Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 2865. Mr. BURRIS 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.

SA 2866. Mr. SPECTER 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.

SA 2867. Mr. SPECTER 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.

SA 2868. Mr. BURRIS 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.

SA 2869. Mr. NELSON of Florida (for himself, Mr. ROCKEFELLER, Mr. BEGICH, Mr. LEAHY, Mr. BROWN, Ms. STABENOW, and Mrs. SHAHEEN) 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.

SA 2870. Mr. WHITEHOUSE proposed an amendment to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra.

SA 2871. Mr. BROWN (for himself and Mrs. HUTCHISON) 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.

SA 2872. Mr. BROWN 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.

SA 2873. Mr. BROWN 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.

SA 2874. Mr. BROWN 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.

SA 2875. Mr. BROWN 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.

SA 2876. Mr. BROWN 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.

SA 2877. Mr. BROWN 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.

SA 2878. Mr. CARDIN 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.

SA 2879. Mr. CARDIN 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 2860. Mr. FEINGOLD 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 797, strike line 11 and all that follows through page 801, line 4, and insert the following:

SEC. 3102A. ELIMINATION OF GEOGRAPHIC PHYSICIAN WORK ADJUSTMENT FACTOR FROM GEOGRAPHIC INDICES USED TO ADJUST PAYMENTS UNDER THE PHYSICIAN FEE SCHEDULE.

(a) FINDINGS.—Congress finds the following:

(1) Variations in the geographic physician work adjustment factors under section 1848(e) of the Social Security Act (42 U.S.C. 1395w–4(e)) result in inequity between localities in payments under the Medicare physician fee schedule.

(2) Beneficiaries under the Medicare program that reside in areas where such adjustment factors are high have relatively more access to services that are paid based on such fee schedule.

(3) There are a number of studies indicating that the market for health care professionals has become nationalized and historically low labor costs in rural and small urban areas have disappeared.

(4) Elimination of the adjustment factors described in paragraph (1) would equalize the reimbursement rate for services reimbursed under the Medicare physician fee schedule while remaining budget-neutral.

(b) ELIMINATION.—Section 1848(e) of the Social Security Act (42 U.S.C. 1395w–4(e)) is amended—

(1) in paragraph (1)(A)(iii), by striking ''an index'' and inserting ''for services provided before January 1, 2010, an index''; and

(2) in paragraph (2), by inserting '', for services provided before January 1, 2010,'' after ''paragraph (4)), and''.

(c) BUDGET NEUTRALITY ADJUSTMENT FOR ELIMINATION OF GEOGRAPHIC PHYSICIAN WORK ADJUSTMENT FACTOR.—Section 1848(d) of the Social Security Act (42 U.S.C. 1395w–4(d)) is amended—

(1) in paragraph (1)(A), by striking ''The conversion'' and inserting ''Subject to paragraph (10), the conversion''; and

(2) by adding at the end the following new paragraph:

''(10) BUDGET NEUTRALITY ADJUSTMENT FOR ELIMINATION OF GEOGRAPHIC PHYSICIAN WORK ADJUSTMENT FACTOR.—Before applying an update for a year under this subsection, the Secretary shall (if necessary) provide for an adjustment to the conversion factor for that year to ensure that the aggregate payments under this part in that year shall be equal to aggregate payments that would have been made under such part in that year if the amendments made by section 3102A(b) of the Patient Protection and Affordable Care Act had not been enacted.''.

SEC. 3102B. CLINICAL ROTATION DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary shall establish a demonstration project that provides for demonstration grants designed to provide financial or other incentives to hospitals to attract educators and clinical practitioners so that hospitals that serve beneficiaries under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who are residents of underserved areas may host clinical rotations.

(b) DURATION OF PROJECT.—The demonstration project shall be conducted over a 5-year period.

(c) WAIVER.—The Secretary shall waive such provisions of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq. and 1395 et seq.) as may be necessary to conduct the demonstration project under this section.

(d) REPORTS.—The Secretary shall submit to the appropriate committees of Congress interim reports on the demonstration project and a final report on such project within 6 months after the conclusion of the project, together with recommendations for such legislation or administrative action as the Secretary determines to be appropriate.

(e) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out this section, $20,000,000.

(f) DEFINITIONS.—In this section:

(1) HOSPITAL.—The term ''hospital'' means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) that had indirect or direct costs of medical education during the most recent cost reporting period preceding the date of enactment of this Act.

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

(3) UNDERSERVED AREA.—The term ''underserved area'' means such medically underserved urban areas and medically underserved rural areas as the Secretary may specify.

SEC. 3102C. MEDICARE RURAL HEALTH CARE QUALITY IMPROVEMENT DEMONSTRATION PROJECTS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish not more that 10 demonstration projects to provide for improvements, as recommended by the Institute of Medicine, in the quality of health care provided to individuals residing in rural areas.

(2) ACTIVITIES.—Activities under the projects may include public health surveillance, emergency room videoconferencing, virtual libraries, telemedicine, electronic health records, data exchange networks, and any other activities determined appropriate by the Secretary.

(3) CONSULTATION.—The Secretary shall consult with the Office of Rural Health Policy of the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services in carrying out the provisions of this section.

(b) DURATION.—Each demonstration project under this section shall be conducted over a 4-year period.

(c) DEMONSTRATION PROJECT SITES.—The Secretary shall ensure that the demonstration projects under this section are conducted at a variety of sites representing the diversity of rural communities in the United States.

(d) WAIVER.—The Secretary shall waive such provisions of titles XI and XVIII of the

Social Security Act (42 U.S.C. 1301 et seq. and 1395 et seq.) as may be necessary to conduct the demonstration projects under this section.

(e) INDEPENDENT EVALUATION.—The Secretary shall enter into an arrangement with an entity that has experience working directly with rural health systems for the conduct of an independent evaluation of the demonstration projects conducted under this section.

(f) REPORTS.—The Secretary shall submit to the appropriate committees of Congress interim reports on each demonstration project and a final report on such project within 6 months after the conclusion of the project. Such reports shall include recommendations regarding the expansion of the project to other areas and recommendations for such other legislative or administrative action as the Secretary determines appropriate.

(g) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out this section, $50,000,000.

SEC. 3102D. ENSURING PROPORTIONAL REPRESENTATION OF INTERESTS OF RURAL AREAS ON THE MEDICARE PAYMENT ADVISORY COMMISSION.

(a) IN GENERAL.—Section 1805(c)(2) of the Social Security Act (42 U.S.C. 1395b–6(c)(2)) is amended—

(1) in subparagraph (A), by inserting ''consistent with subparagraph (E)'' after ''rural representatives''; and

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

''(E) PROPORTIONAL REPRESENTATION OF INTERESTS OF RURAL AREAS.—In order to provide a balance between urban and rural representatives under subparagraph (A), the proportion of members who represent the interests of health care providers and Medicare beneficiaries located in rural areas shall be no less than the proportion, of the total number of Medicare beneficiaries, who reside in rural areas.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to appointments made to the Medicare Payment Advisory Commission after the date of the enactment of this Act.

SEC. 3102E. IMPLEMENTATION OF GAO RECOMMENDATIONS REGARDING GEOGRAPHIC ADJUSTMENT INDICES UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall implement the recommendations contained in the March 2005 GAO report 05–119 entitled ''Medicare Physician Fees: Geographic Adjustment Indices are Valid in Design, but Data and Methods Need Refinement.''.

SA 2861. Mr. FEINGOLD 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 appropriate place in subtitle C of title IV, insert the following:

SEC. 4___. AUTOMATED DEFIBRILLATION IN ADAM'S MEMORY ACT.

Section 312 of the Public Health Service Act (42 U.S.C. 244) is amended—

(1) in subsection (c)(6), after ''clearinghouse'' insert '', that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death,''; and

(2) in the first sentence of subsection (e), by striking ''fiscal year 2003'' and all that follows through ''2006'' and inserting ''for each of fiscal years 2003 through 2014''.

SA 2862. Mr. KOHL (for himself, Mr. GRASSLEY, Mr. FEINGOLD, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. NELSON of Florida, and Mr. BROWN) submitted an amendment intended to be proposed by him 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 appropriate place, insert the following:

TITLE ____—PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

SEC. __01. SHORT TITLE.

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

SEC. __02. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by—

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

''SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

''(2) PRESUMPTION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

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

''(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

''(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

''(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

''(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

''(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

''(4) the revenue the ANDA filer would have received by winning the patent litigation;

''(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

''(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and

''(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

''(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive, although such evidence may be relevant to the fact finder's determination under this section.

''(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market the ANDA product in the United States prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

''(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

''(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

''(e) REGULATIONS AND ENFORCEMENT.—

''(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

''(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

''(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 C.F.R. 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that

section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(g) PENALTIES.—

''(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

''(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

''(A) the nature, circumstances, extent, and gravity of the violation;

''(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(h) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

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

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

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

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

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

''(8) NDA HOLDER.—The term 'NDA holder' means—

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

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

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

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

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

''(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act .''.

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 28(a)(1) of that Act entered into after November 15, 2009. Section 28(g) of the Federal Trade Commission Act, as added by this section, shall not apply to agreements entered into before the date of enactment of this title.

SEC. __03. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking ''the Commission the'' and inserting the following: ''the Commission—

''(1) the'';

(2) striking the period and inserting ''; and''; and

(3) inserting at the end the following:

''(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).''.

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

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

SEC. __04. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

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

SEC. __05. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking ''or'' after the semicolon;

(2) in subparagraph (E), by inserting ''or'' after the semicolon; and

(3) inserting after subparagraph (E) the following:

''(F) under section 28;''.

SEC. __06. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section __02, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. __07. SEVERABILITY.

If any provision of this title, an amendment made 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 title or amendments to any person or circumstance shall not be affected thereby.

SA 2863. Mr. VITTER 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 Act of 2009''

SEC. 10002. PURPOSES.

The purposes of this title are to—

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

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

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

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

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

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

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

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

SEC. 10003. AMENDMENTS TO SECTION 804 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

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

''(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

''(D) an intravenously injected drug;

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

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

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

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

''(B) is not—

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

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

''(iii) a photoreactive drug.

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

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

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

''(10) WHOLESALER.—

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

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

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

''(b) REGULATIONS.—Not later than 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2009, the Secretary, after consultation with the United States Trade Representative and the Commissioner of the U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists, pharmacies, and wholesalers to import qualifying drugs from permitted countries into the United States.''.

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

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

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

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

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

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

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

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

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

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

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

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

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

''(ii) export only qualifying drugs;

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

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

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

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

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

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

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

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

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

''(iii) approve or disapprove the application.

''(B) DISAPPROVAL OF APPLICATION.—

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

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

''(3) LIST.—The Secretary shall—

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

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

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

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

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

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

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

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

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

''(j) IMPORTATION BY INDIVIDUALS.—

''(1) IN GENERAL.—Not later than 180 days after the enactment of the Pharmaceutical Market Access Act of 2009, the Secretary shall by regulation permit an individual to import a drug from a permitted country to the United States if the drug is—

''(A) a qualifying drug;

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 10004. REGISTRATION FEES.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

''PART 6—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION

''SEC. 743. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

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

''(b) COLLECTION.—

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

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

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

''(c) FEE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (b)(1), the amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the amendments made by the Pharmaceutical Market Access Act of 2009 in the subsequent fiscal year.

''(2) LIMITATION.—

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

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

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

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

''(2) developing, implementing, and maintaining a system to determine registered exporters' compliance with the registration conditions under the Pharmaceutical Market Access Act of 2009, including when shipments of qualifying drugs are offered for import into the United States; and

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

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2009, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

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

''(2) FAILURE TO PAY.—If a registered exporter subject to a fee under this section fails to pay the fee, the Secretary shall not permit the registered exporter to engage in exportation to the United States or offering for exportation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

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

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

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

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

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

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

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

SEC. 10005. COUNTERFEIT-RESISTANT TECHNOLOGY.

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

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

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

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

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

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

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

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

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

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

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

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

''(c) STANDARDS FOR PACKAGING.—

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

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to

such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

''(d) EFFECTIVE DATE.—This section shall take effect 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2009.''.

SEC. 10006. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after subsection (k) the following:

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

SEC. 10007. PATENTS.

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

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

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

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) that was first sold abroad by or under authority of the owner or licensee of such patent.''.

SEC. 10008. OTHER ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as amended by section 10003, is amended by adding at the end the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(3) PRESUMPTION AND AFFIRMATIVE DEFENSE.—

''(A) PRESUMPTION.—A difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) created after January 1, 2009, between a prescription drug for distribution in the United States and the drug for distribution in a permitted country shall be presumed under paragraph (1)(F) to be for the purpose of restricting importation of the drug into the United States under this section.

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

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

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

''(4) EFFECT OF SUBSECTION.—

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

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B 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.

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

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

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

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—The attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction for a violation of paragraph (1) to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

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

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

''(ii) NOTICE.—

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

''(aa) written notice of that action; and

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

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

''(B) INTERVENTION.—

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

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

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

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

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A),

nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

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

''(D) ACTIONS BY THE COMMISSION.—

''(i) IN GENERAL.—In any case in which an action is instituted by or on behalf of the Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

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

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

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

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

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

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

''(i) is an inhabitant; or

''(ii) may be found.

''(G) LIMITATION OF ACTIONS.—Any action under this paragraph to enforce a cause of action under this subsection by the Federal Trade Commission or the attorney general of a State shall be forever barred unless commenced within 5 years after the Federal Trade Commission, or the attorney general, as the case may be, knew or should have known that the cause of action accrued. No cause of action barred under existing law on the effective date of the Pharmaceutical Market Access Act of 2009 shall be revived by such Act.

''(H) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

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

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

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

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

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

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

(c) SUSPENSION AND TERMINATION OF EXPORTERS.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)), as amended by section 10003(g), is amended by—

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

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

(2) adding at the end the following:

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

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

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

''(ii) If the Secretary determines that, under color of the registration, the registered exporter has exported a drug that is not a qualifying drug, or a drug that does not meet the criteria under this section, or has exported a qualifying drug to an individual in violation of this section, the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registered exporter involved an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

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

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

SEC. 10009. AUTHORIZATION OF APPROPRIATIONS.

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

SA 2864. Mr. VITTER 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:

On page 156, line 4, strike all through page 157, line 7, and insert the following:

(D) REQUIREMENT OF MEMBERS OF CONGRESS TO ENROLL IN THE PUBLIC OPTION.—

(i) REQUIREMENT.—Notwithstanding any other provision of law, all Members of Congress shall be enrolled in the community health insurance option when established by the Secretary.

(ii) INELIGIBLE FOR FEHBP.—Effective on the date on which the community health insurance option is established by the Secretary, no Member of Congress shall be eligible to participate in a health benefits plan under chapter 89 of title 5, United States Code.

(iii) EMPLOYER CONTRIBUTION.—

(I) IN GENERAL.—The Secretary of the Senate or the Chief Administrative Officer of the House of Representatives shall pay the amount determined under subclause (II) to—

(aa) the appropriate community health insurance option; or

(bb) in the case of a Member of Congress who resides in a State which opts out of providing a community health insurance option and is enrolled in a plan offered through an Exchange, the appropriate Exchange.

(II) AMOUNT OF EMPLOYER CONTRIBUTION.—The Director of the Office of Personnel Management shall determine the amount of the employer contribution for each Member of Congress enrolled in a community health insurance option. The amount shall be equal to the employer contribution for the health benefits plan under chapter 89 of title 5, United States Code, with the greatest number of enrollees, except that the contribution shall be actuarially adjusted for age.

(iv) MILITARY MEDICAL TREATMENT FACILITIES AND THE OFFICE OF THE ATTENDING PHYSICIAN.—

(I) IN GENERAL.—Notwithstanding any other provision of law, a Member of Congress may not receive health care or medical treatment at any military medical treatment facility or at the Office of the Attending Physician.

(II) EXCEPTION.—Subclause (I) shall not apply to any case of a medical emergency in which the life of a Member of Congress is in immediate danger.

(v) DEFINITIONS.—In this subparagraph:

(I) COMMUNITY HEALTH INSURANCE OPTION.—The term ''community health insurance option'' means the health insurance established by the Secretary under section 1323.

(II) MEMBER OF CONGRESS.—The term ''Member of Congress'' means any member of the House of Representatives or the Senate.

SA 2865. Mr. BURRIS 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:

On page 1249 between lines 6 and 7, insert the following:

(b) HOSPITAL COMPARE PATIENT SURVEYS.—

(1) IN GENERAL.—In implementing the Hospital Compare patient survey program, the Director of the Agency for Healthcare Research and Quality shall, in addition to collecting other information to reduce health disparities, collect information concerning—

(A) whether hospital staff effectively address cultural and linguistic barriers that may prevent patients from receiving quality health care; and

(B) whether hospital health promotion programs are effectively marketed in the community served by the hospital.

(2) REQUIREMENT TO TAKE INTO ACCOUNT SURVEY IN COMMUNITY HEALTH NEEDS ASSESSMENTS.—Section 501(r)(3)(B) of the Internal Revenue Code of 1986, as added by section 9007, is amended striking ''and'' at the end of clause (i), by redesignating clause (ii) as clause (iii), and by inserting after clause (i) the following new clause:

''(ii) takes into account the information collected under the Hospital Compare patient survey program, and''.

SA 2866. Mr. SPECTER 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 of subtitle D of title IV, insert the following:

SEC. 4307. CURES ACCELERATION NETWORK.

(a) SHORT TITLE.—This section may be cited as the ''Cures Acceleration Network Act of 2009''.

(b) REQUIREMENT FOR THE DIRECTOR OF NIH TO ESTABLISH A CURES ACCELERATION NETWORK.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (22), by striking ''and'' at the end;

(2) in paragraph (23), by striking the period and inserting ''; and''; and

(3) by inserting after paragraph (23), the following:

''(24) implement the Cures Acceleration Network described in section 402C.''.

(c) ACCEPTING GIFTS TO SUPPORT THE CURES ACCELERATION NETWORK.—Section 499(c)(1) of the Public Health Service Act (42 U.S.C. 290b(c)(1)) is amended by adding at the end the following:

''(E) The Cures Acceleration Network described in section 402C.''.

(d) ESTABLISHMENT OF THE CURES ACCELERATION NETWORK.—Part A of title IV of the Public Health Service Act is amended by inserting after section 402B (42 U.S.C. 282b) the following:

''SEC. 402C. CURES ACCELERATION NETWORK.

''(a) DEFINITIONS.—In this section:

''(1) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351 of the Public Health Service Act.

''(2) DRUG; DEVICE.—The terms 'drug' and 'device' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(3) HIGH NEED CURE.—The term 'high need cure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, biological product (as that term is defined by section 262(i)), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act) that, in the determination of the Director of NIH—

''(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

''(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

''(4) MEDICAL PRODUCT.—The term 'medical product' means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

''(b) ESTABLISHMENT OF THE CURES ACCELERATION NETWORK.—Subject to the appropriation of funds as described in subsection (g), there is established within the Office of the Director of NIH a program to be known as the Cures Acceleration Network (referred to in this section as 'CAN'), which shall—

''(1) be under the direction of the Director of NIH, taking into account the recommendations of a CAN Review Board (referred to in this section as the 'Board'), described in subsection (d); and

''(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

''(c) FUNCTIONS.—The functions of the CAN are to—

''(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

''(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

''(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

''(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

''(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

''(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

''(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

''(C) connecting interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act.

''(d) CAN BOARD.—

''(1) ESTABLISHMENT.—There is established a Cures Acceleration Network Review Board (referred to in this section as the 'Board'), which shall advise the Director of NIH on the conduct of the activities of the Cures Acceleration Network.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—

''(i) APPOINTMENT.—The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

''(ii) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the 'Chairperson') and one Vice Chairperson.

''(B) TERMS.—

''(i) IN GENERAL.—Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

''(ii) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

''(C) QUALIFICATIONS.—

''(i) IN GENERAL.—The Secretary shall appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

''(ii) EXPERTISE.—The Secretary shall select individuals based upon the following requirements:

''(I) For each of the fields of—

''(aa) basic research;

''(bb) medicine;

''(cc) biopharmaceuticals;

''(dd) discovery and delivery of medical products;

''(ee) bioinformatics and gene therapy;

''(ff) medical instrumentation; and

''(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

''(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

''(III) At least 8 individuals shall represent disease advocacy organizations.

''(3) EX-OFFICIO MEMBERS.—

''(A) APPOINTMENT.—In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

''(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

''(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

''(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

''(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

''(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

''(B) TERMS.—Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

''(4) RESPONSIBILITIES OF THE BOARD AND THE DIRECTOR OF NIH.—

''(A) RESPONSIBILITIES OF THE BOARD.—

''(i) IN GENERAL.—The Board shall advise, and provide recommendations to, the Director of NIH with respect to—

''(I) policies, programs, and procedures for carrying out the duties of the Director of NIH under this section; and

''(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

''(ii) REPORT.—In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

''(B) RESPONSIBILITIES OF THE DIRECTOR OF NIH.—With respect to each recommendation

provided by the Board under subparagraph (A)(i), the Director of NIH shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of NIH indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

''(5) MEETINGS.—

''(A) IN GENERAL.—The Board shall meet 4 times per calendar year, at the call of the Chairperson.

''(B) QUORUM; REQUIREMENTS; LIMITATIONS.—

''(i) QUORUM.—A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

''(ii) CHAIRPERSON OR VICE CHAIRPERSON.—Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

''(iii) DIVERSE REPRESENTATION.—At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

''(6) COMPENSATION AND TRAVEL EXPENSES.—

''(A) COMPENSATION.—Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the Untied States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

''(B) TRAVEL EXPENSES.—Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b) of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

''(e) GRANT PROGRAM.—

''(1) SUPPORTING INNOVATION.—To carry out the purposes described in this section, the Director of NIH shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

''(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies;

''(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

''(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

''(2) ELIGIBLE ENTITIES.—To receive assistance under paragraph (1), an entity shall—

''(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

''(B) submit an application containing—

''(i) a detailed description of the project for which the entity seeks such grant or contract;

''(ii) a timetable for such project;

''(iii) an assurance that the entity will submit—

''(I) interim reports describing the entity's—

''(aa) progress in carrying out the project; and

''(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

''(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

''(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

''(C) provide such additional information as the Director of NIH may require.

''(3) AWARDS.—

''(A) THE CURES ACCELERATION PARTNERSHIP AWARDS.—

''(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

''(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of NIH the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

''(iii) MATCHING FUNDS.—As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of NIH may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

''(B) THE CURES ACCELERATION GRANT AWARDS.—

''(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

''(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of NIH may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

''(C) THE CURES ACCELERATION FLEXIBLE RESEARCH AWARDS.—If the Director of NIH determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of NIH shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

''(4) SUSPENSION OF AWARDS FOR DEFAULTS, NONCOMPLIANCE WITH PROVISIONS AND PLANS, AND DIVERSION OF FUNDS; REPAYMENT OF FUNDS.—The Director of NIH may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

''(5) AUDITS.—The Director of NIH may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

''(6) CLOSEOUT PROCEDURES.—At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

''(7) REVIEW.—A determination by the Director of NIH as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

''(f) COMPETITIVE BASIS OF AWARDS.—Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For purposes of carrying out this section, there are authorized to be appropriated $500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

''(2) LIMITATION ON USE OF FUNDS OTHERWISE APPROPRIATED.—No funds appropriated under this Act, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.''.

SA 2867. Mr. SPECTER 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 appropriate place in title IV, insert the following:

SEC. ___. INCREASE IN FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH.

(a) AUTHORIZATION OF APPROPRIATIONS.—Section 402A(a) of the Public Health Service Act (42 U.S.C. 282a(a)) is amended by striking paragraphs (1) through (3) and inserting the following:

''(1) $40,000,000,000 for fiscal year 2010; and

''(2) such sums as may be necessary for each of fiscal years 2011 and 2012.''.

(b) OFFICE OF THE DIRECTOR.—Section 402A(b) of the Public Health Service Act (42 U.S.C. 282a(b)) is amended by striking ''2007 through 2009'' and inserting ''2010 through 2012''.

SA 2868. Mr. BURRIS 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:

On page 147, line 19, strike ''and''.

On page 147, line 21, strike the period and insert ''; and''.

On page 147, between lines 21 and 22, insert the following:

''(E) the implementation of activities that reduce health care disparities, including through the use of language services, community outreach, and cultural competency training.''.

SA 2869. Mr. NELSON of Florida (for himself, Mr. ROCKEFELLER, Mr. BEGICH, Mr. LEAHY, Mr. BROWN, Ms. STABENOW, and Mrs. SHAHEEN) 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:

On page 974, between lines 9 and 10, insert the following:

(b) ELIMINATION OF COVERAGE GAP.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is further amended—

(1) in paragraph (3)(A), by striking ''and (7)'' and inserting '', (7), and (8)'';

(2) in paragraph (4)(B)(i), by inserting ''subject to paragraph (8)'' after ''purposes of this part''; and

(3) by adding at the end the following new paragraph:

''(8) PHASED-IN ELIMINATION OF COVERAGE GAP.—

''(A) IN GENERAL.—For each year beginning with 2011, the Secretary shall consistent with this paragraph progressively increase the initial coverage limit (described in subsection (b)(3)) and decrease the annual out-of-pocket threshold from the amounts otherwise computed until there is a continuation of coverage from the initial coverage limit for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4).

''(B) INCREASE IN INITIAL COVERAGE LIMIT.—For a year beginning with 2011, the initial coverage limit otherwise computed without regard to this paragraph shall be increased by ½ of the cumulative phase-in percentage (as defined in subparagraph (D)(ii) for the year) times the out-of-pocket gap amount (as defined in subparagraph (E)) for the year.

''(C) DECREASE IN ANNUAL OUT-OF-POCKET THRESHOLD.—For a year beginning with 2011, the annual out-of-pocket threshold otherwise computed without regard to this paragraph shall be decreased by ½ of the cumulative phase-in percentage of the out-of-pocket gap amount for the year multiplied by 1.75.

''(D) PHASE–IN.—For purposes of this paragraph:

''(i) ANNUAL PHASE-IN PERCENTAGE.—The term 'annual phase-in percentage' means—

''(I) for 2011, 13 percent;

''(II) for 2012, 2013, 2014, and 2015, 5 percent;

''(III) for 2016 through 2018, 7.5 percent; and

''(IV) for 2019 and each subsequent year, 10 percent.

''(ii) CUMULATIVE PHASE-IN PERCENTAGE.—The term 'cumulative phase-in percentage' means for a year the sum of the annual phase-in percentage for the year and the annual phase-in percentages for each previous year beginning with 2011, but in no case more than 100 percent.

''(E) OUT-OF-POCKET GAP AMOUNT.—For purposes of this paragraph, the term 'out-of-pocket gap amount' means for a year the amount by which—

''(i) the annual out-of-pocket threshold specified in paragraph (4)(B) for the year (as determined as if this paragraph did not apply), exceeds

''(ii) the sum of—

''(I) the annual deductible under paragraph (1) for the year; and

''(II) ¼ of the amount by which the initial coverage limit under paragraph (3) for the year (as determined as if this paragraph did not apply) exceeds such annual deductible.''.

(c) REQUIRING DRUG MANUFACTURERS TO PROVIDE DRUG REBATES FOR FULL-BENEFIT DUAL ELIGIBLES.—

(1) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (e)(1), in the matter before subparagraph (A), by inserting ''and subsection (f)'' after ''this subsection''; and

(B) by adding at the end the following new subsection:

''(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

''(1) IN GENERAL.—In this part, the term 'covered part D drug' does not include any drug or biologic that is manufactured by a manufacturer that has not entered into and have in effect a rebate agreement described in paragraph (2).

''(2) REBATE AGREEMENT.—A rebate agreement under this subsection shall require the manufacturer to provide to the Secretary a rebate for each rebate period (as defined in paragraph (6)(B)) ending after December 31, 2010, in the amount specified in paragraph (3) for any covered part D drug of the manufacturer dispensed after December 31, 2010, to any full-benefit dual eligible individual (as defined in paragraph (6)(A)) for which payment was made by a PDP sponsor under part D or a MA organization under part C for such period. Such rebate shall be paid by the manufacturer to the Secretary not later than 30 days after the date of receipt of the information described in section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3).

''(3) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

''(A) IN GENERAL.—The amount of the rebate specified under this paragraph for a manufacturer for a rebate period, with respect to each dosage form and strength of any covered part D drug provided by such manufacturer and dispensed to a full-benefit dual eligible individual, shall be equal to the product of—

''(i) the total number of units of such dosage form and strength of the drug so provided and dispensed for which payment was made by a PDP sponsor under part D or a MA organization under part C for the rebate period (as reported under section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3)); and

''(ii) the amount (if any) by which—

''(I) the Medicaid rebate amount (as defined in subparagraph (B)) for such form, strength, and period, exceeds

''(II) the average Medicare drug program full-benefit dual eligible rebate amount (as defined in subparagraph (C)) for such form, strength, and period.

''(B) MEDICAID REBATE AMOUNT.—For purposes of this paragraph, the term 'Medicaid rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by the manufacturer for a rebate period—

''(i) in the case of a single source drug or an innovator multiple source drug, the amount specified in paragraph (1)(A)(ii) of section 1927(b) plus the amount, if any, specified in paragraph (2)(A)(ii) of such section, for such form, strength, and period; or

''(ii) in the case of any other covered outpatient drug, the amount specified in paragraph (3)(A)(i) of such section for such form, strength, and period.

''(C) AVERAGE MEDICARE DRUG PROGRAM FULL-BENEFIT DUAL ELIGIBLE REBATE AMOUNT.—For purposes of this subsection, the term 'average Medicare drug program full-benefit dual eligible rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by a manufacturer for a rebate period, the sum, for all PDP sponsors under part D and MA organizations administering a MA–PD plan under part C, of—

''(i) the product, for each such sponsor or organization, of—

''(I) the sum of all rebates, discounts, or other price concessions (not taking into account any rebate provided under paragraph (2) for such dosage form and strength of the drug dispensed, calculated on a per-unit basis, but only to the extent that any such rebate, discount, or other price concession applies equally to drugs dispensed to full-benefit dual eligible Medicare drug plan enrollees and drugs dispensed to PDP and MA–PD enrollees who are not full-benefit dual eligible individuals; and

''(II) the number of the units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in the prescription drug plans administered by the PDP sponsor or the MA–PD plans administered by the MA–PD organization; divided by

''(ii) the total number of units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in all prescription drug plans administered by PDP sponsors and all MA–PD plans administered by MA–PD organizations.

''(4) LENGTH OF AGREEMENT.—The provisions of paragraph (4) of section 1927(b) (other than clauses (iv) and (v) of subparagraph (B)) shall apply to rebate agreements under this subsection in the same manner as such paragraph applies to a rebate agreement under such section.

''(5) OTHER TERMS AND CONDITIONS.—The Secretary shall establish other terms and conditions of the rebate agreement under this subsection, including terms and conditions related to compliance, that are consistent with this subsection.

''(6) DEFINITIONS.—In this subsection and section 1860D–12(b)(7):

''(A) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL.—The term 'full-benefit dual eligible individual' has the meaning given such term in section 1935(c)(6).

''(B) REBATE PERIOD.—The term 'rebate period' has the meaning given such term in section 1927(k)(8).''.

(2) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURES RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

(A) REQUIREMENTS FOR PDP SPONSORS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

''(7) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

''(A) IN GENERAL.—For purposes of the rebate under section 1860D–2(f) for contract years beginning on or after January 1, 2011, each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan shall require that the sponsor comply with subparagraphs (B) and (C).

''(B) REPORT FORM AND CONTENTS.—Not later than 60 days after the end of each rebate period (as defined in section 1860D–2(f)(6)(B)) within such a contract year to which such section applies, a PDP sponsor of a prescription drug plan under this part shall report to each manufacturer—

''(i) information (by National Drug Code number) on the total number of units of each dosage, form, and strength of each drug of such manufacturer dispensed to full-benefit dual eligible Medicare drug plan enrollees under any prescription drug plan operated by the PDP sponsor during the rebate period;

''(ii) information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period;

''(iii) information on the extent to which such price discounts, price concessions, and rebates apply equally to full-benefit dual eligible Medicare drug plan enrollees and PDP enrollees who are not full-benefit dual eligible Medicare drug plan enrollees; and

''(iv) any additional information that the Secretary determines is necessary to enable the Secretary to calculate the average Medicare drug program full-benefit dual eligible rebate amount (as defined in paragraph (3)(C) of such section), and to determine the amount of the rebate required under this section, for such form, strength, and period.

Such report shall be in a form consistent with a standard reporting format established by the Secretary.

''(C) SUBMISSION TO SECRETARY.—Each PDP sponsor shall promptly transmit a copy of the information reported under subparagraph (B) to the Secretary for the purpose of audit oversight and evaluation.

''(D) CONFIDENTIALITY OF INFORMATION.—The provisions of subparagraph (D) of section 1927(b)(3), relating to confidentiality of information, shall apply to information reported by PDP sponsors under this paragraph in the same manner that such provisions apply to information disclosed by manufacturers or wholesalers under such section, except—

''(i) that any reference to 'this section' in clause (i) of such subparagraph shall be treated as being a reference to this section;

''(ii) the reference to the Director of the Congressional Budget Office in clause (iii) of such subparagraph shall be treated as including a reference to the Medicare Payment Advisory Commission; and

''(iii) clause (iv) of such subparagraph shall not apply.

''(E) OVERSIGHT.—Information reported under this paragraph may be used by the Inspector General of the Department of Health and Human Services for the statutorily authorized purposes of audit, investigation, and evaluations.

''(F) PENALTIES FOR FAILURE TO PROVIDE TIMELY INFORMATION AND PROVISION OF FALSE INFORMATION.—In the case of a PDP sponsor—

''(i) that fails to provide information required under subparagraph (B) on a timely basis, the sponsor is subject to a civil money penalty in the amount of $10,000 for each day in which such information has not been provided; or

''(ii) that knowingly (as defined in section 1128A(i)) provides false information under such subparagraph, the sponsor is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).''.

(B) APPLICATION TO MA ORGANIZATIONS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following:

''(D) REPORTING REQUIREMENT RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Section 1860D–12(b)(7).''.

(3) DEPOSIT OF REBATES INTO MEDICARE PRESCRIPTION DRUG ACCOUNT.—Section 1860D–16(c) of such Act (42 U.S.C. 1395w–116(c)) is amended by adding at the end the following new paragraph:

''(6) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Amounts paid under a rebate agreement under section 1860D–2(f) shall be deposited into the Account and shall be used to pay for all or part of the gradual elimination of the coverage gap under section 1860D–2(b)(7).''.

(d) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 3301 of this Act is amended by adding at the end the following new subsection:

''(e) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—The amendments made by this section shall cease to be effective as of the date on which there is a continuation of coverage from the initial coverage limit for expenditures incurred through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4).''.

SA 2870. Mr. WHITEHOUSE proposed an amendment 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; as follows:

At the appropriate place, insert the following:

SEC. ___. SENSE OF THE SENATE PROMOTING FISCAL RESPONSIBILITY.

(a) FINDINGS.—The Senate makes the following findings:

(1) Based on Congressional Budget Office (CBO) estimates, this Act will reduce the Federal deficit between 2010 and 2019.

(2) CBO projects this Act will continue to reduce budget deficits after 2019.

(3) Based on CBO estimates, this Act will extend the solvency of the Medicare HI Trust Fund.

(4) This Act will increase the surplus in the Social Security Trust Fund, which should be reserved to strengthen the finances of Social Security.

(5) The initial net savings generated by the Community Living Assistance Services and Supports (CLASS) program are necessary to ensure the long-term solvency of that program.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the additional surplus in the Social Security Trust Fund generated by this Act should be reserved for Social Security and not spent in this Act for other purposes; and

(2) the net savings generated by the CLASS program should be reserved for the CLASS program and not spent in this Act for other purposes.

SA 2871. Mr. BROWN (for himself and Mrs. HUTCHISON) 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:

On page 97, between lines 6 and 7, insert the following:

''SEC. 2710. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

''(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs; and

''(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

''(2) ROUTINE PATIENT COSTS.—

''(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

''(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

''(i) the investigational item, device, or service, itself;

''(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

''(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

''(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

''(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

''(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

''(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

''(2) Either—

''(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

''(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a

group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical trial (including a phase I, phase II, phase III, or phase IV trial) that is conducted in relation to the treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

''(A) The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

''(i) The National Institutes of Health.

''(ii) The Centers for Disease Control and Prevention.

''(iii) The Agency for Health Care Research and Quality.

''(iv) The Centers for Medicare & Medicaid Services.

''(v) A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

''(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

''(vii) Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) The study or investigation is conducted in accordance with the requirements for investigational new drugs or investigational devices under the Federal Food, Drug, and Cosmetic Act.

''(C) The study or investigation is a clinical trial of a drug or device that is exempt from the requirements described under subparagraph (B).

''(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

''(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

''(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term 'life-threatening condition' means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

''(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

''(g) APPLICATION TO FEHBP.—Notwithstanding any provision of chapter 89 of title 5, United States Code, this section shall apply to health plans offered under the program under such chapter.

''(h) PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section.''.

SA 2872. Mr. BROWN 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:

On page 1465, between lines 12 and 13, insert the following:

SEC. 5506. COUNTING RESIDENT TIME IN CERTAIN HOSPITALS.

(a) GME.—Section 1886(h)(4) of the Social Security Act (42 U.S.C. 1395ww(h)(4)), as amended by sections 5504 and 5505, is amended—

(1) in subparagraph (E), by striking ''and (K)'' and inserting '', (K), and (L)''; and

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

''(L) COUNTING RESIDENT TIME IN CERTAIN HOSPITALS.—

''(i) IN GENERAL.—Such rules shall provide that all the time spent by a resident under an approved medical training program in a hospital described in clause (ii) shall be counted toward the determination of full-time equivalency by the hospital that incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in the hospital described in clause (ii).

''(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that—

''(I) trains 3 or fewer full-time equivalent residents annually;

''(II) consents, not later than 1 year after the date on which the residents involved begin training under such approved medical training program (and annually thereafter), to forgo payments for direct graduate medical education costs under this subsection for such residents; and

''(III) has not had an approved FTE resident amount determined for the hospital under paragraph (2) as of the date on which such residents begin such training.''.

(b) IME.—Section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)), as amended by section 5505, is amended by adding at the end the following new clause:

''(xi) The provisions of subparagraph (L) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.''.

(c) CONFORMING AMENDMENT.—Section 1886(h)(2) of such Act (42 U.S.C. 1395 ww(h)(2)) is amended by adding at the end the following new subparagraph:

''(G) EXCEPTION TO DETERMINATION OF PER RESIDENT AMOUNT.—The Secretary shall not determine an approved FTE resident amount under this paragraph for any hospital described in paragraph (4)(L)(ii).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to cost reporting periods beginning on or after January 1, 2009.

SA 2873. Mr. BROWN 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 1390, strike line 25 and all that follows through line 21 on page 1393, and insert the following:

''(4) to identify and refer underserved populations to appropriate healthcare agencies and community-based programs and organizations in order to increase access to quality healthcare services and to eliminate duplicative care; or

''(5) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

''(c) APPLICATION.—Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

''(d) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

''(1) propose to target geographic areas—

''(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

''(B) with a high percentage of residents who suffer from chronic diseases; or

''(C) with a high infant mortality rate;

''(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

''(3) have documented community activity and experience with community health workers.

''(e) COLLABORATION WITH ACADEMIC INSTITUTIONS AND THE ONE-STOP DELIVERY SYSTEM.—The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions and one-stop delivery systems under section 134(c) of the Workforce Investment Act of 1998. Nothing in this section shall be construed to require such collaboration.

''(f) EVIDENCE-BASED INTERVENTIONS.—The Secretary shall encourage community health worker programs receiving funding under this section to implement a process or an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such a payment.

''(g) QUALITY ASSURANCE AND COST EFFECTIVENESS.—The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

''(h) MONITORING.—The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

''(i) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2010 through 2014.

''(k) DEFINITIONS.—In this section:

''(1) COMMUNITY HEALTH WORKER.—The term 'community health worker' means an individual who promotes health or nutrition within the community in which the individual resides—

SA 2874. Mr. BROWN 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:

On page 1069, line 1, insert ''community health workers,'' after ''social workers,''.

SA 2875. Mr. BROWN 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:

On page 536, line 10, insert ''community health worker,'' after ''social worker,''.

SA 2876. Mr. BROWN 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:

On page 816, after line 20, insert the following:

SEC. 3115. WAIVER OF MEDICARE DME SURETY BOND REQUIREMENT FOR CERTAIN DME SUPPLIERS.

Section 1834(a)(16) of the Social Security Act (42 U.S.C. 1395m(a)(16)) is amended by adding at the end the following new sentence: ''The requirement for a surety bond described in subparagraph (B) shall not apply in the case of a pharmacy or supplier that exclusively provides eyeglasses or contact lenses as described in section 1861(s)(8) that (i) is enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies and has been issued (which may include renewal of) a provider number (as described in the first sentence of this paragraph) for at least 5 years, and (ii) for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has never been imposed.''.

SA 2877. Mr. BROWN 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:

On page 869, between lines 14 and 15, insert the following:

SEC. 3143. REIMBURSEMENT FOR TOTAL BODY ORTHOTIC MANAGEMENT FOR CERTAIN NURSING HOME PATIENTS.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall issue product codes that qualified practitioners and suppliers may use to receive reimbursement under section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) for qualified total body orthotic management devices used for the treatment of nonambulatory individuals with severe musculoskeletal conditions who are in the full-time care of skilled nursing facilities (as defined in section 1861(j) of such Act (42 U.S.C. 1395x(j))). In issuing such codes, the Secretary shall take all steps necessary to prevent fraud and abuse.

(b) QUALIFIED TOTAL BODY ORTHOTIC MANAGEMENT DEVICE.—For purposes of this section, the term ''qualified total body orthotic management device'' means a medically-prescribed device which—

(1) consists of custom fitted individual braces with adjustable points at the hips, knee, ankle, elbow, and wrist, but only if—

(A) the individually adjustable braces are attached to a frame which is an integral component of the device and cannot function or be used apart from the frame; and

(B) the frame is designed such that it serves no purpose without the braces; and

(2) is designed to—

(A) improve function;

(B) retard progression of musculoskeletal deformity; or

(C) restrict, eliminate, or assist in the functioning of lower and upper extremities and pelvic, spinal, and cervical regions of the body affected by injury, weakness, or deformity, of an individual for whom stabilization of affected areas of the body, or relief of pressure points, is required for medical reasons.

SA 2878. Mr. CARDIN 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 appropriate place, insert the following:

TITLE ___MINORITY HEALTH

SEC. ___01. OFFICE OF MINORITY HEALTH.

(a) IN GENERAL.—Section 1707 of the Public Health Service Act (42 U.S.C. 300u–6) is amended—

(1) in subsection (a), by striking ''within the Office of Public Health and Science and all that follows through the end'' and inserting ''. The Office of Minority Health as existing on the date of enactment of the Patient Protection and Affordable Care Act shall be transferred to the Office of the Secretary in such manner that there is established in the Office of the Secretary, the Office of Minority Health, which shall be headed by the Deputy Assistant Secretary for Minority Health who shall report directly to the Secretary, and shall retain and maintain an Advisory Committee on Minority Health as provided for under subsection (c).'' and

(2) by striking subsection (b) and inserting the following:

''(b) DUTIES.—With respect to improving the health of racial and ethnic minority groups, the Secretary, acting through the Deputy Assistant Secretary, shall carry out the following:

''(1) Establish, implement, monitor, and evaluate short-range and long-range goals and objectives and oversee all other activities within the Public Health Service that relate to disease prevention, health promotion, service delivery, and research concerning minority groups. The heads of each of the agencies of the Service shall consult with the Deputy Assistant Secretary to ensure the coordination of such activities.

''(2) Oversee all activities within the Department of Health and Human Services that relate to reducing or eliminating disparities in health and health care in racial and ethnic minority populations and in rural and underserved communities, including coordinating—

''(A) the design of programs, support for programs, and the evaluation of programs;

''(B) the monitoring of trends in health and health care;

''(C) research efforts;

''(D) the training of health providers; and

''(E) information and education programs and campaigns.

''(3) Enter into interagency and intra-agency agreements with other agencies of the Public Health Service.

''(4) Ensure that the Federal health agencies and the National Center for Health Statistics collect data on the health status and health care of each minority group, using at a minimum the categories specified in the 1997 OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity as required under subtitle B and available language standards.

''(5) Provide technical assistance to States, local agencies, territories, Indian tribes, and entities for activities relating to the elimination of racial and ethnic disparities in health and health care.

''(6) Support a national minority health resource center to carry out the following:

''(A) Facilitate the exchange of information regarding matters relating to health information, health promotion and wellness, preventive health services, clinical trials, health information technology, and education in the appropriate use of health services.

''(B) Facilitate timely access to culturally and linguistically appropriate information.

''(C) Assist in the analysis of such information.

''(D) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance).

''(7) Carry out programs to improve access to health care services for individuals with limited English proficiency.

''(8) Carry out programs to improve access to health care services and to improve the quality of health care services for individuals with low functional health literacy. As used in the preceding sentence, the term 'functional health literacy' means the ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

''(9) Advise in matters related to the development, implementation, and evaluation of health professions education on decreasing disparities in health care outcomes, with focus on cultural competency as a method of eliminating disparities in health and health care in racial and ethnic minority populations.

''(10) Assist health care professionals, community and advocacy organizations, academic centers and public health departments in the design and implementation of programs that will improve the quality of health outcomes by strengthening the provider-patient relationship.

''(11) In carrying our this subsection—

''(A) award grants, contracts, enter into memoranda of understanding, cooperative,

interagency, intra-agency and other agreements with public and nonprofit private entities, agencies, as well as Departmental and Cabinet agencies and organizations; and

''(B) award grants, contracts, enter into memoranda of understanding, cooperative and other agreements with organizations that are indigenous human resource providers in communities of color to assure improved health status of racial and ethnic minorities.

''(12) Directly or through contracts with public and private entities, agencies, and nonprofit organizations, provide for evaluations of projects carried out with awards made the Office and for the dissemination of information developed as a result of such projects.'';

(3) by redesignating subsections (f) through (h) as subsections (g) through (i), respectively;

(4) by inserting after subsection (e) the following:

''(f) PREPARATION OF HEALTH PROFESSIONALS TO PROVIDE HEALTH CARE TO MINORITY POPULATIONS.—The Secretary, in collaboration with the Director of the Bureau of Health Professions and the Deputy Assistant Secretary for Minority Health, shall require that health professional schools that receive Federal funds train future health professionals to provide culturally and linguistically appropriate health care to diverse populations.''; and

(5) by striking subsection (i) (as so redesignated) and inserting the following:

''(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2011 through 2016.''.

(b) TRANSFER OF FUNCTIONS.—There are transferred to the Office of Minority Health in the office of the Secretary of Health and Human Services, the Deputy Assistant Secretary for Minority Health who shall report directly to the Secretary of Health and Human Services. All duties, responsibilities, accountabilities and functions exercised by the Deputy Assistant Secretary for Minority Health and by the Office of Minority Health of the Public Health Service prior to the date of enactment of this section shall transfer with the Office and the Deputy Assistant Secretary for Minority Health, including all personnel and compensation authority, all delegation and assignment authority, all committees including the Advisory Committee on Minority Health and other committees, entities and councils, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

(1) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this paragraph; and

(2) transfers with the Deputy Assistant Secretary for Minority Health are in effect at the time this section takes effect, or were final before the date of enactment of this section and are to become effective on or after such date, transfers with and to the Office of Minority Health within the Office of the Secretary and remain the authority, responsibility and accountability of the Office; shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, a court of competent jurisdiction, or by operation of law.

(c) REPORTS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, and every second year thereafter, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under section 1707 of the Public Health Service Act (as amended by this section) during the period for which the report is being prepared.

(2) AGENCY REPORTS.—Not later than 1 year after the date of enactment of this section, and biennially thereafter, the heads of each of the agencies of the Public Health Service shall submit to the Deputy Assistant Secretary for Minority Health a report summarizing the minority health activities of each of the respective agencies.

SEC. ___02. ESTABLISHMENT OF INDIVIDUAL OFFICES OF MINORITY HEALTH WITHIN AGENCIES OF THE PUBLIC HEALTH SERVICE.

Title XVII of the Public Health Service Act (42 U.S.C. 300u et seq.) is amended by inserting after section 1707 the following section:

''SEC. 1707A. INDIVIDUAL OFFICES OF MINORITY HEALTH WITHIN PUBLIC HEALTH SERVICE.

''(a) IN GENERAL.—The head of each agency specified in subsection (b)(1) shall establish within the agency an office to be known as the Office of Minority Health. The head of each such Office shall be appointed by the head of the agency within which the Office is established, and shall report directly to the head of the agency. The head of such agency shall carry out this section (as this section relates to the agency) acting through such Director.

''(b) SPECIFIED AGENCIES.—

''(1) IN GENERAL.—The agencies referred to in subsection (a) are the following:

''(A) The Centers for Disease Control and Prevention.

''(B) The Health Resources and Services Administration.

''(C) The Substance Abuse and Mental Health Services Administration.

''(D) The Agency for Healthcare Research and Quality.

''(E) The Food and Drug Administration.

''(c) COMPOSITION.—The head of each specified agency shall ensure that the officers and employees of the minority health office of the agency are, collectively, experienced in carrying out community-based health programs for each of the various racial and ethnic minority groups that are present in significant numbers in the United States.

''(d) DUTIES.—Each head of a minority health office shall establish and monitor the programs of the specified agency of such office in order to carry out the following:

''(1) Determine the extent to which the purposes of the programs are being carried out with respect to racial and ethnic minority groups;

''(2) Determine the extent to which members of such groups are represented among the Federal officers and employees who administer the programs; and

''(3) Make recommendations to the head of such agency on carrying out the programs with respect to such groups. In the case of programs that provide services, such recommendations shall include recommendations toward ensuring that—

''(A) the services are equitably delivered with respect to racial and ethnic minority groups; and

''(B) the programs provide the services in the language and cultural context that is most appropriate for the individuals for whom the services are intended.

''(e) FUNDING.—

''(1) ALLOCATIONS.—Of the amounts appropriated for a specified agency for a fiscal year, the Secretary must designate an appropriate amount of funds for the purpose of carrying out activities under this section through the minority health office of the agency. In reserving an amount under the preceding sentence for a minority health office for a fiscal year, the Secretary shall reduce, by substantially the same percentage, the amount that otherwise would be available for each of the programs of the designated agency involved.

''(2) AVAILABILITY OF FUNDS FOR STAFFING.—The purposes for which amounts made available under paragraph may be expended by a minority health office include the costs of employing staff for such office.''.

SEC. ___03. OFFICE OF MINORITY HEALTH AT THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish within the Centers for Medicare & Medicaid Services an Office of Minority Health (referred to in this section as the ''Office'').

(b) DUTIES.—The Office shall be responsible for the coordination and facilitation of activities of the Centers for Medicare & Medicaid Services to improve minority health and health care and to reduce racial and ethnic disparities in health and health care, which shall include—

(1) creating a strategic plan, which shall be made available for public review, to improve the health and health care of Medicare, Medicaid, and SCHIP beneficiaries;

(2) promoting agency-wide policies relating to health care delivery and financing that could have a beneficial impact on the health and health care of minority populations;

(3) assisting health plans, hospitals, and other health entities in providing culturally and linguistically appropriate health care services;

(4) increasing awareness and outreach activities for minority health care consumers and providers about the causes and remedies for health and health care disparities;

(5) developing grant programs and demonstration projects to identify, implement and evaluate innovative approaches to improving the health and health care of minority beneficiaries in the Medicare, Medicaid, and SCHIP programs;

(6) considering incentive programs relating to reimbursement that would reward health entities for providing quality health care for minority populations using established benchmarks for quality of care;

(7) collaborating with the compliance office to ensure compliance with the anti-discrimination provisions under title VI of the Civil Rights Act of 1964;

(8) identifying barriers to enrollment in public programs under the jurisdiction of the Centers for Medicare & Medicaid Services;

(9) monitoring and evaluating on a regular basis the success of minority health programs and initiatives;

(10) publishing an annual report about the activities of the Centers for Medicare & Medicaid Services relating to minority health improvement; and

(11) other activities determined appropriate by the Secretary of Health and Human Services.

(c) STAFF.—The staff at the Office shall include—

(1) one or more individuals with expertise in minority health and racial and ethnic health disparities; and

(2) one or more individuals with expertise in health care financing and delivery in underserved communities.

(d) COORDINATION.—In carrying out its duties under this section, the Office shall coordinate with—

(1) the Office of Minority Health in the Office of the Secretary of Health and Human Services;

(2) the National Institute for Minority Health and Health Disparities (as so redesignated by section __05) in the National Institutes of Health; and

(3) the Office of Minority Health in the Centers for Disease Control and Prevention.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums may be necessary for each of fiscal years 2011 through 2016.

SEC. ___04. OFFICE OF MINORITY AFFAIRS AT THE FOOD AND DRUG ADMINISTRATION.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1011. OFFICE OF MINORITY AFFAIRS.

''(a) IN GENERAL.—Not later than 60 days after the date of enactment of this section, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an Office of Minority Affairs (referred to in this section as the 'Office').

''(b) DUTIES.—The Office shall be responsible for the coordination and facilitation of activities of the Food and Drug Administration to improve minority health and health care and to reduce racial and ethnic disparities in health and health care, which shall include—

''(1) promoting policies in the development and review of medical products that reduce racial and ethnic disparities in health and health care;

''(2) encouraging appropriate data collection, analysis, and dissemination of racial and ethnic differences using, at a minimum, the categories described in the 1997 Office of Management and Budget standards, in response to different therapies in both adult and pediatric populations;

''(3) providing, in coordination with other appropriate government agencies, education, training, and support to increase participation of minority patients and physicians in clinical trials;

''(4) collecting and analyzing data using, at a minimum, the categories described in the 1997 Office of Management and Budget standards, on the number of participants from minority racial and ethnic backgrounds in clinical trials used to support medical product approvals;

''(5) the identification of methods to reduce language and literacy barriers; and

''(6) publishing an annual report about the activities of the Food and Drug Administration pertaining to minority health.

''(c) STAFF.—The staff of the Office shall include—

''(1) one or more individuals with expertise in the design and conduct of clinical trials of drugs, biological products, and medical devices; and

''(2) one or more individuals with expertise in therapeutic classes or disease states for which medical evidence suggests a difference based on race or ethnicity.

''(d) COORDINATION.—In carrying out its duties under this section, the Office shall coordinate with—

''(1) the Office of Minority Health in the Office of the Secretary of Health and Human Services;

''(2) the National Institute for Minority Health and Health Disparities in the National Institutes of Health; and

''(3) the Office of Minority Health in the Centers for Disease Control and Prevention.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2011 through 2016.''.

SEC. ___05. NATIONAL INSTITUTE FOR MINORITY HEALTH AND HEALTH DISPARITIES.

(a) REDESIGNATION.—

(1) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(A) in section 401(b)(24), by striking ''National Center on Minority Health and Health Disparities'' and inserting ''National Institute for Minority Health and Health Disparities''; and

(B) in subpart 6 of part E—

(i) in the subpart heading, by striking ''Center'' and inserting ''Institute'';

(ii) in the headings of sections 485E and 485H, by striking ''**CENTER**'' and inserting ''**INSTITUTE**''; and

(iii) by striking (other than in section 485E(i)(1)) the term ''Center'' each place it appears and inserting ''Institute''.

(2) REFERENCES.—Any reference in any law, map, regulation, document, paper, or other record of the United States to the National Center on Minority Health and Health Disparities shall be deemed to be a reference to the National Institute for Minority Health and Health Disparities.

(b) DUTIES; AUTHORITIES; FUNDING.—Section 485E of the Public Health Service Act (42 U.S.C. 287c–31) is amended—

(1) by amending subsection (e) to read as follows:

''(e) DUTIES OF THE DIRECTOR.—

''(1) INTERAGENCY COORDINATION OF MINORITY HEALTH AND HEALTH DISPARITY ACTIVITIES.—With respect to minority health and health disparities, the Director of the Institute shall plan, coordinate, and evaluate research and other activities conducted or supported by the institutes and centers of the National Institutes of Health. In carrying out the preceding sentence, the Director of the Institute shall evaluate the minority health and health disparity activities of each of such institutes and centers and shall provide for the periodic reevaluation of such activities. Such institutes and centers shall be responsible for providing information to the Institute, including data on clinical trials funded or conducted by these institutes and centers.

''(2) CONSULTATIONS.—The Director of the Institute shall carry out this subpart (including developing and revising the plan and budget required by subsection (f) in consultation with the heads of the institutes and centers of the National Institutes of Health, the advisory councils of such institutes and centers, and the advisory council established pursuant to subsection (j).

''(3) COORDINATION OF ACTIVITIES.—The Director of the Institute—

''(A) shall act as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority or other health disparities;

''(B) shall represent the health disparities research program of the National Institutes of Health, including the minority health and other health disparities research program, at all relevant executive branch task forces, committees, and planning activities; and

''(C) shall maintain communications with all relevant agencies of the Public Health Service, including the Indian Health Service, and various other departments and agencies of the Federal Government to ensure the timely transmission of information concerning advances in minority health disparities research and other health disparities research among these various agencies for dissemination to affected communities and health care providers.'';

(2) by amending subsection (f) to read as follows:

''(f) STRATEGIC PLAN.—

''(1) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of the Institute, in consultation with the Director of NIH, the Directors of the other institutes and centers of the National Institutes of Health, and the advisory council established pursuant to subsection (j), shall—

''(A) annually review and revise a strategic plan (referred to in this section as 'the plan') and budget for the conduct and support of all minority health disparity research and other health disparity research activities of the institutes and centers of the National Institutes of Health that include time-based targeted objectives with measurable outcomes and assure that the annual review and revision of the plan uses an established trans-National Institutes of Health process subject to timely review, approval, and dissemination;

''(B) ensure that the plan and budget establish priorities among the health disparities research activities that such agencies are authorized to carry out;

''(C) ensure that the plan and budget establish objectives regarding such activities, describe the means for achieving the objectives, and designate the date by which the objectives are expected to be achieved;

''(D) ensure that all amounts appropriated for such activities are expended in accordance with the plan and budget;

''(E) annually submit to Congress a report on the progress made with respect to the plan; and

''(F) create and implement a plan for the systemic review of research activities supported by the National Institutes of Health that are within the mission of both the Institute and other institutes and centers of the National Institutes of Health, including by establishing mechanisms for—

''(i) tracking minority health and health disparity research conducted within the institutes and centers assessing the appropriateness of this research with regard to the overall goals and objectives of the plan;

''(ii) the early identification of applications and proposals for grants, contracts, and cooperative agreements supporting extramural training, research, and development, that are submitted to the institutes and centers that are within the mission of the Institute;

''(iii) providing the Institute with the written descriptions and scientific peer review results of such applications and proposals;

''(iv) enabling the institutes and centers to consult with the Director of the Institute prior to final approval of such applications and proposals; and

''(v) reporting to the Director of the Institute all such applications and proposals that are approved for funding by the institutes and centers.

''(2) CERTAIN COMPONENTS OF PLAN AND BUDGET.—With respect to health disparities research activities of the agencies of the National Institutes of Health, the Director of the Institute shall ensure that the plan and budget under paragraph (1) provide for—

''(A) basic research and applied research, including research and development with respect to products;

''(B) research that is conducted by the agencies;

''(C) research that is supported by the agencies;

''(D) proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

''(E) behavioral research and social sciences research, which may include cultural and linguistic research in each of the agencies.

''(3) MINORITY HEALTH DISPARITIES RESEARCH.—The plan and budget under paragraph (1) shall include a separate statement of the plan and budget for minority health disparities research.'';

(3) by amending subsection (h) to read as follows:

''(h) RESEARCH ENDOWMENTS.—

''(1) IN GENERAL.—The Director of the Institute shall carry out a program to facilitate minority health and health disparities research and other health disparities research by providing research endowments at—

''(A) centers of excellence under section 736; and

''(B) centers of excellence under section 485F.

''(2) ELIGIBILITY.—The Director of the Institute shall provide for a research endowment under paragraph (1) only if the institution involved meets the following conditions:

''(A) The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national average of endowment funds at institutions that conduct similar biomedical research or training of health professionals.

''(B) The application of the institution under paragraph (1) regarding a research endowment has been recommended pursuant to technical and scientific peer review and has been approved by the advisory council established pursuant to subsection (j).

''(C) The institution at any time was deemed to be eligible to receive a grant under section 736 and at any time received a research endowment under paragraph (1).''; and

(4) by adding at the end the following:

''(k) FUNDING.—

''(1) FULL FUNDING BUDGET.—

''(A) IN GENERAL.—With respect to a fiscal year, the Director of the Institute shall prepare and submit directly to the President, for review and transmittal to Congress, a budget estimate for carrying out the plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, the directors of the other institutes and centers of the National Institutes of Health, and the advisory council established pursuant to subsection (j). The budget estimate shall include an estimate of the number and type of personnel needs for the Institute.

''(B) AMOUNTS NECESSARY.—The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the institutes and centers of the National Institutes of Health to carry out all minority health and health disparities activities determined by the Director of the Institute to be appropriate, without regard to the probability that such amounts will be appropriated.

''(2) ALTERNATE BUDGETS.—

''(A) IN GENERAL.—With respect to a fiscal year, the Director of the Institute shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the plan for such year.

''(B) DESCRIPTION.—With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the plan are as follows:

''(i) The budget estimate submitted under paragraph (1).

''(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

''(I) continuing the conduct by the institutes and centers of the National Institutes of Health of existing minority health and health disparity activities (if approved for continuation), and continuing the support of such activities by the institutes and centers in the case of projects or programs for which the institutes or centers have made a commitment of continued support; and

''(II) carrying out activities that are in addition to activities specified in subclause (I), only for which the Director determines there is the most substantial need.

''(iii) Such other budget estimates as the Director of the Institute determines to be appropriate.''.

SA 2879. Mr. CARDIN 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:

On page 974, between lines 9 and 10, insert the following:

SEC. 3316. HHS STUDIES AND REPORTS ON MEDICAID BENEFICIARIES AND DUAL ELIGIBLE INDIVIDUALS RECEIVING CARE IN HOME AND COMMUNITY-BASED SETTINGS.

(a) STUDY AND REPORT ON DUAL ELIGIBLES.—Not later than 180 days after the date of enactment of this Act, the Secretary shall conduct a study and submit to Congress a report that—

(1) analyzes whether dual eligible individuals (as described under subsection (c)(1)) have income levels, prescription drug requirements, and types and levels of disability that are comparable to dual eligible individuals for whom cost-sharing is eliminated under section 1860D–14(a)(1)(D)(i) of the Social Security Act (42 U.S.C. 1395w–114(a)(1)(D)(i)), as amended by section 3309;

(2) determines whether dual eligible individuals have adequate access to prescription medication; and

(3) provides recommendations to address any deficiencies in regard to access to prescription drugs by dual eligible individuals, including an analysis regarding elimination of cost sharing for all such individuals under the prescription drug program under part D of title XVIII of the Social Security Act.

(b) STUDY AND REPORT ON SSI LOW-INCOME MEDICAID BENEFICIARIES.—Not later than 12 months after the date of enactment of this Act, the Secretary shall conduct a study and submit to Congress a report that—

(1) determines whether benefits provided to SSI Medicaid beneficiaries (as described under subsection (c)(2)) under the supplemental security income program are sufficient to cover expenses for room and board that are incurred by such beneficiaries;

(2) analyzes the process used for determining the amount of benefits provided to SSI Medicaid beneficiaries under the supplemental security income program, including whether such amounts—

(A) adequately reflect expenses for room and board that are incurred by such beneficiaries; and

(B) are sufficient to meet the needs of beneficiaries who are disabled; and

(3) identifies methods to provide additional support for SSI Medicaid beneficiaries in covering their expenses for room and board, including benefits provided under Housing and Urban Development programs and other housing assistance programs, the supplemental nutrition assistance program established under the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.), and other methods as determined appropriate by the Secretary.

(c) DEFINITIONS.—In this section:

(1) DUAL ELIGIBLE INDIVIDUAL.—The term ''dual eligible individual'' means an individual who is—

(A) entitled to benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under part B of such title;

(B) entitled to medical assistance under a State plan under title XIX of such Act;

(C) not an institutionalized individual or couple (as defined in section 1902(q)(1)(B) of such Act (42 U.S.C. 1396a(q)(1)(B))); and

(D) receiving home and community-based services under a State Medicaid plan (or a waiver of such plan) under title XIX of the Social Security Act.

(2) SSI MEDICAID BENEFICIARY.—The term ''SSI Medicaid beneficiary'' means an individual who—

(A) is eligible for medical assistance under a State plan or waiver under title XIX of the Social Security Act and is enrolled in such plan or waiver;

(B) receives benefits under the supplemental security income program under title XVI of the Social Security Act (42 U.S.C. 1381 et seq.); and

(C) receives home and community-based services (including such services provided in an assisted living facility).

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

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on December 3, 2009, at 10 a.m.

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

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to meet during the session of the Senate on December 3, 2009.

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

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate to conduct a hearing on December 3, 2009, at 10 a.m., in Room SD–366 of the Dirksen Senate Office Building.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on December 3, 2009, at 9 a.m., to hold a hearing entitled ''Afghanistan: Assessing the Road Ahead.''