by the Secretary
14 as if it were a manufacturing change
15 to the U.S. label drug under section
16 506A.

17 “(II) STANDARD OF REVIEW.—
18 Except as provided in subclause (III),
19 the Secretary shall review and approve
20 or disapprove the difference in a no-
21 tice submitted under clause (i), if re-
22 quired under section 506A, using the
23 safe and effective standard for ap-
24 proving or disapproving a manufac-
25 turing change under section 506A.

1 “(III) BIOEQUIVALENCE.—If the
2 Secretary would approve the dif-
3 ference in a notice submitted under
4 clause (i) using the safe and effective
5 standard under section 506A and if
6 the Secretary determines that the
7 qualifying drug is not bioequivalent to
8 the U.S. label drug, the Secretary
9 may—

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

21 “(bb) decline to approve the
22 difference if the Secretary deter-
23 mines that the availability of
24 both the qualifying drug and the

1 U.S. label drug would pose a
2 threat to the public health.

3 “(IV) REVIEW BY THE SEC-
4 RETARY.—The Secretary shall review
5 and approve or disapprove the dif-
6 ference in a notice submitted under
7 clause (i), if required under section
8 506A, not later than 120 days after
9 the date on which the notice is sub-
10 mitted.

11 “(V) ESTABLISHMENT INSPEC-
12 TION.—If review of such difference
13 would require an inspection of the es-
14 tablishment in which the qualifying
15 drug is manufactured—

16 “(aa) such inspection by the
17 Secretary shall be authorized;
18 and

19 “(bb) the Secretary may rely
20 on a satisfactory report of a good
21 manufacturing practice inspec-
22 tion of the establishment from a
23 permitted country whose regu-
24 latory system the Secretary rec-
25 ognizes as equivalent under a

1 mutual recognition agreement, as
2 provided under section 510(i)(3),
3 section 803, or part 26 of title
4 21, Code of Federal Regulations
5 (or any corresponding successor
6 rule or regulation).

7 “(vii) PUBLICATION OF INFORMATION
8 ON NOTICES.—

9 “(I) IN GENERAL.—Through the
10 Internet website of the Food and
11 Drug Administration and a toll-free
12 telephone number, the Secretary shall
13 readily make available to the public a
14 list of notices submitted under clause
15 (i).

16 “(II) CONTENTS.—The list under
17 subclause (I) shall include the date on
18 which a notice is submitted and
19 whether—

20 “(aa) a notice is under re-
21 view;

22 “(bb) the Secretary has or-
23 dered that importation of the
24 qualifying drug from a permitted
25 country cease; or

1 “(cc) the importation of the
2 drug is permitted under sub-
3 section (a).

4 “(III) UPDATE.—The Secretary
5 shall promptly update the Internet
6 website with any changes to the list.

7 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
8 ING PRIOR APPROVAL.—In the case of a notice
9 under subparagraph (B)(i) that includes a dif-
10 ference that would, under section 506A(c) or
11 (d)(3)(B)(i), require the approval of a supple-
12 mental application before the difference could
13 be made to the U.S. label drug the following
14 shall occur:

15 “(i) Promptly after the notice is sub-
16 mitted, the Secretary shall notify reg-
17 istered exporters, registered importers, the
18 Federal Trade Commission, and the State
19 attorneys general that the notice has been
20 submitted with respect to the qualifying
21 drug involved.

22 “(ii) If the Secretary has not made a
23 determination whether such a supple-
24 mental application regarding the U.S. label
25 drug would be approved or disapproved by

1 the date on which the qualifying drug in-
2 volved is to be introduced for commercial
3 distribution in a permitted country, the
4 Secretary shall—

5 “(I) order that the importation of
6 the qualifying drug involved from the
7 permitted country not begin until the
8 Secretary completes review of the no-
9 tice; and

10 “(II) promptly notify registered
11 exporters, registered importers, the
12 Federal Trade Commission, and the
13 State attorneys general of the order.

14 “(iii) If the Secretary determines that
15 such a supplemental application regarding
16 the U.S. label drug would not be approved,
17 the Secretary shall—

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country cease, or provide
21 that an order under clause (ii), if any,
22 remains in effect;

23 “(II) notify the permitted coun-
24 try that approved the qualifying drug

1 for commercial distribution of the de-
2 termination; and

3 “(III) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 State attorneys general of the deter-
7 mination.

8 “(iv) If the Secretary determines that
9 such a supplemental application regarding
10 the U.S. label drug would be approved, the
11 Secretary shall—

12 “(I) vacate the order under
13 clause (ii), if any;

14 “(II) consider the difference to
15 be a variation provided for in the ap-
16 proved application for the U.S. label
17 drug;

18 “(III) permit importation of the
19 qualifying drug under subsection (a);
20 and

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

1 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
2 QUIRING PRIOR APPROVAL.—In the case of a
3 notice under subparagraph (B)(i) that includes
4 a difference that would, under section
5 506A(d)(3)(B)(ii), not require the approval of a
6 supplemental application before the difference
7 could be made to the U.S. label drug the fol-
8 lowing shall occur:

9 “(i) During the period in which the
10 notice is being reviewed by the Secretary,
11 the authority under this subsection to im-
12 port the qualifying drug involved continues
13 in effect.

14 “(ii) If the Secretary determines that
15 such a supplemental application regarding
16 the U.S. label drug would not be approved,
17 the Secretary shall—

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country cease;

21 “(II) notify the permitted coun-
22 try that approved the qualifying drug
23 for commercial distribution of the de-
24 termination; and

1 “(III) promptly notify registered
2 exporters, registered importers, the
3 Federal Trade Commission, and the
4 State attorneys general of the deter-
5 mination.

6 “(iii) If the Secretary determines that
7 such a supplemental application regarding
8 the U.S. label drug would be approved, the
9 difference shall be considered to be a vari-
10 ation provided for in the approved applica-
11 tion for the U.S. label drug.

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

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

23 “(ii) may not order that the importa-
24 tion of the qualifying drug involved cease;
25 and

1 “(iii) shall promptly notify registered
2 exporters and registered importers.

3 “(F) DIFFERENCES IN ACTIVE INGRE-
4 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
5 FORM, OR STRENGTH.—

6 “(i) IN GENERAL.—A person who
7 manufactures a drug approved under sec-
8 tion 505(b) shall submit an application
9 under section 505(b) for approval of an-
10 other drug that is manufactured for dis-
11 tribution in a permitted country by or for
12 the person that manufactures the drug ap-
13 proved under section 505(b) if—

14 “(I) there is no qualifying drug
15 in commercial distribution in per-
16 mitted countries whose combined pop-
17 ulation represents at least 50 percent
18 of the total population of all permitted
19 countries with the same active ingre-
20 dient or ingredients, route of adminis-
21 tration, dosage form, and strength as
22 the drug approved under section
23 505(b); and

24 “(II) each active ingredient of
25 the other drug is related to an active

1 ingredient of the drug approved under
2 section 505(b), as defined in clause
3 (v).

4 “(ii) APPLICATION UNDER SECTION
5 505(b).—The application under section
6 505(b) required under clause (i) shall—

7 “(I) request approval of the other
8 drug for the indication or indications
9 for which the drug approved under
10 section 505(b) is labeled;

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

23 “(III) include a right of reference
24 to the application for the drug ap-
25 proved under section 505(b); and

1 “(IV) include such additional in-
2 formation as the Secretary may re-
3 quire.

4 “(iii) TIMING OF SUBMISSION OF AP-
5 PLICATION.—An application under section
6 505(b) required under clause (i) shall be
7 submitted to the Secretary not later than
8 the day on which the information referred
9 to in clause (ii)(II) is submitted to the gov-
10 ernment of the permitted country.

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

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

22 “(I) the same; or

23 “(II) different salts, esters, or
24 complexes of the same moiety.

25 “(3) SECTION 502; LABELING.—

1 “(A) IMPORTATION BY REGISTERED IM-
2 PORTER.—

3 “(i) IN GENERAL.—In the case of a
4 qualifying drug that is imported or offered
5 for import by a registered importer, such
6 drug shall be considered to be in compli-
7 ance with section 502 and the labeling re-
8 quirements under the approved application
9 for the U.S. label drug if the qualifying
10 drug bears—

11 “(I) a copy of the labeling ap-
12 proved for the U.S. label drug under
13 section 505, without regard to wheth-
14 er the copy bears any trademark in-
15 volved;

16 “(II) the name of the manufac-
17 turer and location of the manufac-
18 turer;

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

21 “(IV) the name, location, and
22 registration number of the importer;
23 and

1 “(V) the National Drug Code
2 number assigned to the qualifying
3 drug by the Secretary.

4 “(ii) REQUEST FOR COPY OF THE LA-
5 BELING.—The Secretary shall provide such
6 copy to the registered importer involved,
7 upon request of the importer.

8 “(iii) REQUESTED LABELING.—The
9 labeling provided by the Secretary under
10 clause (ii) shall—

11 “(I) include the established
12 name, as defined in section 502(e)(3),
13 for each active ingredient in the quali-
14 fying drug;

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

18 “(III) if required under para-
19 graph (2)(B)(vi)(III), a prominent ad-
20 visory that the qualifying drug is safe
21 and effective but not bioequivalent to
22 the U.S. label drug; and

23 “(IV) if the inactive ingredients
24 of the qualifying drug are different

1 from the inactive ingredients for the
2 U.S. label drug, include—

3 “(aa) a prominent notice
4 that the ingredients of the quali-
5 fying drug differ from the ingre-
6 dients of the U.S. label drug and
7 that the qualifying drug must be
8 dispensed with an advisory to
9 people with allergies about this
10 difference and a list of ingredi-
11 ents; and

12 “(bb) a list of the ingredi-
13 ents of the qualifying drug as
14 would be required under section
15 502(e).

16 “(B) IMPORTATION BY INDIVIDUAL.—

17 “(i) IN GENERAL.—In the case of a
18 qualifying drug that is imported or offered
19 for import by a registered exporter to an
20 individual, such drug shall be considered to
21 be in compliance with section 502 and the
22 labeling requirements under the approved
23 application for the U.S. label drug if the
24 packaging and labeling of the qualifying
25 drug complies with all applicable regula-

1 tions promulgated under sections 3 and 4
2 of the Poison Prevention Packaging Act of
3 1970 (15 U.S.C. 1471 et seq.) and the la-
4 beling of the qualifying drug includes—

5 “(I) directions for use by the
6 consumer;

7 “(II) the lot number assigned by
8 the manufacturer;

9 “(III) the name and registration
10 number of the exporter;

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

16 “(V) if the inactive ingredients of
17 the drug are different from the inac-
18 tive ingredients for the U.S. label
19 drug—

20 “(aa) a prominent advisory
21 that persons with an allergy
22 should check the ingredient list
23 of the drug because the ingredi-
24 ents of the drug differ from the

1 ingredients of the U.S. label
2 drug; and

3 “(bb) a list of the ingredi-
4 ents of the drug as would be re-
5 quired under section 502(e); and

6 “(VI) a copy of any special label-
7 ing that would be required by the Sec-
8 retary had the U.S. label drug been
9 dispensed by a pharmacist in the
10 United States, without regard to
11 whether the special labeling bears any
12 trademark involved.

13 “(ii) REQUEST FOR COPY OF SPECIAL
14 LABELING AND INGREDIENT LIST.—The
15 Secretary shall provide to the registered
16 exporter involved a copy of the special la-
17 beling, the advisory, and the ingredient list
18 of the drug, upon request of the exporter.

19 “(iii) REQUESTED LABELING AND IN-
20 GREDIENT LIST.—The labeling and ingre-
21 dient list provided by the Secretary under
22 clause (ii) shall—

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

1 for each active ingredient in the drug;
2 and

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

6 “(4) SECTION 501; ADULTERATION.—A quali-
7 fying drug that is imported or offered for import
8 under subsection (a) shall be considered to be in
9 compliance with section 501 if the drug is in compli-
10 ance with subsection (c).

11 “(5) STANDARDS FOR REFUSING ADMISSION.—
12 A drug exported under subsection (a) from a reg-
13 istered exporter or imported by a registered importer
14 may be refused admission into the United States if
15 1 or more of the following applies:

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

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

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

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

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

4 “(F) The Secretary becomes aware that—

5 “(i) the drug may be counterfeit;

6 “(ii) the drug may have been pre-
7 pared, packed, or held under insanitary
8 conditions; or

9 “(iii) the methods used in, or the fa-
10 cilities or controls used for, the manufac-
11 turing, processing, packing, or holding of
12 the drug do not conform to good manufac-
13 turing practice.

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

17 “(H) The Secretary has under section
18 505(e) withdrawn approval of the drug.

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

21 “(J) If the drug is imported or offered for
22 import by a registered importer without submis-
23 sion of a notice in accordance with subsection
24 (d)(4).

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

4 “(i) The shipping container for such
5 drug does not bear the markings required
6 under subsection (d)(2).

7 “(ii) The markings on the shipping
8 container appear to be counterfeit.

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

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

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

18 “(2) the exporter employs persons that are li-
19 censed under the law of the permitted country in
20 which the exporter is located to dispense prescription
21 drugs in sufficient number to dispense safely the
22 drugs exported by the exporter to individuals, and
23 the exporter assigns to those persons responsibility
24 for dispensing such drugs to individuals.

1 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
2 TION.—

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

7 “(A) The drug is accompanied by a copy of
8 a prescription for the drug, which prescrip-
9 tion—

10 “(i) is valid under applicable Federal
11 and State laws; and

12 “(ii) was issued by a practitioner who,
13 under the law of a State of which the indi-
14 vidual is a resident, or in which the indi-
15 vidual receives care from the practitioner
16 who issues the prescription, is authorized
17 to administer prescription drugs.

18 “(B) The drug is accompanied by a copy
19 of the documentation that was required under
20 the law or regulations of the permitted country
21 in which the exporter is located, as a condition
22 of dispensing the drug to the individual.

23 “(C) The copies referred to in subpara-
24 graphs (A)(i) and (B) are marked in a manner
25 sufficient—

1 “(i) to indicate that the prescription,
2 and the equivalent document in the per-
3 mitted country in which the exporter is lo-
4 cated, have been filled; and

5 “(ii) to prevent a duplicative filling by
6 another pharmacist.

7 “(D) The individual has provided to the
8 registered exporter a complete list of all drugs
9 used by the individual for review by the individ-
10 uals who dispense the drug.

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

13 “(F) The drug is not an ineligible subpart
14 H drug. For purposes of this section, a pre-
15 scription drug is an ‘ineligible subpart H drug’
16 if the drug was approved by the Secretary
17 under subpart H of part 314 of title 21, Code
18 of Federal Regulations (relating to accelerated
19 approval), with restrictions under section 520 of
20 such part to assure safe use, and the Secretary
21 has published in the Federal Register a notice
22 that the Secretary has determined that good
23 cause exists to prohibit the drug from being im-
24 ported pursuant to this subsection.

1 “(2) NOTICE REGARDING DRUG REFUSED AD-
2 MISSION.—If a registered exporter ships a drug to
3 an individual pursuant to subsection (a)(2)(B) and
4 the drug is refused admission to the United States,
5 a written notice shall be sent to the individual and
6 to the exporter that informs the individual and the
7 exporter of such refusal and the reason for the re-
8 fusal.

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

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

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

14 “(B) maintain samples of each lot of a
15 qualifying drug required under this section for
16 not less than 2 years.

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

20 “(A) in the case of an importer, at the
21 place of business of the importer at which the
22 importer initially receives the qualifying drug
23 after importation; or

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

4 “(k) DRUG RECALLS.—

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

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

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

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

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

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

21 “(B) monitor recalls and withdrawals of
22 qualifying drugs in the country using any infor-
23 mation that is available to the public in any
24 media.

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

6 “(1) DRUG LABELING.—When a qualifying drug that
7 is imported into the United States by an importer under
8 subsection (a) is dispensed by a pharmacist to an indi-
9 vidual, the pharmacist shall provide that the packaging
10 and labeling of the drug complies with all applicable regu-
11 lations promulgated under sections 3 and 4 of the Poison
12 Prevention Packaging Act of 1970 (15 U.S.C. 1471 et
13 seq.) and include with any other labeling provided to the
14 individual the following:

15 “(1) The lot number assigned by the manufac-
16 turer.

17 “(2) The name and registration number of the
18 importer.

19 “(3) If the inactive ingredients of the drug are
20 different from the inactive ingredients for the U.S.
21 label drug—

22 “(A) a prominent advisory that persons
23 with allergies should check the ingredient list of
24 the drug because the ingredients of the drug

1 differ from the ingredients of the U.S. label
2 drug; and

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

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

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

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

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

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

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

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

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

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

9 “(E) knowingly fail to submit a notice
10 under subsection (g)(2)(B)(i), knowingly fail to
11 submit such a notice on or before the date spec-
12 ified in subsection (g)(2)(B)(v) or as otherwise
13 required under subsection (e) (3), (4), and (5)
14 of section 4 of the Pharmaceutical Market Ac-
15 cess and Drug Safety Act of 2005, knowingly
16 submit such a notice that makes a materially
17 false, fictitious, or fraudulent statement, or
18 knowingly fail to provide promptly any informa-
19 tion requested by the Secretary to review such
20 a notice;

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

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

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

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

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

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

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

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

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

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

15 “(2) AFFIRMATIVE DEFENSE.—

16 “(A) DISCRIMINATION.—It shall be an af-
17 firmative defense to a charge that a manufac-
18 turer has discriminated under subparagraph
19 (A), (B), (C), (D), or (M) of paragraph (1) that
20 the higher price charged for a prescription drug
21 sold to a person, the denial, restriction, or delay
22 of supplies of a prescription drug to a person,
23 the refusal to do business with a person, or
24 other discriminatory activity against a person,
25 is not based, in whole or in part, on—

1 “(i) the person exporting or importing
2 a qualifying drug into the United States
3 under this section; or

4 “(ii) the person distributing, selling,
5 or using a qualifying drug imported into
6 the United States under this section.

7 “(B) DRUG DIFFERENCES.—It shall be an
8 affirmative defense to a charge that a manufac-
9 turer has caused there to be a difference de-
10 scribed in subparagraph (G) of paragraph (1)
11 that—

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

14 “(ii) the Secretary has determined
15 that the difference was necessary to im-
16 prove the safety or effectiveness of the
17 drug;

18 “(iii) the person manufacturing the
19 drug for distribution in the United States
20 has given notice to the Secretary under
21 subsection (g)(2)(B)(i) that the drug for
22 distribution in the United States is not dif-
23 ferent from a drug for distribution in per-
24 mitted countries whose combined popu-
25 lation represents at least 50 percent of the

1 total population of all permitted countries;

2 or

3 “(iv) the difference was not caused, in
4 whole or in part, for the purpose of re-
5 stricting importation of the drug into the
6 United States under this section.

7 “(3) EFFECT OF SUBSECTION.—

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

16 “(B) DISCOUNTS TO INSURERS, HEALTH
17 PLANS, PHARMACY BENEFIT MANAGERS, AND
18 COVERED ENTITIES.—Nothing in this sub-
19 section shall be construed to—

20 “(i) prevent or restrict a manufac-
21 turer of a prescription drug from providing
22 discounts to an insurer, health plan, phar-
23 macy benefit manager in the United
24 States, or covered entity in the drug dis-
25 count program under section 340B of the

1 Public Health Service Act (42 U.S.C.
2 256b) in return for inclusion of the drug
3 on a formulary;

4 “(ii) require that such discounts be
5 made available to other purchasers of the
6 prescription drug; or

7 “(iii) prevent or restrict any other
8 measures taken by an insurer, health plan,
9 or pharmacy benefit manager to encourage
10 consumption of such prescription drug.

11 “(C) CHARITABLE CONTRIBUTIONS.—
12 Nothing in this subsection shall be construed
13 to—

14 “(i) prevent a manufacturer from do-
15 nating a prescription drug, or supplying a
16 prescription drug at nominal cost, to a
17 charitable or humanitarian organization,
18 including the United Nations and affili-
19 ates, or to a government of a foreign coun-
20 try; or

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

23 “(4) ENFORCEMENT.—

24 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-
25 TICE.—A violation of this subsection shall be

1 treated as a violation of a rule defining an un-
2 fair or deceptive act or practice prescribed
3 under section 18(a)(1)(B) of the Federal Trade
4 Commission Act (15 U.S.C. 57a(a)(1)(B)).

5 “(B) ACTIONS BY THE COMMISSION.—The
6 Federal Trade Commission—

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

15 “(ii) may seek monetary relief three-
16 fold the damages sustained, in addition to
17 any other remedy available to the Federal
18 Trade Commission under the Federal
19 Trade Commission Act (15 U.S.C. 41 et
20 seq.).

21 “(5) ACTIONS BY STATES.—

22 “(A) IN GENERAL.—

23 “(i) CIVIL ACTIONS.—In any case in
24 which the attorney general of a State has
25 reason to believe that an interest of the

1 residents of that State have been adversely
2 affected by any manufacturer that violates
3 paragraph (1), the attorney general of a
4 State may bring a civil action on behalf of
5 the residents of the State, and persons
6 doing business in the State, in a district
7 court of the United States of appropriate
8 jurisdiction to—

9 “(I) enjoin that practice;

10 “(II) enforce compliance with
11 this subsection;

12 “(III) obtain damages, restitu-
13 tion, or other compensation on behalf
14 of residents of the State and persons
15 doing business in the State, including
16 threefold the damages; or

17 “(IV) obtain such other relief as
18 the court may consider to be appro-
19 priate.

20 “(ii) NOTICE.—

21 “(I) IN GENERAL.—Before filing
22 an action under clause (i), the attor-
23 ney general of the State involved shall
24 provide to the Federal Trade Commis-
25 sion—

1 “(aa) written notice of that
2 action; and

3 “(bb) a copy of the com-
4 plaint for that action.

5 “(II) EXEMPTION.—Subclause
6 (I) shall not apply with respect to the
7 filing of an action by an attorney gen-
8 eral of a State under this paragraph,
9 if the attorney general determines
10 that it is not feasible to provide the
11 notice described in that subclause be-
12 fore filing of the action. In such case,
13 the attorney general of a State shall
14 provide notice and a copy of the com-
15 plaint to the Federal Trade Commis-
16 sion at the same time as the attorney
17 general files the action.

18 “(B) INTERVENTION.—

19 “(i) IN GENERAL.—On receiving no-
20 tice under subparagraph (A)(ii), the Fed-
21 eral Trade Commission shall have the right
22 to intervene in the action that is the sub-
23 ject of the notice.

24 “(ii) EFFECT OF INTERVENTION.—If
25 the Federal Trade Commission intervenes

1 in an action under subparagraph (A), it
2 shall have the right—

3 “(I) to be heard with respect to
4 any matter that arises in that action;
5 and

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

7 “(C) CONSTRUCTION.—For purposes of
8 bringing any civil action under subparagraph
9 (A), nothing in this subsection shall be con-
10 strued to prevent an attorney general of a State
11 from exercising the powers conferred on the at-
12 torney general by the laws of that State to—

13 “(i) conduct investigations;

14 “(ii) administer oaths or affirmations;

15 or

16 “(iii) compel the attendance of wit-
17 nesses or the production of documentary
18 and other evidence.

19 “(D) ACTIONS BY THE COMMISSION.—In
20 any case in which an action is instituted by or
21 on behalf of the Federal Trade Commission for
22 a violation of paragraph (1), a State may not,
23 during the pendency of that action, institute an
24 action under subparagraph (A) for the same

1 violation against any defendant named in the
2 complaint in that action.

3 “(E) VENUE.—Any action brought under
4 subparagraph (A) may be brought in the dis-
5 trict court of the United States that meets ap-
6 plicable requirements relating to venue under
7 section 1391 of title 28, United States Code.

8 “(F) SERVICE OF PROCESS.—In an action
9 brought under subparagraph (A), process may
10 be served in any district in which the defend-
11 ant—

12 “(i) is an inhabitant; or

13 “(ii) may be found.

14 “(G) MEASUREMENT OF DAMAGES.—In
15 any action under this paragraph to enforce a
16 cause of action under this subsection in which
17 there has been a determination that a defend-
18 ant has violated a provision of this subsection,
19 damages may be proved and assessed in the ag-
20 gregate by statistical or sampling methods, by
21 the computation of illegal overcharges or by
22 such other reasonable system of estimating ag-
23 gregate damages as the court in its discretion
24 may permit without the necessity of separately
25 proving the individual claim of, or amount of

1 damage to, persons on whose behalf the suit
2 was brought.

3 “(H) EXCLUSION ON DUPLICATIVE RE-
4 LIEF.—The district court shall exclude from the
5 amount of monetary relief awarded in an action
6 under this paragraph brought by the attorney
7 general of a State any amount of monetary re-
8 lief which duplicates amounts which have been
9 awarded for the same injury.

10 “(6) EFFECT ON ANTITRUST LAWS.—Nothing
11 in this subsection shall be construed to modify, im-
12 pair, or supersede the operation of the antitrust
13 laws. For the purpose of this subsection, the term
14 ‘antitrust laws’ has the meaning given it in the first
15 section of the Clayton Act, except that it includes
16 section 5 of the Federal Trade Commission Act to
17 the extent that such section 5 applies to unfair
18 methods of competition.

19 “(7) MANUFACTURER.—In this subsection, the
20 term ‘manufacturer’ means any entity, including any
21 affiliate or licensee of that entity, that is engaged
22 in—

23 “(A) the production, preparation, propaga-
24 tion, compounding, conversion, or processing of
25 a prescription drug, either directly or indirectly

1 by extraction from substances of natural origin,
2 or independently by means of chemical syn-
3 thesis, or by a combination of extraction and
4 chemical synthesis; or

5 “(B) the packaging, repackaging, labeling,
6 relabeling, or distribution of a prescription
7 drug.”.

8 (2) PROHIBITED ACTS.—The Federal Food,
9 Drug, and Cosmetic Act is amended—

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

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

17 “(A) a sale at retail made pursuant to dis-
18 pensing the drug to a customer of the pharmacist or
19 organization; or

20 “(B) a sale or trade of the drug to a pharmacy
21 or a wholesaler registered to import drugs under sec-
22 tion 804.

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

1 “(3) The making of a materially false, fictitious, or
2 fraudulent statement or representation, or a material
3 omission, in a notice under clause (i) of section
4 804(g)(2)(B) or in an application required under section
5 804(g)(2)(F), or the failure to submit such a notice or
6 application.

7 “(4) The importation of a drug in violation of a reg-
8 istration condition or other requirement under section
9 804, the falsification of any record required to be main-
10 tained, or provided to the Secretary, under such section,
11 or the violation of any registration condition or other re-
12 quirement under such section.”; and

13 (B) in section 303(a) (21 U.S.C. 333(a)),
14 by striking paragraph (6) and inserting the fol-
15 lowing:

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

21 (3) AMENDMENT OF CERTAIN PROVISIONS.—

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

1 “(g) With respect to a prescription drug that is im-
2 ported or offered for import into the United States by an
3 individual who is not in the business of such importation,
4 that is not shipped by a registered exporter under section
5 804, and that is refused admission under subsection (a),
6 the Secretary shall notify the individual that—

7 “(1) the drug has been refused admission be-
8 cause the drug was not a lawful import under sec-
9 tion 804;

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

12 “(3) the individual may under section 804 law-
13 fully import certain prescription drugs from export-
14 ers registered with the Secretary under section 804;
15 and

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

21 (B) ESTABLISHMENT REGISTRATION.—

22 Section 510(i) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360(i)) is amended in
24 paragraph (1) by inserting after “import into
25 the United States” the following: “, including a

1 drug that is, or may be, imported or offered for
2 import into the United States under section
3 804,”.

4 (C) EFFECTIVE DATE.—The amendments
5 made by this subsection shall take effect on the
6 date that is 90 days after the date of enactment
7 of this Act.

8 (4) EXHAUSTION.—

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

11 (i) by redesignating subsections (h)
12 and (i) as (i) and (j), respectively; and

13 (ii) by inserting after subsection (g)
14 the following:

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

21 (B) RULE OF CONSTRUCTION.—Nothing in
22 the amendment made by paragraph (1) shall be
23 construed to affect the ability of a patent owner
24 or licensee to enforce their patent, subject to
25 such amendment.

1 (5) EFFECT OF SECTION 804.—

2 (A) IN GENERAL.—Section 804 of the Fed-
3 eral Food, Drug, and Cosmetic Act, as added
4 by subsection (a), shall permit the importation
5 of qualifying drugs (as defined in such section
6 804) into the United States without regard to
7 the status of the issuance of implementing reg-
8 ulations—

9 (i) from exporters registered under
10 such section 804 on the date that is 90
11 days after the date of enactment of this
12 Act; and

13 (ii) from permitted countries, as de-
14 fined in such section 804, by importers
15 registered under such section 804 on the
16 date that is 1 year after the date of enact-
17 ment of this Act.

18 (B) REVIEW OF REGISTRATION BY CER-
19 TAIN EXPORTERS.—

20 (i) REVIEW PRIORITY.—In the review
21 of registrations submitted under subsection
22 (b) of such section 804, registrations sub-
23 mitted by entities in Canada that are sig-
24 nificant exporters of prescription drugs to
25 individuals in the United States as of the

1 date of enactment of this Act will have pri-
2 ority during the 90 day period that begins
3 on such date of enactment.

4 (ii) PERIOD FOR REVIEW.—During
5 such 90-day period, the reference in sub-
6 section (b)(2)(A) of such section 804 to 90
7 days (relating to approval or disapproval of
8 registrations) is, as applied to such enti-
9 ties, deemed to be 30 days.

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

18 (iv) FIRST YEAR LIMIT ON NUMBER
19 OF EXPORTERS.—During the 1-year period
20 beginning on the date of enactment of this
21 Act, the Secretary of Health and Human
22 Services (referred to in this section as the
23 “Secretary”) may limit the number of reg-
24 istered exporters under such section 804 to
25 not less than 50, so long as the Secretary

1 gives priority to those exporters with dem-
2 onstrated ability to process a high volume
3 of shipments of drugs to individuals in the
4 United States.

5 (v) SECOND YEAR LIMIT ON NUMBER
6 OF EXPORTERS.—During the 1-year period
7 beginning on the date that is 1 year after
8 the date of enactment of this Act, the Sec-
9 retary may limit the number of registered
10 exporters under such section 804 to not
11 less than 100, 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 (vi) FURTHER LIMIT ON NUMBER OF
17 EXPORTERS.—The Secretary shall report
18 to Congress to request the authority to im-
19 pose a limitation on the number of reg-
20 istered exporters under such section 804
21 during any period beginning on a date that
22 is not less than 2 years after the date of
23 enactment of this Act if the Secretary de-
24 termines that—

1 (I) a limitation on the number of
2 registered exporters is necessary for
3 the effective and efficient enforcement
4 of the requirements of such section
5 804 with respect to such exporters;
6 and

7 (II) such limitation will not re-
8 strict the ability of individuals to im-
9 port prescription drugs for personal
10 use from registered exporters under
11 such section 804.

12 (C) LIMITS ON NUMBER OF IMPORTERS.—

13 (i) FIRST YEAR LIMIT ON NUMBER OF
14 IMPORTERS.—During the 1-year period be-
15 ginning on the date that is 1 year after the
16 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 100 (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 imported into the United States.

3 (ii) SECOND YEAR LIMIT ON NUMBER
4 OF IMPORTERS.—During the 1-year period
5 beginning on the date that is 2 years after
6 the date of enactment of this Act, the Sec-
7 retary may limit the number of registered
8 importers under such section 804 to not
9 less than 200 (of which at least a signifi-
10 cant number shall be groups of phar-
11 macies, to the extent feasible given the ap-
12 plications submitted by such groups), so
13 long as the Secretary gives priority to
14 those importers with demonstrated ability
15 to process a high volume of shipments of
16 drugs to individuals in the United States.

17 (iii) FURTHER LIMIT ON NUMBER OF
18 IMPORTERS.—The Secretary shall report to
19 Congress to request the authority to im-
20 pose a limitation on the number of reg-
21 istered importers under such section 804
22 during any period beginning on a date that
23 is not less than 3 years after the date of
24 enactment of this Act if the Secretary de-
25 termines that—

1 (I) a limitation on the number of
2 registered importers is necessary for
3 the effective and efficient enforcement
4 of the requirements of such section
5 804 with respect to such importers;
6 and

7 (II) such limitation will not re-
8 strict the ability of individuals to pur-
9 chase qualifying drugs imported under
10 such section 804 or savings available
11 to individuals by purchasing such
12 qualifying drugs.

13 (D) NOTICES FOR DRUGS FOR IMPORT
14 FROM CANADA.—The notice with respect to a
15 qualifying drug introduced for commercial dis-
16 tribution in Canada as of the date of enactment
17 of this Act that is required under subsection
18 (g)(2)(B)(i) of such section 804 shall be sub-
19 mitted to the Secretary not later than 30 days
20 after the date of enactment of this Act if—

21 (i) the U.S. label drug (as defined in
22 such section 804) for the qualifying drug is
23 1 of the 100 prescription drugs with the
24 highest dollar volume of sales in the
25 United States based on the 12 calendar

1 month period most recently completed be-
2 fore the date of enactment of this Act; or

3 (ii) the notice is a notice under sub-
4 section (g)(2)(B)(i)(II) of such section
5 804.

6 (E) NOTICE FOR DRUGS FOR IMPORT
7 FROM OTHER COUNTRIES.—The notice with re-
8 spect to a qualifying drug introduced for com-
9 mercial distribution in a permitted country
10 other than Canada as of the date of enactment
11 of this Act that is required under subsection
12 (g)(2)(B)(i) of such section 804 shall be sub-
13 mitted to the Secretary not later than 180 days
14 after the date of enactment of this Act if—

15 (i) the U.S. label drug for the quali-
16 fying drug is 1 of the 100 prescription
17 drugs with the highest dollar volume of
18 sales in the United States based on the 12
19 calendar month period that is first com-
20 pleted on the date that is 120 days after
21 the date of enactment of this Act; or

22 (ii) the notice is a notice under sub-
23 section (g)(2)(B)(i)(II) of such section
24 804.

1 (F) NOTICE FOR OTHER DRUGS FOR IM-
2 PORT.—

3 (i) GUIDANCE ON SUBMISSION
4 DATES.—The Secretary shall by guidance
5 establish a series of submission dates for
6 the notices under subsection (g)(2)(B)(i) of
7 such section 804 with respect to qualifying
8 drugs introduced for commercial distribu-
9 tion as of the date of enactment of this Act
10 and that are not required to be submitted
11 under subparagraph (D) or (E).

12 (ii) CONSISTENT AND EFFICIENT USE
13 OF RESOURCES.—The Secretary shall es-
14 tablish the dates described under clause (i)
15 so that such notices described under such
16 clause are submitted and reviewed at a
17 rate that allows consistent and efficient
18 use of the resources and staff available to
19 the Secretary for such reviews. Review of
20 all such notices shall be completed not
21 later than 5 years after the date of enact-
22 ment of this Act.

23 (iii) PRIORITY FOR DRUGS WITH
24 HIGHER SALES.—The Secretary shall es-
25 tablish the dates described under clause (i)

1 so that the Secretary reviews the notices
2 described under such clause with respect to
3 qualifying drugs with higher dollar volume
4 of sales in the United States before the no-
5 tices with respect to drugs with lower sales
6 in the United States.

7 (G) NOTICES FOR DRUGS APPROVED
8 AFTER EFFECTIVE DATE.—The notice required
9 under subsection (g)(2)(B)(i) of such section
10 804 for a qualifying drug first introduced for
11 commercial distribution in a permitted country
12 (as defined in such section 804) after the date
13 of enactment of this Act shall be submitted to
14 and reviewed by the Secretary as provided
15 under subsection (g)(2)(B) of such section 804,
16 without regard to subparagraph (D), (E), or
17 (F).

18 (H) REPORT.—Beginning with fiscal year
19 2007, not later than 90 days after the end of
20 each fiscal year during which the Secretary re-
21 views a notice referred to in subparagraph (D),
22 (E), or (F), the Secretary shall submit a report
23 to Congress concerning the progress of the
24 Food and Drug Administration in reviewing the

1 notices referred to in subparagraphs (D), (E),
2 and (F).

3 (I) USER FEES.—

4 (i) EXPORTERS.—When establishing
5 an aggregate total of fees to be collected
6 from exporters under subsection (f)(2) of
7 such section 804, the Secretary shall,
8 under subsection (f)(3)(C)(i) of such sec-
9 tion 804, estimate the total price of drugs
10 imported under subsection (a) of such sec-
11 tion 804 into the United States by reg-
12 istered exporters during fiscal year 2007 to
13 be \$1,000,000,000.

14 (ii) IMPORTERS.—When establishing
15 an aggregate total of fees to be collected
16 from importers under subsection (e)(2) of
17 such section 804, the Secretary shall,
18 under subsection (e)(3)(C)(i) of such sec-
19 tion 804, estimate the total price of drugs
20 imported under subsection (a) of such sec-
21 tion 804 into the United States by reg-
22 istered importers during—

23 (I) fiscal year 2007 to be
24 \$1,000,000,000; and

1 (II) fiscal year 2008 to be
2 \$10,000,000,000.

3 (iii) FISCAL YEAR 2008 ADJUST-
4 MENT.—

5 (I) REPORTS.—Not later than
6 February 20, 2008, registered import-
7 ers shall report to the Secretary the
8 total price and the total volume of
9 drugs imported to the United States
10 by the importer during the 4-month
11 period from October 1, 2007, through
12 January 31, 2008.

13 (II) REESTIMATE.—Notwith-
14 standing subsection (e)(3)(C)(ii) of
15 such section 804 or clause (ii), the
16 Secretary shall reestimate the total
17 price of qualifying drugs imported
18 under subsection (a) of such section
19 804 into the United States by reg-
20 istered importers during fiscal year
21 2008. Such reestimate shall be equal
22 to—

23 (aa) the total price of quali-
24 fying drugs imported by each im-

1 porter as reported under sub-
2 clause (I); multiplied by

3 (bb) 3.

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

16 (iv) ANNUAL REPORT.—

17 (I) FOOD AND DRUG ADMINIS-
18 TRATION.—Beginning with fiscal year
19 2007, not later than 180 days after
20 the end of each fiscal year during
21 which fees are collected under sub-
22 section (e), (f), or (g)(2)(B)(iv) of
23 such section 804, the Secretary shall
24 prepare and submit to the House of
25 Representatives and the Senate a re-

1 port on the implementation of the au-
2 thority for such fees during such fis-
3 cal year and the use, by the Food and
4 Drug Administration, of the fees col-
5 lected for the fiscal year for which the
6 report is made and credited to the
7 Food and Drug Administration.

8 (II) CUSTOMS AND BORDER CON-
9 TROL.—Beginning with fiscal year
10 2007, not later than 180 days after
11 the end of each fiscal year during
12 which fees are collected under sub-
13 section (e) or (f) of such section 804,
14 the Secretary of Homeland Security,
15 in consultation with the Secretary of
16 the Treasury, shall prepare and sub-
17 mit to the House of Representatives
18 and the Senate a report on the use,
19 by the Bureau of Customs and Border
20 Protection, of the fees, if any, trans-
21 ferred by the Secretary to the Bureau
22 of Customs and Border Protection for
23 the fiscal year for which the report is
24 made.

25 (6) IMPLEMENTATION OF SECTION 804.—

1 (A) INTERIM RULE.—The Secretary may
2 promulgate an interim rule for implementing
3 section 804 of the Federal Food, Drug, and
4 Cosmetic Act, as added by subsection (a) of this
5 section.

6 (B) NO NOTICE OF PROPOSED RULE-
7 MAKING.—The interim rule described under
8 subparagraph (A) may be developed and pro-
9 mulgated by the Secretary without providing
10 general notice of proposed rulemaking.

11 (C) FINAL RULE.—Not later than 1 year
12 after the date on which the Secretary promul-
13 gates an interim rule under subparagraph (A),
14 the Secretary shall, in accordance with proce-
15 dures under section 553 of title 5, United
16 States Code, promulgate a final rule for imple-
17 menting such section 804, which may incor-
18 porate by reference provisions of the interim
19 rule provided for under subparagraph (A), to
20 the extent that such provisions are not modi-
21 fied.

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

24 (A) with regard to the availability of quali-
25 fying drugs for import for personal use from an

1 exporter registered with and approved by the
2 Food and Drug Administration under section
3 804 of the Federal Food, Drug, and Cosmetic
4 Act, as added by this section, including infor-
5 mation on how to verify whether an exporter is
6 registered and approved by use of the Internet
7 website of the Food and Drug Administration
8 and the toll-free telephone number required by
9 this Act;

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

17 (C) with regard to the availability at do-
18 mestic retail pharmacies of qualifying drugs im-
19 ported under such section 804 by domestic
20 wholesalers and pharmacies registered with and
21 approved by the Food and Drug Administra-
22 tion.

23 (8) EFFECT ON ADMINISTRATION PRACTICES.—

24 Notwithstanding any provision of this Act (and the
25 amendments made by this Act), nothing in this Act

1 (or the amendments made by this Act) shall be con-
2 strued to change, limit, or restrict the practices of
3 the Food and Drug Administration or the Bureau of
4 Customs and Border Protection in effect on January
5 1, 2004, with respect to the importation of prescrip-
6 tion drugs into the United States by an individual,
7 on the person of such individual, for personal use.

8 (c) DISPOSITION OF CERTAIN DRUGS DENIED AD-
9 MISSION INTO UNITED STATES.—

10 (1) IN GENERAL.—Chapter VIII of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et
12 seq.), as amended by this section, is further amend-
13 ed by adding at the end the following section:

14 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-
15 MISSION.**

16 “(a) IN GENERAL.—The Secretary of Homeland Se-
17 curity shall deliver to the Secretary a shipment of drugs
18 that is imported or offered for import into the United
19 States if—

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

22 “(2)(A) the shipping container for such drugs
23 does not bear the markings required under section
24 804(d)(2); or

1 “(B) the Secretary has requested delivery of
2 such shipment of drugs.

3 “(b) NO BOND OR EXPORT.—Section 801(b) does
4 not authorize the delivery to the owner or consignee of
5 drugs delivered to the Secretary under subsection (a) pur-
6 suant to the execution of a bond, and such drugs may not
7 be exported.

8 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
9 Secretary shall destroy a shipment of drugs delivered by
10 the Secretary of Homeland Security to the Secretary
11 under subsection (a) if—

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

16 “(2) in the case of drugs that are not imported
17 or offered for import from a registered exporter
18 under section 804, the drugs are in violation of a
19 standard referred to in section 801(a) or 801(d)(1).

20 “(d) CERTAIN PROCEDURES.—

21 “(1) IN GENERAL.—The delivery and destruc-
22 tion of drugs under this section may be carried out
23 without notice to the importer, owner, or consignee
24 of the drugs except as required by section 801(g) or
25 section 804(i)(2). The issuance of receipts for the

1 drugs, and recordkeeping activities regarding the
2 drugs, may be carried out on a summary basis.

3 “(2) OBJECTIVE OF PROCEDURES.—Procedures
4 promulgated under paragraph (1) shall be designed
5 toward the objective of ensuring that, with respect to
6 efficiently utilizing Federal resources available for
7 carrying out this section, a substantial majority of
8 shipments of drugs subject to described in sub-
9 section (c) are identified and destroyed.

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

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

20 (2) PROCEDURES.—Procedures for carrying out
21 section 805 of the Federal Food, Drug, and Cos-
22 metic Act, as added by this subsection, shall be es-
23 tablished not later than 90 days after the date of the
24 enactment of this Act.

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

4 (d) CIVIL ACTIONS REGARDING PROPERTY.—

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

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

14 “(A) to enjoin such alienation or disposition of
15 property; or

16 “(B) for a restraining order to—

17 “(i) prohibit any person from withdrawing,
18 transferring, removing, dissipating, or disposing
19 of any such property or property of equivalent
20 value; and

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

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

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

4 (e) WHOLESALE DISTRIBUTION OF DRUGS; STATE-
5 MENTS REGARDING PRIOR SALE, PURCHASE, OR
6 TRADE.—

7 (1) STRIKING OF EXEMPTIONS; APPLICABILITY
8 TO REGISTERED EXPORTERS.—Section 503(e) of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 353(e)) is amended—

11 (A) in paragraph (1)—

12 (i) by striking “and who is not the
13 manufacturer or an authorized distributor
14 of record of such drug”;

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

17 (iii) by striking subparagraph (B) and
18 inserting the following:

19 “(B) The fact that a drug subject to subsection (b)
20 is exported from the United States does not with respect
21 to such drug exempt any person that is engaged in the
22 business of the wholesale distribution of the drug from
23 providing the statement described in subparagraph (A) to
24 the person that receives the drug pursuant to the export
25 of the drug.

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

16 “(ii) When the Secretary promulgates a final rule to
17 establish such alternative requirements, the final rule in
18 addition shall, with respect to the registration condition
19 established in clause (i) of section 804(c)(3)(B), establish
20 a condition equivalent to the alternative requirements, and
21 such equivalent condition may be met in lieu of the reg-
22 istration condition established in such clause (i).”;

23 (B) in paragraph (2)(A), by adding at the
24 end the following: “The preceding sentence may
25 not be construed as having any applicability

1 with respect to a registered exporter under sec-
2 tion 804.”; and

3 (C) in paragraph (3), by striking “and
4 subsection (d)—” in the matter preceding sub-
5 paragraph (A) and all that follows through “the
6 term ‘wholesale distribution’ means” in sub-
7 paragraph (B) and inserting the following: “and
8 subsection (d), the term ‘wholesale distribution’
9 means”.

10 (2) CONFORMING AMENDMENT.—Section
11 503(d) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 353(d)) is amended by adding at the
13 end the following:

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

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

21 (3) EFFECTIVE DATE.—

22 (A) IN GENERAL.—The amendments made
23 by subparagraphs (A) and (C) of paragraph (1)
24 and by paragraph (2) shall take effect on Janu-
25 ary 1, 2011.

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

11 (C) HIGH-RISK DRUGS.—

12 (i) IN GENERAL.—Notwithstanding
13 subparagraph (A), the Secretary of Health
14 and Human Services (referred to in this
15 section as the “Secretary”) may apply the
16 amendments made by subparagraphs (A)
17 and (C) of paragraph (1) and by para-
18 graph (2) before January 1, 2011, with re-
19 spect to a prescription drug if the Sec-
20 retary—

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

23 (II) publishes the determination
24 and the basis for the determination in
25 the Federal Register.

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

12 (iii) LIMITATION.—The Secretary may
13 make the determination under clause (i)
14 with respect to not more than 50 drugs be-
15 fore January 1, 2011.

16 (D) EFFECT WITH RESPECT TO REG-
17 ISTERED EXPORTERS.—The amendment made
18 by paragraph (1)(B) shall take effect on the
19 date that is 90 days after the date of enactment
20 of this Act.

21 (E) ALTERNATIVE REQUIREMENTS.—The
22 Secretary shall issue regulations to establish the
23 alternative requirements, referred to in the
24 amendment made by paragraph (1)(A), that
25 take effect not later than—

1 (i) January 1, 2009, with respect to a
2 prescription drug determined under sub-
3 paragraph (C)(i) to be at high risk for
4 being counterfeited; and

5 (ii) January 1, 2011, with respect to
6 all other prescription drugs.

7 (F) INTERMEDIATE REQUIREMENTS.—
8 With respect to the prescription drugs described
9 under subparagraph (E)(ii), the Secretary shall
10 by regulation require the use of standardized
11 anti-counterfeiting or track-and-trace tech-
12 nologies on such prescription drugs at the case
13 and pallet level effective not later than January
14 1, 2010.

15 (f) INTERNET SALES OF PRESCRIPTION DRUGS.—

16 (1) IN GENERAL.—Chapter V of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
18 seq.) is amended by inserting after section 503A the
19 following:

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

21 **“(a) REQUIREMENTS REGARDING INFORMATION ON**
22 **INTERNET SITE.—**

23 **“(1) IN GENERAL.—**A person may not dispense
24 a prescription drug pursuant to a sale of the drug
25 by such person if—

1 “(A) the purchaser of the drug submitted
2 the purchase order for the drug, or conducted
3 any other part of the sales transaction for the
4 drug, through an Internet site;

5 “(B) the person dispenses the drug to the
6 purchaser by mailing or shipping the drug to
7 the purchaser; and

8 “(C) such site, or any other Internet site
9 used by such person for purposes of sales of a
10 prescription drug, fails to meet each of the re-
11 quirements specified in paragraph (2), other
12 than a site or pages on a site that—

13 “(i) are not intended to be accessed
14 by purchasers or prospective purchasers; or

15 “(ii) provide an Internet information
16 location tool within the meaning of section
17 231(e)(5) of the Communications Act of
18 1934 (47 U.S.C. 231(e)(5)).

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

23 “(A) Each page of the site shall include ei-
24 ther the following information or a link to a
25 page that provides the following information:

1 “(i) The name of such person.

2 “(ii) Each State in which the person
3 is authorized by law to dispense prescrip-
4 tion drugs.

5 “(iii) The address and telephone num-
6 ber of each place of business of the person
7 with respect to sales of prescription drugs
8 through the Internet, other than a place of
9 business that does not mail or ship pre-
10 scription drugs to purchasers.

11 “(iv) The name of each individual who
12 serves as a pharmacist for prescription
13 drugs that are mailed or shipped pursuant
14 to the site, and each State in which the in-
15 dividual is authorized by law to dispense
16 prescription drugs.

17 “(v) If the person provides for medical
18 consultations through the site for purposes
19 of providing prescriptions, the name of
20 each individual who provides such con-
21 sultations; each State in which the indi-
22 vidual is licensed or otherwise authorized
23 by law to provide such consultations or
24 practice medicine; and the type or types of

1 health professions for which the individual
2 holds such licenses or other authorizations.

3 “(B) A link to which paragraph (1) applies
4 shall be displayed in a clear and prominent
5 place and manner, and shall include in the cap-
6 tion for the link the words ‘licensing and con-
7 tact information’.

8 “(b) INTERNET SALES WITHOUT APPROPRIATE
9 MEDICAL RELATIONSHIPS.—

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

13 “(A) for purposes of such dispensing or
14 sale, the purchaser communicated with the per-
15 son through the Internet;

16 “(B) the patient for whom the drug was
17 dispensed or purchased did not, when such
18 communications began, have a prescription for
19 the drug that is valid in the United States;

20 “(C) pursuant to such communications, the
21 person provided for the involvement of a practi-
22 tioner, or an individual represented by the per-
23 son as a practitioner, and the practitioner or
24 such individual issued a prescription for the
25 drug that was purchased;

1 “(D) the person knew, or had reason to
2 know, that the practitioner or the individual re-
3 ferred to in subparagraph (C) did not, when
4 issuing the prescription, have a qualifying med-
5 ical relationship with the patient; and

6 “(E) the person received payment for the
7 dispensing or sale of the drug.

8 For purposes of subparagraph (E), payment is re-
9 ceived if money or other other valuable consideration
10 is received.

11 “(2) EXCEPTIONS.—Paragraph (1) does not
12 apply to—

13 “(A) the dispensing or selling of a pre-
14 scription drug pursuant to telemedicine prac-
15 tices sponsored by—

16 “(i) a hospital that has in effect a
17 provider agreement under title XVIII of
18 the Social Security Act (relating to the
19 Medicare program); or

20 “(ii) a group practice that has not
21 fewer than 100 physicians who have in ef-
22 fect provider agreements under such title;
23 or

24 “(B) the dispensing or selling of a pre-
25 scription drug pursuant to practices that pro-

1 mote the public health, as determined by the
2 Secretary by regulation.

3 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

4 “(A) IN GENERAL.—With respect to
5 issuing a prescription for a drug for a patient,
6 a practitioner has a qualifying medical relation-
7 ship with the patient for purposes of this sec-
8 tion if—

9 “(i) at least one in-person medical
10 evaluation of the patient has been con-
11 ducted by the practitioner; or

12 “(ii) the practitioner conducts a med-
13 ical evaluation of the patient as a covering
14 practitioner.

15 “(B) IN-PERSON MEDICAL EVALUATION.—

16 A medical evaluation by a practitioner is an in-
17 person medical evaluation for purposes of this
18 section if the practitioner is in the physical
19 presence of the patient as part of conducting
20 the evaluation, without regard to whether por-
21 tions of the evaluation are conducted by other
22 health professionals.

23 “(C) COVERING PRACTITIONER.—With re-
24 spect to a patient, a practitioner is a covering
25 practitioner for purposes of this section if the

1 practitioner conducts a medical evaluation of
2 the patient at the request of a practitioner who
3 has conducted at least one in-person medical
4 evaluation of the patient and is temporarily un-
5 available to conduct the evaluation of the pa-
6 tient. A practitioner is a covering practitioner
7 without regard to whether the practitioner has
8 conducted any in-person medical evaluation of
9 the patient involved.

10 “(4) RULES OF CONSTRUCTION.—

11 “(A) INDIVIDUALS REPRESENTED AS
12 PRACTITIONERS.—A person who is not a practi-
13 tioner (as defined in subsection (e)(1)) lacks
14 legal capacity under this section to have a
15 qualifying medical relationship with any patient.

16 “(B) STANDARD PRACTICE OF PHAR-
17 MACY.—Paragraph (1) may not be construed as
18 prohibiting any conduct that is a standard prac-
19 tice in the practice of pharmacy.

20 “(C) APPLICABILITY OF REQUIRE-
21 MENTS.—Paragraph (3) may not be construed
22 as having any applicability beyond this section,
23 and does not affect any State law, or interpre-
24 tation of State law, concerning the practice of
25 medicine.

1 “(c) ACTIONS BY STATES.—

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

17 “(2) NOTICE.—The State shall serve prior writ-
18 ten notice of any civil action under paragraph (1) or
19 (5)(B) upon the Secretary and provide the Secretary
20 with a copy of its complaint, except that if it is not
21 feasible for the State to provide such prior notice,
22 the State shall serve such notice immediately upon
23 instituting such action. Upon receiving a notice re-
24 specting a civil action, the Secretary shall have the
25 right—

1 “(A) to intervene in such action;

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

4 “(C) to file petitions for appeal.

5 “(3) CONSTRUCTION.—For purposes of bring-
6 ing any civil action under paragraph (1), nothing in
7 this chapter shall prevent an attorney general of a
8 State from exercising the powers conferred on the
9 attorney general by the laws of such State to con-
10 duct investigations or to administer oaths or affir-
11 mations or to compel the attendance of witnesses or
12 the production of documentary and other evidence.

13 “(4) VENUE; SERVICE OF PROCESS.—Any civil
14 action brought under paragraph (1) in a district
15 court of the United States may be brought in the
16 district in which the defendant is found, is an inhab-
17 itant, or transacts business or wherever venue is
18 proper under section 1391 of title 28, United States
19 Code. Process in such an action may be served in
20 any district in which the defendant is an inhabitant
21 or in which the defendant may be found.

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

23 “(A) Nothing contained in this section
24 shall prohibit an authorized State official from
25 proceeding in State court on the basis of an al-

1 leged violation of any civil or criminal statute of
2 such State.

3 “(B) In addition to actions brought by an
4 attorney general of a State under paragraph
5 (1), such an action may be brought by officers
6 of such State who are authorized by the State
7 to bring actions in such State on behalf of its
8 residents.

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

12 “(e) GENERAL DEFINITIONS.—For purposes of this
13 section:

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

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

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

22 “(f) INTERNET-RELATED DEFINITIONS.—

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

1 “(A) The term ‘Internet’ means collectively
2 the myriad of computer and telecommunications
3 facilities, including equipment and operating
4 software, which comprise the interconnected
5 world-wide network of networks that employ the
6 transmission control protocol/internet protocol,
7 or any predecessor or successor protocols to
8 such protocol, to communicate information of
9 all kinds by wire or radio.

10 “(B) The term ‘link’, with respect to the
11 Internet, means one or more letters, words,
12 numbers, symbols, or graphic items that appear
13 on a page of an Internet site for the purpose
14 of serving, when activated, as a method for exe-
15 cuting an electronic command—

16 “(i) to move from viewing one portion
17 of a page on such site to another portion
18 of the page;

19 “(ii) to move from viewing one page
20 on such site to another page on such site;
21 or

22 “(iii) to move from viewing a page on
23 one Internet site to a page on another
24 Internet site.

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

4 “(D)(i) The terms ‘site’ and ‘address’, with
5 respect to the Internet, mean a specific location
6 on the Internet that is determined by Internet
7 Protocol numbers. Such term includes the do-
8 main name, if any.

9 “(ii) The term ‘domain name’ means a
10 method of representing an Internet address
11 without direct reference to the Internet Protocol
12 numbers for the address, including methods
13 that use designations such as ‘.com’, ‘.edu’,
14 ‘.gov’, ‘.net’, or ‘.org’.

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

18 “(2) AUTHORITY OF SECRETARY.—The Sec-
19 retary may by regulation modify any definition
20 under paragraph (1) to take into account changes in
21 technology.

22 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
23 TISING.—No provider of an interactive computer service,
24 as defined in section 230(f)(2) of the Communications Act
25 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services

1 shall be liable under this section for dispensing or selling
2 prescription drugs in violation of this section on account
3 of another person's selling or dispensing such drugs, pro-
4 vided that the provider of the interactive computer service
5 or of advertising services does not own or exercise cor-
6 porate control over such person.”.

7 (2) INCLUSION AS PROHIBITED ACT.—Section
8 301 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 331) is amended by inserting after sub-
10 section (k) the following:

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

13 (3) INTERNET SALES OF PRESCRIPTION DRUGS;
14 CONSIDERATION BY SECRETARY OF PRACTICES AND
15 PROCEDURES FOR CERTIFICATION OF LEGITIMATE
16 BUSINESSES.—In carrying out section 503B of the
17 Federal Food, Drug, and Cosmetic Act (as added by
18 this section), the Secretary of Health and Human
19 Services shall take into consideration the practices
20 and procedures of public or private entities that cer-
21 tify that businesses selling prescription drugs
22 through Internet sites are legitimate businesses, in-
23 cluding practices and procedures regarding disclo-
24 sure formats and verification programs.

1 (4) REPORTS REGARDING INTERNET-RELATED
2 VIOLATIONS OF FEDERAL AND STATE LAWS ON DIS-
3 PENSING OF DRUGS.—

4 (A) IN GENERAL.—The Secretary of
5 Health and Human Services (referred to in this
6 paragraph as the “Secretary”) shall, pursuant
7 to the submission of an application meeting the
8 criteria of the Secretary, make an award of a
9 grant or contract to the National Clearinghouse
10 on Internet Prescribing (operated by the Fed-
11 eration of State Medical Boards) for the pur-
12 pose of—

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

16 (ii) reporting such sites to State med-
17 ical licensing boards and State pharmacy
18 licensing boards, and to the Attorney Gen-
19 eral and the Secretary, for further inves-
20 tigation; and

21 (iii) submitting, for each fiscal year
22 for which the award under this subsection
23 is made, a report to the Secretary describ-
24 ing investigations undertaken with respect
25 to violations described in clause (i).

1 (B) AUTHORIZATION OF APPROPRIA-
2 TIONS.—For the purpose of carrying out sub-
3 paragraph (A), there is authorized to be appro-
4 priated \$100,000 for each of the fiscal years
5 2006 through 2008.

6 (5) EFFECTIVE DATE.—The amendments made
7 by paragraphs (1) and (2) take effect 90 days after
8 the date of enactment of this Act, without regard to
9 whether a final rule to implement such amendments
10 has been promulgated by the Secretary of Health
11 and Human Services under section 701(a) of the
12 Federal Food, Drug, and Cosmetic Act. The pre-
13 ceding sentence may not be construed as affecting
14 the authority of such Secretary to promulgate such
15 a final rule.

16 (g) IMPORTATION EXEMPTION UNDER CONTROLLED
17 SUBSTANCES IMPORT AND EXPORT ACT.—Section
18 1006(a)(2) of the Controlled Substances Import and Ex-
19 port Act (21 U.S.C. 956(a)(2)) is amended by striking
20 “not import the controlled substance into the United
21 States in an amount that exceeds 50 dosage units of the
22 controlled substance.” and inserting “import into the
23 United States not more than 10 dosage units combined
24 of all such controlled substances.”.

1 **SEC. 7. REASONABLE PRICE AGREEMENT FOR FEDERALLY**
2 **FUNDED RESEARCH.**

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

16 (b) CONSIDERATION OF COMPETITIVE BIDDING.—In
17 cases where the Federal Government conveys or licenses
18 exclusive rights to federally funded research under sub-
19 section (a), consideration shall be given to mechanisms for
20 determining reasonable prices which are based upon a
21 competitive bidding process. When appropriate, the mech-
22 anisms should be considered where—

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

25 (2) qualified bidders compete on the basis of
26 the least sales revenues before prices are adjusted in

1 accordance with a cost based reasonable pricing for-
2 mula;

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

7 (4) qualified bidders compete on the basis of
8 the shortest period of exclusivity; or

9 (5) qualified bidders compete under other com-
10 petitive bidding systems.

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

14 (c) WAIVER.—No waiver shall take effect under sub-
15 section (a) before the public is given notice of the proposed
16 waiver and provided a reasonable opportunity to comment
17 on the proposed waiver. A decision to grant a waiver shall
18 set out the Secretary's finding that such a waiver is in
19 the public interest.

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

22 (a) ONGOING STUDY.—The Comptroller General of
23 the United States shall conduct an ongoing study and
24 analysis of the prescription medicine benefit program
25 under part D of the medicare program under title XVIII

1 of the Social Security Act (as added by section 4 of this
2 Act), including an analysis of each of the following:

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

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

10 (3) The success of such program in reducing
11 medication error and adverse medicine reactions and
12 improving quality of care, and whether it is probable
13 that the program has resulted in savings through re-
14 duced hospitalizations and morbidity due to medica-
15 tion errors and adverse medicine reactions.

16 (4) Whether patient medical record confiden-
17 tiality is being maintained and safe-guarded.

18 (5) Such other issues as the Comptroller Gen-
19 eral may consider.

20 (b) REPORTS.—The Comptroller General shall issue
21 such reports on the results of the ongoing study described
22 in (a) as the Comptroller General shall deem appropriate
23 and shall notify Congress on a timely basis of significant
24 problems in the operation of the part D prescription medi-

1 cine program and the need for legislative adjustments and
2 improvements.

3 (c) MISCELLANEOUS STUDIES AND REPORTS.—

4 (1) STUDY ON METHODS TO ENCOURAGE ADDI-
5 TIONAL RESEARCH ON BREAKTHROUGH PHARMA-
6 CEUTICALS.—

7 (A) IN GENERAL.—The Secretary of
8 Health and Human Services shall seek the ad-
9 vice of the Secretary of the Treasury on pos-
10 sible tax and trade law changes to encourage
11 increased original research on new pharma-
12 ceutical breakthrough products designed to ad-
13 dress disease and illness.

14 (B) REPORT.—Not later than January 1,
15 2007, the Secretary shall submit to Congress a
16 report on such study. The report shall include
17 recommended methods to encourage the phar-
18 maceutical industry to devote more resources to
19 research and development of new covered prod-
20 ucts than it devotes to overhead expenses.

21 (2) STUDY ON PHARMACEUTICAL SALES PRAC-
22 TICES AND IMPACT ON COSTS AND QUALITY OF
23 CARE.—

24 (A) IN GENERAL.—The Secretary of
25 Health and Human Services shall conduct a

1 study on the methods used by the pharma-
2 ceutical industry to advertise and sell to con-
3 sumers and educate and sell to providers.

4 (B) REPORT.—Not later than January 1,
5 2007, the Secretary shall submit to Congress a
6 report on such study. The report shall include
7 the estimated direct and indirect costs of the
8 sales methods used, the quality of the informa-
9 tion conveyed, and whether such sales efforts
10 leads (or could lead) to inappropriate pre-
11 scribing. Such report may include legislative
12 and regulatory recommendations to encourage
13 more appropriate education and prescribing
14 practices.

15 (3) STUDY ON COST OF PHARMACEUTICAL RE-
16 SEARCH.—

17 (A) IN GENERAL.—The Secretary of
18 Health and Human Services shall conduct a
19 study on the costs of, and needs for, the phar-
20 maceutical research and the role that the tax-
21 payer provides in encouraging such research.

22 (B) REPORT.—Not later than January 1,
23 2007, the Secretary shall submit to Congress a
24 report on such study. The report shall include
25 a description of the full-range of taxpayer-as-

1 sisted programs impacting pharmaceutical re-
2 search, including tax, trade, government re-
3 search, and regulatory assistance. The report
4 may also include legislative and regulatory rec-
5 ommendations that are designed to ensure that
6 the taxpayer's investment in pharmaceutical re-
7 search results in the availability of pharma-
8 ceuticals at reasonable prices.

9 (4) REPORT ON PHARMACEUTICAL PRICES IN
10 MAJOR FOREIGN NATIONS.—Not later than January
11 1, 2007, the Secretary of Health and Human Serv-
12 ices shall submit to Congress a report on the retail
13 price of major pharmaceutical products in various
14 developed nations, compared to prices for the same
15 or similar products in the United States. The report
16 shall include a description of the principal reasons
17 for any price differences that may exist.

18 **SEC. 9. MEDIGAP TRANSITION PROVISIONS.**

19 (a) IN GENERAL.—Notwithstanding any other provi-
20 sion of law, no new medicare supplemental policy that pro-
21 vides coverage of expenses for prescription drugs may be
22 issued under section 1882 of the Social Security Act on
23 or after January 1, 2007, to an individual unless it re-
24 places a medicare supplemental policy that was issued to

1 that individual and that provided some coverage of ex-
2 penses for prescription drugs.

3 (b) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN
4 PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE.—

5 (1) IN GENERAL.—The issuer of a medicare
6 supplemental policy—

7 (A) may not deny or condition the issuance
8 or effectiveness of a medicare supplemental pol-
9 icy that has a benefit package classified as “A”,
10 “B”, “C”, “D”, “E”, “F”, or “G” (under the
11 standards established under subsection (p)(2) of
12 section 1882 of the Social Security Act, 42
13 U.S.C. 1395ss) and that is offered and is avail-
14 able for issuance to new enrollees by such
15 issuer;

16 (B) may not discriminate in the pricing of
17 such policy, because of health status, claims ex-
18 perience, receipt of health care, or medical con-
19 dition; and

20 (C) may not impose an exclusion of bene-
21 fits based on a pre-existing condition under
22 such policy,

23 in the case of an individual described in paragraph
24 (2) who seeks to enroll under the policy not later
25 than 63 days after the date of the termination of en-

1 rollment described in such paragraph and who sub-
2 mits evidence of the date of termination or
3 disenrollment along with the application for such
4 medicare supplemental policy.

5 (2) INDIVIDUAL COVERED.—An individual de-
6 scribed in this paragraph is an individual who—

7 (A) enrolls in a prescription drug plan
8 under part D of title XVIII of the Social Secu-
9 rity Act; and

10 (B) at the time of such enrollment was en-
11 rolled and terminates enrollment in a medicare
12 supplemental policy which has a benefit pack-
13 age classified as “H”, “I”, or “J” under the
14 standards referred to in paragraph (1)(A) or
15 terminates enrollment in a policy to which such
16 standards do not apply but which provides ben-
17 efits for prescription drugs.

18 (3) ENFORCEMENT.—The provisions of para-
19 graph (1) shall be enforced as though they were in-
20 cluded in section 1882(s) of the Social Security Act
21 (42 U.S.C. 1395ss(s)) on and after January 1,
22 2007.

23 (4) DEFINITIONS.—For purposes of this sub-
24 section, the term “medicare supplemental policy”

1 has the meaning given such term in section 1882(g)
2 of the Social Security Act (42 U.S.C. 1395ss(g)).

○