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