and through modernization of the health insurance marketplace; which was ordered to lie on the table.

SA 3926. Mr. NELSON of Nebraska submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3927. Mr. DORGAN (for himself, Ms. SNOWE, Mr. KENNEDY, Mr. MCCAIN, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3928. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3929. Mr. COBURN submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3930. Mr. COBURN (for himself, Mr. BROWNBACK, and Mr. GRAHAM) submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3931. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3932. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3933. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 3924 submitted by Ms. SNOWE (for herself, Mr. BYRD, Mr. TALENT, and Mr. DOMENICI) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3934. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3899 submitted by Mr. DURBIN (for himself, Mrs. LINCOLN, Mr. REID, Mr. BAUCUS, Mr. KENNEDY, Mrs. CLINTON, Mr. KERRY, Mr. BINGAMAN, Ms. CANTWELL, Mr. PRYOR, Mr. HARKIN, Mr. OBAMA, Mr. LAUTENBERG, Mr. SCHUMER, Mr. KOHL, Mr. LIEBERMAN, Mr. DODD, Mr. DAYTON, Mr. JOHNSON, Mr. MENENDEZ, Mrs. BOXER, Mr. NELSON of Florida, Ms. MIKULSKI, Ms. STABENOW, Mr. CARPER, and Mr. ROCKEFELLER) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3935. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3925 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3936. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3919 submitted by Mr. DODD and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3937. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3918 submitted by Mr. DODD (for himself and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3938. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3916 submitted by Mr. REID (for himself, Mrs. CLINTON, Mrs. MURRAY, and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3939. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3912 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3940. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3913 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3941. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3907 submitted by Mr. BAUCUS and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3942. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3900 submitted by Mr. CARPER (for himself and Mrs. FEINSTEIN) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3943. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3866 submitted by Mr. SMITH and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3944. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3892 submitted by Ms. COLLINS (for herself and Mr. Bingaman) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3945. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3880 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3946. Mr. NELSON of Nebraska submitted an amendment intended to be proposed to amendment SA 3924 submitted by Ms. SNOWE (for herself, Mr. BYRD, Mr. TALENT, and Mr. DOMENICI) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3947. Mr. NELSON, of Nebraska submitted an amendment intended to be proposed to amendment SA 3926 submitted by Mr. NELSON of Nebraska and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3948. Ms. SNOWE submitted an amendment intended to be proposed to amendment SA 3926 submitted by Mr. NELSON of Nebraska and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3949. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3900 submitted by Mr. CARPER (for himself and Mrs. FEINSTEIN) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3950. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3866 submitted by Mr. SMITH and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3951. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3892 submitted by Ms. COLLINS (for herself and Mr. BINGAMAN) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3952. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3880 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3953. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3907 submitted by Mr. BAUCUS and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3954. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3919 submitted by Mr. DODD and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3955. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3913 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3956. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3916 submitted by Mr. REID (for himself, Mrs. CLINTON, Mrs. MURRAY, and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3957. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3918 submitted by Mr. DODD (for himself and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3958. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3925 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

SA 3959. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3912 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 3925. Mr. KENNEDY submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____. LIMITATION ON APPLICATION OF CERTAIN PROVISIONS RELATING TO DIABETES.

Notwithstanding any other provision of this Act (or an amendment made by this Act), any provision of this Act (or amendment) that has the effect of—

(1) increasing premiums for health insurance coverage for individuals with diabetes;

(2) permitting a health insurance issuer to deny coverage for medical items or services needed to treat, mitigate, or cure diabetes; or

(3) limiting the ability of a State to enforce State laws that prohibit premium increases or denials of coverage described in paragraphs (1) or (2);

shall not apply and shall not be enforced.

At the appropriate place, insert the following:

SEC. ____. LIMITATION ON APPLICATION OF CERTAIN PROVISIONS RELATING TO CANCER.

Notwithstanding any other provision of this Act (or an amendment made by this Act), any provision of this Act (or amendment) that has the effect of—

(1) increasing premiums for health insurance coverage for individuals with cancer;

(2) permitting a health insurance issuer to deny coverage for medical items or services needed to treat, mitigate, or cure cancer; or

(3) limiting the ability of a State to enforce State laws that prohibit premium increases or denials of coverage described in paragraphs (1) or (2);

shall not apply and shall not be enforced.

At the appropriate place, insert the following:

SEC. ____. LIMITATION ON APPLICATION OF CERTAIN PROVISIONS RELATING TO CARDIOVASCULAR DISEASE.

Notwithstanding any other provision of this Act (or an amendment made by this Act), any provision of this Act (or amendment) that has the effect of—

(1) increasing premiums for health insurance coverage for individuals with cardiovascular disease;

(2) permitting a health insurance issuer to deny coverage for medical items or services

needed to treat, mitigate, or cure cardiovascular disease; or

(3) limiting the ability of a State to enforce State laws that prohibit premium increases or denials of coverage described in paragraphs (1) or (2);

shall not apply and shall not be enforced.

At the appropriate place, insert the following:

SEC. ___. LIMITATION ON APPLICATION OF CERTAIN PROVISIONS RELATING TO MENTAL ILLNESS.

Notwithstanding any other provision of this Act (or an amendment made by this Act), any provision of this Act (or amendment) that has the effect of—

(1) increasing premiums for health insurance coverage for individuals with a mental illness;

(2) permitting a health insurance issuer to deny coverage for medical items or services needed to treat, mitigate, or cure a mental illness; or

(3) limiting the ability of a State to enforce State laws that prohibit premium increases or denials of coverage described in paragraphs (1) or (2);

shall not apply and shall not be enforced.

At the appropriate place, insert the following:

SEC. ___. LIMITATION ON APPLICATION OF CERTAIN PROVISIONS RELATING TO BRAIN INJURY.

Notwithstanding any other provision of this Act (or an amendment made by this Act), any provision of this Act (or amendment) that has the effect of—

(1) increasing premiums for health insurance coverage for individuals with a brain injury;

(2) permitting a health insurance issuer to deny coverage for medical items or services needed to treat, mitigate, or cure a brain injury; or

(3) limiting the ability of a State to enforce State laws that prohibit premium increases or denials of coverage described in paragraphs (1) or (2);

shall not apply and shall not be enforced.

SA 3926. Mr. NELSON of Nebraska submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

On page 1 of the amendment, strike all after the part heading and insert the following:

"SEC. 2921. DEFINITIONS.

''In this part:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted a law providing that small group and large group health insurers in such State may offer and sell products in accordance with the List of Required Benefits and the Terms of Application as provided for in section 2922(b)

''(2) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the List of Required Benefits and Terms of Application in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other applicable State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the List of Required Benefits and Terms of Application, and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such group health coverage) and filed with the State pursuant to subparagraph (B), a description in the insurer's contract of the List of Required Benefits and a description of the Terms of Application, including a description of the benefits to be provided, and that adherence to such standards is included as a term of such contract.

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the small group or large group health insurance markets, including with respect to small business health plans, except that such term shall not include excepted benefits (as defined in section 2791(c)).

''(4) LIST OF REQUIRED BENEFITS.—The term 'List of Required Benefits' means the List issued under section 2922(a).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that is not an adopting State.

''(6) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''(7) STATE PROVIDER FREEDOM OF CHOICE LAW.—The term 'State Provider Freedom of Choice Law' means a State law requiring that a health insurance issuer, with respect to health insurance coverage, not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law.

''(8) TERMS OF APPLICATION.—The term 'Terms of Application' means terms provided under section 2922(a).

"SEC. 2922. OFFERING AFFORDABLE PLANS.

''(a) LIST OF REQUIRED BENEFITS.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the National Association of Insurance Commissioners, shall issue by interim final rule a list (to be known as the 'List of Required Benefits') of covered benefits, services, or categories of providers that are required to be provided by health insurance issuers, in each of the small group and large group markets, in at least 26 States as a result of the application of State covered benefit, service, and category of provider mandate laws. With respect to plans sold to or through small business health plans, the List of Required Benefits applicable to the small group market shall apply.

''(b) TERMS OF APPLICATION.—

''(1) STATE WITH MANDATES.—With respect to a State that has a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such State mandate shall, subject to paragraph (3) (concerning uniform application), apply to a coverage plan or plan in, as applicable, the small group or large group market or through a small business health plan in such State.

''(2) STATES WITHOUT MANDATES.—With respect to a State that does not have a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such mandate shall not apply, as applicable, to a coverage plan or plan in the small group or large group market or through a small business health plan in such State.

''(3) UNIFORM APPLICATION OF LAWS.—

''(A) IN GENERAL.—With respect to a State described in paragraph (1), in applying a covered benefit, service, or category of provider mandate that is on the List of Required Benefits under subsection (a) the State shall permit a coverage plan or plan offered in the small group or large group market or through a small business health plan in such State to apply such benefit, service, or category of provider coverage in a manner consistent with the manner in which such coverage is applied under one of the three most heavily subscribed national health plans offered under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code (as determined by the Secretary in consultation with the Director of the Office of Personnel Management), and consistent with the Publication of Benefit Applications under subsection (c). In the event a covered benefit, service, or category of provider appearing in the List of Required Benefits is not offered in one of the three most heavily subscribed national health plans offered under the Federal Employees Health Benefits Program, such covered benefit, service, or category of provider requirement shall be applied in a manner consistent with the manner in which such coverage is offered in the remaining most heavily subscribed plan of the remaining Federal Employees Health Benefits Program plans, as determined by the Secretary, in consultation with the Director of the Office of Personnel Management.

''(B) EXCEPTION REGARDING STATE PROVIDER FREEDOM OF CHOICE LAWS.—Notwithstanding subparagraph (A), in the event a category of provider mandate is included in the List of Covered Benefits, any State Provider Freedom of Choice Law (as defined in section 2921(7)) that is in effect in any State in which such category of provider mandate is in effect shall not be preempted, with respect to that category of provider, by this part.

''(c) PUBLICATION OF BENEFIT APPLICATIONS.—Not later than 3 months after the date of enactment of this title, and on the first day of every calendar year thereafter, the Secretary, in consultation with the Director of the Office of Personnel Management, shall publish in the Federal Register a description of such covered benefits, services, and categories of providers covered in that calendar year by each of the three most heavily subscribed nationally available Federal Employee Health Benefits Plan options which are also included on the List of Required Benefits.

''(d) EFFECTIVE DATES.—

''(1) SMALL BUSINESS HEALTH PLANS.—With respect to health insurance provided to participating employers of small business health plans, the requirements of this part (concerning lower cost plans) shall apply beginning on the date that is 12 months after the date of enactment of this title.

''(2) NON-ASSOCIATION COVERAGE.—With respect to health insurance provided to groups or individuals other than participating employers of small business health plans, the requirements of this part shall apply beginning on the date that is 15 months after the date of enactment of this title.

''(e) UPDATING OF LIST OF REQUIRED BENEFITS.—Not later than 2 years after the date

on which the list of required benefits is issued under subsection (a), and every 2 years thereafter, the Secretary, in consultation with the National Association of Insurance Commissioners, shall update the list based on changes in the laws and regulations of the States. The Secretary shall issue the updated list by regulation, and such updated list shall be effective upon the first plan year following the issuance of such regulation.''.

SA 3927. Mr. DORGAN (for himself, Ms. SNOWE, Mr. KENNEDY, Mr. MCCAIN, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—IMPORTATION OF PRESCRIPTION DRUGS

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2006''.

SEC. ___2. 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 seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years; and

(6) allowing open pharmaceutical markets could save American consumers at least $38,000,000,000 each year.

SEC. ___3. 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. ___4. 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 ___3, is further amended by inserting after section 803 the following:

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

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

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

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

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

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

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

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

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

''(A) by a registered importer; or

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

''(4) DEFINITIONS.—

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

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

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

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

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

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

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

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

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

''(iv) is not—

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

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

''(aa) a therapeutic DNA plasmid product;

''(bb) a therapeutic synthetic peptide product;

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

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

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

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(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 sufficient for testing by the Secretary.

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

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

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

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

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

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

''(II) samples of such drugs;

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

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

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

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

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

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

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

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

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

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

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

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

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

''(aa) a notice is under review;

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

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

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

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to 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) LICENSING AS PHARMACIST.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

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

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

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

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

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

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

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

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

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

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

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

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

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

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

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

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

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

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

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

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

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

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

''(k) DRUG RECALLS.—

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

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

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

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

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

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

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

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

''(l) DRUG LABELING 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 2006, 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 title; 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 fiscal year 2006, 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 fiscal year 2006 to be $1,000,000,000.

(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) fiscal year 2006 to be $1,000,000,000; and

(ii) fiscal year 2007 to be $10,000,000,000.

(C) FISCAL YEAR 2007 ADJUSTMENT.—

(i) REPORTS.—Not later than February 20, 2007, 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, 2006, through January 31, 2007.

(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 fiscal year 2007. 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, 2007, from each importer so that the aggregate total of fees collected under subsection (e)(2) for fiscal year 2007 does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during fiscal year 2007 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.—Beginning with fiscal year 2006, not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER CONTROL.—Beginning with fiscal year 2006, 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 designate 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), nothing in this title (or the amendments made by this title) shall be construed to change, limit, or restrict the practices of the Food and Drug Administration or the Bureau of Customs and Border Protection in effect on January 1, 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.

(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. ___5. 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 ___3, 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. ___6. 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 ___4.

(3) HIGH-RISK DRUGS.—

(A) IN GENERAL.—Notwithstanding paragraph (1), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may apply the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) before January 1, 2010, with respect to a prescription drug if the Secretary—

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

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

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

(C) LIMITATION.—The Secretary may make the determination under subparagraph (A) with respect to not more than 50 drugs before January 1, 2010.

(4) 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.

(5) 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—

(A) January 1, 2008, with respect to a prescription drug determined under paragraph (3)(A) to be at high risk for being counterfeited; and

(B) January 1, 2010, with respect to all other prescription drugs.

(6) INTERMEDIATE REQUIREMENTS.—With respect to the prescription drugs described under paragraph (5)(B), the Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on such prescription drugs at the case and pallet level effective not later than January 1, 2008.

(7) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than January 1, 2007, require that the packaging of any prescription drug incorporates—

(i) overt optically variable counterfeit-resistant technologies that—

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

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

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

(IV) 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 clause (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. ___7. 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 fiscal years 2006 through 2008.

(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. ___8. 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 title.

(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. ___9. 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.''.

SA 3928. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

In part II of subtitle A of title XXIX of the Public Health Services Act, as added by section 201 of the amendment, at the end of section 2921 insert the following:

''SEC. 29___. LIMITATION ON APPLICATION OF CERTAIN BENEFIT, SERVICE, OR PROVIDER MANDATES.

''Notwithstanding any other provision of this title, a specific mandate regarding a covered benefit, service, or category of provider, other than a mandate applicable as provided for under a basic option or an enhanced option (as such terms are defined for purposes of this title) under this title, shall not apply with respect to health insurance coverage provided by a health insurance issuer if the application of such specific mandate to such coverage would, based on applicable standards of actuarial practice, result in an increase in premiums of at least 1 percent.

SA 3929. Mr. COBURN submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the appropriate place in subtitle B of title XXIX of the Public Health Service Act, as added by section 301 of the bill, insert the following:

SEC. ___. CONGRESSIONAL APPROVAL OF STANDARDS.

Notwithstanding any other provision of this subtitle, the harmonized standards certified by the Secretary under this section shall not take effect with respect to any State until the date that is 18 months after Congress has adopted a Concurrent Resolution that provides for the approval of such standards. The preceding sentence shall apply to any modifications or amendments to such harmonized standards as may be made by the Secretary.

SA 3930. Mr. COBURN (for himself, Mr. BROWNBACK, and Mr. GRAHAM) submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

In section 801(b) of the Employee Retirement Income Security Act of 1974, as added by section 101(a) of the amendment, strike paragraph (1) and insert the following:

''(1) is organized and maintained in good faith, with a constitution and bylaws specifically stating its purpose and providing for periodic meetings on at least an annual basis, as a bona fide trade association, a bona fide industry association (including a rural electric cooperative association or a rural telephone cooperative association), a bona fide professional association, a convention or association of churches (within the meaning of section 170(b)(1)(A)(i) of the Internal Revenue Code of 1986), or a bona fide chamber of commerce (or similar bona fide business association, including a corporation or similar organization that operates on a cooperative basis (within the meaning of section 1381 of the Internal Revenue Code of 1986)), for substantial purposes other than that of obtaining medical care, except that for purposes of this part, any such association, convention or association, or chamber shall not be required to comply with certain benefit requirements of this part if such compliance is prohibited by the bona fide religious or cultural beliefs of the association, convention or association, or chamber;''.

SA 3931. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. RULE OF CONSTRUCTION RELATING TO PREGNANCY.

Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) limit the application of section 701(k) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(k)), commonly referred to as the Pregnancy Discrimination Act;

(2) limit the application of section 701(d)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181(d)(3)) or section 2701(d)(3) of the Public Health Service Act (42 U.S.C. 300gg(d)(3)), relating to prohibiting the use of pregnancy as a preexisting condition; and

(3) limit the application of section 711 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185) or section 2704 of the Public Health Service Act (42 U.S.C. 300gg-4), relating to benefits for mothers and newborns;

to small business health plans and other health insurance coverage to which this Act (or amendments) apply.

SA 3932. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike title III and insert the following:

TITLE III—HARMONIZATION OF HEALTH INSURANCE STANDARDS

SEC. 301. HEALTH INSURANCE STANDARDS HARMONIZATION.

Title XXIX of the Public Health Service Act (as added by section 201) is amended by adding at the end the following:

''Subtitle B—Standards Harmonization

''SEC. 2931. DEFINITIONS.

''In this subtitle:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted the harmonized standards adopted under this subtitle in their entirety and as the exclusive laws of the State that relate to the harmonized standards.

''(2) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the harmonized standards in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the harmonized standards published pursuant to section 2933(d), and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent

annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such health coverage) and filed with the State pursuant to subparagraph (B), a description of the harmonized standards published pursuant to section 2933(g)(2) and an affirmation that such standards are a term of the contract.

''(3) HARMONIZED STANDARDS.—The term 'harmonized standards' means the standards certified by the Secretary under section 2933(d).

''(4) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the health insurance market, except that such term shall not include excepted benefits (as defined in section 2791(c).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that fails to enact, within 18 months of the date on which the Secretary certifies the harmonized standards under this subtitle, the harmonized standards in their entirety and as the exclusive laws of the State that relate to the harmonized standards.

''(6) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''SEC. 2932. STATE FLEXIBILITY RELATING TO HEALTH INSURANCE LAWS.

''(a) EFFECTIVENESS OF SUBTITLE.—

''(1) IN GENERAL.—The provisions of this subtitle shall take effect unless, not later than 3 years after the date of the enactment of this subtitle, an adequate number of the States (as defined in paragraph (2) have enacted harmonized laws and regulations governing the provision of health insurance within the State.

''(2) ADEQUATE NUMBER OF THE STATES.—For purposes of paragraph (1), an adequate number of the States is, with respect to the date that is 3 years after the date of enactment of this subtitle, the number of States necessary to ensure that at least 75 percent of the health insurance premium volume of the United States is covered under health insurance coverage to which this subtitle applies.

''(b) HARMONIZATION REQUIRED.—States shall be deemed to have enacted harmonized laws and regulations necessary to satisfy subsection (a)(1) if an adequate number of States as provided for in subsection (a)(2) establish harmonized State health insurance laws in those areas and insuch a manner as described in section 2933(b)(1).

''(c) DETERMINATION.—

''(1) NAIC DETERMINATION.—At the end of the 3-year period beginning on the date of the enactment of this subtitle, the National Association of Insurance Commissioners (hereafter in this subtitle referred to as the 'NAIC') shall determine, in consultation with the insurance commissioners or chief insurance regulatory officials of the States, whether the harmonization required by subsection (b) has been achieved.

''(2) APPLICATION OF HARMONIZED STANDARD UNDER SECTION 2933.—If the NAIC determines under paragraph (1) that the harmonization required under subsection (b) has not occurred, the provisions of section 2933, and the harmonized standards under this section, take effect as provided for in this subtitle.

''(3) JUDICIAL REVIEW.—The appropriate United States district court shall have exclusive jurisdiction over any challenge to the NAIC's determination under this section and such court shall apply the standards set forth in section 706 of title 5, United States Code, when reviewing any such challenge.

''(d) CONTINUED APPLICATION.—If, at any time, the harmonization required by subsection (b) no longer exists, the provisions of this subtitle shall take effect 2 years after the date on which such harmonization ceases to exist, unless the harmonization required by such subsection is satisfied before the expiration of that 2-year period.

''SEC. 2933. HARMONIZED STANDARDS.

''(a) BOARD.—

''(1) ESTABLISHMENT.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the NAIC, shall establish the Health Insurance Consensus Standards Board (referred to in this subtitle as the 'Board') to develop recommendations that harmonize inconsistent State health insurance laws in accordance with the procedures described in subsection (b).

''(2) COMPOSITION.—

''(A) IN GENERAL.—The Board shall be composed of the following voting members to be appointed by the Secretary after considering the recommendations of professional organizations representing the entities and constituencies described in this paragraph:

''(i) Four State insurance commissioners as recommended by the National Association of Insurance Commissioners, of which 2 shall be Democrats and 2 shall be Republicans, and of which one shall be designated as the chairperson and one shall be designated as the vice chairperson.

''(ii) Four representatives of State government, two of which shall be governors of States and two of which shall be State legislators, and two of which shall be Democrats and two of which shall be Republicans.

''(iii) Four representatives of health insurers, of which one shall represent insurers that offer coverage in the small group market, one shall represent insurers that offer coverage in the large group market, one shall represent insurers that offer coverage in the individual market, and one shall represent carriers operating in a regional market.

''(iv) Two representatives of insurance agents and brokers.

''(v) Two independent representatives of the American Academy of Actuaries who have familiarity with the actuarial methods applicable to health insurance.

''(B) EX OFFICIO MEMBER.—A representative of the Secretary shall serve as an ex officio member of the Board.

''(3) ADVISORY PANEL.—The Secretary shall establish an advisory panel to provide advice to the Board, and shall appoint its members after considering the recommendations of professional organizations representing the entities and constituencies identified in this paragraph:

''(A) Two representatives of small business health plans.

''(B) Two representatives of employers, of which one shall represent small employers and one shall represent large employers.

''(C) Two representatives of consumer organizations.

''(D) Two representatives of health care providers.

''(4) QUALIFICATIONS.—The membership of the Board shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, health plans, providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

''(5) ETHICAL DISCLOSURE.—The Secretary shall establish a system for public disclosure by members of the Board of financial and other potential conflicts of interest relating to such members. Members of the Board shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).

''(6) DIRECTOR AND STAFF.—Subject to such review as the Secretary deems necessary to assure the efficient administration of the Board, the chair and vice-chair of the Board may—

''(A) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

''(B) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

''(C) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Board (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

''(D) make advance, progress, and other payments which relate to the work of the Board;

''(E) provide transportation and subsistence for persons serving without compensation; and

''(F) prescribe such rules as it deems necessary with respect to the internal organization and operation of the Board.

''(7) TERMS.—The members of the Board shall serve for the duration of the Board. Vacancies in the Board shall be filled as needed in a manner consistent with the composition described in paragraph (2).

''(b) DEVELOPMENT OF HARMONIZED STANDARDS.—

''(1) IN GENERAL.—In accordance with the process described in subsection (c), the Board shall identify and recommend nationally harmonized standards for each of the following process categories:

''(A) FORM FILING AND RATE FILING.—Form and rate filing standards shall be established which promote speed to market and include the following defined areas for States that require such filings:

''(i) Procedures for form and rate filing pursuant to a streamlined administrative filing process.

''(ii) Timeframes for filings to be reviewed by a State if review is required before they are deemed approved.

''(iii) Timeframes for an eligible insurer to respond to State requests following its review.

''(iv) A process for an eligible insurer to self-certify.

''(v) State development of form and rate filing templates that include only non-preempted State law and Federal law requirements for eligible insurers with timely updates.

''(vi) Procedures for the resubmission of forms and rates.

''(vii) Disapproval rationale of a form or rate filing based on material omissions or violations of non-preempted State law or Federal law with violations cited and explained.

''(viii) For States that may require a hearing, a rationale for hearings based on violations of non-preempted State law or insurer requests.

''(B) MARKET CONDUCT REVIEW.—Market conduct review standards shall be developed which provide for the following:

''(i) Mandatory participation in national databases.

''(ii) The confidentiality of examination materials.

''(iii) The identification of the State agency with primary responsibility for examinations.

''(iv) Consultation and verification of complaint data with the eligible insurer prior to State actions.

''(v) Consistency of reporting requirements with the recordkeeping and administrative practices of the eligible insurer.

''(vi) Examinations that seek to correct material errors and harmful business practices rather than infrequent errors.

''(vii) Transparency and publishing of the State's examination standards.

''(viii) Coordination of market conduct analysis.

''(ix) Coordination and nonduplication between State examinations of the same eligible insurer.

''(x) Rationale and protocols to be met before a full examination is conducted.

''(xi) Requirements on examiners prior to beginning examinations such as budget planning and work plans.

''(xii) Consideration of methods to limit examiners' fees such as caps, competitive bidding, or other alternatives.

''(xiii) Reasonable fines and penalties for material errors and harmful business practices.

''(C) PROMPT PAYMENT OF CLAIMS.—The Board shall establish prompt payment standards for eligible insurers based on standards similar to those applicable to the Social Security Act as set forth in section 1842(c)(2) of such Act (42 U.S.C. 1395u(c)(2)). Such prompt payment standards shall be consistent with the timing and notice requirements of the claims procedure rules to be specified under subparagraph (D), and shall include appropriate exceptions such as for fraud, nonpayment of premiums, or late submission of claims.

''(D) INTERNAL REVIEW.—The Board shall establish standards for claims procedures for eligible insurers that are consistent with the requirements relating to initial claims for benefits and appeals of claims for benefits under the Employee Retirement Income Security Act of 1974 as set forth in section 503 of such Act (29 U.S.C. 1133) and the regulations thereunder.

''(2) RECOMMENDATIONS.—The Board shall recommend harmonized standards for each element of the categories described in subparagraph (A) through (D) of paragraph (1) within each such market. Notwithstanding the previous sentence, the Board shall not recommend any harmonized standards that disrupt, expand, or duplicate the benefit, service, or provider mandate standards provided in the Benefit Choice Standards pursuant to section 2922(a).

''(c) PROCESS FOR IDENTIFYING HARMONIZED STANDARDS.—

''(1) IN GENERAL.—The Board shall develop recommendations to harmonize inconsistent State insurance laws with respect to each of the process categories described in subparagraphs (A) through (D) of subsection (b)(1).

''(2) REQUIREMENTS.—In adopting standards under this section, the Board shall consider the following:

''(A) Any model acts or regulations of the National Association of Insurance Commissioners in each of the process categories described in subparagraphs (A) through (D) of subsection (b)(1).

''(B) Substantially similar standards followed by a plurality of States, as reflected in existing State laws, relating to the specific process categories described in subparagraphs (A) through (D) of subsection (b)(1).

''(C) Any Federal law requirement related to specific process categories described in subparagraphs (A) through (D) of subsection (b)(1).

''(D) In the case of the adoption of any standard that differs substantially from those referred to in subparagraphs (A), (B), or (C), the Board shall provide evidence to the Secretary that such standard is necessary to protect health insurance consumers or promote speed to market or administrative efficiency.

''(E) The criteria specified in clauses (i) through (iii) of subsection (d)(2)(B).

''(d) RECOMMENDATIONS AND CERTIFICATION BY SECRETARY.—

''(1) RECOMMENDATIONS.—Not later than 18 months after the date on which all members of the Board are selected under subsection (a), the Board shall recommend to the Secretary the certification of the harmonized standards identified pursuant to subsection (c).

''(2) CERTIFICATION.—

''(A) IN GENERAL.—Not later than 120 days after receipt of the Board's recommendations under paragraph (1), the Secretary shall certify the recommended harmonized standards as provided for in subparagraph (B), and issue such standards in the form of an interim final regulation.

''(B) CERTIFICATION PROCESS.—The Secretary shall establish a process for certifying the recommended harmonized standard, by category, as recommended by the Board under this section. Such process shall—

''(i) ensure that the certified standards for a particular process area achieve regulatory harmonization with respect to health plans on a national basis;

''(ii) ensure that the approved standards are the minimum necessary, with regard to substance and quantity of requirements, to protect health insurance consumers and maintain a competitive regulatory environment; and

''(iii) ensure that the approved standards will not limit the range of group health plan designs and insurance products, such as catastrophic coverage only plans, health savings accounts, and health maintenance organizations, that might otherwise be available to consumers.

''(3) APPLICATION AND EFFECTIVE DATE.—The standards certified by the Secretary under paragraph (2) shall apply and become effective on the date on which the NAIC makes the determination described in section 2932(c)(2).

''(e) TERMINATION.—The Board shall terminate and be dissolved after making the recommendations to the Secretary pursuant to subsection (d)(1).

''(f) ONGOING REVIEW.—Not earlier than 3 years after the termination of the Board under subsection (e), and not earlier than every 3 years thereafter, the Secretary, in consultation with the National Association of Insurance Commissioners and the entities and constituencies represented on the Board and the Advisory Panel, shall prepare and submit to the appropriate committees of Congress a report that assesses the effect of the harmonized standards applied under this section on access, cost, and health insurance market functioning. The Secretary may, based on such report and applying the process established for certification under subsection (d)(2)(B), in consultation with the National Association of Insurance Commissioners and the entities and constituencies represented on the Board and the Advisory Panel, update the harmonized standards through notice and comment rulemaking.

''(g) PUBLICATION.—

''(1) LISTING.—The Secretary shall maintain an up to date listing of all harmonized standards certified under this section on the Internet website of the Department of Health and Human Services.

''(2) SAMPLE CONTRACT LANGUAGE.—The Secretary shall publish on the Internet website of the Department of Health and Human Services sample contract language that incorporates the harmonized standards certified under this section, which may be used by insurers seeking to qualify as an eligible insurer. The types of harmonized standards that shall be included in sample contract language are the standards that are relevant to the contractual bargain between the insurer and insured.

''(h) STATE ADOPTION AND ENFORCEMENT.—Not later than 18 months after the certification by the Secretary of harmonized standards under this section, the States may adopt such harmonized standards (and become an adopting State) and, in which case, shall enforce the harmonized standards pursuant to State law.

''SEC. 2934. APPLICATION AND PREEMPTION.

''(a) SUPERCEDING OF STATE LAW.—

''(1) IN GENERAL.—The harmonized standards certified under this subtitle and applied as provided for in section 2933(d)(3), shall supersede any and all State laws of a nonadopting State insofar as such State laws relate to the areas of harmonized standards as applied to an eligible insurer, or health insurance coverage issued by a eligible insurer, including with respect to coverage issued to a small business health plan, in a nonadopting State.

''(2) NONADOPTING STATES.—This subtitle shall supersede any and all State laws of a nonadopting State (whether enacted prior to or after the date of enactment of this title) insofar as they may—

''(A) prohibit an eligible insurer from offering, marketing, or implementing health insurance coverage consistent with the harmonized standards; or

''(B) have the effect of retaliating against or otherwise punishing in any respect an eligible insurer for offering, marketing, or implementing health insurance coverage consistent with the harmonized standards under this subtitle.

''(b) SAVINGS CLAUSE AND CONSTRUCTION.—

''(1) NONAPPLICATION TO ADOPTING STATES.—Subsection (a) shall not apply with respect to adopting States.

''(2) NONAPPLICATION TO CERTAIN INSURERS.—Subsection (a) shall not apply with respect to insurers that do not qualify as eligible insurers who offer health insurance coverage in a nonadopting State.

''(3) NONAPPLICATION WHERE OBTAINING RELIEF UNDER STATE LAW.—Subsection (a)(1) shall not supercede any State law of a nonadopting State to the extent necessary to permit individuals or the insurance department of the State (or other State agency) to obtain relief under State law to require an eligible insurer to comply with the harmonized standards under this subtitle.

''(4) NO EFFECT ON PREEMPTION.—In no case shall this subtitle be construed to limit or affect in any manner the preemptive scope of sections 502 and 514 of the Employee Retirement Income Security Act of 1974. In no case shall this subtitle be construed to create any cause of action under Federal or State law or enlarge or affect any remedy available under the Employee Retirement Income Security Act of 1974.

''(c) EFFECTIVE DATE.—This section shall apply beginning on the date that is 18 months after the date on harmonized standards are certified by the Secretary under this subtitle.

''SEC. 2935. CIVIL ACTIONS AND JURISDICTION.

''(a) IN GENERAL.—The district courts of the United States shall have exclusive jurisdiction over civil actions involving the interpretation of this subtitle.

''(b) ACTIONS.—An eligible insurer may bring an action in the district courts of the United States for injunctive or other equitable relief against any officials or agents of

a nonadopting State in connection with any conduct or action, or proposed conduct or action, by such officials or agents which violates, or which would if undertaken violate, section 2933.

''(c) DIRECT FILING IN COURT OF APPEALS.—At the election of the eligible insurer, an action may be brought under subsection (b) directly in the United States Court of Appeals for the circuit in which the nonadopting State is located by the filing of a petition for review in such Court.

''(d) EXPEDITED REVIEW.—

''(1) DISTRICT COURT.—In the case of an action brought in a district court of the United States under subsection (b), such court shall complete such action, including the issuance of a judgment, prior to the end of the 120-day period beginning on the date on which such action is filed, unless all parties to such proceeding agree to an extension of such period.

''(2) COURT OF APPEALS.—In the case of an action brought directly in a United States Court of Appeal under subsection (c), or in the case of an appeal of an action brought in a district court under subsection (b), such Court shall complete all action on the petition, including the issuance of a judgment, prior to the end of the 60-day period beginning on the date on which such petition is filed with the Court, unless all parties to such proceeding agree to an extension of such period.

''(e) STANDARD OF REVIEW.—A court in an action filed under this section, shall render a judgment based on a review of the merits of all questions presented in such action and shall not defer to any conduct or action, or proposed conduct or action, of a nonadopting State.

''SEC. 2936. AUTHORIZATION OF APPROPRIATIONS; RULE OF CONSTRUCTION.

''(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subtitle.

''(b) HEALTH SAVINGS ACCOUNTS.—Nothing in this subtitle shall be construed to create any mandates for coverage of any benefits below the deductible levels set for any health savings account-qualified health plan pursuant to section 223 of the Internal Revenue Code of 1986.''.

SA 3933. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 3924 submitted by Ms. SNOWE (for herself, Mr. BYRD, Mr. TALENT, and Mr. DOMENICI) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after the part heading in the amendment and insert the following:

''SEC. 2921. DEFINITIONS.

''In this part:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted the Benefit Choice Standards in their entirety and as the exclusive laws of the State that relate to benefit, service, and provider mandates in the group and individual insurance markets.

''(2) BENEFIT CHOICE STANDARDS.—The term 'Benefit Choice Standards' means the Standards issued under section 2922.

''(3) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the Benefit Choice Standards in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the Benefit Choice Standards, and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such group health coverage) and filed with the State pursuant to subparagraph (B), a description in the insurer's contract of the Benefit Choice Standards and that adherence to such Standards is included as a term of such contract.

''(4) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the group or individual health insurance markets, except that such term shall not include excepted benefits (as defined in section 2791(c)).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that is not an adopting State.

''(6) SMALL GROUP INSURANCE MARKET.—The term 'small group insurance market' shall have the meaning given the term 'small group market' in section 2791(e)(5).

''(7) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''SEC. 2922. OFFERING AFFORDABLE PLANS.

''(a) BENEFIT CHOICE OPTIONS.—

''(1) DEVELOPMENT.—Not later than 6 months after the date of enactment of this title, the Secretary shall issue, by interim final rule, Benefit Choice Standards that implement the standards provided for in this part.

''(2) BASIC OPTIONS.—The Benefit Choice Standards shall provide that a health insurance issuer in a State, may offer a coverage plan or plan in the small group market, individual market, large group market, or through a small business health plan, that does not comply with one or more mandates regarding covered benefits, services, or category of provider as may be in effect in such State with respect to such market or markets (either prior to or following the date of enactment of this title), if such issuer also offers in such market or markets an enhanced option as provided for in paragraph (3) of the List of Required Benefits option as provided for in paragraph (5).

''(3) ENHANCED OPTION.—A health insurance issuer issuing a basic option as provided for in paragraph (2) shall also offer to purchasers (including, with respect to a small business health plan, the participating employers of such plan) an enhanced option, which shall at a minimum include such covered benefits, services, and categories of providers as are covered by a State employee coverage plan in one of the 5 most populous States as are in effect in the calendar year in which such enhanced option is offered.

''(4) PUBLICATION OF BENEFITS.—Not later than 3 months after the date of enactment of this title, and on the first day of every calendar year thereafter, the Secretary shall publish in the Federal Register such covered benefits, services, and categories of providers covered in that calendar year by the State employee coverage plans in the 5 most populous States.

''(5) LIST OF REQUIRED BENEFITS OPTION.—

''(A) IN GENERAL.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the National Association of Insurance Commissioners, shall issue by interim final rule a list (to be known as the 'List of Required Benefits') of covered benefits, services, or categories of providers that are required to be provided by health insurance issuers, in each of the small group and large group markets, in at least 26 States as a result of the application of State covered benefit, service, and category of provider mandate laws. With respect to plans sold to or through small business health plans, the List of Required Benefits applicable to the small group market shall apply.

''(B) APPLICATION.—The provision of paragraph (2) relating to the offering of a basic option plan under this part shall, in addition to allowing such option to be offered if the enhanced option under paragraph (3) is offered, permit such basic option to be offered if the health insurance issuer also offers an option providing coverage for the List of Required Benefits under subparagraph (A).

''(b) EFFECTIVE DATES.—

''(1) SMALL BUSINESS HEALTH PLANS.—With respect to health insurance provided to participating employers of small business health plans, the requirements of this part (concerning lower cost plans) shall apply beginning on the date that is 12 months after the date of enactment of this title.

''(2) NON-ASSOCIATION COVERAGE.—With respect to health insurance provided to groups or individuals other than participating employers of small business health plans, the requirements of this part shall apply beginning on the date that is 15 months after the date of enactment of this title.''.

SA 3934. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3899 submitted by Mr. DURBIN (for himself, Mrs. LINCOLN, Mr. REID, Mr. BAUCUS, Mr. KENNEDY, Mrs. CLINTON, Mr. KERRY, Mr. BINGAMAN, Ms. CANTWELL, Mr. PRYOR, Mr. HARKIN, Mr. OBAMA, Mr. LAUTENBERG, Mr. SCHUMER, Mr. KOHL, Mr. LIEBERMAN, Mr. DODD, Mr. DAYTON, Mr. JOHNSON, Mr. MENENDEZ, Mrs. BOXER, Mr. NELSON of Florida, Ms. MIKULSKI, Ms. STABENOW, Mr. CARPER, and Mr. ROCKEFELLER) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

On page 34 of the amendment, strike lines 14 through 18, and insert the following:

SEC. 16. EFFECTIVE DATE AND TERMINATION.

(a) EFFECTIVE DATE.—Except as provided in section 10(e), this Act shall take effect on the date of enactment of this Act and shall apply to contracts that take effect with respect to calendar year 2007 and each calendar year thereafter.

(b) TERMINATION.—The provisions of this Act shall not apply and shall be repealed on

the date on which the Director of the Office of Personal Management certifies to Congress that the Director, with respect to a plan year, is unable to contract with a sufficient number of insurance carriers under this Act to provide at least an equal number of State and national health plan choices as are available under the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code, in such plan year.

SA 3935. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3925 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of diabetes supplies, education, and treatment; and treatments or medical items for individuals with cancer; and treatment or services needed to treat or cure cardiovascular disease.

SA 3936. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3919 submitted by Mr. DODD and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of services for newborns and children, including pediatric and well-child care and immunizations.

SA 3937. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3918 submitted by Mr. DODD (for himself and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of services for beneficiaries participating in clinical trials.

SA 3938. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3916 submitted by Mr. REID (for himself, Mrs. CLINTON, Mrs. MURRAY, and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of prescription contraceptive drugs, or devices as approved by the Food and Drug Administration or generic equivalents approved as substitutable.

SA 3939. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3912 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of a preventive service that is recommended by the United States Preventive Services Task Force through a rating of ''A'' or ''B.''

SA 3940. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3913 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of obesity screening and counseling.

SA 3941. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3907 submitted by Mr. BAUCUS and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of maternity care or related pre- and post-natal care for women and their infants.

SA 3942. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3900 submitted by Mr. CARPER (for himself and Mrs. FEINSTEIN) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of cancer screenings, including screening for breast, cervical, prostate, uterine, skin, colon, and stomach cancer.

SA 3943. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3866 submitted by Mr. SMITH and intended to be proposed to

the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of Mental Health Parity.

SA 3944. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3892 submitted by Ms. COLLINS (for herself and Mr. BINGAMAN) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of diabetes treatment, education, supplies, and prescription drugs.

SA 3945. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3880 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Strike all after ''SEC.'' in the amendment and insert the following:

___. REVIEW OF HEALTH INSURANCE COVERAGE.

Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the extent to which health insurance provided to groups and individuals, including health insurance provided to participating employers of small business health plans, includes coverage of medical items and services for the treatment of diabetes.

SA 3946. Mr. NELSON of Nebraska submitted an amendment intended to be proposed to amendment SA 3924 submitted by Ms. SNOWE (for herself, Mr. BYRD, Mr. TALENT, and Mr. DOMENICI) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Beginning on page 1 of the amendment, strike all after the part heading and insert the following:

''SEC. 2921. DEFINITIONS.

''In this part:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted a law providing that small group, individual, and large group health insurers in such State may offer and sell products in accordance with the List of Required Benefits and the Terms of Application as provided for in section 2922(b)

''(2) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the List of Required Benefits and Terms of Application in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other applicable State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the List of Required Benefits and Terms of Application, and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such group health coverage) and filed with the State pursuant to subparagraph (B), a description in the insurer's contract of the List of Required Benefits and a description of the Terms of Application, including a description of the benefits to be provided, and that adherence to such standards is included as a term of such contract.

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the small group, individual, or large group health insurance markets, including with respect to small business health plans, except that such term shall not include excepted benefits (as defined in section 2791(c)).

''(4) LIST OF REQUIRED BENEFITS.—The term 'List of Required Benefits' means the List issued under section 2922(a).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that is not an adopting State.

''(6) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''(7) STATE PROVIDER FREEDOM OF CHOICE LAW.—The term 'State Provider Freedom of Choice Law' means a State law requiring that a health insurance issuer, with respect to health insurance coverage, not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law.

''(8) TERMS OF APPLICATION.—The term 'Terms of Application' means terms provided under section 2922(a).

''SEC. 2922. OFFERING AFFORDABLE PLANS.

''(a) LIST OF REQUIRED BENEFITS.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the National Association of Insurance Commissioners, shall issue by interim final rule a list (to be known as the 'List of Required Benefits') of covered benefits, services, or categories of providers that are required to be provided by health insurance issuers, in each of the small group, individual, and large group markets, in at least 26 States as a result of the application of State covered benefit, service, and category of provider mandate laws. With respect to plans sold to or through small business health plans, the List of Required Benefits applicable to the small group market shall apply.

''(b) TERMS OF APPLICATION.—

''(1) STATE WITH MANDATES.—With respect to a State that has a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such State mandate shall, subject to paragraph (3) (concerning uniform application), apply to a coverage plan or plan in, as applicable, the small group, individual, or large group market or through a small business health plan in such State.

''(2) STATES WITHOUT MANDATES.—With respect to a State that does not have a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such mandate shall not apply, as applicable, to a coverage plan or plan in the small group, individual, or large group market or through a small business health plan in such State.

''(3) UNIFORM APPLICATION OF LAWS.—

''(A) IN GENERAL.—With respect to a State described in paragraph (1), in applying a covered benefit, service, or category of provider mandate that is on the List of Required Benefits under subsection (a) the State shall permit a coverage plan or plan offered in the small group, individual, or large group market or through a small business health plan in such State to apply such benefit, service, or category of provider coverage in a manner consistent with the manner in which such coverage is applied under one of the three most heavily subscribed national health plans offered under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code (as determined by the Secretary in consultation with the Director of the Office of Personnel Management), and consistent with the Publication of Benefit Applications under subsection (c). In the event a covered benefit, service, or category of provider appearing in the List of Required Benefits is not offered in one of the three most heavily subscribed national health plans offered under the Federal Employees Health Benefits Program, such covered benefit, service, or category of provider requirement shall be applied in a manner consistent with the manner in which such coverage is offered in the remaining most heavily subscribed plan of the remaining Federal Employees Health Benefits Program plans, as determined by the Secretary, in consultation with the Director of the Office of Personnel Management.

''(B) EXCEPTION REGARDING STATE PROVIDER FREEDOM OF CHOICE LAWS.—Notwithstanding

subparagraph (A), in the event a category of provider mandate is included in the List of Covered Benefits, any State Provider Freedom of Choice Law (as defined in section 2921(7)) that is in effect in any State in which such category of provider mandate is in effect shall not be preempted, with respect to that category of provider, by this part.

''(c) PUBLICATION OF BENEFIT APPLICATIONS.—Not later than 3 months after the date of enactment of this title, and on the first day of every calendar year thereafter, the Secretary, in consultation with the Director of the Office of Personnel Management, shall publish in the Federal Register a description of such covered benefits, services, and categories of providers covered in that calendar year by each of the three most heavily subscribed nationally available Federal Employee Health Benefits Plan options which are also included on the List of Required Benefits.

''(d) EFFECTIVE DATES.—

''(1) SMALL BUSINESS HEALTH PLANS.—With respect to health insurance provided to participating employers of small business health plans, the requirements of this part (concerning lower cost plans) shall apply beginning on the date that is 12 months after the date of enactment of this title.

''(2) NON-ASSOCIATION COVERAGE.—With respect to health insurance provided to groups or individuals other than participating employers of small business health plans, the requirements of this part shall apply beginning on the date that is 15 months after the date of enactment of this title.

''(e) UPDATING OF LIST OF REQUIRED BENEFITS.—Not later than 2 years after the date on which the list of required benefits is issued under subsection (a), and every 2 years thereafter, the Secretary, in consultation with the National Association of Insurance Commissioners, shall update the list based on changes in the laws and regulations of the States. The Secretary shall issue the updated list by regulation, and such updated list shall be effective upon the first plan year following the issuance of such regulation.''.

SA 3947. Mr. NELSON of Nebraska submitted an amendment intended to be proposed to amendment SA 3926 submitted by Mr. NELSON of Nebraska and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

Beginning on page 1 of the amendment, strike all after the part heading and insert the following:

''SEC. 2921. DEFINITIONS.

''In this part:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted a law providing that small group, individual, and large group health insurers in such State may offer and sell products in accordance with the List of Required Benefits and the Terms of Application as provided for in section 2922(b)

''(2) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the List of Required Benefits and Terms of Application in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other applicable State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the List of Required Benefits and Terms of Application, and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such group health coverage) and filed with the State pursuant to subparagraph (B), a description in the insurer's contract of the List of Required Benefits and a description of the Terms of Application, including a description of the benefits to be provided, and that adherence to such standards is included as a term of such contract.

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the small group, individual, or large group health insurance markets, including with respect to small business health plans, except that such term shall not include excepted benefits (as defined in section 2791(c)).

''(4) LIST OF REQUIRED BENEFITS.—The term 'List of Required Benefits' means the List issued under section 2922(a).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that is not an adopting State.

''(6) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''(7) STATE PROVIDER FREEDOM OF CHOICE LAW.—The term 'State Provider Freedom of Choice Law' means a State law requiring that a health insurance issuer, with respect to health insurance coverage, not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law.

''(8) TERMS OF APPLICATION.—The term 'Terms of Application' means terms provided under section 2922(a).

''SEC. 2922. OFFERING AFFORDABLE PLANS.

''(a) LIST OF REQUIRED BENEFITS.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the National Association of Insurance Commissioners, shall issue by interim final rule a list (to be known as the 'List of Required Benefits') of covered benefits, services, or categories of providers that are required to be provided by health insurance issuers, in each of the small group, individual, and large group markets, in at least 26 States as a result of the application of State covered benefit, service, and category of provider mandate laws. With respect to plans sold to or through small business health plans, the List of Required Benefits applicable to the small group market shall apply.

''(b) TERMS OF APPLICATION.—

''(1) STATE WITH MANDATES.—With respect to a State that has a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such State mandate shall, subject to paragraph (3) (concerning uniform application), apply to a coverage plan or plan in, as applicable, the small group, individual, or large group market or through a small business health plan in such State.

''(2) STATES WITHOUT MANDATES.—With respect to a State that does not have a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such mandate shall not apply, as applicable, to a coverage plan or plan in the small group, individual, or large group market or through a small business health plan in such State.

''(3) UNIFORM APPLICATION OF LAWS.—

''(A) IN GENERAL.—With respect to a State described in paragraph (1), in applying a covered benefit, service, or category of provider mandate that is on the List of Required Benefits under subsection (a) the State shall permit a coverage plan or plan offered in the small group, individual, or large group market or through a small business health plan in such State to apply such benefit, service, or category of provider coverage in a manner consistent with the manner in which such coverage is applied under one of the three most heavily subscribed national health plans offered under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code (as determined by the Secretary in consultation with the Director of the Office of Personnel Management), and consistent with the Publication of Benefit Applications under subsection (c). In the event a covered benefit, service, or category of provider appearing in the List of Required Benefits is not offered in one of the three most heavily subscribed national health plans offered under the Federal Employees Health Benefits Program, such covered benefit, service, or category of provider requirement shall be applied in a manner consistent with the manner in which such coverage is offered in the remaining most heavily subscribed plan of the remaining Federal Employees Health Benefits Program plans, as determined by the Secretary, in consultation with the Director of the Office of Personnel Management.

''(B) EXCEPTION REGARDING STATE PROVIDER FREEDOM OF CHOICE LAWS.—Notwithstanding subparagraph (A), in the event a category of provider mandate is included in the List of Covered Benefits, any State Provider Freedom of Choice Law (as defined in section 2921(7)) that is in effect in any State in which such category of provider mandate is in effect shall not be preempted, with respect to that category of provider, by this part.

''(c) PUBLICATION OF BENEFIT APPLICATIONS.—Not later than 3 months after the date of enactment of this title, and on the first day of every calendar year thereafter, the Secretary, in consultation with the Director of the Office of Personnel Management, shall publish in the Federal Register a description of such covered benefits, services, and categories of providers covered in that calendar year by each of the three most heavily subscribed nationally available Federal Employee Health Benefits Plan options which are also included on the List of Required Benefits.

''(d) EFFECTIVE DATES.—

''(1) SMALL BUSINESS HEALTH PLANS.—With respect to health insurance provided to participating employers of small business health plans, the requirements of this part (concerning lower cost plans) shall apply beginning on the date that is 12 months after the date of enactment of this title.

''(2) NON-ASSOCIATION COVERAGE.—With respect to health insurance provided to groups or individuals other than participating employers of small business health plans, the

requirements of this part shall apply beginning on the date that is 15 months after the date of enactment of this title.

''(e) UPDATING OF LIST OF REQUIRED BENEFITS.—Not later than 2 years after the date on which the list of required benefits is issued under subsection (a), and every 2 years thereafter, the Secretary, in consultation with the National Association of Insurance Commissioners, shall update the list based on changes in the laws and regulations of the States. The Secretary shall issue the updated list by regulation, and such updated list shall be effective upon the first plan year following the issuance of such regulation.''.

SA 3948. Ms. SNOWE submitted an amendment intended to be proposed to amendment SA 3926 submitted by Mr. NELSON of Nebraska and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

On page 1 of the amendment, strike all after line 3 and insert the following:

''In this part:

''(1) ADOPTING STATE.—The term 'adopting State' means a State that has enacted a law providing that small group health insurers in such State may offer and sell products in accordance with the List of Required Benefits and the Terms of Application as provided for in section 2922(b)

''(2) ELIGIBLE INSURER.—The term 'eligible insurer' means a health insurance issuer that is licensed in a nonadopting State and that—

''(A) notifies the Secretary, not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage consistent with the List of Required Benefits and Terms of Application in a nonadopting State;

''(B) notifies the insurance department of a nonadopting State (or other applicable State agency), not later than 30 days prior to the offering of coverage described in this subparagraph, that the issuer intends to offer health insurance coverage in that State consistent with the List of Required Benefits and Terms of Application, and provides with such notice a copy of any insurance policy that it intends to offer in the State, its most recent annual and quarterly financial reports, and any other information required to be filed with the insurance department of the State (or other State agency) by the Secretary in regulations; and

''(C) includes in the terms of the health insurance coverage offered in nonadopting States (including in the terms of any individual certificates that may be offered to individuals in connection with such group health coverage) and filed with the State pursuant to subparagraph (B), a description in the insurer's contract of the List of Required Benefits and a description of the Terms of Application, including a description of the benefits to be provided, and that adherence to such standards is included as a term of such contract.

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means any coverage issued in the small group insurance markets, including with respect to small business health plans, except that such term shall not include excepted benefits (as defined in section 2791(c)).

''(4) LIST OF REQUIRED BENEFITS.—The term 'List of Required Benefits' means the List issued under section 2922(a).

''(5) NONADOPTING STATE.—The term 'nonadopting State' means a State that is not an adopting State.

''(6) STATE LAW.—The term 'State law' means all laws, decisions, rules, regulations, or other State actions (including actions by a State agency) having the effect of law, of any State.

''(7) STATE PROVIDER FREEDOM OF CHOICE LAW.—The term 'State Provider Freedom of Choice Law' means a State law requiring that a health insurance issuer, with respect to health insurance coverage, not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law.

''(8) TERMS OF APPLICATION.—The term 'Terms of Application' means terms provided under section 2922(a).

''SEC. 2922. OFFERING AFFORDABLE PLANS.

''(a) LIST OF REQUIRED BENEFITS.—Not later than 3 months after the date of enactment of this title, the Secretary, in consultation with the National Association of Insurance Commissioners, shall issue by interim final rule a list (to be known as the 'List of Required Benefits') of covered benefits, services, or categories of providers that are required to be provided by health insurance issuers, in each of the small group markets, in at least 26 States as a result of the application of State covered benefit, service, and category of provider mandate laws. With respect to plans sold to or through small business health plans, the List of Required Benefits applicable to the small group market shall apply.

''(b) TERMS OF APPLICATION.—

''(1) STATE WITH MANDATES.—With respect to a State that has a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such State mandate shall, subject to paragraph (3) (concerning uniform application), apply to a coverage plan or plan in, as applicable, the small group market or through a small business health plan in such State.

''(2) STATES WITHOUT MANDATES.—With respect to a State that does not have a covered benefit, service, or category of provider mandate in effect that is covered under the List of Required Benefits under subsection (a), such mandate shall not apply, as applicable, to a coverage plan or plan in the small group market or through a small business health plan in such State.

''(3) UNIFORM APPLICATION OF LAWS.—

''(A) IN GENERAL.—With respect to a State described in paragraph (1), in applying a covered benefit, service, or category of provider mandate that is on the List of Required Benefits under subsection (a) the State shall permit a coverage plan or plan offered in the small group market or through a small business health plan in such State to apply such benefit, service, or category of provider coverage in a manner consistent with the manner in which such coverage is applied under one of the three most heavily subscribed national health plans offered under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code (as determined by the Secretary in consultation with the Director of the Office of Personnel Management), and consistent with the Publication of Benefit Applications under subsection (c). In the event a covered benefit, service, or category of provider appearing in the List of Required Benefits is not offered in one of the three most heavily subscribed national health plans offered under the Federal Employees Health Benefits Program, such covered benefit, service, or category of provider requirement shall be applied in a manner consistent with the manner in which such coverage is offered in the remaining most heavily subscribed plan of the remaining Federal Employees Health Benefits Program plans, as determined by the Secretary, in consultation with the Director of the Office of Personnel Management.

''(B) EXCEPTION REGARDING STATE PROVIDER FREEDOM OF CHOICE LAWS.—Notwithstanding subparagraph (A), in the event a category of provider mandate is included in the List of Covered Benefits, any State Provider Freedom of Choice Law (as defined in section 2921(7)) that is in effect in any State in which such category of provider mandate is in effect shall not be preempted, with respect to that category of provider, by this part.

''(c) PUBLICATION OF BENEFIT APPLICATIONS.—Not later than 3 months after the date of enactment of this title, and on the first day of every calendar year thereafter, the Secretary, in consultation with the Director of the Office of Personnel Management, shall publish in the Federal Register a description of such covered benefits, services, and categories of providers covered in that calendar year by each of the three most heavily subscribed nationally available Federal Employee Health Benefits Plan options which are also included on the List of Required Benefits.

''(d) EFFECTIVE DATES.—

''(1) SMALL BUSINESS HEALTH PLANS.—With respect to health insurance provided to participating employers of small business health plans, the requirements of this part (concerning lower cost plans) shall apply beginning on the date that is 12 months after the date of enactment of this title.

''(2) NON-ASSOCIATION COVERAGE.—With respect to health insurance provided to groups or individuals other than participating employers of small business health plans, the requirements of this part shall apply beginning on the date that is 15 months after the date of enactment of this title.

''(e) UPDATING OF LIST OF REQUIRED BENEFITS.—Not later than 2 years after the date on which the list of required benefits is issued under subsection (a), and every 2 years thereafter, the Secretary, in consultation with the National Association of Insurance Commissioners, shall update the list based on changes in the laws and regulations of the States. The Secretary shall issue the updated list by regulation, and such updated list shall be effective upon the first plan year following the issuance of such regulation.''.

SA 3949. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3900 submitted by Mr. CARPER (for himself and Mrs. FEINSTEIN) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)'' of cancer screenings for breast, cervical, prostate, colon, skin, and stomach cancer.

SA 3950. Mr. ENZI submitted an amendment intended to be proposed to

amendment SA 3866 submitted by Mr. SMITH and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Mental Health Parity

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SA 3951. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3982 submitted by Ms. COLLINS (for herself and Mr. BINGAMAN) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)'' of diabetes treatment, education, supplies, and prescription drugs.

SA 3952. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3880 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)'' of medical items and services for the treatment of diabetes.

SA 3953. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3907 submitted by Mr. BAUCUS and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Cancer screening, including screening for breast, cervical, prostate, uterine, skin, colon and stomach cancer.

SA 3954. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3919 submitted by Mr. DODD and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Services for newborns and children, including pediatric and well-child care and immunizations.

SA 3955. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3913 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Obesity screening and counseling.

SA 3956. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3916 submitted by Mr. REID (for himself, Mrs. CLINTON, Mrs. MURRAY, and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Prescription contraceptive drugs, or devices as approved by the Food and Drug Administration or generic equivalents approved as a substitute.

SA 3957. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3918 submitted by Mr. DODD (for himself and Mr. MENENDEZ) and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Services for beneficiaries participating in clinical trials.

SA 3958. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3925 submitted by Mr. KENNEDY and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)''. Diabetes supplies, education and treatment; and treatments or medical items for individuals with cancer, and treatments or services needed to treat or are cardiovascular diseases.

SA 3959. Mr. ENZI submitted an amendment intended to be proposed to amendment SA 3912 submitted by Mr. HARKIN and intended to be proposed to the bill S. 1955, to amend title I of the Employee Retirement Security Act of 1974 and the Public Health Service Act to expand health care access and reduce costs through the creation of small business health plans and through modernization of the health insurance marketplace; which was ordered to lie on the table; as follows:

At the end of the amendment, insert before the period the following: '', except that nothing in this section shall be construed to supersede the provisions of section 2922 (regarding coverage requirements)'' of maternity care or related pre- and post-natal care for women and their infants.

NOTICES OF HEARINGS/MEETINGS

COMMITTEE ON INDIAN AFFAIRS

Mr. MCCAIN. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on Wednesday, May 17, 2006, at 9:30 a.m. in Room 485 of the Russell Senate Office Building to conduct an oversight hearing on Suicide Prevention Programs and their Application in Indian Country.

Those wishing additional information may contact the Indian Affairs Committee at 224–2251.

COMMITTEE ON INDIAN AFFAIRS

Mr. MCCAIN. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on Thursday, May 25, 2006, at 9:30 a.m. in Room 485 of the Russell Senate Office Building to conduct an oversight hearing on Indian Education.

Those wishing additional information may contact the Indian Affairs Committee at 224–2251.

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. CRAIG. Mr. President, I would like to announce for the information of