(4) learning difficulties;

Whereas those disabilities may require ongoing physical therapy and surgeries;

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood have a considerable impact on children, families, and society;

Whereas very little is known about the cause, treatment, and prevention of childhood stroke;

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for childhood stroke;

Whereas early diagnosis and treatment of childhood stroke greatly improves the chances that the affected child will recover and not experience a recurrence; and

Whereas the Children's Hospital of Philadelphia should be commended for its initiative in creating the Nation's first program dedicated to pediatric stroke patients: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 5, 2007 as ''National Childhood Stroke Awareness Day''; and

(2) urges the people of the United States to support the efforts, programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke.

AMENDMENTS SUBMITTED AND PROPOSED

SA 983. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 984. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 985. Mr. BROWNBACK (for himself and Mr. BROWN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 986. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 987. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 988. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 989. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 990. Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON, of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) submitted an amendment intended to be proposed by him to the bill S. 1082, supra.

SA 991. Mr. KOHL (for himself, Mr. GRASSLEY, Mr. LEAHY, and Mr. SCHUMER) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 992. Mr. KOHL submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 993. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 994. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 995. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 996. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 997. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 998. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 999. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1000. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1001. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1002. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1003. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1004. Ms. LANDRIEU proposed an amendment to the bill S. 1082, supra.

SA 1005. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1006. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1007. Mr. REID (for Mr. BUNNING) proposed an amendment to the resolution S. Res. 162, commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers.

TEXT OF AMENDMENTS

SA 983. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle E of title II, insert the following:

SEC. ___. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of nonvisible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of

this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

SA 984. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE—IMPORTATION OF PRESCRIPTION DRUGS

SEC. __01. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Market Access Act of 2007''.

SEC. __02. FINDINGS.

Congress finds as follows:

(1) Americans unjustly pay up to 1,000 percent more to fill their prescriptions than consumers in other countries.

(2) The United States is the world's largest market for pharmaceuticals yet consumers still pay the world's highest prices.

(3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.

(4) Prescription drug costs are a leading cause of the growth in United States health care spending, which reached nearly $2,000,000,0000 in 2005, of which spending on prescription drugs amounted to $200,700,000,000.

(5) According to the Congressional Budget Office, American seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years.

(6) Allowing open pharmaceutical markets could save American consumers at least $635,000,000,000 of their own money.

SEC. __03. PURPOSES.

The purposes of this title are to—

(1) give all Americans immediate relief from the outrageously high cost of pharmaceuticals;

(2) reverse the perverse economics of the American pharmaceutical market;

(3) allow the importation of prescription drugs only if the drugs and facilities where such drugs are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics;

(4) ensure continued integrity to the prescription drug supply of the United States by—

(A) requiring that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies;

(B) requiring Internet pharmacies to register with the United States Government for Americans to verify authenticity before purchases over the Internet;

(C) requiring all foreign sellers to register with United States Government and submit to facility inspections by the Government without prior notice; and

(D) limiting the eligible countries from which prescription drugs may be imported to Canada, member countries of the European Union, and other highly industrialized nations with safe pharmaceutical infrastructures.

SEC. __04. AMENDMENTS TO SECTION 804 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITIONS.—Section 804(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)) is amended to read as follows:

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacy, group of pharmacies, pharmacist, or wholesaler.

''(2) PERMITTED COUNTRY.—The term 'permitted country' means Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, the United Kingdom, Iceland, Liechtenstein, and Norway, except that the Secretary—

''(A) may add a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area has a pharmaceutical infrastructure that is substantially equivalent or superior to the pharmaceutical infrastructure of the United States, taking into consideration pharmacist qualifications, pharmacy storage procedures, the drug distribution system, the drug dispensing system, and market regulation; and

''(B) may remove a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area does not have such a pharmaceutical infrastructure.

''(3) PHARMACIST.—The term 'pharmacist' means a person licensed by the relevant governmental authority to practice pharmacy, including the dispensing and selling of prescription drugs.

''(4) PHARMACY.—The term 'pharmacy' means a person that is licensed by the relevant governmental authority to engage in the business of selling prescription drugs that employs 1 or more pharmacists.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

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

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery; or

''(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

''(6) QUALIFYING DRUG.—The term 'qualifying drug' means a prescription drug that—

''(A) is approved pursuant to an application submitted under section 505(b)(1); and

''(B) is not—

''(i) a drug manufactured through 1 or more biotechnology processes;

''(ii) a drug that is required to be refrigerated; or

''(iii) a photoreactive drug.

''(7) QUALIFYING INTERNET PHARMACY.—The term 'qualifying Internet pharmacy' means a registered exporter that dispenses qualifying drugs to individuals over an Internet website.

''(8) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(9) REGISTERED EXPORTER.—The term 'registered exporter' means a person that is in the business of exporting a drug to persons in the United States (or that seeks to be in such business), for which a registration under this section has been approved and is in effect.

''(10) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).''.

(b) REGULATIONS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended to read as follows:

''(b) REGULATIONS.—Not later than 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2007, the Secretary, after consultation with the United States Trade Representative and the Commissioner of the Bureau of Customs and Border Protection, shall promulgate regulations permitting pharmacists, pharmacies, and wholesalers to import qualifying drugs from permitted countries into the United States.''.

(c) LIMITATION.—Section 804(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(c)) is amended by striking ''prescription drug'' each place it appears and inserting ''qualifying drug''.

(d) INFORMATION AND RECORDS.—Section 804(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(d)(1)) is amended—

(1) by striking subparagraph (G) and redesignating subparagraphs (H) through (N) as subparagraphs (G) through (M), respectively;

(2) in subparagraph (H) (as so redesignated), by striking ''telephone number, and professional license number (if any)'' and inserting ''and telephone number''; and

(3) in subparagraph (L) (as so redesignated), by striking ''(J) and (L)'' and inserting ''(I) and (K)''.

(e) TESTING.—Section 804(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(e)) is amended to read as follows:

''(e) TESTING.—The regulations under subsection (b) shall require that the testing described under subparagraphs (I) and (K) of subsection (d)(1) be conducted by the importer of the qualifying drug, unless the qualifying drug is subject to the requirements under section 505C for counterfeit-resistant technologies.''.

(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—Section 804(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(f)) is amended to read as follows:

''(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—

''(1) IN GENERAL.—Any person that seeks to be a registered exporter (referred to in this subsection as the 'registrant') shall submit to the Secretary a registration that includes the following:

''(A) The name of the registrant and identification of all places of business of the registrant that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the registrant;

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

''(i) make its places of business that relate to qualifying drugs (including warehouses and other facilities owned or controlled by, or operated for, the exporter) and records available to the Secretary for on-site inspections, without prior notice, for the purpose of determining whether the registrant is in compliance with this Act's requirements;

''(ii) export only qualifying drugs;

''(iii) export only to persons authorized to import the drugs;

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

''(v) monitor compliance with registration conditions and report any noncompliance promptly;

''(vi) submit a compliance plan showing how the registrant will correct violations, if any; and

''(vii) promptly notify the Secretary of changes in the registration information of the registrant.

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

''(A) IN GENERAL.—Not later than 90 days after receiving a completed registration from a registrant, the Secretary shall—

''(i) notify such registrant of receipt of the registration;

''(ii) assign such registrant a registration number; and

''(iii) approve or disapprove the application.

''(B) DISAPPROVAL OF APPLICATION.—

''(i) IN GENERAL.—The Secretary shall disapprove a registration, and notify the registrant of such disapproval, if the Secretary has reason to believe that such registrant is not in compliance with a registration condition.

''(ii) SUBSEQUENT APPROVAL.—The Secretary may subsequently approve a registration that was denied under clause (i) if the Secretary finds that the registrant is in compliance with all registration conditions.

''(3) LIST.—The Secretary shall—

''(A) maintain an up-to-date list of registered exporters (including qualifying Internet pharmacies that sell qualifying drugs to individuals);

''(B) make such list available to the public on the Internet site of the Food and Drug Administration and via a toll-free telephone number; and

''(C) update such list promptly after the approval of a registration under this subsection.

''(4) EDUCATION OF CONSUMERS.—The Secretary shall carry out activities, by use of the Internet website and toll-free telephone number under paragraph (3), that educate consumers with regard to the availability of qualifying drugs for import for personal use under this section, including information on how to verify whether an exporter is registered.

''(5) INSPECTION OF IMPORTERS AND REGISTERED EXPORTERS.—The Secretary shall inspect the warehouses, other facilities, and records of importers and registered exporters as often as the Secretary determines necessary to ensure that such importers and registered exporters are in compliance with this section.''.

(g) SUSPENSION OF IMPORTATION.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)) is amended by—

(1) striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b)''; and

(2) by adding after the period at the end the following: ''The Secretary shall reinstate the importation by a specific importer upon a determination by the Secretary that the violation has been corrected and that the importer has demonstrated that further violations will not occur. This subsection shall not apply to a prescription drug imported by an individual, or to a prescription drug shipped to an individual by a qualifying Internet pharmacy.''.

(h) WAIVER AUTHORITY FOR INDIVIDUALS.—Section 804(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(j)) is amended to read as follows:

''(j) IMPORTATION BY INDIVIDUALS.—

''(1) IN GENERAL.—Not later than 180 days after the enactment of the Pharmaceutical Market Access Act of 2007, the Secretary shall by regulation permit an individual to import a drug from a permitted country to the United States if the drug is—

''(A) a qualifying drug;

''(B) imported from a licensed pharmacy or qualifying Internet pharmacy;

''(C) for personal use by an individual, or family member of the individual, not for resale;

''(D) in a quantity that does not exceed a 90-day supply during any 90-day period; and

''(E) accompanied by a copy of a prescription for the drug, which—

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

''(ii) was issued by a practitioner who is authorized to administer prescription drugs.

''(2) DRUGS DISPENSED OUTSIDE THE UNITED STATES.—An individual may import a drug from a country that is not a permitted country if—

''(A) the drug was dispensed to the individual while the individual was in such country, and the drug was dispensed in accordance with the laws and regulations of such country;

''(B) the individual is entering the United States and the drug accompanies the individual at the time of entry;

''(C) the drug is approved for commercial distribution in the country in which the drug was obtained;

''(D) the drug does not appear to be adulterated; and

''(E) the quantity of the drug does not exceed a 14-day supply.''.

(i) REPEAL OF CERTAIN PROVISIONS.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended by striking subsections (l) and (m).

SEC. __05. REGISTRATION FEES.

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

''PART 5—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION

''SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

''(a) REGISTRATION FEE.—The Secretary shall establish a registration fee program under which a registered exporter under section 804 shall be required to pay an annual fee to the Secretary in accordance with this subsection.

''(b) COLLECTION.—

''(1) COLLECTION ON INITIAL REGISTRATION.—A fee under this section shall be payable for the fiscal year in which the registered exporter first submits a registration under section 804 (or reregisters under that section if that person has withdrawn its registration and subsequently reregisters) in a amount of $10,000, due on the date the exporter first submits a registration to the Secretary under section 804.

''(2) COLLECTION IN SUBSEQUENT YEARS.—After the fee is paid for the first fiscal year, the fee described under this subsection shall be payable on or before October 1 of each year.

''(3) ONE FEE PER FACILITY.—The fee shall be paid only once for each registered exporter for a fiscal year in which the fee is payable.

''(c) FEE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (b)(1), the amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the amendments made by the Pharmaceutical Market Access Act of 2007 in the subsequent fiscal year.

''(2) LIMITATION.—

''(A) IN GENERAL.—The aggregate total of fees collected under this section shall not exceed 1 percent of the total price of drugs exported annually to the United States by registered exporters under this section.

''(B) REASONABLE ESTIMATE.—Subject to the limitation described in subparagraph (A), a fee under this subsection for an exporter shall be an amount that is a reasonable estimate by the Secretary of the annual share of the exporter of the volume of drugs exported by exporters under this section.

''(d) USE OF FEES.—The fees collected under this section shall be used for the sole purpose of administering this section with respect to registered exporters, including the costs associated with—

''(1) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug;

''(2) developing, implementing, and maintaining a system to determine registered exporters' compliance with the registration conditions under the Pharmaceutical Market Access Act of 2007, including when shipments of qualifying drugs are offered for import into the United States; and

''(3) inspecting such shipments, as necessary, when offered for import into the United States to determine if any such shipment should be refused admission.

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(2) FAILURE TO PAY.—If a registered exporter subject to a fee under this section fails to pay the fee, the Secretary shall not

permit the registered exporter to engage in exportation to the United States or offering for exportation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

''(1) FEE ESTABLISHMENT.—Not later than 60 days before the beginning of each fiscal year, the Secretary shall—

''(A) publish registration fees under this section for that fiscal year;

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

''(C) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2007, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(A) implementation of the registration fee authority during the fiscal year; and

''(B) the use by the Secretary of the fees collected during the fiscal year for which the report is made.''.

SEC. __06. COUNTERFEIT-RESISTANT TECHNOLOGY.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(z) If it is a drug subject to section 503(b), unless the packaging of such drug complies with the requirements of section 505C for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACKAGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to that used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of non-visible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), manufacturers of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

''(d) EFFECTIVE DATE.—This section shall take effect 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2007.''.

SEC. __07. PROHIBITED ACTS.

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 failure to register in accordance with section 804(f) or to import or offer to import a prescription drug in violation of a suspension order under section 804(g).''.

SEC. __08. PATENTS.

Section 271 of title 35, United States Code, is amended—

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

(2) 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 (21 U.S.C. 384) 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.''.

SEC. __09. OTHER ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (as amended in section __04) is amended by adding at the end the following:

''(l) UNFAIR OR DISCRIMINATORY ACTS AND PRACTICES.—

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

''(A) discriminate by charging a higher price for a prescription drug sold to a person in a permitted country that exports a prescription drug to the United States under this section than the price that is charged to another person that is in the same country and that does not export a prescription drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a person that distributes, sells, or uses a prescription 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 prescription drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying supplies of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

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

''(E) discriminate by specifically restricting or delaying the supply of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(F) 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 for the purpose of restricting importation of the drug into the United States under this section;

''(G) refuse to allow an inspection authorized under this section of an establishment that manufactures a prescription drug that may be imported or offered for import under this section;

''(H) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug that may be imported or offered for import under this section to good manufacturing practice under this Act;

''(I) become a party to a licensing or other agreement related to a prescription drug that fails to provide for compliance with all requirements of this section with respect to such prescription drug or that has the effect of prohibiting importation of the drug under this section; or

''(J) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages in, or to impede, delay, or block the process for, the importation of a prescription drug under this section.

''(2) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has discriminated under subparagraph (A), (B), (C), (D), or (E) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial of supplies of a prescription drug to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on—

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

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

''(3) PRESUMPTION AND AFFIRMATIVE DEFENSE.—

''(A) PRESUMPTION.—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) created after January 1, 2007, between a prescription drug for distribution in the United States and the drug for distribution in a permitted country shall be presumed under paragraph (1)(H) to be for the purpose of restricting importation of the drug into the United States under this section.

''(B) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to the presumption under subparagraph (A) that—

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

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

''(4) 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 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.

''(5) 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.

''(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 were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained.

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—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 for a violation of paragraph (1) 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 Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

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

''(ii) EFFECT OF INTERVENTION.—If the 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.—

''(i) IN GENERAL.—In any case in which an action is instituted by or on behalf of the 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.

''(ii) INTERVENTION.—An attorney general of a State may intervene, on behalf of the residents of that State, in an action instituted by the Commission.

''(iii) EFFECT OF INTERVENTION.—If an attorney general of a State intervenes in an action instituted by the Commission, such attorney general 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.

''(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) LIMITATION OF ACTIONS.—Any action under this paragraph to enforce a cause of action under this subsection by the Federal Trade Commission or the attorney general of a State shall be forever barred unless commenced within 5 years after the Federal Trade Commission, or the attorney general, as the case may be, knew or should have known that the cause of action accrued. No cause of action barred under existing law on the effective date of the Pharmaceutical Market Access Act of 2007 shall be revived by such Act.

''(H) 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.

''(I) 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.

''(7) 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.

''(8) 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.''.

(b) REGULATIONS.—The Federal Trade Commission shall promulgate regulations to carry out the enforcement program under section 804(l) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) SUSPENSION AND TERMINATION OF EXPORTERS.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (as amended by section __04(g)) (21 U.S.C. 384(g)) is amended by—

(1) striking ''SUSPENSION OF IMPORTATION.—The Secretary'' and inserting ''SUSPENSION OF IMPORTATION.—

''(1) IN GENERAL.—The Secretary''; and

(2) adding at the end the following:

''(2) SUSPENSION AND TERMINATION OF EXPORTERS.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under subsection (f) by a registered exporter:

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

''(ii) If the Secretary determines that, under color of the registration, the registered exporter has exported a drug that is not a qualifying drug, or a drug that does not meet the criteria under this section, or has exported a qualifying drug to an individual in violation of this section, 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 registered exporter involved 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 determines that the registered exporter 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 subsection (f) of a registered exporter if the Secretary determines that the registered exporter 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 registered exporter. 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 of a registered exporter is terminated, any registration submitted under subsection (f) by such exporter or a person who is a partner in the export enterprise or a principal officer in such enterprise, and any registration prepared with the assistance of such exporter or such a person, has no legal effect under this section.''.

SEC. __10. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this title (and the amendments made by this title).

SA 985. Mr. BROWNBACK (for himself and Mr. BROWN) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

''(2) AIDS DRUG.—The term 'AIDS drug' means a drug indicated for treating HIV.

''(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

''(4) NEGLECTED OR TROPICAL DISEASE.—The term 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

''(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

''(5) PRIORITY REVIEW.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

''(6) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

''(7) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' means a product that—

''(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

''(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

''(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection is not included in such application.''.

SA 986. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

TITLE—DOMESTIC PET TURTLE MARKET ACCESS

SEC. ___. SHORT TITLE.

This title may be cited as the ''Domestic Pet Turtle Market Access Act of 2007''.

SEC. ___. FINDINGS.

Congress makes the following findings:

(1) Pet turtles less than 10.2 centimeters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat turtles for salmonella, and make them safe for sale, has greatly advanced since 1975. Treatments exist that can nearly eradicate salmonella from turtles, and individuals are more aware of the causes of salmonella, how to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regiment that allows the turtle to be maintained safe from salmonella.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat the turtles for salmonella and maintain a safe pet.

SEC. ___. SALE OF BABY TURTLES.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer or other commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the turtle is raised, shipped, and sold using methods that are proven to keep the turtle free of salmonella, using salmonella safety standards that are comparable to such standards relating to other animals, including reptiles and amphibians, that are allowed for sale as pets, or animal products that are allowed for sale as food products;

(2) the Administration has approved a plan submitted by the turtle farmer or commercial retail seller involved relating to compliance with paragraph (1); and

(3) the farmer or other commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if the turtle is not properly handled and safely maintained;

(ii) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iii) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(B) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and

(C) a statement that buyers of pet turtles should not abandon the turtle or abandon it outside, as the turtle may become an invasive species to the local community, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

(b) PLAN.—

(1) IN GENERAL.—A turtle farmer or other commercial seller that desires to sell a turtle as provided for under subsection (a) shall submit a plan to the Food and Drug Administration that details the manner in which the farmer or seller will ensure compliance with the requirements of subsection (a)(1) with respect to the turtles involved. The plan shall include use of non-antibiotic compounds that suppress or eliminate the presence of salmonella in turtle hatchlings.

(2) ACTION BY FDA.—Not later 30 days after the date on which the Food and Drug Administration receives a plan under paragraph (1), the Administration shall accept or reject such plan. If such plan is rejected, the Administration shall provide clear, specific guidance on the reasons for such rejection. The Administration may only reject such a plan if it is determined that the plan fails to achieve the same salmonella safety standards as such standards relating to other animals, including reptiles and amphibians, that are allowed for sale as pets, or animal products that are allowed for sale as food products.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit the Food and Drug Administration to hold the sale of turtles less than 10.2 centimeters in

diameter as a pet to any greater salmonella safety standard applicable to other reptiles or amphibians sold as pets, animals sold as pets, or food products regulated by such Administration.

SA 987. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. HEAD START ACT AMENDMENT IMPOSING PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

The Head Start Act (42 U.S.C. 9831 et seq.) is amended by adding at the end the following:

''SEC. 657A. PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

''(a) IN GENERAL.—A Head Start agency shall obtain written parental consent before administration of any nonemergency intrusive physical examination of a child in connection with participation in a program under this subchapter.

''(b) DEFINITION.—The term 'nonemergency intrusive physical examination' means, with respect to a child, a physical examination that—

''(1) is not immediately necessary to protect the health or safety of the child involved or the health or safety of another individual; and

''(2) requires incision or is otherwise invasive, or involves exposure of private body parts.''.

SA 988. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CHILD MEDICATION SAFETY.

(a) REQUIRED POLICIES AND PROCEDURES.—

(1) IN GENERAL.—As a condition of receiving funds under any program or activity administered by the Secretary of Education, not later than 1 year after the date of enactment of this section, each State shall develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription for substances covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug as a condition of attending school or receiving services.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to create a Federal prohibition against teachers and other school personnel consulting or sharing classroom-based observations with parents or guardians regarding a student's academic performance or behavior in the classroom or school, or regarding the need for evaluation for special education or related services under section 612(a)(3) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(3)).

(3) PROHIBITION OF PAYMENT OF FUNDS.—No Federal education funds may be paid to any local educational agency or other instrument of government that uses the refusal of a parent or legal guardian to provide a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug for such individual's child as the basis of a charge of child abuse, child neglect, education neglect, or medical neglect until the agency or instrument demonstrates that it is no longer using such refusal as a basis of a child abuse, child neglect, education neglect, or medical neglect charge.

(b) DEFINITIONS.—In this section:

(1) CHILD.—The term ''child'' means any person within the age limits for which the State provides free public education.

(2) PSYCHOTROPIC DRUG.—The term ''psychotropic drug'' means a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is not a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) but is—

(A) used in the diagnosis, treatment, or prevention of a disease; and

(B) intended to have an altering effect on perception, emotion, or behavior.

(3) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(c) GAO STUDY AND REVIEW.—

(1) REVIEW.—The Comptroller General of the United States shall conduct a review of—

(A) the variation among States in definitions of psychotropic medications as used in regard to State jurisdiction over public education;

(B) the prescription rates of medications used in public schools to treat children diagnosed with attention deficit disorder, attention deficit hyperactivity disorder, and other disorders or illnesses;

(C) which medications used to treat such children in public schools are listed under the Controlled Substances Act; and

(D) which medications used to treat such children in public schools are not listed under the Controlled Substances Act, including the properties and effects of any such medications, including the incidence of hallucinations, psychosis, violence, suicide, heart problems, significant weight gain, or diabetes that students may experience while on these medications.

(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall prepare and submit a report that contains the results of the review under paragraph (1).

SA 989. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. REQUIRED INFORMATION IN DIRECT-TO-CONSUMER TELEVISION AND RADIO ADVERTISEMENTS.

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: ''In addition to the requirements under the preceding sentence, in the case of an advertisement of a prescription drug presented directly to consumers in television or radio format that states the name of the drug and its medical indications, unless the audio portion of such advertisement includes a listing of all information in full about adverse reactions, contraindications, and precautions listed in the patient or professional labeling of the drug approved under this Act.''.

SA 990. Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the appropriate place, insert the following:

TITLE ___—IMPORTATION OF PRESCRIPTION DRUGS

SEC. _01. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2007''.

SEC. _02. FINDINGS.

Congress finds that—

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

(2) 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;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) 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;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. _03. 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.

SEC. _04. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section _03, 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;

''(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; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(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 subclause (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 pharmaceutical 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 withdraw 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 compliance 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 registration 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 determines 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 determines 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 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 necessary 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 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 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 container 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 reason 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 2.5 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 subsequent 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 2.5 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 reported 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 section 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 Secretary 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 introduced 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 shall—

''(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 import 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 effective 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) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) 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 described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) 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) EXPORTER LICENSURE IN PERMITTED COUNTRY.—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 more 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 AND PACKAGING.—

''(1) IN GENERAL.—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 shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) 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.

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

''(i) 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

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

''(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

''(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 2007, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information 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) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer 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.

''(4) 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.

''(5) 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.).

''(6) 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 Commission 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.

''(7) 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.

''(8) 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.''.

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

(1) 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

(2) 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.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) 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.''.

(2) 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,''.

(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 title.

(d) EXHAUSTION.—

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

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

(B) 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.''.

(2) 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.

(e) EFFECT OF SECTION 804.—

(1) 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—

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

(B) 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 title.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) 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 title will have priority during the 90 day period that begins on such date of enactment.

(B) 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.

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

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this title, 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.

(E) 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 title, 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.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning on a date that is 2 or more years after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, 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.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, 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.

(B) 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 title, 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 into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) 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 title 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 title if—

(A) 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

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

(5) 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 title 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 title if—

(A) 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 title; or

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

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) 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 title and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A) 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. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph 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.

(7) 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 title shall be submitted to and reviewed by the Secretary as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this title, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) 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 the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) 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) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, 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 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), 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 the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

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

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year 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 such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—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.—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.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Government of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

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

(f) IMPLEMENTATION OF SECTION 804.—

(1) 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.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), 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 paragraph (1), to the extent that such provisions are not modified.

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

(1) 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 title;

(2) 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;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. __05. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section __04, 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.''.

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

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

SEC. __06. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) 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—

(1) in paragraph (1)—

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

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

(C) 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).'';

(2) 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

(3) 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''.

(b) 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.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2010.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this title with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section __04.

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

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2010.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this title.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this title, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

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

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. __07. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) 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 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 inhabitant, 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.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

(c) 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 subsection (a) of 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.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection 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—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) 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

(C) 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 subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this title, 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.

SEC. __08. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) 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:

''(g) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

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

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

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(I) The extent to which the payment system or person knowingly permits restricted transactions.

''(II) The history of the payment system or person in connection with permitting restricted transactions.

''(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.''.

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

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (g)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this title.

SEC. __09. 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. __10. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not affected thereby.

SA 991. Mr. KOHL (for himself, Mr. GRASSLEY, Mr. LEAHY, and Mr. SCHUMER) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, insert the following:

TITLE ___PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Preserve Access to Affordable Generics Act''.

SEC. __02. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—The Congress finds that—

(1) prescription drugs make up 11 percent of the national health care spending but are 1 of the largest and fastest growing health care expenditures;

(2) 56 percent of all prescriptions dispensed in the United States are generic drugs, yet they account for only 13percent of all expenditures;

(3) generic drugs, on average, cost 63 percent less than their brand-name counterparts;

(4) consumers and the health care system would benefit from free and open competition in the pharmaceutical market and the removal of obstacles to the introduction of generic drugs;

(5) full and free competition in the pharmaceutical industry, and the full enforcement of antitrust law to prevent anticompetitive practices in this industry, will lead to lower prices, greater innovation, and inure to the general benefit of consumers.

(6) the Federal Trade Commission has determined that some brand name pharmaceutical manufacturers collude with generic drug manufacturers to delay the marketing of competing, low-cost, generic drugs;

(7) collusion by the brand name pharmaceutical manufacturers is contrary to free competition, to the interests of consumers, and to the principles underlying antitrust law;

(8) in 2005, 2 appellate court decisions reversed the Federal Trade Commission's longstanding position, and upheld settlements that include pay-offs by brand name pharmaceutical manufacturers to generic manufacturers designed to keep generic competition off the market;

(9) in the 6 months following the March 2005 court decisions, the Federal Trade Commission found there were three settlement agreements in which the generic received compensation and agreed to a restriction on its ability to market the product;

(10) the FTC found that more than ⅔ of the approximately ten settlement agreements made in 2006 include a pay-off from the brand in exchange for a promise by the generic company to delay entry into the market; and

(11) settlements which include a payment from a brand name manufacturer to a generic manufacturer to delay entry by generic drugs are anti-competitive and contrary to the interests of consumers.

(b) PURPOSES.—The purposes of this title are—

(1) to enhance competition in the pharmaceutical market by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market;

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive agreements and collusion in the pharmaceutical industry; and

(3) to clarify the law to prohibit payments from brand name to generic drug manufacturers with the purpose to prevent or delay the entry of competition from generic drugs.

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Clayton Act (15 U.S.C. 12 et seq.) is amended by inserting after section 28 the following:

"SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MARKETING.

''(a) It shall be unlawful under this Act for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim which—

''(1) an ANDA filer receives anything of value; and

''(2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.

''(b) Nothing in this section shall prohibit a resolution or settlement of patent infringement claim in which the value paid by the NDA holder to the ANDA filer as a part of the resolution or settlement of the patent infringement claim includes no more than the right to market the ANDA product prior to the expiration of the patent that is the basis for the patent infringement claim.

''(c) In this section:

''(1) The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

''(2) The term 'agreement resolving or settling a patent infringement claim' includes, any agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

''(4) The term 'ANDA filer' means a party who has filed an ANDA with the Federal Drug Administration.

''(5) The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

''(7) The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(8) The term 'NDA holder' means—

''(A) the party that received FDA approval to market a drug product pursuant to an NDA;

''(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subclauses (i) and (ii) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

''(10) The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.''.

(b) REGULATIONS.—The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements described in the section 29 of the Clayton Act, as added by subsection (a), if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under section 29 of the Clayton Act.

SEC. __04. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 3155 note) is amended by—

(1) striking ''the Commission the'' and inserting ''the Commission (1) the''; and

(2) inserting before the period at the end the following: ''; and (2) a description of the subject matter of any other agreement the parties enter into within 30 days of an entering into an agreement covered by subsection (a) or (b)''.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.''.

SEC. __05. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 28 of the Clayton Act or'' after ''that the agreement has violated''.

SEC. __06. STUDY BY THE FEDERAL TRADE COMMISSION.

(a) REQUIREMENT FOR A STUDY.—Not later than 180 days after the date of enactment of this Act and pursuant to its authority under section 6(a) of the Federal Trade Commission Act (15 U.S.C. 46(a)) and its jurisdiction to prevent unfair methods of competition, the Federal Trade Commission shall conduct a study regarding—

(1) the prevalence of agreements in patent infringement suits of the type described in section 29 of the Clayton Act, as added by this title, during the last 5 years;

(2) the impact of such agreements on competition in the pharmaceutical market; and

(3) the prevalence in the pharmaceutical industry of other anticompetitive agreements among competitors or other practices that are contrary to the antitrust laws, and the impact of such agreements or practices on competition in the pharmaceutical market during the last 5 years.

(b) CONSULTATION.—In conducting the study required under this section, the Federal Trade Commission shall consult with the Antitrust Division of the Department of Justice regarding the Justice Department's findings and investigations regarding anticompetitive practices in the pharmaceutical market, including criminal antitrust investigations completed by the Justice Department with respect to practices or conduct in the pharmaceutical market.

(c) REQUIREMENT FOR A REPORT.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit a report to the Judiciary Committees of Senate and House of Representatives, and to the Department of Justice regarding the findings of the study conducted under subsection (a). This report shall contain the Federal Trade Commission's recommendation as to whether any amendment to the antitrust laws should be enacted to correct any substantial lessening of competition found during the study.

(d) FEDERAL AGENCY CONSIDERATION.—Upon receipt of the report required by subsection (c), the Attorney General or the Chairman of the Federal Trade Commission, as appropriate, shall consider whether any additional

enforcement action is required to restore competition or prevent a substantial lessening of competition occurring as a result of the conduct or practices that were the subject of the study conducted under subsection (b).

SEC. __07. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Federal Trade Commission such sums as may be necessary to carry out the provisions of this title.

SA 992. Mr. KOHL submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended by adding at the end the following:

''(G)(i) Notwithstanding any other provision of law, any petition submitted under section 10.30 or section 10.35 of title 21, Code of Federal Regulations (or any successor regulation), shall include a statement that to the petitioner's best knowledge and belief, the petition—

''(I) includes all information and views on which the petitioner relies, including all representative data and information known to the petitioner that is favorable or unfavorable to the petition;

''(II) is well grounded in fact and is warranted by law;

''(III) is not submitted for an improper purpose, such as to harass or cause unnecessary delay (including unnecessary delay of competition or agency action); and

''(IV) does not contain a materially false, misleading, or fraudulent statement.

''(ii) The Secretary shall investigate, on receipt of a complaint, a request under clause (vi), or on its own initiative, any petition submitted under such section 10.30 or section 10.35 (or any successor regulation), that—

''(I) does not comply with the requirements of clause (i);

''(II) may have been submitted for an improper purpose as described in clause (i)(III); or

''(III) may contain a materially false, misleading, or fraudulent statement as described in clause (i)(IV).

''(iii) If the Secretary finds that the petitioner has knowingly and willingly submitted the petition for an improper purpose as described in clause (i)(III), or which contains a materially false, misleading, or fraudulent statement as described in clause (i)(IV), the Secretary may—

''(I) impose a civil penalty of not more than $1,000,000, plus attorneys fees and costs of reviewing the petition and any related proceedings;

''(II) suspend the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation), for a period of not more than 10 years;

''(III) revoke permanently the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation); or

''(IV) dismiss the petition at issue in its entirety.

''(iv) If the Secretary takes an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, the Secretary shall refer that petition to the Federal Trade Commission for further action as the Federal Trade Commission finds appropriate.

''(v) In determining whether to take an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, and in determining the amount of any civil penalty or the length of any suspension imposed under that clause, the Secretary shall consider the specific circumstances of the situation, such as the gravity and seriousness of the violation involved, the amount of resources expended in reviewing the petition at issue, the effect on marketing of competing drugs of the pendency of the improperly submitted petition, including whether the timing of the submission of the petition appears to have been calculated to cause delay in the marketing of any drug awaiting approval, and whether the petitioner has a history of submitting petitions in violation of this subparagraph.

''(vi)(I) Any person aggrieved by a petition filed under such section 10.30 or section 10.35 (or any successor regulation), including a person filing an application under subsection (b)(2) or (j) of this section to which such petition relates, may request that the Secretary initiate an investigation described under clause (ii) for an enforcement action described under clause (iii).

''(II) The aggrieved person shall specify the basis for its belief that the petition at issue is false, misleading, fraudulent, or submitted for an improper purpose. The aggrieved person shall certify that the request is submitted in good faith, is well grounded in fact, and not submitted for any improper purpose. Any aggrieved person who knowingly and intentionally violates the preceding sentence shall be subject to the civil penalty described under clause (iii)(I).

''(vii) The Secretary shall take final agency action with respect to a petition filed under such section 10.30 or section 10.35 (or any successor regulation) regarding an abbreviated new drug application within 6 months of receipt of such petition. The Secretary shall not extend such 6-month review period, even with consent of the petitioner, for any reason, including based upon the submission of comments relating to a petition or supplemental information supplied by the petitioner. If the Secretary has not taken final agency action on a petition regarding an abbreviated new drug application by the date that is 6 months after the date of receipt of the petition, such petition shall be deemed to have been denied on such date.

''(viii) The Secretary may promulgate regulations to carry out this subparagraph, including to determine whether petitions filed under such section 10.30 or section 10.35 (or any successor regulation) merit enforcement action by the Secretary under this subparagraph.''.

SA 993. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE __—INTERNET PHARMACIES

SEC. __01. SHORT TITLE.

This title may be cited as the ''Safe Internet Pharmacy Act of 2007''.

SEC. __02. INTERNET PHARMACIES.

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. INTERNET PHARMACIES.

''(a) DEFINITIONS.—In this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) DESIGNATED PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'designated payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or to facilitate restricted transactions.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network constructed primarily to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

''(7) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(9) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

''(10) OTHER DEFINITIONS.—

''(A) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(B) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(C) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

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

''(ii) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

''(D) FINANCIAL INSTITUTION.—The term 'financial institution'—

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

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

''(E) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to dispense or dispensing a prescription drug to an individual.

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy whose principal place of business is located outside the United States, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(cc) the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States;

''(dd) the Internet pharmacy expressly and affirmatively agrees to be subject to the jurisdiction of the United States and any of its States or territories where it engages in commerce; and

''(ee) the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection;

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void;

''(v) verification that the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy; and

''(vi) assurance that the Internet pharmacy will comply with the requirements under subparagraphs (B) and (C).

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription from a treating provider.

''(v) A distinctive tamper resistant seal to identify that the Internet pharmacy is licensed.

''(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

''(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

''(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

''(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient before and after the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(III) Submit those reports within 3 days of receipt and the response of the Internet pharmacy to the Food and Drug Administration in a manner determined appropriate by the Secretary.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a valid prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) If the prescription for any drug other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) is received from an individual or the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act), the validity of the prescription shall be confirmed with the treating provider as described in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall—

''(i) assign an identification number to the Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensing application; and

''(iii) if the Internet pharmacy is in compliance with the conditions under paragraph (2), issue a license not later than 60 days after receipt of a licensing application from the Internet pharmacy.

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensing applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) DATABASE.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a database of the Internet pharmacies licensed under this section.

''(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) FEES.—

''(A) IN GENERAL.—

''(i) LICENSING APPLICATION FEE.—The Secretary shall establish a licensing application fee to be paid by all applicants.

''(ii) RENEWAL FEE.—The Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

''(B) COLLECTION.—

''(i) COLLECTION OF LICENSING APPLICATION FEE.—A licensing application fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon the submission to the Secretary of such licensing application.

''(ii) COLLECTION OF RENEWAL FEES.—After the licensing application fee is paid for the first fiscal year of licensure, the yearly renewal fee, as established under subparagraph (C), shall be payable on or before October 1 of each subsequent fiscal year.

''(iii) ONE FEE PER INTERNET PHARMACY.—The licensing application fee and yearly renewal fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

''(C) FEE AMOUNT.—The amount of the licensing application fee and the yearly renewal fee for an Internet pharmacy shall be determined each year by the Secretary based on the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

''(D) ANNUAL FEE DETERMINATION.—

''(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall determine the amount of the licensing application fee and the yearly renewal fee for that fiscal year.

''(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the amount of the licensing application fee and the yearly renewal fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fees.

''(E) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to carry out this section.

''(F) FAILURE TO PAY FEE.—

''(i) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(G) REPORTS.—Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

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

''(6) SUSPENSION.—

''(A) IN GENERAL.—If the Secretary determines that an Internet pharmacy is engaged in a pattern of violations of any of the requirements of this Act, the Secretary may immediately order the suspension of the license of the Internet pharmacy.

''(B) APPEAL OF SUSPENSION ORDER.—An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

''(C) FAILURE TO ACT.—If, during the 30-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

''(D) NO JUDICIAL REVIEW.—An order under this paragraph shall not be subject to judicial review.

''(7) TERMINATION OF LICENSE.—The Secretary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

''(A) has demonstrated a pattern of noncompliance with this section;

''(B) has made an untrue statement of material fact in its licensing application; or

''(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

''(8) RENEWAL EVALUATION.—

''(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

''(B) EVALUATION OF INTERNET PHARMACIES.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(9) CONTRACT FOR OPERATION OF PROGRAM.—

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

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

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—No provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) or an advertising service provider shall be liable under this section on account of another person's selling or dispensing of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

''(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

''(1) REGULATIONS.—Not later than 180 days after designating a system under subsection (a)(2), the Board shall promulgate regulations that require—

''(A) an operator of a credit card system that is a designated payment system, an operator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

''(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

''(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to prevent the introduction of a restricted transaction in a designated payment or the completion of restricted transactions using a designated payment system; and

''(B) to the extent practicable, permit any designated payment system, or person described in subsection (a)(2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(A) IN GENERAL.—A designated payment system, or a person described in subsection (a)(2)(B), that is subject to a regulation or an order issued under this subsection, and any participant in such payment system, that—

''(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

''(ii) prevents or otherwise refuses to honor a nonrestricted transaction in an effort to implement the policies and procedures under this subsection or to otherwise comply with this section, shall not be liable to any party for such action.

''(B) COMPLIANCE WITH THIS SUBSECTION.—A person described in subsection (a)(2)(B) meets the requirements of this subsection, if any, if the person relies on and complies with the policies and procedures of a designated payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the designated payment system comply with the requirements of the regulations under paragraph (1)(B).

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

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

''(i) The extent to which the payment system or person knowingly permits restricted transactions.

''(ii) The history of the payment system or person in connection with permitting restricted transactions.

''(iii) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the payment system or person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the payment system or person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

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

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) 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 paragraph (1).

''(g) TRANSACTIONS PERMITTED.—A designated payment system or person subject to a regulation or an order issued under subsection (e) may engage in transactions with licensed and unlicensed Internet pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with subsection (e). A person subject to a regulation or an order issued under subsection (e) and the agents and employees of that person shall not be found to be in violation of, or liable under, any Federal, State, or other law for engaging in any such transaction.

''(h) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a designated payment system or person subject to a regulation or an order issued under subsection (e) under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to an Internet pharmacy.

''(i) TIMING OF REQUIREMENTS.—A designated payment system or a person subject to a regulation under subsection (e) shall adopt policies and procedures reasonably designed to comply with any regulations required under subsection (e) not later than 180 days after the date on which such final regulations are issued.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The sale, under section 511, of a drug that is not a prescription drug, the sale of such a prescription drug without a valid prescription from a treating provider, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(2) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(3) The advertisement related to a prescription drug through any media including sales presentation, direct communication (including telephone, facsimile, or electronic mail), by an unlicensed Internet pharmacy.

''(4) The provision of an untrue statement of material fact in the licensing application of an Internet pharmacy.

''(5) For purposes of this subsection, any term used in this subsection that is also used in section 511 shall have the meaning given that term in section 511.''.

(c) LINKS TO UNLICENSED INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an unlicensed Internet pharmacy (as defined in such section 511), the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, links to a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

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

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511;

''(C) shall specify the provider to which the relief applies; and

''(D) shall specifically identify the location of the website to be removed or to which access is to be disabled.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall promulgate interim final regulations to carry out the amendments made by this section.

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

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

''(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SA 994. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.

(a) 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 506C the following:

''SEC. 507. DRUG SAFETY.

''(a) ESTABLISHMENT OF THE CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.—There is established within the Food and Drug Administration a Center for Postmarket Evaluation and Research for Drugs and Biologics (referred to in the section as the 'Center'). The Director of the Center shall report directly to the Commissioner of Food and Drugs.

''(b) DUTIES OF THE CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.—

''(1) RESPONSIBILITIES OF DIRECTOR.—The Director of the Center, in consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, shall—

''(A) conduct postmarket risk assessment of drugs approved under section 505 of this Act and of biological products licensed under section 351 of the Public Health Service Act;

''(B) conduct and improve postmarket surveillance of approved drugs and licensed biological products using postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies (including studies required under subsection (d) or (e)), and any other resources that the Director of the Center determines appropriate;

''(C) determine whether a study is required under subsection (d) or (e) and consult with the sponsors of drugs and biological products to ensure that such studies are completed by the date, and according to the terms, specified by the Director of the Center;

''(D) contract, or require the sponsor of an application or the holder of an approved application or license to contract, with the holders of domestic and international patient databases to conduct epidemiologic and other observational studies;

''(E) determine, based on postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, and any clinical or observational studies (including studies required under subsection (d) or (e)), and any other resources that the Director of the Center determines appropriate, whether a drug or biological product may present an unreasonable risk to the health of patients or the general public, and take corrective action if such an unreasonable risk may exist;

''(F) make information about the safety and effectiveness of approved drugs and licensed biological products available to the public and healthcare providers in a timely manner; and

''(G) conduct other activities as the Director of the Center determines appropriate to ensure the safety and effectiveness of all drugs approved under section 505 and all biological products licensed under section 351 of the Public Health Service Act.

''(2) DETERMINATION OF UNREASONABLE RISK.—In determining whether a drug or biological product may present an unreasonable risk to the health of patients or the general public, the Director of the Center, in consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, shall consider the risk in relation to the known benefits of such drug or biological product.

''(c) SECRETARIAL AUTHORITY.—

''(1) IN GENERAL.—Approval of a drug under section 505 of this Act or issuance of a license for a biological product under section 351 of the Public Health Service Act may be subject to the requirement that the sponsor conduct 1 or more postmarket studies as described in subsection (d) or (e) of this section, or other postmarket studies as required by the Secretary, to validate the safety and effectiveness of the drug or biological product.

''(2) DEFINITION.—For purposes of this section, the term 'postmarket' means—

''(A) with respect to a drug, after approval of an application under section 505; and

''(B) with respect to a biological product, after licensure under section 351 of the Public Health Service Act.

''(d) PREAPPROVAL REVIEW.—

''(1) REVIEW OF APPLICATION.—

''(A) IN GENERAL.—

''(i) REVIEW.—At any time before a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, the Director of the Center shall review the application (or supplement to the application), and any analyses associated with the application, of such drug or biological product.

''(ii) EFFECT OF APPROVAL OR LICENSURE.—The approval of a drug under section 505 or the licensure of a biological product under such section 351 shall not affect the continuation and completion of a review under clause (i).

''(B) LIMITATION.—In no case shall the review under subparagraph (A) delay a decision with respect to an application for a drug under section 505 of this Act or for a biological product under section 351 of the Public Health Service Act.

''(2) RESULT OF REVIEW.—The Director of the Center may, based on the review under paragraph (1)—

''(A) require that the sponsor of the application agree to conduct 1 or more postmarket studies to determine the safety or effectiveness of a drug or biological product, including such safety or effectiveness as compared to other drugs or biological products, to be completed by a date, and according to the terms, specified by the Director of the Center; or

''(B) contract, or require the sponsor of the application to contract, with a holder of a domestic or an international patient database to conduct 1 or more epidemiologic or other observational studies.

''(e) POSTMARKETING STUDIES OF DRUG SAFETY.—

''(1) IN GENERAL.—At any time after a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, the Director of the Center, may—

''(A) require that the holder of an approved application or license conduct 1 or more studies to determine the safety or effectiveness of such drug or biological product, including such safety and effectiveness as compared to other drugs or biological products, to be completed by a date, and according to the terms, specified by such Director; or

''(B) contract, or require the holder of the approved application or license to contract, with a holder of a domestic or an international patient database to conduct 1 or more epidemiologic or other observational studies.

''(2) REVIEW OF OUTSTANDING STUDIES.—Not later than 90 days after the date of enactment of the Food and Drug Administration Safety Act of 2007, the Director of the Center shall—

''(A) review and publish a list in the Federal Register of any postmarketing studies outstanding on the date of enactment of the Food and Drug Administration Safety Act of 2007; and

''(B) as the Director determines appropriate, require the sponsor of a study described in subparagraph (A) to conduct such study under this subsection.

''(f) PUBLICATION OF PROGRESS REPORTS AND COMPLETED STUDIES.—

''(1) IN GENERAL.—The Director of the Center shall require that the sponsor of a study under subsection (d) or (e) submit to the Secretary—

''(A) not less frequently than every 90 days, an up-to-date report describing the progress of such study; and

''(B) upon the completion date of such study, the results of such study.

''(2) COMPLETION DATE.—For purposes of this section, the completion date of such study shall be determined by the Director of the Center.

''(g) DETERMINATIONS BY DIRECTOR.—

''(1) RESULTS OF STUDY.—The Director of the Center shall determine, upon receipt of the results of a study required under subsection (d) or (e)—

''(A) whether the drug or biological product studied may present an unreasonable risk to the health of patients or the general public; and

''(B) what, if any, corrective action under subsection (k) shall be taken to protect patients and the public health.

''(2) RESULTS OF EVIDENCE.—The Director of the Center may, at any time, based on the empirical evidence from postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies (including studies required under subsection (d) or (e)), or any other resources that the Director of the Center determines appropriate—

''(A) make a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public; and

''(B) order a corrective action under subsection (k) be taken to protect patients and the public health.

''(3) REQUIRED CONSULTATION AND CONSIDERATIONS.—Before making a determination under paragraph (2), ordering a study under subsection (d) or (e), or taking a corrective action under subsection (k), the Director of the Center shall—

''(A) consult with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate; and

''(B) consider—

''(i) the benefit-to-risk profile of the drug or biological product;

''(ii) the effect that a corrective action, or failure to take corrective action, will have on the patient population that relies on the drug or biological product; and

''(iii) the extent to which the drug or biological product presents a meaningful therapeutic benefit as compared to other available treatments.

''(h) PUBLIC INFORMATION.—Periodically, but not less often than every 90 days, the Secretary shall make available to the public, by publication in the Federal Register and posting on an Internet website, the following information:

''(1) Studies required under subsection (d) or (e) including—

''(A) the type of study;

''(B) the nature of the study;

''(C) the primary and secondary outcomes of the study;

''(D) the date the study was required under subsection (d) or (e) or was agreed to by the sponsor;

''(E) the deadline for completion of the study; and

''(F) if the study has not been completed by the deadline under subparagraph (E), a statement that explains why.

''(2) The periodic progress reports and results of completed studies described under subsection (f).

''(3) Any determinations made by the Director of the Center under subsection (g), including—

''(A) reasons for the determination, including factual basis for such determination;

''(B) reference to supporting empirical data; and

''(C) an explanation that describes why contrary data is insufficient.

''(i) DRUG ADVISORY COMMITTEE.—The Drug Safety and Risk Management Advisory Committee within the Center of the Food and Drug Administration shall—

''(1) meet not less frequently than every 180 days; and

''(2) make recommendations to the Director of the Center with respect to—

''(A) which drugs and biological products should be the subject of a study under subsection (d) or (e);

''(B) the design and duration for studies under subsection (d) or (e);

''(C) which drugs and biological products may present an unreasonable risk to the health of patients or the general public; and

''(D) appropriate corrective actions under subsection (k).

''(j) PENALTIES.—

''(1) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor of a drug or biological product or other entity has failed to complete a study required under subsection (d) or (e) by the date or to the terms specified by the Secretary under such subsection, the Secretary may order such sponsor or other entity to—

''(A) complete the study in a specified time;

''(B) revise the study to comply with the terms specified by the Secretary under subsection (d) or (e); or

''(C) pay a civil penalty.

''(2) AMOUNT OF PENALTIES.—

''(A) IN GENERAL.—The civil penalty ordered under paragraph (1) shall be $250,000 for the first 30-day period after the date specified by the Secretary that the study is not completed, and shall double in amount for every 30-day period thereafter that the study is not completed.

''(B) LIMITATION.—In no case shall a penalty under subparagraph (A) exceed $2,000,000 for any 30-day period.

''(3) NOTIFICATION OF PENALTY.—The Secretary shall publish in the Federal Register any civil penalty ordered under this subsection.

''(k) RESULT OF DETERMINATION.—

''(1) IN GENERAL.—If the Director of the Center makes a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public under subsection (g), such Director shall order a corrective action, as described under paragraph (2).

''(2) CORRECTIVE ACTIONS.—The corrective action described under subsection (g)—

''(A) may include—

''(i) requiring a change to the drug or biological product label by a date specified by the Director of the Center;

''(ii) modifying the approved indication of the drug or biological product to restrict use to certain patients;

''(iii) placing restriction on the distribution of the drug or biological product to ensure safe use;

''(iv) requiring the sponsor of the drug or biological product or license to establish a patient registry;

''(v) requiring patients to sign a consent form prior to receiving a prescription of the drug or biological product;

''(vi) requiring the sponsor to monitor sales and usage of the drug or biological product to detect unsafe use;

''(vii) requiring patient or physician education; and

''(viii) requiring the establishment of a risk management plan by the sponsor; and

''(B) shall include the requirements with respect to promotional material under subsection (l)(1).

''(3) PENALTIES.—

''(A) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor of a drug or biological product has failed to take the corrective action ordered by the Director of the Center under this subsection or has failed to comply with subsection (l)(2), the Secretary may order such sponsor to pay a civil penalty.

''(B) AMOUNT OF PENALTIES.—

''(i) IN GENERAL.—The civil penalty ordered under subparagraph (A) shall be $250,000 for the first 30-day period that the sponsor does not comply with the order under paragraph (1), and shall double in amount for every 30-day period thereafter that the order is not complied with.

''(ii) LIMITATION.—In no case shall a penalty under clause (i) exceed $2,000,000 for any 30-day period.

''(C) NOTIFICATION OF PENALTY.—The Secretary shall publish in the Federal Register any civil penalty ordered under this paragraph.

''(l) PROMOTION MATERIAL.—

''(1) SAFETY ISSUE.—If the Director of the Center makes a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public under subsection (g), such Director, in consultation with the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration, shall—

''(A) notwithstanding section 502(n), require that the sponsor of such drug or biological product submit to the Director of the Center copies of all promotional material with respect to the drug or biological product not less than 30 days prior to the dissemination of such material; and

''(B) require that all promotional material with respect to the drug or biological product include certain disclosures, which shall be displayed prominently and in a manner easily understood by the general public, including—

''(i) a statement that describes the unreasonable risk to the health of patients or the general public as determined by the Director of the Center;

''(ii) a statement that encourages patients to discuss potential risks and benefits with their healthcare provider;

''(iii) a description of the corrective actions required under subsection (k);

''(iv) where appropriate, a statement explaining that there may be products available to treat the same disease or condition that present a more favorable benefit-to-risk profile, and that patients should talk to their healthcare provider about the risks and benefits of alternative treatments;

''(v) a description of any requirements of outstanding clinical and observational studies, including the purpose of each study; and

''(vi) contact information to report a suspected adverse reaction.

''(2) NEW PRODUCTS; OUTSTANDING STUDIES.—For the first 2-year period after a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, and with respect to drugs and biological products for which there are outstanding study requirements under subsection (d) or (e), the Director of the Center, in consultation with the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration, shall—

''(A) notwithstanding section 502(n), require that the sponsor of such drug or biological product submit to the Director of the Center copies of all promotional material with respect to the drug or biological product not less than 30 days prior to the dissemination of such material; and

''(B) require that all promotional material with respect to the drug or biological product include certain disclosures, which shall be displayed prominently and in a manner easily understood by the general public, including—

''(i) a statement explaining that the drug or biological product is newly approved or licensed or the subject of outstanding clinical or observational studies, as the case may be, and, as a result, not all side effects or drug interactions may be known;

''(ii) the number of people in which the drug or biological product has been studied and the duration of time during which the drug or biological product has been studied;

''(iii) a statement that encourages patients to discuss the potential risks and benefits of treatment with their healthcare provider;

''(iv) a description of any requirements of outstanding clinical and observational studies, including the purpose of each study; and

''(v) contact information to report a suspected adverse reaction.

''(3) EFFECT OF VOLUNTARY SUBMISSION.—Paragraphs (1)(A) and (2)(A) shall not apply to the sponsor of a drug or biological product if such sponsor has voluntarily submitted to the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration all promotional material with respect to the drug or biological product prior to the dissemination of such material.

''(m) WITHDRAWAL OR SUSPENSION OF APPROVAL OR LICENSURE.—

''(1) IN GENERAL.—The Director of the Center, may withdraw or suspend approval of a drug or licensure of a biological product using expedited procedures (as prescribed by the Secretary in regulations promulgated not later than 1 year after the date of enactment of the Food and Drug Administration Safety Act of 2007, which shall include an opportunity for an informal hearing) after consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, and any other person as determined appropriate by the Director of the Center, if—

''(A) the Director of the Center makes a determination that the drug or biological product may present an unreasonable risk to the health of patients or the general public, and that risk cannot be satisfactorily alleviated by a corrective action under subsection (k); or

''(B) the sponsor fails to comply with an order or requirement under this section.

''(2) PUBLIC INFORMATION.—The Secretary shall make available to the public, by publication in the Federal Register and posting on an Internet website, the details of the consultation described in paragraph (1), including—

''(A) the reason for the determination to withdraw, suspend, or failure to withdraw or suspend, approval for the drug or licensure for the biological product;

''(B) the factual basis for such determination;

''(C) reference to supporting empirical data;

''(D) an explanation that describes why contrary data is insufficient; and

''(E) the position taken by each individual consulted.

''(n) EFFECT OF SECTION.—The authorities conferred by this section shall be separate from and in addition to the authorities conferred by section 505B.

''(o) ADMINISTRATION OF SECTION.—The provisions of this section shall be carried out by the Secretary, acting through the Director of the Center.''.

(b) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by inserting after subsection (j) the following:

''(k) If it is a drug or biological product for which the sponsor of an application or holder of an approved application or license has not complied with an order or requirement under section 507.''.

(c) REPORT ON DEVICES.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, the Director of the Center for Postmarket Evaluation and Research for Drugs and Biologics, and the Director of the Center for Devices and Radiological Health, shall submit to Congress a report that—

(1) identifies gaps in the current process of postmarket surveillance of devices approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.);

(2) includes recommendations on ways to improve gaps in postmarket surveillance of devices; and

(3) identifies the changes in authority needed to make those improvements, recognizing the legitimate differences between devices and other medical products regulated by the Food and Drug Administration.

(d) TRANSFER OF FUNCTIONS.—The functions and duties of the Office of Surveillance and Epidemiology, including the Drug Safety

and Risk Management Advisory Committee, of the Food and Drug Administration on the day before the date of enactment of this Act shall be transferred to the Center for Postmarket Evaluation and Research for Drugs and Biologics established under section 507 of the Federal Food, Drug, and Cosmetic Act (as added by this section). The Center for Postmarket Evaluation and Research for Drugs and Biologics shall be a separate entity within the Food and Drug Administration and shall not be an administrative office of the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section (and the amendments made by this section)—

(1) $50,000,000 for fiscal year 2008;
(2) $75,000,000 for fiscal year 2009;
(3) $100,000,000 for fiscal year 2010;
(4) $125,000,000 for fiscal year 2011; and
(5) $150,000,000 for fiscal year 2012.

SA 995. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle E of title II, insert the following:

SEC. 2__. AUTHORITY OF THE OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY; CHIEF SAFETY OFFICER.

(a) AUTHORITY.—With respect to all actions of the Food and Drug Administration related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, the Office of Surveillance and Epidemiology (or successor office) of such Administration and the Office of New Drugs (or successor office) of such Administration shall make decisions jointly. In the event of a disagreement with respect to an action related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, between such 2 offices, the Commissioner of Food and Drugs shall make the decision with respect to such action.

(b) CHIEF SAFETY OFFICER.—Notwithstanding any other provision of law, the Director of the Office of Surveillance and Epidemiology (or successor office) of the Food and Drug Administration shall serve as the Chief Postmarket Drug Safety Officer within the Food and Drug Administration. In such capacity, the Director shall serve as a liaison between the Office of the Commissioner of Food and Drugs and employees of the Food and Drug Administration. To ensure drug safety concerns are identified and promptly evaluated and resolved, any employee of the Center for Drug Evaluation and Research within the Food and Drug Administration who has drug safety concerns may report such concerns to the Chief Postmarket Drug Safety Officer.

SA 996. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 251 of the bill, add the following:

''(r) CERTIFICATION OF INFORMATION.—When submitting information in support of a new drug application or a supplemental new drug application, the sponsor shall certify, in writing, that all clinical trials, federally or privately funded, whether conducted within or outside the United States, related to the safety or efficacy of the drug under review, have been submitted to the Food and Drug Administration.''.

SA 997. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike clause (i) of section 402(j)(3)(A) of the Public Health Service Act, as added by this bill, and insert the following:

''(i) IN GENERAL.—

''(I) REQUIREMENT.—Not later than 90 days after the date of enactment of the Food and Drug Administration Revitalization Act, for all clinical trials (except as provided in subclause (II)), whether federally or privately funded, conducted to test the safety or efficacy (including comparative efficacy), of any drug or device (including those drugs or devices approved or cleared by the Secretary), the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(aa) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(bb) not later than 30 days after such information becomes publicly available, as applicable.

''(II) EXCEPTION.—The requirement of subclause (I) shall not apply to phase I clinical investigations conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

''(III) VOLUNTARY SUBMISSION.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit to the Secretary results information for a clinical trial described in subclause (II).

At the end section 402(j)(4) of the Public Health Service Act, as added by this bill, insert the following:

''(F) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

''(i) IN GENERAL.—With respect to clinical trials described in clause (ii), the responsible party shall submit to the Secretary the information required under this subsection. The Secretary shall ensure that such information and the results of such clinical trials are made available to the public in a timely manner and as soon as practicable after receiving such information. Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this subsection, and the appropriate remedies and sanctions under this section shall apply.

''(ii) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this clause if—

''(I) such trial is conducted outside of the United States; and

''(II) the data from such trial is—

''(aa) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351 of this Act; or

''(bb) used in advertising or labeling to make a claim about the drug or device involved.

SA 998. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in section 505(o) of the Federal, Food, Drug, and Cosmetic, as added by section 202, insert the following:

''(9) CIVIL MONETARY PENALTY.—Notwithstanding any other provision of this Act, an applicant (as such term is defined for purposes of this section) that knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under this subsection shall be subject to a civil money penalty of $250,000 for the first 30-day period that the applicant is in noncompliance, and such amount shall double for every 30-day period thereafter that the requirement is not complied with, not to exceed $2,000,000.''.

SA 999. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 251 of the bill, add the following:

''(r) CERTIFICATION OF INFORMATION.—

''(1) CERTIFICATION.—

''(A) REQUIREMENT.—When submitting information in support of a new drug application or a supplemental new drug application, the sponsor shall certify, in writing, that the information submitted to the Food and Drug Administration complies with the requirements of this Act and that such information is not false or misleading.

''(B) FAILURE TO SUBMIT.—If the sponsor fails to provide a certification as required under subparagraph (A), the Secretary shall transmit to such sponsor a notice stating that such sponsor shall submit the certification by a date determined by the Secretary. If, by the date specified by the Secretary in the notice under this subparagraph, the Secretary has not received the certification, the Secretary, after providing the opportunity for a hearing, shall order such sponsor to pay a civil monetary penalty of $10,000 for each day after such date that such certification is not submitted.

''(C) ADDITIONAL CIVIL MONETARY PENALTY.—If the Secretary determines, after notice and opportunity for a hearing, that a sponsor knew or should have known that the information submitted in support of a new drug application or a supplemental new drug application was false or inaccurate, the Secretary shall order such sponsor to pay a civil monetary penalty of not less than $100,000, but not to exceed $2,000,000.

''(2) REQUIRED STATEMENT.—The certification under paragraph (1) shall include a statement that all clinical trials, federally or privately funded, whether conducted within or outside the United States, related to the safety or efficacy of the drug under review, have been submitted to the Food and Drug Administration.

''(3) CLINICAL COMPARISON STUDIES.—

''(A) IN GENERAL.—The Secretary shall deposit funds collected under paragraph (1)

into an account and use such funds shall be used, after consultation with the Director of the Agency for Healthcare Research and Quality, to fund studies that compare the clinical effectiveness of 2 or more treatments for similar diseases or conditions.

''(B) PRIORITY LIST.—The Secretary shall award funding under subparagraph (A) based on a priority list established, not later than 6 months after the date of enactment of this Act, by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

''(4) DRUG CONSULTATIONS.—Not later than 90 days after the date of the completion of a written consultation on a drug concerning the drug's safety, as conducted by the Office of Surveillance and Epidemiology, regardless of whether such consultation was initiated by such Office or by an entity outside of the Office, the Commissioner of Food and Drugs shall make available to the public a full copy of such consultation.

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter or amend section 301(j) of this Act or section 1905 of title 18, United States Code.''.

SA 1000. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ___FDA EMPLOYEE PROTECTIONS

SEC. ___01. SHORT TITLE.

This title may be cited as the ''FDA Employee Rights Protection Act''.

SEC. ___02. EMPLOYEES' RIGHT TO PETITION CONGRESS.

The right of all employees of the Food and Drug Administration, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, shall not be interfered with or denied by any employee of the Food and Drug Administration, the Department of Health and Human Services, the Department of Justice, or any other employee of the Executive Branch of the Federal Government.

SEC. _03. PENALTIES.

Any individual who intentionally or willfully obstructs, impedes, or otherwise interferes with an employee's right to furnish information as described in section ___02 shall be subject to a fine of not less than $10,000 per violation, or imprisoned for not more than 1 year, or both.

SA 1001. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SUBPOENA AUTHORITY OF THE COMMISSIONER OF FOOD AND DRUGS.

(a) IN GENERAL.—Section 310 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337) is amended by adding at the end the following:

''(c) For the purpose of—

''(1) any hearing, investigation, or other proceeding respecting a violation of this Act,

''(2) any hearing, investigation, or other proceeding to determine if a person is in compliance with a standard or other requirement under this Act, or

''(3) any hearing, investigation, or other proceeding to establish a standard or other requirement under this Act,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary evidence. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding may be required from any place in the United States or in any territory or possession of the United States. Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person's last known dwelling place or principal place of business. A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service. Witnesses so subpoenaed shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

''(d) In case of a refusal to obey a subpoena duly served upon any person under subsection (c), any district court of the United States for the judicial district in which such person charged with refusal to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence, or both. The failure to obey such order of the court may be punished by the court as contempt thereof.''.

(b) ENFORCEMENT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(jj) The failure or refusal to obey a subpoena issued by the Commissioner under section 310(c).''.

SA 1002. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. REQUIREMENT TO DOCUMENT CONTACT WITH DRUG SPONSORS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 251, is further amended by adding at the end the following:

''(r) REQUIREMENT TO DOCUMENT CONTACT WITH DRUG SPONSOR.—Each employee of the Food and Drug Administration shall document, in writing, each communication or contact, and the purpose of such communication or contact, that such official has with a sponsor of a drug for which an application is filled pursuant to subsection (b) or (j).''.

SA 1003. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

After section 211 of the bill, insert the following:

SEC. 211A. REQUIREMENT TO SUBMIT INFORMATION ELECTRONICALLY.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by this Act, is further amended by adding at the end the following:

''SEC. 567. REQUIREMENT TO SUBMIT INFORMATION ELECTRONICALLY.

''Not later than 5 years after the date of enactment of the Food and Drug Administration Revitalization Act, the Secretary shall ensure that any information required to be submitted to the Food and Drug Administration under section 505, 505A, 505B, 506A, 506B, 510, 512, 513, 515, 519, 520, or 526 is submitted in electronic form that is interoperable with the Food and Drug Administration's information technology systems.''.

SA 1004. Ms. LANDRIEU proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the bill, add the following:

TITLE ___DOMESTIC PET TURTLE MARKET ACCESS

SEC. ___. SHORT TITLE.

This title may be cited as the ''Domestic Pet Turtle Market Access Act of 2007''.

SEC. ___. FINDINGS.

Congress makes the following findings:

(1) Pet turtles less than 10.2 centimeters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat turtles for salmonella, and make them safe for sale, has greatly advanced since 1975. Treatments exist that can nearly eradicate salmonella from turtles, and individuals are more aware of the causes of salmonella, how to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regiment that allows the turtle to be maintained safe from salmonella.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat these turtles for salmonella.

SEC. ___. SALE OF BABY TURTLES.

(a) Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, wholesaler or commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the State or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a State license to breed, hatch, propagate, raise, grow, receive, ship, transport, export, or sell pet turtles or pet turtle eggs;

(2) such State or territory requires certification of sanitization that is signed by a veterinarian who is licensed in the State or territory, and approved by the State or territory agency in charge of regulating the sale of pet turtles;

(3) the certification of sanitization requires each turtle to be sanitized or treated for diseases, including salmonella, and is dependant upon using the Siebeling method, or other such proven method, which uses an antibiotic to make the turtle salmonella-free; and

(4) the turtle farmer or commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the possibility that salmonella can recolonize in turtles;

(ii) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if the turtle is not properly handled and safely maintained;

(iii) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iv) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(B) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and

(C) a statement that buyers of pet turtles should not abandon the turtle or abandon it outside, as the turtle may become an invasive species to the local community, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

(b) FDA REVIEW OF STATE PROTECTIONS.—The Food and Drug Administration may, after providing an opportunity for the affected State to respond, restrict the sale of a turtle only if the Secretary of Health and Human Services determines that the actual implementation of State health protections described in subsection (a) are insufficient to protect consumers against infectious diseases acquired from such turtles at the time of sale.

SA 1005. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used in fresh meat that are capable of artificially keeping such meat red beyond the point of spoilage of such meat, create a health risk or are misleading to consumers.

SA 1006. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505(o)(6) of the Federal Food, Drug, and Cosmetic Act, as added by section 202 of the bill, insert the following:

''(H) In a case where a drug may be prescribed only by a physician with particular training or experience, or who is specially certified, a health care provider who is not so certified or trained to prescribe the drug may enter into a cooperation plan with a physician who has particular training or experience, or is specially certified, in order to prescribe such drug with the informed consent of the patient. The Commissioner of Food and Drugs shall determine the requirements for such cooperation plan.

SA 1007. Mr. REID (for Mr. BUNNING) proposed an amendment to the resolution S. Res. 162, commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers; as follows:

On page 2, strike the first whereas clause and insert:

Whereas peace officers are on the front lines in protecting the schools and schoolchildren of the United States;

AUTHORTIY FOR COMMITTEES TO MEET

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Agriculture, Nutrition and Forestry be authorized to conduct a hearing during the session of the Senate on Tuesday, May 1, 2007 at 2 p.m. in 328A, Senate Russell Office Building. The purpose of this Committee hearing will be to consider conservation policy recommendations for the farm bill.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to hold a hearing during the session of the Senate on Tuesday, May 1, 2007, at 2:30 p.m., in room 253 of the Russell Senate Office Building. The purpose of the hearing is to examine Electronic On-Board Recorders (EOBRs) and Truck Driver Fatigue, and related regulations to be issued by the Federal Motor Carrier Safety Administration.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the Session of the Senate on Tuesday, May 1, 2007, at 10 a.m., in 215 Dirksen Senate Office Building, to hear testimony on ''Advanced Technology Vehicles: The Road Ahead.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be authorized to meet on Tuesday, May 1, 2007, at 9:30 a.m. to consider the nomination of Howard C. Weizmann to be Deputy Director of the Office of Personnel Management.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary be authorized to meet to conduct a hearing on Process Patents for Tuesday, May 1, 2007, at 2:30 p.m. in Dirksen Senate Office Building Room 226.

Witness list: Wayne Herrington, Assistant General Counsel, United States International Trade Commission, Washington, DC; John R. Thomas, Professor of Law, Georgetown University Law Center, Washington, DC; Mike Kirk, Executive Director, American Intellectual Property Law Association, Arlington, VA; and Christopher A. Cotropia, Professor of Law, Richmond School of Law, Richmond, VA.

The PRESIDING OFFICER. Without objection, it is so ordered.

SEAPOWER SUBCOMMITTEE

Mr. SCHUMER. Mr: President, I ask unanimous consent that the Seapower Subcommittee of the Committee on Armed Services be authorized to meet during the session of the Senate on Tuesday, May 1, 2007, at 2:30 p.m., in open session to receive testimony on Department of Defense Transportation programs in review of the defense authorization request for fiscal year 2008 and the future years defense program.

The PRESIDING OFFICER. Without objection, it is so ordered.

SELECT COMMITTEE ON INTELLIGENCE

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on May 1, 2007 at 2:30 p.m. to hold a hearing.

The PRESIDING OFFICER. Without object it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. REED. Mr. President, I ask unanimous consent that Jessica Gerrity, a fellow in my office, be accorded the privilege of the floor.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, I ask unanimous consent that Adam Solander, an intern on my staff, be granted floor privileges during the debate on the Food and Drug Administration Revitalization Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. HATCH. Mr. President, I ask unanimous consent that Remy Yucel, a fellow in my staff, be granted the privilege of the floor for the pendency of the consideration of S. 1082, including any conference report.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.