

in this legislation are taken into account, these two individuals would pay \$1,478 for their health insurance. But if they get married, their bill will increase to \$2,308, a marriage penalty of \$830, if you are at the 150 percent of poverty level or below. If you are at 150 percent of poverty or below, you don't have marginal income to mess around with. You need everything you have just to provide the basics. So if you are looking at this increase in the marriage penalty of \$830, you are saying: We can't afford to get married.

Is that the signal we want to send from the Federal Government? No. Everybody in this body would say that.

Let's take a pair of individuals earning 250 percent of the poverty level. One has no children; the other has two children. Unmarried they will, after subsidies, pay \$5,865 for their health coverage. If they decide to marry, they will face a penalty of \$2,050.

Let's turn to the new Medicare tax that will go into effect in 2013. The tax will apply to wage and salary income as well as certain business income for individuals. The tax will apply to income of that type for above \$200,000 for individuals and \$250,000 for joint filers.

The penalty is obvious on its face. Let's take an example. Two unmarried individuals earn \$200,000 each, and their total Medicare taxes would be \$11,600. But if they get married, the penalty is \$750. Or take two individuals, one making \$150,000 and the other \$200,000. Single, their Medicare taxes total \$10,150; if they get married, they will pay an additional \$500. This is on top of the marriage penalties that two earners face under current law. The marriage penalty is there. I don't think it is as significant as for the low-income individuals, but it is here as well.

My point is, why on Earth would that even be built into the base of the bill, particularly on the low-income couples? Why on Earth would you build in a marriage penalty on people who can't afford it? If combined income is over \$250,000, you can afford another \$500. I am willing to agree with that. But not this couple that is making at 150 percent of poverty or 250 percent of poverty, one with two kids. They can't afford that. Why on Earth would you build it into this? This is ridiculous that it be placed in the proposal. It makes no sense.

Creating and expanding on the penalties for marriage makes zero sense. Families are a critical determinant of the well-being of our society. Family structure also has a significant impact on economic well-being, on education, and the effect on the social fabric of this Nation is positive.

It is a fundamental law of economics that when you tax something, you get less of it. Why would we tax marriage, particularly for low-income individuals, when it is the best chance for those children involved with this couple to have a stable environment, if they will form a solid marriage unit? And we are going to tax it and discour-

age it. That is wrong. That is wrong as a policy matter.

There is a number of other problems I have had with this overall bill. This piece of it absolutely makes no sense to me, why we would do something like this. I urge my colleagues to vote against this bill, to take these sorts of things out, to take them out of the base law. Unfortunately, in the United States today, this is kind of repeating what already takes place in food stamps, what takes place in health benefits for low-income individuals right now. They cannot afford to get married or they lose their benefits. It is ridiculous. We ought to give people bonuses for getting married, not penalties for getting married. Now we are going to add to it by putting it in this health insurance bill. It is wrong and it is bad policy.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Alaska.

MORNING BUSINESS

Mr. BEGICH. Mr. President, I ask unanimous consent that the Senate proceed to a period of morning business, with Senators permitted to speak for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

NOMINATION OF ALAN D. SOLOMONT

Mr. GRASSLEY. Mr. President, on September 21, 2009, I announced my intention to object to proceeding to the nomination of Alan D. Solomont to be the Ambassador to Spain because of the incomplete responses that the Corporation for National and Community Service, CNCS, had provided to my document requests regarding the removal of its Inspector General, Gerald Walpin. Mr. Solomont was the chairman of the board of CNCS at the time that my requests went unanswered, and he began the process that led to Mr. Walpin's removal by contacting the White House Counsel's Office on May 20, 2009.

Since September 21, the White House produced approximately 1,900 additional pages of previously withheld documents. During that time, my staff conducted a series of negotiations with CNCS and the White House Counsel's Office over the hundreds of pages of remaining documents that were being withheld or had been redacted. As a result of these negotiations, this week the White House authorized and CNCS provided: 1. descriptions of the information redacted from several CNCS documents, 2. 37-previously produced documents with substantive redactions removed, and 3. 370 pages of previously withheld documents. In addition, the White House made Mr. Solomont available for a follow-up interview on December 8, 2009, so that he could be questioned about new information that had been learned from these documents

and other sources since his initial interview on July 15, 2009.

In order to obtain this additional information, I agreed to no longer object to proceeding to Mr. Solomont's nomination if the White House took these steps. I have kept my word and informed leadership that I no longer intend to object. However, I remain concerned about the accuracy and completeness of Mr. Solomont's answers to questions during both his July 15 and December 8, 2009 interviews. I understand Congressman ISSA of the House Committee on Oversight and Government Reform shares those concerns and has sent a letter to Mr. Solomont to that effect.

Although CNCS has produced a total of approximately 3,000 pages of material responsive to my request, the record should also be clear that the White House continues to withhold 46 documents, on grounds of deliberative process and attorney work product privileges. The White House did not provide a detailed log of the documents being withheld despite my requests. I will continue to seek answers to the remaining questions in this matter.

AMENDMENTS SUBMITTED AND PROPOSED

SA 3199. Mr. CORKER submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table.

SA 3200. Mr. MCCAIN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 3199. Mr. CORKER submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 399, strike line 10 and all that follows through page 403, line 17, and insert the following:

“(y) INCREASED FMAP FOR MEDICAL ASSISTANCE FOR NEWLY ELIGIBLE MANDATORY INDIVIDUALS.—

“(1) 100 PERCENT FMAP.—Notwithstanding subsection (b), the Federal medical assistance percentage determined for a State that is one of the 50 States or the District of Columbia with respect to amounts expended for medical assistance for newly eligible individuals described in subclause (VIII) or (IX) of section 1902(a)(10)(A)(i) shall be equal to 100 percent.

“(2) DEFINITIONS.—In this subsection:

“(A) NEWLY ELIGIBLE.—The term ‘newly eligible’ means an individual described in subclause (VIII) or (IX) of section 1902(a)(10)(A)(i) who, on the date of enactment of the Patient Protection and Affordable Care Act, is not eligible under the State plan or under a waiver of the plan for full benefits or for benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2), or is eligible but not enrolled (or is on a waiting list) for such benefits or coverage through a waiver under the plan that has a capped or limited enrollment that is full. Such term includes an individual for whom the State elects to provide medical assistance prior to January 1, 2014, under section 1902(k)(2).”

“(B) FULL BENEFITS.—The term ‘full benefits’ means, with respect to an individual, medical assistance for all services covered under the State plan under this title that is not less in amount, duration, or scope, or is determined by the Secretary to be substantially equivalent, to the medical assistance available for an individual described in section 1902(a)(10)(A)(i).”

(4) MEDICAL CARE ACCESS PROTECTION ACT.—

(A) SHORT TITLE.—This paragraph may be cited as the “Medical Care Access Protection Act of 2009” or the “MCAP Act”.

(B) FINDINGS AND PURPOSE.—

(i) FINDINGS.—

(I) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(II) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(III) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(aa) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(bb) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(cc) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(C) PURPOSE.—It is the purpose of this paragraph to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(i) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(ii) reduce the incidence of “defensive medicine” and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(iii) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(iv) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(v) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

(D) DEFINITIONS.—In this paragraph:

(i) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term “alternative dispute resolution system” or “ADR” means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(ii) CLAIMANT.—The term “claimant” means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(iii) COLLATERAL SOURCE BENEFITS.—The term “collateral source benefits” means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(I) any State or Federal health, sickness, income-disability, accident, or workers’ compensation law;

(II) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(III) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(IV) any other publicly or privately funded program.

(iv) COMPENSATORY DAMAGES.—The term “compensatory damages” means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(v) CONTINGENT FEE.—The term “contingent fee” includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(vi) ECONOMIC DAMAGES.—The term “economic damages” means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(vii) HEALTH CARE GOODS OR SERVICES.—The term “health care goods or services” means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(viii) HEALTH CARE INSTITUTION.—The term “health care institution” means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(ix) HEALTH CARE LAWSUIT.—The term “health care lawsuit” means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(x) HEALTH CARE LIABILITY ACTION.—The term “health care liability action” means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(xi) HEALTH CARE LIABILITY CLAIM.—The term “health care liability claim” means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(xii) HEALTH CARE PROVIDER.—

(I) IN GENERAL.—The term “health care provider” means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(II) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this paragraph, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under clause (I).

(xiii) MALICIOUS INTENT TO INJURE.—The term “malicious intent to injure” means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(xiv) **NONECONOMIC DAMAGES.**—The term “noneconomic damages” means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(xv) **PUNITIVE DAMAGES.**—The term “punitive damages” means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(xvi) **RECOVERY.**—The term “recovery” means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys’ office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(xvii) **STATE.**—The term “State” means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

(E) **ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**—

(i) **IN GENERAL.**—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(ii) **GENERAL EXCEPTION.**—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(I) fraud;

(II) intentional concealment; or

(III) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(iii) **MINORS.**—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(iv) **RULE 11 SANCTIONS.**—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this Act applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys’ fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable

conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(F) **COMPENSATING PATIENT INJURY.**—

(i) **UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.**—In any health care lawsuit, nothing in this paragraph shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in clause (ii).

(ii) **ADDITIONAL NONECONOMIC DAMAGES.**—

(I) **HEALTH CARE PROVIDERS.**—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as \$250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(II) **HEALTH CARE INSTITUTIONS.**—

(aa) **SINGLE INSTITUTION.**—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as \$250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(bb) **MULTIPLE INSTITUTIONS.**—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as \$250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed \$500,000.

(iii) **NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.**—In any health care lawsuit—

(I) an award for future noneconomic damages shall not be discounted to present value;

(II) the jury shall not be informed about the maximum award for noneconomic damages under clause (ii);

(III) an award for noneconomic damages in excess of the limitations provided for in clause (ii) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(IV) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in clause (ii), the future noneconomic damages shall be reduced first.

(iv) **FAIR SHARE RULE.**—In any health care lawsuit, each party shall be liable for that party’s several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party’s percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this subparagraph, the trier of fact shall determine the proportion of responsibility of each party for the claimant’s harm.

(G) **MAXIMIZING PATIENT RECOVERY.**—

(i) **COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.**—

(I) **IN GENERAL.**—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(II) **CONTINGENCY FEES.**—

(aa) **IN GENERAL.**—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant’s damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(bb) **LIMITATION.**—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(AA) 40 percent of the first \$50,000 recovered by the claimant(s).

(BB) 33½ percent of the next \$50,000 recovered by the claimant(s).

(CC) 25 percent of the next \$500,000 recovered by the claimant(s).

(DD) 15 percent of any amount by which the recovery by the claimant(s) is in excess of \$600,000.

(ii) **APPLICABILITY.**—

(I) **IN GENERAL.**—The limitations in clause (i) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(II) **MINORS.**—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this subparagraph.

(iii) **EXPERT WITNESSES.**—

(I) **REQUIREMENT.**—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(aa) except as required under subclause (II), is a health care professional who—

(AA) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(BB) typically treats the diagnosis or condition or provides the type of treatment under review; and

(bb) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(II) **PHYSICIAN REVIEW.**—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(III) **SPECIALTIES AND SUBSPECIALTIES.**—With respect to a lawsuit described in subclause (I), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with subclause (I)(bb), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(IV) **LIMITATION.**—The limitations in this clause shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

(H) ADDITIONAL HEALTH BENEFITS.—

(i) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(ii) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, clause (i) shall not apply.

(iii) APPLICATION OF PROVISION.—This subparagraph shall apply to any health care lawsuit that is settled or resolved by a fact finder.

(I) PUNITIVE DAMAGES.—

(i) PUNITIVE DAMAGES PERMITTED.—

(I) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(II) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(III) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(aa) whether punitive damages are to be awarded and the amount of such award; and

(bb) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(IV) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(ii) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(I) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(aa) the severity of the harm caused by the conduct of such party;

(bb) the duration of the conduct or any concealment of it by such party;

(cc) the profitability of the conduct to such party;

(dd) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(ee) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(ff) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(II) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or \$250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(iii) LIABILITY OF HEALTH CARE PROVIDERS.—

(I) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(II) MEDICAL PRODUCT.—The term “medical product” means a drug or device intended for humans. The terms “drug” and “device” have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

(J) AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.—

(i) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding \$50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(ii) APPLICABILITY.—This subparagraph applies to all actions which have not been first set for trial or retrial before the effective date of this Act.

(K) EFFECT ON OTHER LAWS.—

(i) GENERAL VACCINE INJURY.—

(I) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(aa) this paragraph shall not affect the application of the rule of law to such an action; and

(bb) any rule of law prescribed by this paragraph in conflict with a rule of law of such title XXI shall not apply to such action.

(II) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this paragraph or otherwise applicable law (as determined under this paragraph) will apply to such aspect of such action.

(ii) SMALLPOX VACCINE INJURY.—

(I) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(aa) this paragraph shall not affect the application of the rule of law to such an action; and

(bb) any rule of law prescribed by this paragraph in conflict with a rule of law of such part C shall not apply to such action.

(II) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the

Public Health Service Act does not apply, then this paragraph or otherwise applicable law (as determined under this paragraph) will apply to such aspect of such action.

(iii) OTHER FEDERAL LAW.—Except as provided in this subparagraph, nothing in this paragraph shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

(L) STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.—

(i) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this paragraph shall preempt, subject to clauses (ii) and (iii), State law to the extent that State law prevents the application of any provisions of law established by or under this paragraph. The provisions governing health care lawsuits set forth in this paragraph supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(I) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this paragraph; or

(II) prohibits the introduction of evidence regarding collateral source benefits.

(ii) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this paragraph shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this paragraph, notwithstanding subparagraph (F)(i).

(iii) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(I) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this paragraph (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(II) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to—

(aa) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this paragraph;

(bb) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(cc) create a cause of action that is not otherwise available under Federal or State law; or

(dd) affect the scope of preemption of any other Federal law.

(M) APPLICABILITY; EFFECTIVE DATE.—This paragraph shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3200. Mr. MCCAIN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr.

DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE X—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 10001. SHORT TITLE.

This title may be cited as the “Pharmaceutical Market Access and Drug Safety Act of 2009”.

SEC. 10002. FINDINGS.

Congress finds that—

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

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

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

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

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

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

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

SEC. 10003. 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. 10004. 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 10003, 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 ophthalmic 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), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

“(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

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

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

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

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

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

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

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

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

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

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

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

“(A) directly from the establishment; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“(II) samples of such drugs;

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

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

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

“(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

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

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

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

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

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

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

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

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

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

“(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

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

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

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

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

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

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

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

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

“(I) a declaration as to whether the Secretary has ordered that importation of the

drug from the permitted country cease under subsection (g)(2)(C) or (D); and

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

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

“(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

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

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

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

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

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

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

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

“(e) IMPORTER FEES.—

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

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

“(3) AMOUNT OF INSPECTION FEE.—

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

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

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

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

“(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

“(C) TOTAL PRICE OF DRUGS.—

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

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

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

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

“(4) USE OF FEES.—

“(A) IN GENERAL.—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) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

“(C) 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.—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) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

“(C) 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.—

“(I) IN GENERAL.—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). 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).

“(II) FEE AMOUNT FOR CERTAIN YEARS.—If no fee amount is in effect under section 736(a)(1)(A)(ii) for a fiscal year, then the amount paid by a person under subclause (I) shall—

“(aa) for the first fiscal year in which no fee amount under such section is in effect, be equal to the fee amount under section 736(a)(1)(A)(ii) for the most recent fiscal year for which such section was in effect, adjusted in accordance with section 736(c); and

“(bb) for each subsequent fiscal year in which no fee amount under such section is in effect, be equal to the applicable fee amount for the previous fiscal year, adjusted in accordance with section 736(c).

“(v) TIMING OF SUBMISSION OF NOTICES.—

“(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the

difference begin less than 120 days after the country requires the difference.

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

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

“(vi) REVIEW BY SECRETARY.—

“(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

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

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

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

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

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

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

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

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

“(vii) PUBLICATION OF INFORMATION ON NOTICES.—

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

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

“(aa) a notice is under review;

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

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

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

“(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under subsection (c) or (d)(3)(B)(i) of section 506A, 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)(I) 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 subparagraph (C) or (D) of paragraph (2).

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

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

“(F) The Secretary becomes aware that—

“(i) the drug may be counterfeit;

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

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

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

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

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

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

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

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

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

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

“(h) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

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

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

“(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

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

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

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

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

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

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

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

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

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

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

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

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

“(j) MAINTENANCE OF RECORDS AND SAMPLES.—

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

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

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

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

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

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

“(k) DRUG RECALLS.—

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

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

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

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

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

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

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

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

“(l) DRUG LABELING AND PACKAGING.—

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

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

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

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

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

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

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

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

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

“(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply

with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

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

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

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

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

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

“(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

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

“(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under paragraphs (3), (4), and (5) of section 1004(e) of the Pharmaceutical Market Access and Drug Safety Act of 2009, 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)(iii), 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 Act.

(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 Act; 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 Act.

(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 Act 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 Act 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 Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(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 Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

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

(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 Act, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs 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 Act, 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 Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act if—

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

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

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

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

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

(9) **USER FEES.**—

(A) **EXPORTERS.**—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to \$1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) **IMPORTERS.**—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

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

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

(C) **SECOND YEAR ADJUSTMENT.**—

(i) **REPORTS.**—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during the 4-month

period from October 1 through January 31 of such fiscal year.

(ii) **REESTIMATE.**—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

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

(II) 3.

(iii) **ADJUSTMENT.**—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during such fiscal year as reestimated under clause (ii).

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

(E) **ANNUAL REPORT.**—

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

(ii) **CUSTOMS AND BORDER PROTECTION.**—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) **SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.**—

(A) **IN GENERAL.**—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional permitted 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 permitted countries under subparagraph (A)—

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

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

(F) **IMPLEMENTATION OF SECTION 804.**—

(1) **INTERIM RULE.**—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and

Cosmetic Act, as added by subsection (a) of this section.

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

(3) **FINAL RULE.**—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

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

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

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

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

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

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

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

SEC. 10005. 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 10004, 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 Act.

(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 Act.

SEC. 10006. 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”;

(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 subpara-

graph 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, 2012.

(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 Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 10004.

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

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2012.

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

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary

shall, not later than 18 months after the date of enactment of this Act, require that the packaging of any prescription drug incorporates—

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

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

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

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

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

(dd) incorporate additional layers of non-visible covert security features up to and including forensic capability, as described in subparagraph (B); or

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

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

SEC. 10007. 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 503B the following:

“SEC. 503C. 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.

“(h) NO EFFECT ON OTHER REQUIREMENTS; COORDINATION.—The requirements of this section are in addition to, and do not supersede, any requirements under the Controlled Substances Act or the Controlled Substances

Import and Export Act (or any regulation promulgated under either such Act) regarding Internet pharmacies and controlled substances. In promulgating regulations to carry out this section, the Secretary shall coordinate with the Attorney General to ensure that such regulations do not duplicate or conflict with the requirements described in the previous sentence, and that such regulations and requirements coordinate to the extent practicable.”

(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 503C.”

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503C of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

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

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the “Secretary”) shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

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

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

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

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. 10008. 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:

“(h) 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 subsection, and the regulations promulgated under this subsection, shall be enforced exclusively 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.

“(11) COMPLIANCE.—A payment system, and any person described in paragraph (2)(B), shall not be deemed to be in violation of paragraph (1)—

“(A)(i) if an alleged violation of paragraph (1) occurs prior to the mandatory compliance date of the regulations issued under paragraph (7); and

“(ii) such entity has adopted or relied on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; or

“(B)(i) if an alleged violation of paragraph (1) occurs after the mandatory compliance date of such regulations; and

“(ii) such entity is in compliance with such regulations.”.

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

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (h)(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 Act.

SEC. 10009. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking “not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.” and inserting “import into the United States not

more than 10 dosage units combined of all such controlled substances.”.

SEC. 10010. SEVERABILITY.

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

SEC. 10011. SENSE OF THE SENATE REGARDING REPORTING.

(a) IN GENERAL.—It is the sense of the Senate that, beginning 180 days after the date of enactment of this Act, and every 180 days thereafter, the Secretary of Health and Human Services should report to Congress on the status of the progress of the provisions of this title (and the amendments made by this title) to permit the importation from certain approved countries of safe and affordable prescription drugs approved by the Food and Drug Administration.

(b) CONTENTS.—Any report submitted under subsection (a) should include a description of the steps being taken by such Secretary to ensure that the implementation of this title (and the amendments made by this title) results in—

(1) the effective oversight of drugs, pharmacies, manufacturers, and registration of importers and exporters in accordance with this title (and such amendments);

(2) a safe prescription drug supply for American consumers; and

(3) cost savings to American consumers.

ORDERS FOR SUNDAY, DECEMBER 13, 2009

Mr. BEGICH. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 1:30 p.m., Sunday, December 13; that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, the time for the two leaders be reserved for their use later in the day, and the Senate resume consideration of the conference report accompanying H.R. 3288, the consolidated appropriations bill, as provided for under the previous order; and that following any leader remarks, the time until 2 p.m. be equally divided and controlled between the two leaders or their designees.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

PROGRAM

Mr. BEGICH. Mr. President, at 2 p.m., the Senate will proceed to a roll-call vote on the adoption of the conference report to accompany H.R. 3288, the consolidated appropriations bill.

ORDER FOR ADJOURNMENT

Mr. BEGICH. Finally, Mr. President, I ask unanimous consent that following the remarks of Senator THUNE and Senator ENZI, the Senate adjourn under the previous order.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senator from South Dakota.

OMNIBUS APPROPRIATIONS AND HEALTH CARE REFORM

Mr. THUNE. Mr. President, I want to address the issue of health care reform, of course, which is the main reason Congress is here this weekend and was here last weekend, and in all likelihood will be here next weekend. But I also think it is important we put these things into an overall context and take a look at the bill we are voting on right now.

We are going to have a vote on final passage tomorrow. We had a cloture vote this morning on a spending bill, and the spending bill—which represents six, I think, appropriations bills that did not get done earlier this year—represents a package of spending that overall increases by 12 percent over last year.

That is an interesting number, given the fact that the Consumer Price Index—which is the sort of, if you will, conduit to which a lot of these decisions that are made around here is tied; in other words, the CPI is what we view to be inflation; and sometimes we say we mark up bills at inflation or inflation plus this or inflation plus that—where the CPI was, ending on October 1 of this year, about two-tenths of 1 percent but in the negative column.

So you have a CPI that is actually negative, an inflation index that is actually negative for most Americans. This, again, is representative of the totality of our economy and what things cost, and that is a lot of times how appropriations bills are measured.

So you have a CPI, Consumer Price Index, that is running in the negative, and yet you have appropriations bills—this one representing, again, as I said earlier, six appropriations bills, individual appropriations bills that did not get done earlier—packaged into one big spending bill that is a 12-percent increase over the previous year.

How can we go to the American people and justify year-over-year spending increases that are 12 percent, when they are having to balance their budgets and tighten their belts and live in an economy where some people are losing their jobs? But certainly everybody is trying, struggling to survive out there. That is true for small businesses. That is true for families. That is true for pretty much everybody, it seems, except the Congress.

Here in Washington, DC, we seem not to be listening to what is happening in America. We are marking up spending bills at 12 percent over last year's level, at a time when the CPI is actually running in the negative—when you have negative cost-of-living increase. Yet we are marking up appropriations bills that represent a 12-percent increase over last year's spending level?

Put that on top of a stimulus bill that passed earlier this year that, with interest, is a \$1 trillion spending bill. So you have a \$1 trillion spending bill with interest passed earlier this year, much of which went to the very same