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110TH CONGRESS
2D SESSION

H. R. 6800

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

IN THE HOUSE OF REPRESENTATIVES

AUGUST 1, 2008

Mr. KUCINICH (for himself, Mr. DEFAZIO, Ms. LEE, Mr. CONYERS, Mr. DAVIS of Illinois, Mr. ABERCROMBIE, Mr. JEFFERSON, Ms. WOOLSEY, Mr. FILNER, Mr. HINCHEY, Mr. JACKSON of Illinois, Mr. ELLISON, Ms. KAPTUR, Mr. GRIJALVA, Ms. HIRONO, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. CUMMINGS, Ms. JACKSON-LEE of Texas, Mr. NADLER, and Mr. CARSON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

SEC. 2. FINDINGS.

Congress makes the following findings:

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

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

(2) Medicare Part D pays on average 30 percent more for drugs than does its federally administered counterpart in Medicaid. That amounted to a windfall worth over $3.7 billion for drug manufacturers in the first two years of the Medicare Part D program.

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

(4) Only 8 percent of enrollees are in a Part D plan that provides any coverage in the ''doughnut hole,'' a period in which there is no coverage of drug costs, which exemplifies the ways in which insurance plans cause significant financial vulnerability for enrollees by providing partial coverage for prescription drugs.

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

care program and that assists with the high cost of prescription medicines and protects such beneficiaries from excessive out-of-pocket costs.

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

(7) The United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world.

(8) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(9) Allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy.

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

SEC. 3. REPEAL AND TRANSITION.

(a) REPEAL OF MEDICARE PART D BENEFIT AND TRANSITION TO NEW MEDICARE PRESCRIPTION MEDICINE BENEFIT PROGRAM.—The amendments made by title I of the Medicare Prescription Drug, Improvement,

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

(b) TRANSITION.—The Secretary of Health and Human Services shall provide for an appropriate transition from administering the Social Security Act in accordance with the amendments made by title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) to administering such Act in accordance with the amendments made by section 4 of this Act.

SEC. 4. PRESCRIPTION MEDICINE BENEFIT PROGRAM.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), as in effect before the insertion of part D under title I of the Medicare Prescrption Drug, Improvement, and Modernization Act of 2003, is amended—

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

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

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

''ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT PROGRAM FOR THE AGED AND DISABLED

''SEC. 1860D–1. There is established a voluntary insurance program to provide prescription medicine benefits, including pharmacy services, in accordance with the provisions of this part for individuals who are aged or disabled or have end-stage renal disease and who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

''SCOPE OF BENEFITS

''SEC. 1860D–2. (a) IN GENERAL.—The benefits provided to an individual enrolled in the insurance program under this part shall consist of—

''(1) payments made, in accordance with the provisions of this part, for covered prescription medicines (as specified in subsection (b)) dispensed by any pharmacy participating in the program under this part (and, in circumstances designated by the Secretary, by a nonparticipating pharmacy), including any specifically named medicine prescribed for the individual by a qualified health care professional regardless of whether the medicine is included in any formulary established under this part if such medi-

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

''(2) charging by pharmacies of the negotiated price—

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

''(B) established with respect to any drugs or classes of drugs described in subparagraphs (A), (B), (D), (E), or (F) of section 1927(d)(2) that are available to individuals receiving benefits under this title.

''(b) COVERED PRESCRIPTION MEDICINES.—

''(1) IN GENERAL.—Covered prescription medicines, for purposes of this part, include all prescription medicines (as defined in section 1860D–10(1)), including smoking cessation agents, except as otherwise provided in this subsection.

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

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

''(B) a drug in any of such classes is certified to be medically necessary by a health care professional.

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

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

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

''PAYMENT OF BENEFITS

''SEC. 1860D–3.

''There shall be paid from the Prescription Medicine Insurance Account within the Supplementary Medical Insurance Trust Fund, in the case of each individual who is enrolled in the insurance program under this part and who purchases covered prescription medicines in a calendar year, 100 percent of the negotiated price for each such covered prescription medicine.

''ELIGIBILITY AND ENROLLMENT

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

''(b) ENROLLMENT.—

''(1) IN GENERAL.—Each individual who satisfies subsection (a) shall be enrolled (or eligible to en-

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

''(2) SINGLE ENROLLMENT PERIOD.—Except as provided in section 1837(i) (as such section applies to this part) or 1860D–8(e), or as otherwise explicitly provided, no individual shall be entitled to enroll in the program under this part at any time after the initial enrollment period without penalty, and in the case of all other late enrollments, the Secretary shall develop a late enrollment penalty for the individual that fully recovers the additional actuarial risk involved providing coverage for the individual.

''(3) SPECIAL ENROLLMENT PERIOD FOR 2009.—

''(A) IN GENERAL.—An individual who first satisfies subsection (a) in 2009 may on or after the date on which they first become eligible and at any time on or before December 31, 2009—

''(i) enroll in the program under this part; and

"(ii) enroll or reenroll in such program after having previously declined or terminated enrollment in such program.

"(B) EFFECTIVE DATE OF COVERAGE.—An individual who enrolls under the program under this part pursuant to subparagraph (A) shall be entitled to benefits under this part beginning on the first day of the month following the month in which such enrollment occurs, but in no case earlier than January 1, 2010.

"(c) PERIOD OF COVERAGE.—

"(1) IN GENERAL.—Except as otherwise provided in this part, an individual's coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

"(2) PART D COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—In addition to the causes of termination specified in section 1838, an individual's coverage under this part shall be terminated if the individual retains coverage under neither the program under part A nor the program under part B, effective on the effective date of termination of coverage under part A or (if later) under part B.

''NO PREMIUM

''SEC. 1860D–5. There is no premium for enrollment under this part.

''PRESCRIPTION MEDICINE INSURANCE ACCOUNT

''SEC. 1860D–6. (a) ESTABLISHMENT.—There is created within the Federal Supplemental Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Medicine Insurance Account' (in this section referred to as the 'Account').

''(b) AMOUNTS IN ACCOUNT.—

''(1) IN GENERAL.—The Account shall consist of—

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

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

''(2) SEPARATION OF FUNDS.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplemental Medical Insurance Trust Fund.

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

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

''ADMINISTRATION OF BENEFITS

''SEC. 1860D–7. (a) THROUGH CMS.—The Secretary shall provide for administration of the benefits under this part through the Centers for Medicare & Medicaid Services in accordance with the provisions of this section. The Administrator of such Centers may enter into contracts with carriers to administer this part in the same manner as the Administrator enters into such contracts to administer part B. Any such contract shall be separate from any contract under section 1842.

''(b) ADMINISTRATION FUNCTIONS.—In carrying out this part, the Administrator (or a carrier under a contract with the Administrator) shall (or in the case of the function described in paragraph (9), may) perform the following functions:

''(1) PARTICIPATION AGREEMENTS, PRICES, AND FEES.—

''(A) NEGOTIATED PRICES.—Establish, through negotiations with medicine manufacturers and wholesalers and pharmacies, a schedule of prices for covered prescription medicines.

''(B) AGREEMENTS WITH PHARMACIES.—Enter into participation agreements under sub-

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

"(i) secure the participation of sufficient numbers of pharmacies to ensure convenient access (including adequate emergency access);

"(ii) permit the participation of any pharmacy in the service area that meets the participation requirements described in subsection (c); and

"(iii) allow for reasonable dispensing and consultation fees for pharmacies.

"(C) LISTS OF PRICES AND PARTICIPATING PHARMACIES.—Ensure that the negotiated prices established under subparagraph (A) and the list of pharmacies with agreements under subsection (c) are regularly updated and readily available to health care professionals authorized to prescribe medicines, participating pharmacies, and enrolled individuals.

"(2) TRACKING OF COVERED ENROLLED INDIVIDUALS.—Maintain accurate, updated records of all enrolled individuals (other than individuals enrolled in a plan under part C).

''(3) PAYMENT AND COORDINATION OF BENEFITS.—

''(A) PAYMENT.—

''(i) Administer claims for payment of benefits under this part and encourage, to the maximum extent possible, use of electronic means for the submissions of claims.

''(ii) Determine amounts of benefit payments to be made.

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

''(B) COORDINATION.—Coordinate with other private benefit providers, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals, including coordination of access to and payment for covered prescription medicines according to an individual's in-service area plan provisions, when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

"(C) EXPLANATION OF BENEFITS.—Furnish to enrolled individuals an explanation of benefits in accordance with section 1806(a), and a notice of the balance of benefits remaining for the current year, whenever prescription medicine benefits are provided under this part (except that such notice need not be provided more often than monthly).

"(4) RULES RELATING TO PROVISION OF BENEFITS.—

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

"(i) formularies (consistent with subparagraph (B));

"(ii) automatic generic medicine substitution (unless the physician specifies otherwise, in which case a 30-day prescription may be dispensed pending a consultation with the physician on whether a generic substitute can be dispensed in the future); and

"(iii) therapeutic interchange.

"(B) REQUIREMENTS WITH RESPECT TO FORMULARIES.—If a formulary is used to contain costs under this part—

"(i) use an advisory committee (or a therapeutics committee) comprised of licensed practicing physicians, pharmacists, and other health care practitioners to develop and manage the formulary;

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

"(iii) disclose to current and prospective enrollees and to participating providers and pharmacies, the nature of the formulary restrictions, including information regarding the medicines included in the formulary.

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

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

''(ii) the reimbursement for a prescribed nonformulary medicine without a restrictive prescription in no case shall be more than the lowest reimbursement for a formulary medicine in the therapeutic class of the prescribed medicine.

''(D) RESTRICTIVE PRESCRIPTION.—For purposes of this section:

''(i) WRITTEN PRESCRIPTIONS.—In the case of a written prescription for a medicine, it is a restrictive prescription only if the prescription indicates, in the writing of the physician or other qualified person prescribing the medicine and with an appropriate phrase (such as 'brand medically necessary') recognized by the Secretary, that a particular medicine product must be dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior thera-

peutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual.

"(ii) TELEPHONE PRESCRIPTIONS.—In the case of a prescription issued by telephone for a medicine, it is a restrictive prescription only if the prescription cannot be longer than 30 days and the physician or other qualified person prescribing the medicine (through use of such an appropriate phrase) states that a particular medicine product must be dispensed, and the physician or other qualified person submits to the pharmacy involved, within 30 days after the date of the telephone prescription, a written confirmation from the physician or other qualified person prescribing the medicine and which indicates with such appropriate phrase that the particular medicine product was required to have been dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior thera-

peutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. Such written confirmation is required to refill the prescription.

''(iii) REVIEW OF RESTRICTIVE PRESCRIPTIONS.—The advisory committee (established under subparagraph (B)(i)) may decide to review a restrictive prescription and, if so, it may approve or disapprove such restrictive prescription. It may not disapprove such restrictive prescription unless it finds that there is no literature approved by the Food and Drug Administration that supports a determination that the particular medicine provides even marginally superior therapeutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. If it disapproves, upon request of the prescribing physician or the enrollee, the committee must provide for a review by an independent contractor of such decision

within 48 hours of the time of submission of the prescription, to determine whether the prescription is an eligible benefit under this part. The Secretary shall ensure that independent contractors so used are completely independent of the contractor or its advisory committee.

''(5) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE.—Have in place effective cost and utilization management, drug utilization review, quality assurance measures, and systems to reduce medical errors, including at least the following, together with such additional measures as the Administrator may specify:

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

''(B) FRAUD AND ABUSE CONTROL.—Activities to control fraud, abuse, and waste, including prevention of diversion of pharmaceuticals to the illegal market.

''(C) MEDICATION THERAPY MANAGEMENT.—

''(i) IN GENERAL.—A program of medicine therapy management and medication administration that is designed to assure that covered outpatient medicines are appropriately used to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

''(ii) ELEMENTS.—Such program may include—

''(I) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means; and

''(II) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means.

''(iii) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed pharmacists and physicians.

''(iv) CONSIDERATIONS IN PHARMACY FEES.—There shall be taken into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

''(6) EDUCATION AND INFORMATION ACTIVITIES.—Have in place mechanisms for disseminating educational and informational materials to enrolled individuals and health care providers designed to encourage effective and cost-effective use of prescription medicine benefits and to ensure that enrolled individuals understand their rights and obligations under the program.

''(7) BENEFICIARY PROTECTIONS.—

''(A) CONFIDENTIALITY OF HEALTH INFORMATION.—Have in effect systems to safeguard the confidentiality of health care information on enrolled individuals, which comply with section 1106 and with section 552a of title 5, United States Code, and meet such additional standards as the Administrator may prescribe.

''(B) GRIEVANCE AND APPEAL PROCEDURES.—Have in place such procedures as the Administrator may specify for hearing and resolving grievances and appeals, including expedited appeals, brought by enrolled individuals against the Administrator or a pharmacy concerning benefits under this part, which shall include procedures equivalent to those specified in subsections (f) and (g) of section 1852.

''(8) RECORDS, REPORTS, AND AUDITS.—

''(A) RECORDS AND AUDITS.—Maintain adequate records, and afford the Administrator access to such records (including for audit purposes).

''(B) REPORTS.—Make such reports and submissions of financial and utilization data as the Administrator may require taking into account standard commercial practices.

''(9) PROPOSAL FOR ALTERNATIVE COINSURANCE AMOUNT.—

''(A) SUBMISSION.—The Administrator may provide for increased Government cost-sharing for generic prescription medicines, prescription medicines on a formulary, or prescrip-

tion medicines obtained through mail order pharmacies.

''(B) CONTENTS.—The proposal submitted under subparagraph (A) shall contain evidence that such increased cost-sharing would not result in an increase in aggregate costs to the Account, including an analysis of differences in projected drug utilization patterns by beneficiaries whose cost-sharing would be reduced under the proposal and those making the cost-sharing payments that would otherwise apply.

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

The Administrator shall negotiate a schedule of prices under paragraph (1)(A), except that nothing in this sentence shall prevent a carrier under a contract with the Administrator from negotiating a lower schedule of prices for covered prescription medicines.

''(c) PHARMACY PARTICIPATION AGREEMENTS.—

''(1) IN GENERAL.—A pharmacy that meets the requirements of this subsection shall be eligible to enter an agreement with the Administrator to furnish covered prescription medicines and pharmacists' services to enrolled individuals.

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

''(A) LICENSING.—The pharmacy and pharmacists shall meet (and throughout the contract period will continue to meet) all applicable State and local licensing requirements.

''(B) LIMITATION ON CHARGES.—Pharmacies participating under this part shall not charge an enrolled individual more than the negotiated price for an individual medicine as established under subsection (b)(1), regardless of whether such individual has attained the benefit limit under section 1860D–3(b), and shall not charge an enrolled individual more than the individual's share of the negotiated price as determined under the provisions of this part.

''(C) PERFORMANCE STANDARDS.—The pharmacy and the pharmacist shall comply with performance standards relating to—

''(i) measures for quality assurance, reduction of medical errors, and participation in the drug utilization review program described in subsection (b)(3)(A);

"(ii) systems to ensure compliance with the confidentiality standards applicable under subsection (b)(5)(A); and

"(iii) other requirements as the Secretary may impose to ensure integrity, efficiency, and the quality of the program.

"(D) DISCLOSURE OF PRICE OF GENERIC MEDICINE.—A pharmacy participating under this part shall inform an enrollee of the difference in price between generic and non-generic equivalents.

"(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-SERVE AREAS.—

"(1) IN GENERAL.—The Secretary shall ensure that all beneficiaries have access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas (as the Secretary may define by regulation).

"(2) SPECIAL ATTENTION DEFINED.—For purposes of paragraph (1), the term 'special attention' may include bonus payments to retail pharmacists in rural areas and any other actions the Secretary determines are necessary to ensure full access to rural and hard-to-serve beneficiaries.

''(3) GAO REPORT.—Not later than two years after the implementation of this part the Comptroller General of the United States shall submit to Congress a report on the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in rural and hard-to-serve areas under this part together with any recommendations of the Comptroller General regarding any additional steps the Secretary may need to take to ensure the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in such areas under this part.

''(e) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—The Secretary is authorized to include in a contract awarded under subsection (b) with a carrier such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate, including—

''(1) bonus and penalty incentives to encourage administrative efficiency;

''(2) incentives under which carriers share in any benefit savings achieved;

''(3) risk-sharing arrangements related to initiatives to encourage savings in benefit payments;

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

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

''(5) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization.

''PROMOTION OF PHARMACEUTICAL RESEARCH ON BREAK-THROUGH MEDICINES WHILE PROVIDING PROGRAM COST CONTAINMENT

''SEC. 1860D–8. (a) MONITORING EXPENDITURES.—The Secretary shall monitor expenditures under this part. On October 1, 2009, the Secretary shall estimate total expenditures under this part for 2010.

''(b) ESTABLISHMENT OF SUSTAINABLE GROWTH RATE.—

''(1) IN GENERAL.—The Secretary shall establish a sustainable growth rate prescription medicine target system for expenditures under this part for each year after 2010.

''(2) INITIAL COMPUTATION.—Such target shall equal the amount of total expenditures estimated for 2010 adjusted by the Secretary's estimate of a sustainable growth rate (in this section referred to as an 'SGR') percentage between 2010 and 2011. Such SGR shall be estimated based on the following:

"(A) Reasonable changes in the cost of production or price of covered pharmaceuticals, but in no event more than the rate of increase in the consumer price index for all urban consumers for the period involved.

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

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

"(D) Productivity index of manufacturers and distributors.

"(E) Percentage of products with patent and market exclusivity protection versus products without patent protection and changes in the availability of generic substitutes.

"(F) Such other factors as the Secretary may determine are appropriate.

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

"(3) COMPUTATION FOR SUBSEQUENT YEARS.—In October of 2011 and each year thereafter, for purposes of setting the SGRs for the succeeding year, the Secretary shall adjust each current year's estimated expenditures by the estimated SGR for the succeeding year, further adjusted for corrections in earlier estimates and the receipt of additional data on previous years spending as follows:

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

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

"(C) TARGET.—An adjustment for any amount (over or under) that expenditures in the current year under this part are estimated to differ from the target amount set for the year. If expenditures in the current year are estimated to be—

"(i) less than the target amount, future target amounts will be adjusted downward; or

"(ii) more than the target amount, the Secretary shall notify all pharmaceutical manufacturers with sales of pharmaceutical prescription medicine products to medicare beneficiaries under this part, of a rebate requirement (except as provided in this subparagraph) to be deposited in the Federal Medicare Prescription Medicine Trust Fund.

"(D) REBATE DETERMINATION.—The amount of the rebate described in subparagraph (C)(ii) may vary among manufacturers and shall be based on the manufacturer's estimated contribution to the expenditure above the target amount, taking into consideration such factors as—

"(i) above average increases in the cost of the manufacturer's product;

"(ii) increases in utilization due to promotion activities of the manufacturer, wholesaler, or retailer;

"(iii) launch prices of new drugs at the same or higher prices as similar drugs already in the marketplace (so-called 'me too' or 'copy-cat' drugs);

''(iv) the role of the manufacturer in delaying the entry of generic products into the market; and

''(v) such other actions by the manufacturer that the Secretary may determine has contributed to the failure to meet the SGR target.

The rebates shall be established under such subparagraph so that the total amount of the rebates is estimated to ensure that the amount the target for the current year is estimated to be exceeded is recovered in lower spending in the subsequent year; except that, no rebate shall be made in any manufacturer's product which the Food and Drug Administration has determined is a breakthrough medicine (as determined under subsection (c)) or an orphan medicine.

''(c) BREAKTHROUGH MEDICINES.—

''(1) DETERMINATION.—For purposes of this section, a medicine is a 'breakthrough medicine' if the Drug Review Board (established under paragraph (3)) determines—

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

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

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

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

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

''(d) NO REVIEW.—The Secretary's determination of the rebate amounts under this section, and the Drug Review Board's determination of what is a breakthrough drug, are not subject to administrative or judicial review.

''APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS

''SEC. 1860D–9.

''There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Prescription Medicine Insurance Account, a Government contribution equal to the aggregate costs payable under this part.

''PRESCRIPTION MEDICINE DEFINED

''SEC. 1860D–10. As used in this part, the term 'prescription medicine' means—

''(1) a drug that may be dispensed only upon a prescription, and that is described in subparagraph (A)(i), (A)(ii), or (B) of section 1927(k)(2); and

''(2) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act, and needles, syringes, and disposable pumps for the administration of such insulin.''.

(b) CONFORMING AMENDMENTS.—

(1) AMENDMENTS TO FEDERAL SUPPLEMENTARY HEALTH INSURANCE TRUST FUND.—Sec-

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

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

(i) by striking ''and'' after ''section 201(i)(1)''; and

(ii) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Medicine Insurance Account established by section 1860D–6'';

(B) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund),'';

(C) in the first sentence of subsection (h), by inserting before the period the following: ''and section 1860D–5(b)(4) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''; and

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

(i) by striking ''and'' after ''section 1840(b)(1)''; and

(ii) by inserting before the period the following: '', section 1860D–5(b)(2) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''.

(2) NO PART D PRESCRIPTION MEDICINE COVERAGE UNDER MA PLANS.—Section 1852(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended by adding at the end the following: ''No Medicare Advantage plan shall provide benefits for coverage provided under part D.''

(3) EXCLUSIONS FROM COVERAGE.—

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

(B) PRESCRIPTION MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)) is amended—

(i) in subparagraph (N), by striking ''and'' at the end;

(ii) in subparagraph (O), by striking the semicolon at the end and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(P) in the case of prescription medicines covered under part D, which are not prescribed in accordance with such part;''.

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

SEC. 5. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRESCRIPTION DRUGS FOR MEDICARE BENEFICIARIES.

(a) PARTICIPATING MANUFACTURERS.—

(1) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase by each pharmacy such covered outpatient drug in the amount described in paragraph (2) at the price described in paragraph (3).

(2) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy is an amount equal to the aggregate amount of the covered outpatient drug sold or distributed by the pharmacy to medicare beneficiaries.

(3) DESCRIPTION OF PRICE.—The price at which a participating manufacturer shall make a covered outpatient drug available for purchase by a pharmacy is the price equal to the lowest of the following:

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

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

(C) The lowest price at which the drug is available (as determined by the Secretary) through importation consistent with the provisions of section 804 of the Federal Food, Drug, and Cosmetic Act.

(b) SPECIAL PROVISION WITH RESPECT TO HOSPICE PROGRAMS.—For purposes of determining the amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy under subsection (a), there shall be included in the calculation of such amount the amount of the covered outpatient drug sold or distributed by a pharmacy to a hospice program. In calculating such amount, only amounts of the covered outpatient drug furnished to a medicare beneficiary enrolled in the hospice program shall be included.

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

(d) REPORTS TO CONGRESS REGARDING EFFECTIVENESS OF SECTION.—

(1) IN GENERAL.—Not later than two years after the date of the enactment of this Act, and annually thereafter, the Secretary shall report to Congress regarding the effectiveness of this section in—

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

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

(2) CONSULTATION.—In preparing such reports, the Secretary shall consult with public health experts, affected industries, organizations representing consumers and older Americans, and other interested persons.

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

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

(1) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of the enactment of this Act, enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

(2) COVERED OUTPATIENT DRUG.—The term ''covered outpatient drug'' has the meaning given that term in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

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

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

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

SEC. 6. IMPORTATION OF CERTAIN PRESCRIPTION DRUGS.

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

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

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

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

"SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

"(a) IMPORTATION OF PRESCRIPTION DRUGS.—

"(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

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

"(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

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

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

"(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

''(A) by a registered importer; or

''(B) from a registered exporter to an individual.

''(4) DEFINITIONS.—

''(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

''(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

''(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

''(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

"(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a drug for which there is a corresponding U.S. label drug.

"(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

"(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

"(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

"(iii) is approved under section 505(c); and

"(iv) is not—

"(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

"(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

"(aa) a therapeutic DNA plasmid product;

"(bb) a therapeutic synthetic peptide product;

"(cc) a monoclonal antibody product for in vivo use; and

"(dd) a therapeutic recombinant DNA-derived product;

"(III) an infused drug, including a peritoneal dialysis solution;

"(IV) an injected drug;

"(V) a drug that is inhaled during surgery; or

"(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed.

"(D) OTHER DEFINITIONS.—For purposes of this section:

"(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under sub-

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

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

"(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

"(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(iv) The term 'pharmacy' means a person that—

"(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

"(II) employs 1 or more pharmacists.

"(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

"(vi) The term 'wholesaler'—

"(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

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

"(E) PERMITTED COUNTRY.—The term 'permitted country' means—

"(i) Australia;

"(ii) Canada;

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

"(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

"(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutial products expires;

"(iv) Japan;

"(v) New Zealand;

"(vi) Switzerland; and

"(vii) a country in which the Secretary determines the following requirements are met:

''(I) The country has statutory or regulatory requirements—

''(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

''(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to with-

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

"(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

"(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

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

"(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

"(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

"(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

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

"(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

"(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

"(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and com-

pliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

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

istration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

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

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter—

"(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

"(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

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

"(II) $1,000,000;

"(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

"(iv) An agreement by the exporter to report to the Secretary—

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

"(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

"(J) In the case of an importer, an agreement by the importer to report to the Secretary—

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

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

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary deter-

mines that the registrant is in compliance with such conditions.

"(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

"(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

"(4) SUSPENSION AND TERMINATION.—

"(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

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

mines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

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

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

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

"(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

"(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

"(1) The drug was manufactured in an establishment—

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

"(B)(i) inspected by the Secretary; or

"(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent

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

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and

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

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

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

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

"(ii) to have access, including on a day-to-day basis, to—

"(I) records of the exporter that relate to the export of such drugs, including financial records; and

"(II) samples of such drugs;

"(iii) to carry out the duties described in paragraph (3); and

"(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

"(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

"(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be nec-

essary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

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

"(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

"(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

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

"(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace tech-

nologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

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

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and

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

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

''(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

''(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

''(E) the country from which the drug is shipped;

''(F) the name and complete contact information for the shipper of the drug;

''(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

"(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

"(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

"(J) such other information as the Secretary may require by regulation.

"(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

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

tainer that is not authorized to bear the markings; and

"(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

"(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

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

"(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that rea-

son be excluded from importation by an importer.

"(C) Reviewing notices under paragraph (4).

"(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

"(E) Determining whether the importer is in compliance with all other registration conditions.

"(e) IMPORTER FEES.—

"(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

"(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

"(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

"(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

"(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 1 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

"(C) TOTAL PRICE OF DRUGS.—

"(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through

June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

"(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

"(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the sub-

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

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

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

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary,

when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 1 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as re-

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

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

"(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

"(4) USE OF FEES.—

"(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

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

only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

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

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under sec-

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

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling); or

''(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

"(aa) the variations provided for in the application; and

"(bb) any difference in labeling (except ingredient labeling).

"(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to which such approval is sought, include the following:

"(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

"(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Sec-

retary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade

Commission and to the State attorneys general.

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

"(v) TIMING OF SUBMISSION OF NOTICES.—

"(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is intro-

duced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice

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

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary may—

''(aa) include in the labeling provided under paragraph (3) a

prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference

would require an inspection of the establishment in which the qualifying drug is manufactured—

"(aa) such inspection by the Secretary shall be authorized; and

"(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

"(vii) PUBLICATION OF INFORMATION ON NOTICES.—

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

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

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could

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

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the

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

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

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

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

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

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

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

port the qualifying drug involved continues in effect.

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

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

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

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for

the person that manufactures the drug approved under section 505(b) if—

"(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

"(II) each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b), as defined in clause (v).

"(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

"(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

"(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

"(III) include a right of reference to the application for the drug approved under section 505(b); and

"(IV) include such additional information as the Secretary may require.

"(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

"(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

"(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

"(I) the same; or

"(II) different salts, esters, or complexes of the same moiety.

"(3) SECTION 502; LABELING.—

"(A) IMPORTATION BY REGISTERED IMPORTER.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

"(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

"(II) the name of the manufacturer and location of the manufacturer;

"(III) the lot number assigned by the manufacturer;

"(IV) the name, location, and registration number of the importer; and

"(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

"(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

"(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

"(I) include the established name, as defined in section 502(e)(3),

for each active ingredient in the qualifying drug;

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

''(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

''(IV) if the inactive ingredients of the qualifying drug are different from the inactive ingredients for the U.S. label drug, include—

''(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

''(bb) a list of the ingredients of the qualifying drug as

would be required under section 502(e).

"(B) IMPORTATION BY INDIVIDUAL.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

"(I) directions for use by the consumer;

"(II) the lot number assigned by the manufacturer;

"(III) the name and registration number of the exporter;

"(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effec-

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

''(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The

Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list of the drug, upon request of the exporter.

''(iii) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (ii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

"(A) The drug is not a qualifying drug.

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

"(C) The Secretary has ordered that importation of the drug from the permitted country cease under paragraph (2) (C) or (D).

"(D) The drug does not comply with paragraph (3) or (4).

"(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

"(F) The Secretary becomes aware that—

"(i) the drug may be counterfeit;

"(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

"(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

"(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

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

"(I) The manufacturer of the drug has instituted a recall of the drug.

"(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

"(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

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

"(ii) The markings on the shipping container appear to be counterfeit.

"(iii) The shipping container or markings appear to have been tampered with.

"(h) LICENSING AS PHARMACIST.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

"(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

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

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

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

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code

of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

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

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

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

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

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

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

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information

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

"(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

"(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

"(l) DRUG LABELING.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and include with any other labeling provided to the individual the following:

"(1) The lot number assigned by the manufacturer.

"(2) The name and registration number of the importer.

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

''(A) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

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

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

''(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

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

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

registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under subsection (e) (3), (4), and (5) of section 4 of the Pharmaceutical Market Access and Drug Safety Act of 2005, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any informa-

tion requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(ii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

"(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

"(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

"(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

"(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

"(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

"(2) AFFIRMATIVE DEFENSE.—

"(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufac-

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

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

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

''(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference described in subparagraph (G) of paragraph (1) that—

''(i) the difference was required by the country in which the drug is distributed;

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

''(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

''(3) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND

COVERED ENTITIES.—Nothing in this subsection shall be construed to—

"(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

"(ii) require that such discounts be made available to other purchasers of the prescription drug; or

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

"(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

"(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization,

including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(4) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal

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

''(5) ACTIONS BY STATES.—

''(A) IN GENERAL.—

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

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

"(IV) obtain such other relief as the court may consider to be appropriate.

"(ii) NOTICE.—

"(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

"(aa) written notice of that action; and

"(bb) a copy of the complaint for that action.

"(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commis-

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

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

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

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

"(iii) compel the attendance of witnesses or the production of documentary and other evidence.

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

"(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

"(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

"(i) is an inhabitant; or

"(ii) may be found.

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

there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(6) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to

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

''(7) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

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

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

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

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

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

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

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section, or the violation of any registration condition or other requirement under such section.''; and

(B) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

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

(3) AMENDMENT OF CERTAIN PROVISIONS.—

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

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

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

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(B) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

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

(4) EXHAUSTION.—

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

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

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

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

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

(5) EFFECT OF SECTION 804.—

(A) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

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

(ii) from permitted countries, as defined in such section 804, by importers

registered under such section 804 on the date that is 1 year after the date of enactment of this Act.

(B) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(i) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this Act will have priority during the 90-day period that begins on such date of enactment.

(ii) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(iii) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this

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

(iv) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

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

of shipments of drugs to individuals in the United States.

(vi) FURTHER LIMIT ON NUMBER OF EXPORTERS.—The Secretary shall report to Congress to request the authority to impose a limitation on the number of registered exporters under such section 804 during any period beginning on a date that is not less than 2 years after the date of enactment of this Act if the Secretary determines that—

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

(II) such limitation will not restrict the ability of individuals to import prescription drugs for personal use from registered exporters under such section 804.

(C) LIMITS ON NUMBER OF IMPORTERS.—

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

ginning on the date that is 1 year after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(ii) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability

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

(iii) FURTHER LIMIT ON NUMBER OF IMPORTERS.—The Secretary shall report to Congress to request the authority to impose a limitation on the number of registered importers under such section 804 during any period beginning on a date that is not less than 3 years after the date of enactment of this Act if the Secretary determines that—

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

(II) such limitation will not restrict the ability of individuals to purchase qualifying drugs imported under such section 804 or savings available to individuals by purchasing such qualifying drugs.

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

qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act if—

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

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

(E) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act if—

(i) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this Act; or

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

(F) NOTICE FOR OTHER DRUGS FOR IMPORT.—

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

(ii) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under clause (i) so that such notices described under such

clause are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. Review of all such notices shall be completed not later than 5 years after the date of enactment of this Act.

(iii) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under clause (i) so that the Secretary reviews the notices described under such clause with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

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

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

(H) REPORT.—Beginning with fiscal year 2009, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in subparagraph (D), (E), or (F), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in subparagraphs (D), (E), and (F).

(I) USER FEES.—

(i) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during fiscal year 2009 to be $1,000,000,000.

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

such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

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

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

(iii) FISCAL YEAR 2010 ADJUSTMENT.—

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

(II) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or clause (ii), the Secretary shall reestimate the total price of qualifying drugs imported

under subsection (a) of such section 804 into the United States by registered importers during fiscal year 2010. Such reestimate shall be equal to—

(aa) the total price of qualifying drugs imported by each importer as reported under subclause (I); multiplied by

(bb) 3.

(III) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1, 2010, from each importer so that the aggregate total of fees collected under paragraph (5)(B) for fiscal year 2010 does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during fiscal year 2008 as reestimated under subclause (II).

(iv) ANNUAL REPORT.—

(I) FOOD AND DRUG ADMINISTRATION.—Beginning with fiscal year

2009, not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.

(II) CUSTOMS AND BORDER CONTROL.—Beginning with fiscal year 2007, not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use,

by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(6) IMPLEMENTATION OF SECTION 804.—

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

(B) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under subparagraph (A) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(C) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under subparagraph (A), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim

rule provided for under subparagraph (A), to the extent that such provisions are not modified.

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

(A) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this Act;

(B) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective; and

(C) with regard to the availability at domestic retail pharmacies of qualifying drugs im-

ported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(8) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this Act (and the amendments made by this Act), nothing in this Act (or the amendments made by this Act) shall be construed to change, limit, or restrict the practices of the Food and Drug Administration or the Bureau of Customs and Border Protection in effect on January 1, 2008, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use.

(c) DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.—

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

"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs

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

"(1) the shipment has a declared value of less than $10,000; and

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

"(B) the Secretary has requested delivery of such shipment of drugs.

"(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

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

"(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

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

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

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

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

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

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

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

(2) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by this subsection, shall be established not later than 90 days after the date of the enactment of this Act.

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

(d) CIVIL ACTIONS REGARDING PROPERTY.—

(1) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following subsection:

''(g)(1) If a person is alienating or disposing of property, or intends to alienate or dispose of property, that is obtained as a result of or is traceable to a drug imported in violation of section 801(a) or 801(d), the Attorney General may commence a civil action in any Federal court—

''(A) to enjoin such alienation or disposition of property; or

''(B) for a restraining order to—

''(i) prohibit any person from withdrawing, transferring, removing, dissipating, or disposing

of any such property or property of equivalent value; and

''(ii) appoint a temporary receiver to administer such restraining order.

''(2) Proceedings under paragraph (1) shall be carried out in the same manner as applies under section 1345 of title 18, United States Code.''.

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

(e) WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.—

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

(A) in paragraph (1)—

(i) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(ii) by striking ''to an authorized distributor of record or''; and

(iii) by striking subparagraph (B) and inserting the following:

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

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

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

established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

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

(C) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

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

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors

with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—The amendments made by subparagraphs (A) and (C) of paragraph (1) and by paragraph (2) shall take effect on January 1, 2013.

(B) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding subparagraph (A), the amendments made by subparagraphs (A) and (C) of paragraph (1) and by paragraph (2) shall take effect on the date that is 90 days after the date of enactment of this Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section.

(C) HIGH-RISK DRUGS.—

(i) IN GENERAL.—Notwithstanding subparagraph (A), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may apply the amendments made by subparagraphs (A) and (C) of paragraph (1) and by paragraph (2) before January 1, 2013, with re-

spect to a prescription drug if the Secretary—

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

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

(ii) PEDIGREE NOT REQUIRED.—Notwithstanding a determination under clause (i) with respect to a prescription drug, the amendments described in such clause shall not apply with respect to a wholesale distribution of such drug if the drug is distributed by the manufacturer of the drug to a person that distributes the drug to a retail pharmacy for distribution to the consumer or patient, with no other intervening transactions.

(iii) LIMITATION.—The Secretary may make the determination under clause (i) with respect to not more than 50 drugs before January 1, 2013.

(D) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by paragraph (1)(B) shall take effect on the

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

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

(i) January 1, 2011, with respect to a prescription drug determined under subparagraph (C)(i) to be at high risk for being counterfeited; and

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

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

(f) INTERNET SALES OF PRESCRIPTION DRUGS.—

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

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

"SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

"(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

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

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

"(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

"(C) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

"(i) are not intended to be accessed by purchasers or prospective purchasers; or

"(ii) provide an Internet information location tool within the meaning of section

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

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

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

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

"(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

"(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

"(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other other valuable consideration is received.

"(2) EXCEPTIONS.—Paragraph (1) does not apply to—

"(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

"(i) a hospital that has in effect a provider agreement under title XVIII of

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

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if—

''(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

''(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

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

section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

''(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as

prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

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

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

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

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

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

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

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

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

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

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

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

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

"(i) to move from viewing one portion of a page on such site to another portion of the page;

"(ii) to move from viewing one page on such site to another page on such site; or

"(iii) to move from viewing a page on one Internet site to a page on another Internet site.

"(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

"(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

"(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.''.

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

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

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

PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(4) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this paragraph as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(i) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(ii) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(iii) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in clause (i).

(B) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subparagraph (A), there is authorized to be appropriated $100,000 for each of the fiscal years 2009 through 2011.

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

(g) IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

SEC. 7. REASONABLE PRICE AGREEMENT FOR FEDERALLY FUNDED RESEARCH.

(a) IN GENERAL.—If any Federal agency or any nonprofit entity undertakes federally funded health care research and development and is to convey or provide a patent or other exclusive right to use such research and development for a drug or other health care technology, such agency or entity shall not make such conveyance or provide such patent or other right until the person who will receive such conveyance or patent or other right first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (c).

(b) CONSIDERATION OF COMPETITIVE BIDDING.—In cases where the Federal Government conveys or licenses exclusive rights to federally funded research under subsection (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—

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

(2) qualified bidders compete on the basis of the least sales revenues before prices are adjusted in accordance with a cost based reasonable pricing formula;

(3) qualified bidders compete on the basis of the least period of time before prices are adjusted in accordance with a cost based reasonable pricing formula;

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

(5) qualified bidders compete under other competitive bidding systems.

Such competitive bidding process may incorporate requirements for minimum levels of expenditures on research, marketing, maximum price, or other factors.

(c) WAIVER.—No waiver shall take effect under subsection (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

SEC. 8. GAO ONGOING STUDIES AND REPORTS ON PROGRAM; MISCELLANEOUS REPORTS.

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

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

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

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

duced hospitalizations and morbidity due to medication errors and adverse medicine reactions.

(4) Whether patient medical record confidentiality is being maintained and safe-guarded.

(5) Such other issues as the Comptroller General may consider.

(b) REPORTS.—The Comptroller General shall issue such reports on the results of the ongoing study described in (a) as the Comptroller General shall deem appropriate and shall notify Congress on a timely basis of significant problems in the operation of the part D prescription medicine program and the need for legislative adjustments and improvements.

(c) MISCELLANEOUS STUDIES AND REPORTS.—

(1) STUDY ON METHODS TO ENCOURAGE ADDITIONAL RESEARCH ON BREAKTHROUGH PHARMACEUTICALS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall seek the advice of the Secretary of the Treasury on possible tax and trade law changes to encourage increased original research on new pharmaceutical breakthrough products designed to address disease and illness.

(B) REPORT.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on such study. The report shall include recommended methods to encourage the pharmaceutical industry to devote more resources to research and development of new covered products than it devotes to overhead expenses.

(2) STUDY ON PHARMACEUTICAL SALES PRACTICES AND IMPACT ON COSTS AND QUALITY OF CARE.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the methods used by the pharmaceutical industry to advertise and sell to consumers and educate and sell to providers.

(B) REPORT.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on such study. The report shall include the estimated direct and indirect costs of the sales methods used, the quality of the information conveyed, and whether such sales efforts leads (or could lead) to inappropriate prescribing. Such report may include legislative and regulatory recommendations to encourage

more appropriate education and prescribing practices.

(3) STUDY ON COST OF PHARMACEUTICAL RESEARCH.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the costs of, and needs for, the pharmaceutical research and the role that the taxpayer provides in encouraging such research.

(B) REPORT.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on such study. The report shall include a description of the full-range of taxpayer-assisted programs impacting pharmaceutical research, including tax, trade, government research, and regulatory assistance. The report may also include legislative and regulatory recommendations that are designed to ensure that the taxpayer's investment in pharmaceutical research results in the availability of pharmaceuticals at reasonable prices.

(4) REPORT ON PHARMACEUTICAL PRICES IN MAJOR FOREIGN NATIONS.—Not later than January 1, 2009, the Secretary of Health and Human Services shall submit to Congress a report on the retail

price of major pharmaceutical products in various developed nations, compared to prices for the same or similar products in the United States. The report shall include a description of the principal reasons for any price differences that may exist.

SEC. 9. MEDIGAP TRANSITION PROVISIONS.

(a) IN GENERAL.—Notwithstanding any other provision of law, no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under section 1882 of the Social Security Act on or after January 1, 2010, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs.

(b) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE.—

(1) IN GENERAL.—The issuer of a medicare supplemental policy—

(A) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as ''A'', ''B'', ''C'', ''D'', ''E'', ''F'', or ''G'' (under the standards established under subsection (p)(2) of section 1882 of the Social Security Act, 42 U.S.C. 1395ss) and that is offered and is avail-

able for issuance to new enrollees by such issuer;

(B) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(C) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in paragraph (2) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

(2) INDIVIDUAL COVERED.—An individual described in this paragraph is an individual who—

(A) enrolls under part D of title XVIII of the Social Security Act; and

(B) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as ''H'', ''I'', or ''J'' under the standards referred to in paragraph (1)(A) or

terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

(3) ENFORCEMENT.—The provisions of paragraph (1) shall be enforced as though they were included in section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) on and after January 1, 2010.

(4) DEFINITIONS.—For purposes of this subsection, the term ''medicare supplemental policy'' has the meaning given such term in section 1882(g) of the Social Security Act (42 U.S.C. 1395ss(g)).

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