Act to ensure that low-income beneficiaries have improved access to health care under the Medicare and Medicaid programs.

S. 1203

At the request of Mr. BAUCUS, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 1203, a bill to amend the Internal Revenue Code of 1986 to extend the research credit through 2010 and to increase and make permanent the alternative simplified research credit, and for other purposes.

At the request of Mr. HATCH, the names of the Senator from Idaho (Mr. CRAPO) and the Senator from Kentucky (Mr. BUNNING) were added as cosponsors of S. 1203, supra.

AMENDMENT NO. 1230

At the request of Mr. JOHANNS, the name of the Senator from Tennessee (Mr. ALEXANDER) was added as a cosponsor of amendment No. 1230 intended to be proposed to H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

AMENDMENT NO. 1256

At the request of Mr. LIEBERMAN, the names of the Senator from Alaska (Ms. MURKOWSKI), the Senator from Maryland (Ms. MIKULSKI), the Senator from Hawaii (Mr. INOUYE), the Senator from Alaska (Mr. BEGICH), the Senator from Wisconsin (Mr. KOHL) and the Senator from Maryland (Mr. CARDIN) were added as cosponsors of amendment No. 1256 proposed to H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

AMENDMENT NO. 1270

At the request of Mr. CORKER, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of amendment No. 1270 intended to be proposed to H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. DURBIN:

S. 1212. A bill to amend the antitrust laws to ensure competitive market-based fees and terms for merchants' access to electronic payment systems; to the Committee on the Judiciary.

Mr. DURBIN. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1212

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Credit Card Fair Fee Act of 2009''.

SEC. 2. DEFINITIONS.

In this Act:

(1) ACCESS.—The term ''access''—

(A) when used as a verb means to use to conduct transaction authorization, clearance, and settlement involving the acceptance of credit cards or debit cards from consumers for payment for goods or services and the receipt of payment for such goods or services; and

(B) when used as a noun means the permission or authority to use to conduct transactions described in subparagraph (A).

(2) ACCESS AGREEMENT.—The term ''access agreement'' means an agreement between 1 or more merchants and 1 or more providers giving the merchant access to a covered electronic payment system, conditioned solely upon the merchant complying with the fees and terms specified in the agreement.

(3) ACQUIRER.—The term ''acquirer''—

(A) means a financial institution that provides services allowing merchants to access an electronic payment system to accept credit cards or debit cards for payment; and

(B) does not include an independent third party processor that may act as the agent of a financial institution described in subparagraph (A) in processing general-purpose credit card or debit card transactions.

(4) ADJUDICATION.—The term ''adjudication'' has the meaning given that term in section 551 of title 5, United States Code, and does not include mediation.

(5) ANTITRUST LAWS.—The term ''antitrust laws''—

(A) has the meaning given that term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)); and

(B) includes—

(i) section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent section 5 applies to unfair methods of competition; and

(ii) State antitrust laws.

(6) CHAIRMAN.—The term ''Chairman'' means the Chairman of the Federal Trade Commission.

(7) COVERED ELECTRONIC PAYMENT SYSTEM.—The term ''covered electronic payment system'' means an electronic payment system that routes information and data to facilitate transaction authorization, clearance, and settlement for not less than 10 percent of the combined dollar value of credit card or debit card payments processed in the United States in the most recent full calendar year.

(8) CREDIT CARD.—The term ''credit card'' means any general-purpose card or other credit device issued or approved for use by a financial institution for use in allowing the cardholder to obtain goods or services on credit on terms specified by that financial institution.

(9) DEBIT CARD.—The term ''debit card'' means any general-purpose card or other device issued or approved for use by a financial institution for use in debiting the account of a cardholder for the purpose of that cardholder obtaining goods or services, whether authorization is signature-based or PIN-based.

(10) ELECTRONIC PAYMENT SYSTEM.—The term ''electronic payment system'' means the proprietary services, infrastructure, and software that route information and data to facilitate transaction authorization, clearance, and settlement and that merchants are required to access in order to accept a specific brand of general-purpose credit cards or debit cards as payment for goods or services.

(11) ELECTRONIC PAYMENT SYSTEM JUDGES.—The term ''Electronic Payment System Judges'' means the Electronic Payment System Judges appointed under section 4(a).

(12) FEES.—The term ''fees'' means any monetary charges, rates, assessments, or other payments imposed by a provider upon a merchant for the merchant to access an electronic payment system.

(13) FINANCIAL INSTITUTION.—The term ''financial institution'' has the meaning given that term in section 603(t) of the Fair Credit Reporting Act (15 U.S.C. 1681a(t)).

(14) ISSUER.—The term ''issuer''—

(A) means a financial institution that issues credit cards or debit cards or approves the use of other devices for use in an electronic payment system; and

(B) does not include an independent third party processor that may act as the agent of a financial institution described in subparagraph (A) in processing general-purpose credit or debit card transactions.

(15) MARKET POWER.—The term ''market power'' means the ability to profitably raise prices above those that would be charged in a perfectly competitive market.

(16) MERCHANT.—The term ''merchant'' means any person who accepts or who seeks to accept credit cards or debit cards in payment for goods or services provided by the person.

(17) NEGOTIATING PARTY.—The term ''negotiating party'' means 1 or more providers of a covered electronic payment system or 1 or more merchants who have access to or who are seeking access to that covered electronic payment system, as the case may be, and who are in the process of negotiating or who have executed a voluntarily negotiated access agreement that is still in effect.

(18) NORMAL RATE OF RETURN.—The term ''normal rate of return'' means the average rate of return that a firm would receive in an industry when conditions of perfect competition prevail.

(19) PROCEEDING PARTY.—The term ''proceeding party'' means collectively all providers of a covered electronic payment system or collectively all merchants who have access to or who are seeking access to that covered electronic payment system, as the case may be, during the period in which the Electronic Payment System Judges are conducting a proceeding under this Act relating to that covered electronic payment system.

(20) PERSON.—The term ''person'' has the meaning given that term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).

(21) PROVIDER.—The term ''provider'' means any person who owns, operates, controls, serves as an issuer for, or serves as an acquirer for a covered electronic payment system.

(22) STATE.—The term ''State'' has the meaning given that term in section 4G(2) of the Clayton Act (15 U.S.C. 15g(2)).

(23) TERMS.—The term ''terms'' means any and all rules and conditions that are applicable to providers of an electronic payment system or to merchants, as the case may be, and that are required in order for merchants to access that electronic payment system.

(24) VOLUNTARILY NEGOTIATED ACCESS AGREEMENT.—The term ''voluntarily negotiated access agreement'' means an access agreement voluntarily negotiated between 1 or more providers of a covered electronic payment system and 1 or more merchants that sets the fees and terms under which the merchant can access that covered electronic payment system.

(25) WRITTEN DIRECT STATEMENTS.—The term ''written direct statements'' means witness statements, testimony, and exhibits to be presented in proceedings under this Act, and such other information that is necessary to establish fees and terms for access to covered electronic payment systems as set forth in regulations issued by the Electronic Payment System Judges under section 5(b)(4).

SEC. 3. ACCESS TO COVERED ELECTRONIC PAYMENT SYSTEMS; LIMITED ANTITRUST IMMUNITY FOR THE NEGOTIATION AND DETERMINATION OF FEES AND TERMS; STANDARDS FOR ESTABLISHMENT OF FEES AND TERMS.

(a) ACCESS TO COVERED ELECTRONIC PAYMENT SYSTEMS.—Access by a merchant to any covered electronic payment system and the fees and terms of such access shall be subject to this Act.

(b) AUTHORITY AND LIMITED ANTITRUST IMMUNITY FOR NEGOTIATIONS OF FEES AND TERMS AND PARTICIPATION IN PROCEEDINGS.—

(1) IN GENERAL.—Notwithstanding any provision of the antitrust laws—

(A) in negotiating fees and terms and participating in any proceedings under subsection (c), any providers of a covered electronic payment system and any merchants who have access to or who are seeking access to that covered electronic payment system may jointly negotiate and agree upon the fees and terms for access to the covered electronic payment system, including through the use of common agents that represent the providers of the covered electronic payment system or the merchants on a nonexclusive basis; and

(B) any providers of a single covered electronic payment system also may jointly determine the proportionate division among such providers of paid fees.

(2) LIMITATIONS.—The immunity from the antitrust laws conferred under this subsection shall not apply to a provider of a covered electronic payment system or to a merchant during any period in which such provider, or such merchant, is engaged in—

(A) any unlawful boycott;

(B) any allocation with a competitor of a geographical area;

(C) any unlawful tying arrangement; or

(D) any exchange of information with, or agreement with, a competitor that is not reasonably required to carry out the negotiations and proceedings described in subsection (c).

(c) ESTABLISHMENT OF FEES AND TERMS.—

(1) VOLUNTARILY NEGOTIATED ACCESS AGREEMENTS.—

(A) AGREEMENTS BETWEEN NEGOTIATING PARTIES.—A voluntarily negotiated access agreement may be executed at any time between 1 or more providers of a covered electronic payment system and 1 or more merchants. With respect to the negotiating parties, such executed voluntarily negotiated access agreement shall supersede any fees or terms established by the Electronic Payment System Judges under paragraph (3) relating to that covered electronic payment system.

(B) FILING AGREEMENTS WITH THE ELECTRONIC PAYMENT SYSTEM JUDGES.—The negotiating parties shall jointly file with the Electronic Payment System Judges—

(i) any voluntarily negotiated access agreement that affects any market in the United States or elsewhere;

(ii) any documentation relating to a voluntarily negotiated access agreement evidencing any consideration being given or any marketing or promotional agreement between the negotiating parties; and

(iii) any amendment to that voluntarily negotiated access agreement or documentation.

(C) TIMING AND AVAILABILITY OF FILINGS.—The negotiating parties to any voluntarily negotiated access agreement executed after the date of enactment of this Act shall jointly file the voluntarily negotiated access agreement, and any documentation or amendment described in subparagraph (B), with the Electronic Payment System Judges not later than 30 days after the date of execution of the voluntarily negotiated access agreement or amendment or the date of the creation of the documentation, as the case may be. The Electronic Payment System Judges shall make publicly available any voluntarily negotiated access agreement, amendment, or accompanying documentation filed under this paragraph.

(2) INITIATION OF PROCEEDINGS.—The proceedings under this subsection to establish fees and terms for access to a covered electronic payment system shall be initiated in accordance with section 6.

(3) PROCEEDINGS.—

(A) IN GENERAL.—The Electronic Payment System Judges shall conduct proceedings as specified under this Act to establish fees and terms for access to a covered electronic payment system. Except as specifically provided in a voluntarily negotiated access agreement, a provider of a covered electronic payment system may not directly or indirectly charge fees or set terms for access to a covered electronic payment system that are not in accordance with the fees and terms established by the Electronic Payment System Judges pursuant to proceedings under this Act.

(B) PERIOD OF APPLICABILITY.—Except as provided in section 6, the fees and terms established under this paragraph with respect to a covered electronic payment system shall apply during the 3-year period beginning on January 1 of the second year following the year in which the proceedings to establish such fees and terms are commenced.

(C) STANDARD FOR ESTABLISHMENT OF FEES AND TERMS BY THE ELECTRONIC PAYMENT SYSTEM JUDGES.—

(i) IN GENERAL.—In establishing fees and terms for access to a covered electronic payment system under subparagraph (A), the Electronic Payment System Judges—

(I) shall be limited to selecting, without modification, 1 of the 2 final offers of fees and terms filed by the proceeding parties pursuant to section 5(c)(2)(A); and

(II) shall select the final offer of fees and terms that most closely represent the fees and terms that would be negotiated in a hypothetical perfectly competitive marketplace for access to an electronic payment system between a willing buyer with no market power and a willing seller with no market power.

(ii) STANDARDS.—In determining which final offer of fees and terms to select, the Electronic Payment System Judges—

(I) shall consider the costs of transaction authorization, clearance, and settlement that are necessary to operate and to access an electronic payment system;

(II) shall consider a normal rate of return in a hypothetical perfectly competitive marketplace;

(III) shall avoid selecting a final offer of fees and terms that would have anticompetitive effects within the issuer market, the acquirer market, or the merchant market;

(IV) may select a final offer that is a schedule of fees and terms that varies based upon cost-based differences in types of credit card and debit card transactions (which may include whether a transaction is of a signature-based, PIN-based, or card-not-present type);

(V) may select a final offer that is a schedule of fees and terms that provides alternative fees and terms for those acquirers or issuers that are regulated by the National Credit Union Administration or that, together with affiliates of the acquirer or issuer, have assets in a total amount of less than $1,000,000,000; and

(VI) may not select a final offer that is a schedule of fees and terms that varies based on type of merchant or volume of transactions (either in number or dollar value).

(D) USE OF EXISTING FEES AND TERMS AS EVIDENCE.—In establishing fees and terms for access to a covered electronic payment system under this paragraph, the Electronic Payment System Judges—

(i) shall decide the weight to be given to any evidence submitted by a proceeding party regarding the fees and terms for access to comparable electronic payment systems, including fees and terms in voluntarily negotiated access agreements filed under paragraph (1); and

(ii) shall give significant weight to fees in a voluntarily negotiated access agreement that are substantially below the fees reflective of the market power of the covered electronic payment systems that existed before the date of enactment of this Act.

SEC. 4. ELECTRONIC PAYMENT SYSTEM JUDGES.

(a) APPOINTMENT.—The Attorney General and the Chairman shall jointly appoint 3 full-time Electronic Payment System Judges, and shall appoint 1 of the 3 Electronic Payment System Judges as the Chief Electronic Payment System Judge.

(b) DUTIES.—The Electronic Payment System Judges shall establish fees and terms for access to covered electronic payment systems in accordance with this Act.

(c) RULINGS.—The Electronic Payment System Judges may make any necessary procedural or evidentiary ruling in a proceeding under this Act and may, before commencing a proceeding under this Act, make any procedural ruling that will apply to a proceeding under this Act.

(d) ADMINISTRATIVE SUPPORT.—The Attorney General and Chairman shall provide the Electronic Payment System Judges with the necessary administrative services related to proceedings under this Act.

(e) LOCATION.—The offices of the Electronic Payment System Judges and staff shall be located in the offices of the Department of Justice or the Federal Trade Commission.

(f) QUALIFICATIONS OF ELECTRONIC PAYMENT SYSTEM JUDGES.—Each Electronic Payment System Judge shall be an attorney who has at least 7 years of legal experience. The Chief Electronic Payment System Judge shall have at least 5 years of experience in adjudications, arbitrations, or court trials. At least 1 Electronic Payment System Judge who is not the Chief Electronic Payment System Judge shall have significant knowledge of electronic payment systems. At least one Electronic Payment System Judge shall have significant knowledge of economics. An individual may serve as an Electronic Payment System Judge only if the individual is free of any financial conflict of interest under the standards established under subsection (m).

(g) STAFF.—The Chief Electronic Payment System Judge shall hire, at minimum, 3 full-time staff members to assist the Electronic Payment System Judges in performing the duties of the Electronic Payment System Judges under this Act.

(h) TERMS.—

(1) INITIAL APPOINTMENTS.—For the first appointments of Electronic Payment System Judges after the date of enactment of this Act—

(A) the Chief Electronic Payment System Judge shall be appointed for a term of 6 years;

(B) 1 Electronic Payment System Judge who is not the Chief Electronic Payment System Judge shall be appointed for a term of 4 years; and

(C) 1 Electronic Payment System Judge who is not the Chief Electronic Payment System Judge shall be appointed for a term of 2 years.

(2) SUBSEQUENT APPOINTMENT.—After the appointments under paragraph (1), an Electronic Payment System Judge shall be appointed for a term of 6 years.

(3) REAPPOINTMENT.—An individual serving as an Electronic Payment System Judge may be reappointed to subsequent terms.

(4) START AND END OF TERMS.—The term of an Electronic Payment System Judge shall begin on the date on which the term of the predecessor of that Electronic Payment System Judge ends. If a successor Electronic Payment System Judge has not been appointed as of the date on which the term of office of an Electronic Payment System Judge ends, the individual serving that term may continue to serve as an interim Electronic Payment System Judge until a successor is appointed.

(i) VACANCIES OR INCAPACITY.—

(1) VACANCIES.—The Attorney General and the Chairman shall act expeditiously to fill any vacancy in the position of Electronic Payment System Judge, and may appoint an interim Electronic Payment System Judge to serve until an Electronic Payment System Judge is appointed to fill the vacancy under this section. An Electronic Payment System Judge appointed to fill a vacancy occurring before the expiration of the term for which the predecessor of that individual was appointed shall be appointed for the remainder of that term.

(2) INCAPACITY.—If an Electronic Payment System Judge is temporarily unable to perform the duties of an Electronic Payment System Judge, the Attorney General and Chairman may appoint an interim Electronic Payment System Judge to perform such duties during the period of such incapacity.

(j) COMPENSATION.—

(1) JUDGES.—The Chief Electronic Payment System Judge shall receive compensation at the rate of basic pay payable for level AL–1 for administrative law judges under section 5372(b) of title 5, United States Code, and each Electronic Payment System Judge who is not the Chief Electronic Payment System Judge shall receive compensation at the rate of basic pay payable for level AL–2 for administrative law judges under such section. The compensation of the Electronic Payment System Judges shall not be subject to any regulations adopted by the Office of Personnel Management under its authority under section 5376(b)(1) of title 5, United States Code.

(2) STAFF MEMBERS.—Of the 3 staff members appointed under subsection (g)—

(A) the rate of pay of 1 staff member shall be not more than the basic rate of pay payable for level 10 of GS–15 of the General Schedule;

(B) the rate of pay of 1 staff member shall be not less than the basic rate of pay payable for GS–13 of the General Schedule and not more than the basic rate of pay payable for level 10 of GS–14 of such Schedule; and

(C) the rate of pay of 1 staff member shall be not less than the basic rate of pay payable for GS–8 of the General Schedule and not more than the basic rate of pay payable for level 10 of GS–11 of such Schedule.

(3) LOCALITY PAY.—All rates of pay established under this subsection shall include locality pay.

(k) INDEPENDENCE OF ELECTRONIC PAYMENT SYSTEM JUDGES.—

(1) IN MAKING DETERMINATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Electronic Payment System Judges—

(i) shall have full independence in establishing fees and terms for access to covered electronic payment systems and in issuing any other ruling under this Act; and

(ii) may consult with the Attorney General and the Chairman on any matter other than a question of fact.

(B) CONSULTATION.—The Electronic Payment System Judges shall consult with the Attorney General and the Chairman regarding any determination or ruling that would require that any act be performed by the Attorney General or the Chairman, and any such determination or ruling shall not be binding upon the Attorney General or the Chairman.

(2) PERFORMANCE APPRAISALS.—

(A) IN GENERAL.—Notwithstanding any other provision of law or any regulation of the Department of Justice or Federal Trade Commission, and subject to subparagraph (B), the Electronic Payment System Judges shall not receive performance appraisals.

(B) RELATING TO SANCTION OR REMOVAL.—To the extent that the Attorney General and the Chairman adopt regulations under subsection (m) relating to the sanction or removal of an Electronic Payment System Judge and such regulations require documentation to establish the cause of such sanction or removal, the Electronic Payment System Judge may receive an appraisal related specifically to the cause of the sanction or removal.

(l) INCONSISTENT DUTIES BARRED.—No Electronic Payment System Judge may undertake duties that conflict with the duties and responsibilities of an Electronic Payment System Judge under this Act.

(m) STANDARDS OF CONDUCT.—The Attorney General and the Chairman shall adopt regulations regarding the standards of conduct, including financial conflict of interest and restrictions against ex parte communications, which shall govern the Electronic Payment System Judges and the proceedings under this Act.

(n) REMOVAL OR SANCTION.—The Attorney General and the Chairman acting jointly may sanction or remove an Electronic Payment System Judge for violation of the standards of conduct adopted under subsection (m), misconduct, neglect of duty, or any disqualifying physical or mental disability. Any such sanction or removal may be made only after notice and opportunity for a hearing. The Attorney General and the Chairman may suspend an Electronic Payment System Judge during the pendency of such a hearing. The Attorney General and the Chairman shall appoint an interim Electronic Payment System Judge during the period of any suspension under this subsection.

SEC. 5. PROCEEDINGS OF ELECTRONIC PAYMENT SYSTEM JUDGES.

(a) PROCEEDINGS.—

(1) IN GENERAL.—The Electronic Payment System Judges shall act in accordance with regulations issued by the Electronic Payment System Judges, the Attorney General, and the Chairman, and on the basis of a written record, prior determinations and interpretations of the Electronic Payment System Judges under this Act, and decisions of the court of appeals of the United States.

(2) JUDGES ACTING AS PANEL AND INDIVIDUALLY.—The Electronic Payment System Judges shall preside over hearings in proceedings under this Act en banc. The Chief Electronic Payment System Judge may designate an Electronic Payment System Judge to preside individually over such collateral and administrative proceedings as the Chief Judge considers appropriate.

(b) PROCEDURES.—

(1) COMMENCEMENT.—The Electronic Payment System Judges shall cause to be published in the Federal Register a notice of commencement of proceedings under section 3(c) to establish fees and terms for access to a covered electronic payment system.

(2) MANDATORY NEGOTIATION PERIOD.—

(A) IN GENERAL.—Promptly after the commencement of a proceeding under section 3(c) to establish fees and terms for access to a covered electronic payment system, the Electronic Payment System Judges shall initiate a period for negotiations for the purpose of achieving a voluntarily negotiated access agreement. Nothing in this paragraph shall preclude the proceeding parties or any members thereof from conducting negotiations before or after the mandatory negotiation period for the purpose of achieving a voluntarily negotiated access agreement.

(B) LENGTH.—The period for negotiations initiated under subparagraph (A) shall be 3 months.

(C) DETERMINATION OF NEED FOR FURTHER PROCEEDINGS.—At the close of the period for negotiations initiated under subparagraph (A), the Electronic Payment System Judges shall determine if further proceedings under this Act are necessary.

(3) PROCEEDING PARTIES IN FURTHER PROCEEDINGS.—

(A) IN GENERAL.—In any further proceeding ordered by the Electronic Payment System Judges under paragraph (2)(C), there shall be only 2 proceeding parties, 1 consisting of all providers of the covered electronic payment system and the other consisting of all merchants that have access to or seek access to the covered electronic payment system. Each proceeding party shall bear its own costs. A provider of a covered electronic payment system or a merchant that has access to or seeks access to the covered electronic payment system may choose not to participate in the proceeding as a member of a proceeding party, but unless such provider or merchant executes a voluntarily negotiated access agreement, such provider or merchant shall be bound by the determination of the Electronic Payment System Judges with regard to the fees and terms for access to the covered electronic payment system.

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph may be construed to prohibit the proceeding parties or any members thereof in a proceeding under subparagraph (A) from negotiating and entering into a voluntarily negotiated access agreement at any other time.

(4) REGULATIONS.—

(A) AUTHORIZATION.—

(i) IN GENERAL.—The Electronic Payment System Judges may issue regulations to carry out the duties of the Electronic Payment System Judges under this Act. All regulations issued by the Electronic Payment System Judges are subject to the approval of the Attorney General and the Chairman. Not later than 120 days after the date on which all Electronic Payment System Judges are appointed under section 4(h)(1), the Electronic Payment System Judges shall issue regulations to govern proceedings under this subsection. In setting these regulations, the Electronic Payment System Judges shall consider the regulations issued by the Copyright Royalty Judges under section 803(b)(6) of title 17, United States Code.

(ii) SCOPE.—The regulations issued under clause (i) shall include regulations regarding

the procedures described in subparagraph (B).

(B) PROCEDURES.—

(i) WRITTEN DIRECT STATEMENTS.—The written direct statements of the proceeding parties shall be filed by a date specified by the Electronic Payment System Judges, which may be not earlier than 4 months, and not later than 5 months, after the end of the voluntary negotiation period under paragraph (2). Notwithstanding the preceding sentence, the Electronic Payment System Judges may allow a proceeding party to file an amended written direct statement based on new information received during the discovery process, not later than 15 days after the end of the discovery period specified in clause (ii).

(ii) DISCOVERY SCHEDULE.—Following the submission to the Electronic Payment System Judges of written direct statements by the proceeding parties, the Electronic Payment System Judges shall meet with the proceeding parties to set a schedule for conducting and completing discovery. Such schedule shall be determined by the Electronic Payment System Judges. Discovery in such proceedings shall be permitted for a period of not longer than 60 days, except for discovery ordered by the Electronic Payment System Judges in connection with the resolution of motions, orders, and disputes pending at the end of such period.

(iii) INITIAL DISCLOSURES.—

(I) IN GENERAL.—In a proceeding under this Act to determine fees and terms for access to a covered electronic payment system, certain persons shall make initial disclosures not later than 30 days after the date of commencement of the proceeding, in accordance with this clause.

(II) ISSUERS, ACQUIRERS, AND OWNERS.—Any person who is 1 of the 10 largest issuers for a covered electronic payment system in terms of number of cards issued, any person who is 1 of the 10 largest acquirers for a covered electronic payment system based on dollar amount of transactions made by merchants they serve, and any person who owns or controls the relevant covered electronic payment system and establishes the terms and conditions through which issuers and acquirers participate in the covered electronic payment system, shall produce to the Electronic Payment System Judges and to both proceedings parties—

(aa) an itemized list of the costs necessary to operate the covered electronic payment system that were incurred by the person during the most recent full calendar year before the initiation of the proceeding; and

(bb) any access agreement between that person and 1 or more merchants with regard to that covered electronic payment system.

(III) MERCHANTS.—Any person who is 1 of the 10 largest merchants using the relevant covered electronic payment system, determined based on dollar amount of transactions made with the covered electronic payment system, shall produce to the Electronic Payment System Judges and to both proceeding parties—

(aa) an itemized list of the costs necessary to access the electronic payment system during the most recent full calendar year prior to the initiation of the proceeding; and

(bb) any access agreement between that person and 1 or more providers with regard to that covered electronic payment system.

(IV) DISAGREEMENT.—Any disagreement regarding whether a person is required to make an initial disclosure under this clause, or the contents of such a disclosure, shall be resolved by the Electronic Payment System Judges.

(iv) DEPOSITIONS.—

(I) IN GENERAL.—In a proceeding under this Act to determine fees and terms for access to a covered electronic payment system, each proceeding party shall be permitted to take depositions of every witness identified by the other proceeding party. Except as provided in subclause (III), each proceeding party also shall be permitted to take 5 additional depositions in the entire proceeding.

(II) ORGANIZATIONAL ENTITIES.—A deposition notice or subpoena may name as the deponent a person who is an individual or a person who is not an individual. Such deposition notice or subpoena shall describe with reasonable particularity the matters on which examination is requested. If the deposition notice or subpoena names a person who is not an individual, the deponent person so named shall designate 1 or more officers, directors, or managing agents, or other individual persons who consent to testify on behalf of the deponent person, and may set forth, for each individual person designated, the matters on which the individual person will testify. A subpoena shall advise a nonparty deponent person of the duty of the deponent person to make such a designation. An individual person designated under this subclause shall testify as to matters known or reasonably available to the deponent person.

(III) ADDITIONAL DEPOSITIONS.—The Electronic Payment System Judges may increase the permitted number of depositions for good cause in exceptional circumstances, and shall resolve any disputes among persons within either proceeding party regarding the allocation of the depositions permitted under this clause.

(v) WRITTEN DISCOVERY.—In a proceeding under this Act to determine fees and terms for access to a covered electronic payment system, each proceeding party shall be permitted to serve written discovery requests on 10 persons. These written discovery requests may include requests for production or inspection, a total of no more than 10 requests for admission in the entire proceeding, and a total of no more than 25 interrogatories in the entire proceeding. The Electronic Payment System Judges may increase the permitted number of requests for admission or interrogatories for good cause in exceptional circumstances, and shall resolve any disputes among persons within either proceeding party regarding the allocation of the requests for admission or interrogatories permitted under this clause.

(vi) SUBPOENAS.—Upon the request of a party to a proceeding to determine fees and terms for access to a covered electronic payment system, the Electronic Payment System Judges may issue a subpoena commanding a person to appear and give testimony, or to produce and permit inspection of documents or tangible things, if the resolution of the proceeding by the Electronic Payment System Judges may be substantially impaired by the absence of such testimony or production of documents or tangible things. A subpoena under this clause shall specify with reasonable particularity the materials to be produced or the scope and nature of the required testimony. Nothing in this clause shall preclude the Electronic Payment System Judges from requesting the production by a person of information or materials relevant to the resolution by the Electronic Payment System Judges of a material issue of fact.

(vii) OBJECTIONS TO DISCOVERY REQUESTS.—

(I) IN GENERAL.—Any objection to a request or subpoena under clause (v) or (vi) shall be resolved by a motion or request to compel production made to the Electronic Payment System Judges in accordance with regulations adopted by the Electronic Payment System Judges. Each motion or request to compel discovery shall be determined by the Electronic Payment System Judges, or by an Electronic Payment System Judge when permitted under subsection (a)(2). Upon such motion or request to compel discovery, the Electronic Payment System Judges may order discovery under regulations established under this paragraph.

(II) CONSIDERATIONS.—In determining whether discovery will be granted under this clause, the Electronic Payment System Judges may consider—

(aa) whether the burden or expense of producing the requested information or materials outweighs the likely benefit, taking into account the needs and resources of the proceeding parties, the importance of the issues at stake, and the probative value of the requested information or materials in resolving such issues;

(bb) whether the requested information or materials would be unreasonably cumulative or duplicative, or are obtainable from another source that is more convenient, less burdensome, or less expensive; and

(cc) whether the proceeding party seeking discovery has had ample opportunity by discovery in the proceeding or by other means to obtain the information sought.

(viii) VOLUNTARILY NEGOTIATED ACCESS AGREEMENTS.—In proceedings to determine fees and terms for access to a covered electronic payment system, the Electronic Payment System Judges shall make available to the proceeding parties all documents filed under section 3(c)(1).

(ix) SETTLEMENT CONFERENCE.—The Electronic Payment System Judges shall order a settlement conference between the proceeding parties to facilitate the presentation of offers of settlement between the parties. The settlement conference shall be held during the 21-day period beginning on the date on which the discovery period ends and shall take place outside the presence of the Electronic Payment System Judges.

(x) DIRECT AND REBUTTAL HEARINGS.—At the conclusion of the 21-day period described in clause (ix), the Electronic Payment System Judges shall determine if further proceedings under this Act are necessary. If the Electronic Payment System Judges determine further proceedings under this Act are necessary, the Electronic Payment System Judges shall schedule a direct hearing of not more than 30 court days and a rebuttal hearing of not more than 20 court days during which both proceeding parties will be allowed to offer witness testimony and documents.

(xi) SPONSORING WITNESSES.—No evidence, including exhibits, may be submitted in the written direct statement or written rebuttal statement of a proceeding party without a sponsoring witness, except for—

(I) requests for admission that have been admitted by the receiving proceeding party;

(II) evidence of which the Electronic Payment System Judges have taken official notice;

(III) incorporation by reference of past records; or

(IV) good cause shown.

(xii) HEARSAY.—Hearsay may be admitted in proceedings under this Act to the extent determined relevant and reliable by the Electronic Payment System Judges.

(xiii) APPLICABILITY OF THE FEDERAL RULES OF EVIDENCE.—To the extent not inconsistent with this subparagraph, the Federal Rules of Evidence shall apply to proceedings under this Act.

(5) PENALTIES FOR FAILURE TO COMPLY WITH A DISCOVERY REQUEST.—

(A) FAILURE TO COMPLY.—A person has failed to comply with a discovery request if the person, or an employee or agent of the person, fails, without substantial justification, to—

(i) make initial disclosures required under paragraph (4)(B)(iii);

(ii) be sworn or answer a question as a deponent after being directed to do so by the Electronic Payment System Judges under clause (iv) or (vi) of paragraph (4)(B);

(iii) answer an interrogatory submitted under paragraph (4)(B)(v);

(iv) produce nonprivileged documents requested under clause (v) or (vi) of paragraph (4)(B); or

(v) admit the genuineness of any document or the truth of any matter as requested under paragraph (4)(B)(v), and the person requesting the admissions thereafter proves the genuineness of the document or the truth of the matter.

(B) FALSE OR MISLEADING RESPONSES.—For purposes of this Act, any disclosure, answer, or response that is false or substantially misleading, evasive, or incomplete shall be deemed a failure to comply with a discovery request.

(C) NEGATIVE INFERENCE IN CURRENT PROCEEDING.—If any person fails to comply with a discovery request, the Electronic Payment System Judges may issue an order that the matters regarding which the order was made or any other designated facts shall be taken to be established for the purposes of the current proceeding in accordance with the claim of the proceeding party seeking discovery and obtaining the order.

(D) CIVIL PENALTY.—

(i) GENERALLY.—Any person who fails to comply with a discovery request under this Act shall be subject to a civil penalty, which shall be assessed by the Electronic Payment System Judges, of not more than $25,000 for each violation. Each day of violation shall constitute a separate violation.

(ii) NOTICE AND HEARINGS.—No civil penalty may be assessed under this subparagraph except under an order of the Electronic Payment System Judges and unless the person accused of the violation was given prior notice and opportunity to request and participate in a hearing before the Electronic Payment System Judges with respect to the violation.

(iii) DETERMINING AMOUNT.—In determining the amount of any penalty assessed under this subparagraph, the Electronic Payment System Judges shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, any prior history of such violations, the degree of culpability, economic benefit or savings (if any) resulting from the violation, and such other matters as justice may require.

(iv) REVIEW.—Any person who requested a hearing with respect to a civil penalty under this subparagraph and who is aggrieved by an order assessing the civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit. Such a petition may be filed not later than 30 days after the date on which the order making such assessment was issued. The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction to enter a judgment affirming, modifying, or setting aside in whole or in part, an order of the Electronic Payment System Judges under this subparagraph, or the court may remand the proceeding to the Electronic Payment System Judges for such further action as the court may direct. The Attorney General shall represent the Electronic Payment System Judges before the court.

(v) ENFORCEMENT.—If any person fails to pay an assessment of a civil penalty after the civil penalty has become a final and unappealable order or after the appropriate court has entered final judgment, the Electronic Payment System Judges shall request the Attorney General to institute a civil action in an appropriate district court of the United States to collect the penalty, and such court shall have jurisdiction to hear and decide any such action. In hearing such action, the court shall have authority to review the violation and the assessment of the civil penalty on the record.

(c) DETERMINATION OF ELECTRONIC PAYMENT SYSTEM JUDGES.—

(1) TIMING.—The Electronic Payment System Judges shall issue a determination in a proceeding not later than the earlier of—

(A) 11 months after the end of the 21-day settlement conference period under subsection (b)(4)(B)(ix); or

(B) 15 days before the date on which the fees and terms in effect for the relevant covered electronic payment system expire.

(2) DETERMINATION.—

(A) FILING OF FINAL OFFER.—Before the commencement of a direct hearing in a proceeding under subsection (b)(4)(B)(x), each proceeding party shall file with the Electronic Payment System Judges and with the other proceeding party a final offer of fees and terms for access to the covered electronic payment system. A proceeding party may not amend a final offer submitted under this subparagraph, except with the express consent of the Electronic Payment System Judges and the other proceeding party.

(B) SELECTION BETWEEN FINAL OFFERS.—After the conclusion of the direct hearing and rebuttal hearing, the Electronic Payment System Judges shall make their determination by selecting 1 of the 2 final offers filed by the proceeding parties. The Electronic Payment System Judges shall make their selection in accordance with the standards described in section 3(c)(3)(C).

(C) VOTING AND DISSENTING OPINIONS.—A final determination of the Electronic Payment System Judges in a proceeding under this Act shall be made by majority vote. An Electronic Payment System Judge dissenting from the majority on any determination under this Act may issue a dissenting opinion, which shall be included with the determination.

(3) REHEARINGS.—

(A) IN GENERAL.—The Electronic Payment System Judges may, in exceptional cases, upon motion of a proceeding party, order a rehearing, after the determination in the proceeding is issued under paragraph (2), on such matters as the Electronic Payment System Judges determine to be appropriate.

(B) TIMING FOR FILING MOTION.—Any motion for a rehearing under subparagraph (A) shall be filed not later than 15 days after the date on which the Electronic Payment System Judges deliver to the parties in the proceeding their initial determination concerning fees and terms.

(C) PARTICIPATION BY OPPOSING PARTY NOT REQUIRED.—In any case in which a rehearing is ordered under this paragraph, any opposing proceeding party shall not be required to participate in the rehearing, except that nonparticipation may give rise to the limitations with respect to judicial review provided for in subsection (d)(1).

(D) NO NEGATIVE INFERENCE.—The Electronic Payment System Judges may not draw a negative inference from lack of participation in a rehearing.

(E) CONTINUITY OF FEES AND TERMS.—

(i) IN GENERAL.—If the decision of the Electronic Payment System Judges on any motion for a rehearing is not rendered before the expiration of the fees and terms in effect for the relevant covered electronic payment system, in the case of a proceeding to determine successor fees and terms for fees and terms that expire on a specified date, the initial determination of the Electronic Payment System Judges that is the subject of the rehearing motion shall be effective as of the day following the date on which the fees and terms that were previously in effect expire.

(ii) FEE PAYMENTS.—The pendency of a motion for a rehearing under this paragraph shall not relieve a person obligated to make fee payments for access to a covered electronic payment system who would be affected by the determination on that motion from paying the fees required and complying with the terms under the relevant determination.

(iii) OVERPAYMENTS AND UNDERPAYMENTS.—Notwithstanding clause (ii), if fees described in clause (ii) are paid—

(I) the recipient of such fees shall, not later than 60 days after the date on which the motion for rehearing is resolved or, if the motion is granted, 60 days after the date on which the rehearing is concluded, return any excess fees described in clause (ii), to the extent necessary to comply with the final determination by the Electronic Payment System Judges of fees and terms for access to the covered electronic payment system; and

(II) a person obligated to make fee payments shall, not later than 60 days after the date on which the motion for rehearing is resolved or, if the motion is granted, 60 days after the date on which the rehearing is concluded, pay the recipient the amount of any underpayment of fees described in clause (ii), to the extent necessary to comply with the final determination by the Electronic Payment System Judges of fees and terms for access to the covered electronic payment system.

(4) CONTENTS OF DETERMINATION.—A determination of the Electronic Payment System Judges shall establish the fees and terms for access to the relevant covered electronic payment system, shall be supported by the written record, and shall set forth the findings of fact relied on by the Electronic Payment System Judges. The Electronic Payment System Judges shall make publicly available in their entirety all determinations issued under this paragraph.

(5) CONTINUING JURISDICTION.—The Electronic Payment System Judges may, with the approval of the Attorney General and the Chairman, issue an amendment to a written determination to correct any technical or clerical errors in the determination in response to unforeseen circumstances that would frustrate the proper implementation of such determination. Such amendment shall be set forth in a written addendum to the determination that shall be distributed to the proceeding parties and shall be published in the Federal Register.

(6) PROTECTIVE ORDER.—The Electronic Payment System Judges may issue such orders as may be appropriate to protect confidential information, including orders excluding confidential information from the record of the determination that is published or made available to the public, except that any fees and terms of an access agreement, including voluntarily negotiated access agreements filed under section 3(c)(1), may not be excluded from publication.

(7) PUBLICATION OF DETERMINATION.—Not later than 60 days after the date on which the Electronic Payment System Judges issue a determination under this subsection, the Attorney General and the Chairman shall cause the determination, and any corrections thereto, to be published in the Federal Register. The Electronic Payment System Judges also shall publicize the determination and any corrections in such other manner as the Attorney General and the Chairman consider appropriate, including publication on the Internet. The Electronic Payment System Judges also shall make the determination, corrections, and the accompanying record available for public inspection and copying.

(8) LATE PAYMENT.—A determination of Electronic Payment System Judges—

(A) may include terms with respect to late payment; and

(B) may not include any provision in such terms described in subparagraph (A) that prevents a provider of a covered electronic payment system from asserting other rights or remedies provided under this Act.

(d) JUDICIAL REVIEW.—

(1) APPEAL.—Any determination of the Electronic Payment System Judges under subsection (c) may, not later than 30 days after the date of publication of the determination in the Federal Register, be appealed, to the United States Court of Appeals for the District of Columbia Circuit, by any aggrieved member of a proceeding party under this Act who would be bound by the determination. Any proceeding party that did not participate in a rehearing may not raise any issue that was the subject of that rehearing at any stage of judicial review of the hearing determination. If no appeal is brought within the 30-day period under this paragraph, the determination of the Electronic Payment System Judges shall be final, and shall take effect as described in paragraph (2).

(2) EFFECT OF FEES AND TERMS.—

(A) FEE PAYMENTS.—The pendency of an appeal under this subsection shall not relieve a person obligated to make fee payments for access to a covered electronic payment system who would be affected by the determination on appeal from paying the fees required and complying with the terms under the relevant determination or regulations.

(B) OVERPAYMENTS AND UNDERPAYMENTS.—Notwithstanding subparagraph (A), if fees described in subparagraph (A) are paid—

(i) the recipient of such fees shall, not later than 60 days after the date on which the appeal is resolved return any excess fees described in subparagraph (A) (and interest thereon, if ordered under paragraph (3)), to the extent necessary to comply with the final determination of fees and terms on appeal; and

(ii) a person obligated to make fee payments shall, not later than 60 days after the date on which the appeal is resolved, pay the recipient the amount of any underpayment of fees described in subparagraph (A) (and interest thereon, if ordered under paragraph (3)), to the extent necessary to comply with the final determination of fees and terms on appeal.

(3) JURISDICTION OF COURT.—If the United States Court of Appeals for the District of Columbia Circuit, under section 706 of title 5, United States Code, modifies or vacates a determination of the Electronic Payment System Judges, the court may enter its own determination with respect to the amount or distribution of fees and costs, and order the repayment of any excess fees, the payment of any underpaid fees, and the payment of interest pertaining respectively thereto, in accordance with its final judgment. The court also may vacate the determination of the Electronic Payment System Judges and remand the case to the Electronic Payment System Judges for further proceedings.

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

SEC. 6. INSTITUTION OF PROCEEDINGS BEFORE ELECTRONIC PAYMENT SYSTEM JUDGES.

(a) INITIAL PROCEEDINGS.—

(1) TIMING.—Proceedings under this Act shall be commenced as soon as practicable after the date of enactment of this Act to establish fees and terms for access to covered electronic payment systems under section 3(c), which shall be effective during the period beginning on January 1, 2011, and ending on December 31, 2012. The Electronic Payment System Judges shall cause notice of commencement of such proceedings to be published in the Federal Register.

(2) PROCEDURES SPECIFIC TO THE INITIAL PROCEEDINGS.—

(A) DISCOVERY PERIOD.—Notwithstanding section 5(b)(4)(B)(ii), discovery in the initial proceedings described in paragraph (1) shall be permitted for a period of 90 days, except for discovery ordered by the Electronic Payment System Judges in connection with the resolution of motions, orders, and disputes pending at the end of such period.

(B) CONSIDERATION OF CHANGES IN FEES AND TERMS BETWEEN DATE OF ENACTMENT AND INITIAL DETERMINATION.—In establishing the fees and terms under section 3(c) for access to covered electronic payment systems, to be effective during the period beginning on January 1, 2011, and ending on December 31, 2012, the Electronic Payment System Judges shall consider changes in fees and terms made by a covered electronic payments system between the date of enactment of this Act and such initial determination. Based upon such consideration, the Electronic Payment System Judges may adjust the fees established for the period beginning on January 1, 2011, and ending on December 31, 2012, to reflect the economic impact such changes had on the parties.

(b) SUBSEQUENT PROCEEDINGS.—After completion of the proceedings required under subsection (a), proceedings under section 3(c) to establish fees and terms for access to covered electronic payment systems shall be commenced in 2011, and every 3 years thereafter.

SEC. 7. GENERAL RULE FOR VOLUNTARILY NEGOTIATED ACCESS AGREEMENTS.

(a) IN GENERAL.—Any fees or terms described in subsection (b) shall remain in effect for such period of time as would otherwise apply to fees and terms established under this Act, except that the Electronic Payment System Judges shall adjust any such fees to reflect inflation during any additional period the fees remain in effect beyond that contemplated in the voluntarily negotiated access agreement.

(b) FEES AND TERMS.—The fees or terms described in this subsection are fees or terms for access to a covered electronic payment system under this Act that—

(1) are agreed upon as part of a voluntarily negotiated access agreement for a period shorter than would otherwise apply under a determination under this Act; and

(2) are adopted by the Electronic Payment System Judges as part of a determination under this Act.

By Mr. BAUCUS (for himself and Mr. CONRAD):

S. 1213. A bill to amend title XI of the Social Security Act to provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Patient-Centered Outcomes Research Trust Fund, and for other purposes; to the Committee on Finance.

Mr. BAUCUS. Mr. President, last year, America spent $2.4 trillion on health care. That is 1/6 of our economy. Yet we ranked last among major industrialized nations in the Commonwealth Fund's National Scorecard on Health System Performance, which ranks the number of deaths that could be prevented before age 75 through effective health care.

Some analysts estimate that as much as 30 percent of our spending is for ineffective, redundant, or inappropriate care. That's care that does nothing to improve the health of Americans.

Our system also leaves nearly 50 million Americans without health coverage and 25 million more with inadequate coverage. Most bankruptcies and foreclosures in America are related to medical costs.

Our system needs reform.

Today, along with Senator CONRAD, the Chairman of the Budget Committee, I am proud to introduce a bill that would improve health care in America by helping doctors and patients to make better, more-informed health care decisions.

This legislation would increase the chances that Americans receive the right care. This bill would provide for research that can help physicians and patients know more about what works best in medicine, and what does not.

Some patients, receive medical treatments that work well. Some patients receive treatments that do not. In many cases, doctors simply don't have enough reliable evidence to decide which treatments are best for which patients.

Rapid innovation and advancements in medicine have led to an ever-changing array of new and sometimes expensive technologies. The age of personalized medicine and genetic engineering will provide even more choices for patients and their physicians. Indeed, both patients and physicians can face great difficulty in choosing among treatment options.

Patients and physicians need more credible information about how treatments for a specific condition compare to each other. Today, the vast majority of medical information shows how treatments work compared to placebos. Most medical information does not show how treatments work compared to each other.

For example, men with prostate cancer have a choice among 3 common treatments surgery, radiation, and chemotherapy. Each approach yields different outcomes in terms of survival, ability to return to work, and other measures of quality of life.

Comparative effectiveness research would compare each approach in a systematic way. That way, doctors and patients would have more information about how options work, and for whom. The bill that I introduce today would do just that.

This bill would facilitate comparisons across a broad spectrum of health care interventions and health care strategies that are used to prevent, treat, diagnose and manage health conditions. By evaluating and comparing what works best, patients and providers can make more informed decisions about care.

More specifically, this bill would create a nonprofit institute that would be responsible for setting national health care research priorities. The institute, called the Patient-Centered Outcomes Research Institute, would be a private

entity. It would be governed by a multi-stakeholder, public-private sector Board of Governors. It would not be an agency of the Federal Government.

Keeping the Institute a private, nonprofit entity would shelter it from potential political influence from both the executive and legislative branches of Government. The independence and expertise of the Institute would result in more credible and more useful research for Americans.

The Institute would set national priorities for comparative effectiveness research and facilitate studies that would help to answer the most pressing questions about what works, and what doesn't.

The Institute would have the authority to contract with experienced Federal agencies—such as the National Institutes of Health and the Agency for Health Care Research and Quality, or with private researchers—to carry out the actual research. The Institute would also be responsible for disseminating the findings of the research in ways that make sense to both patients and providers.

The Institute's work would not happen behind closed doors. The bill would provide opportunities for public input and scientific review of the integrity of the research being conducted. The Institute's meetings would be accessible to the public, and open forums would help to solicit and obtain input on the Institute's activities and agenda. Also, public comment periods would be made available to discuss research findings.

The Institute's work would benefit all Americans who receive health care. So both public and private payers would fund the Institute. After an initial investment from general revenues, the Institute would be funded by an all-payer system, drawing from both public and private sources.

Comparative effectiveness research would not be the ultimate decision maker. Instead, it would provide an additional tool to improve health quality. The Institute would be a health care resource, a scientific entity, a source of knowledge, and a provider of information.

According to the Institute of Medicine, this research would provide better evidence—objective information—so that doctors and patients could make better decisions.

If we are truly to reform our health care system, then we must get more evidence into the hands of the people making medical decisions. This research is not only about reducing health care costs. It is focused on addressing significant gaps in knowledge.

It is not just the academics and economists who agree. Patient advocates like the National Breast Cancer Coalition, provider groups like the American Medical Association, and consumer groups like AARP can see the benefits of this research quite clearly. They have all extended their support.

The American Recovery and Reinvestment Act made a significant investment towards this type of research. But that was just a first step. We must ensure that this research will be sustained in the years to come.

From cars to toasters, Americans are able to readily view and evaluate information about the quality and effectiveness of so many of the items that they buy. It seems only logical that they should have information on what works and what does not when it comes to their health, especially with one in every 6 of this country's dollars leing spent on health care.

It is time for Americans and their doctors to be wield the world's most advanced science, so that the most personal health care decisions, like so many of the other decisions we make, are made with access to the best available information.

I urge my colleagues to support this common-sense measure.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1213

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient-Centered Outcomes Research Act of 2009''.

SEC. 2. COMPARATIVE EFFECTIVENESS RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

''PART D—COMPARATIVE EFFECTIVENESS RESEARCH

''COMPARATIVE EFFECTIVENESS RESEARCH

''SEC. 1181. (a) DEFINITIONS.—In this section:

''(1) BOARD.—The term 'Board' means the Board of Governors established under subsection (f).

''(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—

''(A) IN GENERAL.—The term 'comparative clinical effectiveness research' means research evaluating and comparing the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

''(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, patients.

''(3) COMPARATIVE EFFECTIVENESS RESEARCH.—The term 'comparative effectiveness research' means research evaluating and comparing the implications and outcomes of 2 or more health care strategies to address a particular medical condition for specific patient populations.

''(4) CONFLICTS OF INTEREST.—The term 'conflicts of interest' means associations, including financial and personal, that may be reasonably assumed to have the potential to bias an individual's decisions in matters related to the Institute or the conduct of activities under this section.

''(5) INSTITUTE.—The term 'Institute' means the 'Patient-Centered Outcomes Research Institute' established under subsection (b)(1).

''(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

''(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the ''Patient-Centered Outcomes Research Institute'' which is neither an agency nor establishment of the United States Government.

''(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

''(3) FUNDING OF COMPARATIVE EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the 'PCORTF') under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

''(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative clinical outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

''(d) DUTIES.—

''(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—

''(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for comparative clinical effectiveness research, taking into account factors, including—

''(i) disease incidence, prevalence, and burden in the United States;

''(ii) evidence gaps in terms of clinical outcomes;

''(iii) practice variations, including variations in delivery and outcomes by geography, treatment site, provider type, and patient subgroup;

''(iv) the potential for new evidence concerning certain categories of health care services or treatments to improve patient health and well-being, and the quality of care;

''(v) the effect or potential for an effect on health expenditures associated with a health condition or the use of a particular medical treatment, service, or item;

''(vi) the effect or potential for an effect on patient needs, outcomes, and preferences, including quality of life; and

''(vii) the relevance to assisting patients and clinicians in making informed health decisions.

''(B) ESTABLISHING RESEARCH PROJECT AGENDA.—

''(i) IN GENERAL.—The Institute shall establish and update a research project agenda for comparative clinical effectiveness research to address the priorities identified under subparagraph (A), taking into consideration the types of such research that might address each priority and the relative value (determined based on the cost of conducting such research compared to the potential usefulness of the information produced by such research) associated with the different types of research, and such other factors as the Institute determines appropriate.

''(ii) CONSIDERATION OF NEED TO CONDUCT A SYSTEMATIC REVIEW.—In establishing and updating the research project agenda under clause (i), the Institute shall consider the need to conduct a systematic review of existing research before providing for the conduct of new research under paragraph (2)(A).

''(2) CARRYING OUT RESEARCH PROJECT AGENDA.—

''(A) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—In carrying out the research project agenda established under paragraph (1)(B), the Institute shall provide for the conduct of appropriate research and the synthesis of evidence, in accordance with the methodological standards adopted under paragraph (10), using methods, including the following:

''(i) Systematic reviews and assessments of existing research and evidence.

''(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

''(iii) Any other methodologies recommended by the methodology committee established under paragraph (7) that are adopted by the Board under paragraph (10).

''(B) CONTRACTS FOR THE MANAGEMENT AND CONDUCT OF RESEARCH.—

''(i) IN GENERAL.—The Institute may enter into contracts for the management and conduct of research in accordance with the research project agenda established under paragraph (1)(B) with the following:

''(I) Agencies and instrumentalities of the Federal Government that have experience in conducting comparative clinical effectiveness research, such as the Agency for Healthcare Research and Quality, to the extent that such contracts are authorized under the governing statutes of such agencies and instrumentalities.

''(II) Appropriate private sector research or study-conducting entities that have demonstrated the experience and capacity to achieve the goals of comparative effectiveness research.

''(ii) CONDITIONS FOR CONTRACTS.—A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

''(I) abide by the transparency and conflicts of interest requirements that apply to the Institute with respect to the research managed or conducted under such contract;

''(II) comply with the methodological standards adopted under paragraph (10) with respect to such research;

''(III) take into consideration public comments on the study design that are transmitted by the Institute to the agency, instrumentality, or other entity under subsection (i)(1)(B) during the finalization of the study design and transmit responses to such comments to the Institute, which will publish such comments, responses, and finalized study design in accordance with subsection (i)(3)(A)(iii) prior to the conduct of such research; and

''(IV) in the case where the agency, instrumentality, or other entity is managing or conducting a comparative effectiveness research study for a rare disease, consult with the expert advisory panel for rare disease appointed under paragraph (5)(A)(iii) with respect to such research study.

''(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or co-insurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

''(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis, in order to take into account new research, evolving evidence, advances in medical technology, and changes in the standard of care as they become available, as appropriate.

''(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall—

''(i) be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences; and

''(ii) include members of such subpopulations as subjects in the research as feasible and appropriate.

''(E) DIFFERENCES IN TREATMENT MODALITIES.—Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

''(3) STUDY AND REPORT ON FEASIBILITY OF CONDUCTING RESEARCH IN-HOUSE.—

''(A) STUDY.—The Institute shall conduct a study on the feasibility of conducting research in-house.

''(B) REPORT.—Not later than 5 years after the date of enactment of this section, the Institute shall submit a report to Congress containing the results of the study conducted under subparagraph (A).

''(4) DATA COLLECTION.—

''(A) IN GENERAL.—The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under titles XVIII, XIX, and XXI as the Institute may require to carry out this section. The Institute may also request and, if such request is granted, obtain data from Federal, State, or private entities, including data from clinical databases and registries.

''(B) USE OF DATA.—The Institute shall only use data provided to the Institute under subparagraph (A) in accordance with laws and regulations governing the release and use of such data, including applicable confidentiality and privacy standards.

''(5) APPOINTING EXPERT ADVISORY PANELS.—

''(A) APPOINTMENT.—

''(i) IN GENERAL.—The Institute shall, as appropriate, appoint expert advisory panels to assist in identifying research priorities and establishing the research project agenda under paragraph (1). Panels shall advise the Institute in matters such as identifying gaps in and updating medical evidence in order to ensure that the information produced from such research is clinically relevant to decisions made by clinicians and patients at the point of care.

''(ii) EXPERT ADVISORY PANELS FOR PRIMARY RESEARCH.—The Institute shall appoint expert advisory panels in carrying out the research project agenda under paragraph (2)(A)(ii). Such expert advisory panels shall, upon request, advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including the appropriate comparator technologies, important patient subgroups, and other parameters of the research, as necessary. Upon the request of such agency, instrumentality, or entity, such panels shall be available as a resource for technical questions that may arise during the conduct of such research.

''(iii) EXPERT ADVISORY PANEL FOR RARE DISEASE.—In the case of a comparative effectiveness research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of such research study and determining the relative value and feasibility of conducting such research study.

''(B) COMPOSITION.—

''(i) IN GENERAL.—An expert advisory panel appointed under subparagraph (A) shall include individuals who have experience in the relevant topic, project, or category for which the panel is established, including—

''(I) practicing and research clinicians (including relevant specialists and subspecialists), patients, and representatives of patients; and

''(II) experts in scientific and health services research, health services delivery, and evidence-based medicine.

''(ii) INCLUSION OF REPRESENTATIVES OF MANUFACTURERS OF MEDICAL TECHNOLOGY.—An expert advisory panel appointed under subparagraph (A) may include a representative of each manufacturer of each medical technology that is included under the relevant topic, project, or category for which the panel is established.

''(6) SUPPORTING PATIENT AND CONSUMER REPRESENTATIVES.—The Institute shall provide support and resources to help patient and consumer representatives on the Board and expert advisory panels appointed by the Institute under paragraph (5) to effectively participate in technical discussions regarding complex research topics. Such support shall include initial and continuing education to facilitate effective engagement in activities undertaken by the Institute and may include regular and ongoing opportunities for patient and consumer representatives to interact with each other and to exchange information and support regarding their involvement in the Institute's activities. The Institute shall provide per diem and other appropriate compensation to patient and consumer representatives for their time spent participating in the activities of the Institute under this paragraph.

''(7) ESTABLISHING METHODOLOGY COMMITTEE.—

''(A) IN GENERAL.—The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

''(B) APPOINTMENT AND COMPOSITION.—The methodology committee established under subparagraph (A) shall be composed of not more than 17 members appointed by the Comptroller General of the United States. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee.

''(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative effectiveness research by undertaking, directly or through subcontract, the following activities:

''(i) Not later than 2 years after the date on which the members of the methodology committee are appointed under subparagraph (B), developing and periodically updating the following:

''(I) Establish and maintain methodological standards for comparative clinical effectiveness research on major categories of interventions to prevent, diagnose, or treat a clinical condition or improve the delivery of care. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of such research and for clinical outcomes measures, risk adjustment, and other relevant aspects of research and assessment

with respect to the design of such research. Any methodological standards developed and updated under this subclause shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from relevant experts, stakeholders, and decision makers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative effectiveness research methods (determined as of the date of enactment of the Patient-Centered Outcomes Research Act of 2009).

''(II) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific comparative clinical effectiveness research question.

''(ii) Not later than 3 years after such date, examining the following:

''(I) Methods by which various aspects of the health care delivery system (such as benefit design and performance, and health services organization, management, information communication, and delivery) could be assessed and compared for their relative effectiveness, benefits, risks, advantages, and disadvantages in a scientifically valid and standardized way.

''(II) Methods by which efficiency and value (including the full range of harms and benefits, such as quality of life) could be assessed in a scientifically valid and standardized way.

''(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.—

''(i) IN GENERAL.—Subject to clause (iii), in undertaking the activities described in subparagraph (C), the methodology committee shall—

''(I) consult or contract with 1 or more of the entities described in clause (ii); and

''(II) consult with stakeholders and other entities knowledgeable in relevant fields, as appropriate.

''(ii) ENTITIES DESCRIBED.—The following entities are described in this clause:

''(I) The Institute of Medicine of the National Academies.

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

''(III) The National Institutes of Health.

''(IV) Academic, non-profit, or other private entities with relevant expertise.

''(iii) CONDUCT OF EXAMINATIONS.—The methodology committee shall contract with the Institute of Medicine of the National Academies for the conduct of the examinations described in subclauses (I) and (II) of subparagraph (C)(ii).

''(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee's performance of the functions described in subparagraph (C). Reports submitted under the preceding sentence with respect to the functions described in clause (i) of such subparagraph shall contain recommendations—

''(i) for the Institute to adopt methodological standards developed and updated by the methodology committee under such subparagraph; and

''(ii) for such other action as the methodology committee determines is necessary to comply with such methodological standards.

''(8) PROVIDING FOR A PEER-REVIEW PROCESS FOR PRIMARY RESEARCH.—

''(A) IN GENERAL.—The Institute shall ensure that there is a process for peer review of the research conducted under paragraph (2)(A)(ii). Under such process—

''(i) evidence from research conducted under such paragraph shall be reviewed to assess scientific integrity and adherence to methodological standards adopted under paragraph (10); and

''(ii) a list of the names of individuals contributing to any peer-review process during the preceding year or years shall be made public and included in annual reports in accordance with paragraph (12)(D).

''(B) COMPOSITION.—Such peer-review process shall be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and shall be composed of experts in the scientific field relevant to the research under review.

''(C) USE OF EXISTING PROCESSES.—

''(i) PROCESSES OF ANOTHER ENTITY.—In the case where the Institute enters into a contract or other agreement with another entity for the conduct or management of research under this section, the Institute may utilize the peer-review process of such entity if such process meets the requirements under subparagraphs (A) and (B).

''(ii) PROCESSES OF APPROPRIATE MEDICAL JOURNALS.—The Institute may utilize the peer-review process of appropriate medical journals if such process meets the requirements under subparagraphs (A) and (B).

''(9) DISSEMINATION OF RESEARCH FINDINGS.—

''(A) IN GENERAL.—The Institute shall disseminate research findings to clinicians, patients, and the general public in accordance with the dissemination protocols and strategies adopted under paragraph (10). Research findings disseminated—

''(i) shall convey findings of research so that they are comprehensible and useful to patients and providers in making health care decisions;

''(ii) shall discuss findings and other considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

''(iii) shall include considerations such as limitations of research and what further research may be needed, as appropriate;

''(iv) shall not include practice guidelines, coverage recommendations, or policy recommendations; and

''(v) shall not include any data the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to the use of data under this section.

''(B) DISSEMINATION PROTOCOLS AND STRATEGIES.—The Institute shall develop protocols and strategies for the appropriate dissemination of research findings in order to ensure effective communication of such findings and the use and incorporation of such findings into relevant activities for the purpose of informing higher quality and more effective and timely decisions regarding medical treatments, services, and items. In developing and adopting such protocols and strategies, the Institute shall consult with stakeholders, including practicing clinicians and patients, concerning the types of dissemination that will be most useful to the end users of the information and may provide for the utilization of multiple formats for conveying findings to different audiences.

''(C) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term 'research findings' means the results of a study or assessment.

''(10) ADOPTION.—Subject to subsection (i)(1)(A)(i), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (7)(C)(i), any peer-review process provided under paragraph (8), and dissemination protocols and strategies developed under paragraph (9)(B) by majority vote. In the case where the Institute does not adopt such national priorities, research project agenda, methodological standards, peer-review process, or dissemination protocols and strategies in accordance with the preceding sentence, the national priorities, research project agenda, methodological standards, peer-review process, or dissemination protocols and strategies shall be referred to the appropriate staff or entity within the Institute (or, in the case of the methodological standards, the methodology committee) for further review.

''(11) COORDINATION OF RESEARCH AND RESOURCES AND BUILDING CAPACITY FOR RESEARCH.—

''(A) COORDINATION OF RESEARCH AND RESOURCES.—The Institute shall coordinate research conducted, commissioned, or otherwise funded under this section with comparative clinical effectiveness and other relevant research and related efforts conducted by public and private agencies and organizations in order to ensure the most efficient use of the Institute's resources and that research is not duplicated unnecessarily.

''(B) BUILDING CAPACITY FOR RESEARCH.—The Institute may build capacity for comparative clinical effectiveness research and methodologies, including research training and development of data resources (such as clinical registries), through appropriate activities, including using up to 20 percent of the amounts appropriated or credited to the PCORTF under section 9511(b) of the Internal Revenue Code of 1986 with respect to a fiscal year to fund extramural efforts of organizations such as the Cochrane Collaboration (or a successor organization) and other organizations that develop and maintain a data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

''(C) INCLUSION IN ANNUAL REPORTS.—The Institute shall report on any coordination and capacity building conducted under this paragraph in annual reports in accordance with paragraph (12)(E).

''(12) ANNUAL REPORTS.—The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—

''(A) a description of the activities conducted under this section during the preceding year, including the use of amounts appropriated or credited to the PCORTF under section 9511(b) of the Internal Revenue Code of 1986 to carry out this section, research projects completed and underway, and a summary of the findings of such projects;

''(B) the research project agenda and budget of the Institute for the following year;

''(C) a description of research priorities identified under paragraph (1)(A), dissemination protocols and strategies developed by the Institute under paragraph (9)(B), and methodological standards developed and updated by the methodology committee under paragraph (7)(C)(i) that are adopted under paragraph (10) during the preceding year;

''(D) the names of individuals contributing to any peer-review process provided under paragraph (8) during the preceding year or years, in a manner such that those individuals cannot be identified with a particular research project; and

''(E) a description of efforts by the Institute under paragraph (11) to—

''(i) coordinate the research conducted, commissioned, or otherwise funded under

this section and the resources of the Institute with research and related efforts conducted by other private and public entities; and

''(ii) build capacity for comparative clinical effectiveness research and other relevant research and related efforts through appropriate activities.

''(F) any other relevant information (including information on the membership of the Board, expert advisory panels appointed under paragraph (5), the methodology committee established under paragraph (7), and the executive staff of the Institute, any conflicts of interest with respect to the members of such Board, expert advisory panels, and methodology committee, or with respect to any individuals selected for employment as executive staff of the Institute, and any bylaws adopted by the Board during the preceding year).

''(e) ADMINISTRATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Board shall carry out the duties of the Institute.

''(2) NONDELEGABLE DUTIES.—The activities described in subsections (b)(3)(D), (d)(1), and (d)(10) are nondelegable.

''(f) BOARD OF GOVERNORS.—

''(1) IN GENERAL.—The Institute shall have a Board of Governors, which shall consist of the following members:

''(A) The Secretary of Health and Human Services (or the Secretary's designee).

''(B) The Director of the Agency for Healthcare Research and Quality (or the Director's designee).

''(C) The Director of the National Institutes of Health (or the Director's designee).

''(D) 18 members appointed by the Comptroller General of the United States not later than 6 months after the date of enactment of this section, as follows:

''(i) 3 members representing patients and health care consumers.

''(ii) 3 members representing practicing physicians, including surgeons.

''(iii) 3 members representing agencies that administer public programs, as follows:

''(I) 1 member representing the Centers for Medicare & Medicaid Services who has experience in administering the program under title XVIII.

''(II) 1 member representing agencies that administer State health programs (who may represent the Centers for Medicare & Medicaid Services and have experience in administering the program under title XIX or the program under title XXI or be a governor of a State).

''(III) 1 member representing agencies that administer other Federal health programs (such as a health program of the Department of Defense under chapter 55 of title 10, United States Code, the Federal employees health benefits program under chapter 89 of title 5 of such Code, a health program of the Department of Veterans Affairs under chapter 17 of title 38 of such Code, or a medical care program of the Indian Health Service or of a tribal organization).

''(iv) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

''(v) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

''(vi) 1 member representing nonprofit organizations involved in health services research.

''(vii) 1 member representing organizations that focus on quality measurement and improvement or decision support.

''(viii) 1 member representing independent health services researchers.

''(2) QUALIFICATIONS.—

''(A) DIVERSE REPRESENTATION OF PERSPECTIVES.—The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics.

''(B) CONFLICTS OF INTEREST.—

''(i) IN GENERAL.—In appointing members of the Board under paragraph (1)(D), the Comptroller General of the United States shall take into consideration any conflicts of interest of potential appointees. Any conflicts of interest of members appointed to the Board under paragraph (1) shall be disclosed in accordance with subsection (i)(4)(B).

''(ii) RECUSAL.—A member of the Board shall be recused from participating with respect to a particular research project or other matter considered by the Board in carrying out its research project agenda under subsection (d)(2) in the case where the member (or an immediate family member of such member) has a financial or personal interest directly related to the research project or the matter that could affect or be affected by such participation.

''(3) TERMS.—

''(A) IN GENERAL.—A member of the Board appointed under paragraph (1)(D) shall be appointed for a term of 6 years, except with respect to the members first appointed under such paragraph—

''(i) 6 shall be appointed for a term of 6 years;

''(ii) 6 shall be appointed for a term of 4 years; and

''(iii) 6 shall be appointed for a term of 2 years.

''(B) LIMITATION.—No individual shall be appointed to the Board under paragraph (1)(D) for more than 2 terms.

''(C) EXPIRATION OF TERM.—Any member of the Board whose term has expired may serve until such member's successor has taken office, or until the end of the calendar year in which such member's term has expired, whichever is earlier.

''(D) VACANCIES.—

''(i) IN GENERAL.—Any member appointed to fill a vacancy prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term.

''(ii) VACANCIES NOT TO AFFECT POWER OF BOARD.—A vacancy on the Board shall not affect its powers, but shall be filled in the same manner as the original appointment was made.

''(4) CHAIRPERSON AND VICE-CHAIRPERSON.—

''(A) IN GENERAL.—The Comptroller General of the United States shall designate a Chairperson and Vice-Chairperson of the Board from among the members of the Board appointed under paragraph (1)(D).

''(B) TERM.—The members so designated shall serve as Chairperson and Vice-Chairperson of the Board for a period of 3 years.

''(5) COMPENSATION.—

''(A) IN GENERAL.—A member of the Board shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

''(B) TRAVEL EXPENSES.—While away from home or regular place of business in the performance of duties for the Board, each member of the Board may receive reasonable travel, subsistence, and other necessary expenses.

''(6) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—The Board may—

''(A) employ and fix the compensation of an executive director and such other personnel as may be necessary to carry out the duties of the Institute;

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

''(C) enter into contracts or make other arrangements and make such payments as may be necessary for performance of the duties of the Institute;

''(D) provide travel, subsistence, and per diem compensation for individuals performing the duties of the Institute, including members of any expert advisory panel appointed under subsection (d)(5), members of the methodology committee established under subsection (d)(7), and individuals selected to contribute to any peer-review process under subsection (d)(8); and

''(E) prescribe such rules, regulations, and bylaws as the Board determines necessary with respect to the internal organization and operation of the Institute.

''(7) MEETINGS AND HEARINGS.—The Board shall meet and hold hearings at the call of the Chairperson or a majority of its members. In the case where the Board is meeting on matters not related to personnel, Board meetings shall be open to the public and advertised through public notice at least 7 days prior to the meeting.

''(8) QUORUM.—A majority of the members of the Board shall constitute a quorum for purposes of conducting the duties of the Institute, but a lesser number of members may meet and hold hearings.

''(g) FINANCIAL OVERSIGHT.—

''(1) CONTRACT FOR AUDIT.—The Institute shall provide for the conduct of financial audits of the Institute on an annual basis by a private entity with expertise in conducting financial audits.

''(2) REVIEW OF AUDIT AND REPORT TO CONGRESS.—The Comptroller General of the United States shall—

''(A) review the results of the audits conducted under paragraph (1); and

''(B) submit a report to Congress containing the results of such audits and review.

''(h) GOVERNMENTAL OVERSIGHT.—

''(1) REVIEW AND REPORTS.—

''(A) IN GENERAL.—The Comptroller General of the United States shall review the following:

''(i) Processes established by the Institute, including those with respect to the identification of research priorities under subsection (d)(1)(A) and the conduct of research projects under this section. Such review shall determine whether information produced by such research projects—

''(I) is objective and credible;

''(II) is produced in a manner consistent with the requirements under this section; and

''(III) is developed through a transparent process.

''(ii) The overall effect of the Institute and the effectiveness of activities conducted under this section, including an assessment of—

''(I) the utilization of the findings of research conducted under this section by health care decision makers; and

''(II) the effect of the Institute and such activities on innovation and on the health economy of the United States.

''(B) REPORTS.—Not later than 5 years after the date of enactment of this section, and not less frequently than every 5 years thereafter, the Comptroller General of the United States shall submit a report to Congress containing the results of the review conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

''(2) FUNDING ASSESSMENT.—

''(A) IN GENERAL.—The Comptroller General of the United States shall assess the adequacy and use of funding for the Institute and activities conducted under this section under the PCORTF under section 9511 of the Internal Revenue Code of 1986. Such assessment shall include a determination as to whether, based on the utilization of findings by public and private payers, each of the following are appropriate sources of funding for the Institute, including a determination of whether such sources of funding should be continued or adjusted, or whether other sources of funding not described in clauses (i) through (iii) would be appropriate:

''(i) The transfer of funds from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the PCORTF under section 1183.

''(ii) The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) of subsection (b)(1) of such section 9511.

''(iii) Private sector contributions under subparagraphs (D)(i) and (E)(i) of such subsection (b)(1).

''(B) REPORT.—Not later than 8 years after the date of enactment of this section, the Comptroller General of the United States shall submit a report to Congress containing the results of the assessment conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

''(i) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

''(1) PUBLIC COMMENT PERIODS.—

''(A) IN GENERAL.—The Institute shall provide for a public comment period of not less than 45 and not more than 60 days at the following times:

''(i) Prior to the adoption of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection (d)(7)(C)(i), the peer-review process generally provided under subsection (d)(8), and dissemination protocols and strategies developed by the Institute under subsection (d)(9)(B) in accordance with subsection (d)(10).

''(ii) Prior to the finalization of individual study designs.

''(iii) After the release of draft findings with respect to a systematic review and assessment of existing research and evidence under subsection (d)(2)(A)(i).

''(B) TRANSMISSION OF PUBLIC COMMENTS ON STUDY DESIGN.—The Institute shall transmit public comments submitted during the public comment period described in subparagraph (A)(ii) to the entity conducting research with respect to which the individual study design is being finalized.

''(2) ADDITIONAL FORUMS.—The Institute shall, in addition to the public comment periods described in paragraph (1)(A), support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on the following:

''(A) The identification of research priorities, including research topics, and the establishment of the research project agenda under subparagraphs (A) and (B), respectively, of subsection (d)(1).

''(B) Research findings.

''(C) Any other duties, activities, or processes the Institute determines appropriate.

''(3) PUBLIC AVAILABILITY.—The Institute shall make available to the public and disclose through the official public Internet website of the Institute, and through other forums and media the Institute determines appropriate, the following:

''(A) The process and methods for the conduct of research under this section, including—

''(i) the identity of the entity conducting such research;

''(ii) any links the entity has to industry (including such links that are not directly tied to the particular research being conducted under this section);

''(iii) draft study designs (including research questions and the finalized study design, together with public comments on such study design and responses to such comments);

''(iv) research protocols (including measures taken, methods of research, methods of analysis, research results, and such other information as the Institute determines appropriate) with respect to each medical treatment, service, and item described in subsection (a)(2)(B);

''(v) any key decisions made by the Institute and any appropriate committees of the Institute;

''(vi) the identity of investigators conducting such research and any conflicts of interest of such investigators; and

''(vii) any progress reports the Institute determines appropriate.

''(B) Notice of each of the public comment periods under paragraph (1)(A), including deadlines for public comments for such periods.

''(C) Public comments submitted during each of the public comment periods under paragraph (1)(A), including such public comments submitted on draft findings under clause (iii) of such paragraph.

''(D) Bylaws, processes, and proceedings of the Institute, to the extent practicable and as the Institute determines appropriate.

''(E) Not later than 90 days after receipt by the Institute of a relevant report or research findings, appropriate information contained in such report or findings.

''(4) CONFLICTS OF INTEREST.—The Institute shall—

''(A) in appointing members to an expert advisory panel under subsection (d)(5) and the methodology committee under subsection (d)(7), and in selecting individuals to contribute to any peer-review process under subsection (d)(8) and for employment as executive staff of the Institute, take into consideration any conflicts of interest of potential appointees, participants, and staff; and

''(B) include a description of any such conflicts of interest and conflicts of interest of Board members in the annual report under subsection (d)(12), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

''(j) RULES.—

''(1) GIFTS.—The Institute, or the Board and staff of the Institute acting on behalf of the Institute, may not accept gifts, bequeaths, or donations of services or property.

''(2) ESTABLISHMENT AND PROHIBITION ON ACCEPTING OUTSIDE FUNDING OR CONTRIBUTIONS.—The Institute may not—

''(A) establish a corporation other than as provided under this section; or

''(B) accept any funds or contributions other than as provided under this part.

''(k) RULES OF CONSTRUCTION.—

''(1) COVERAGE.—Nothing in this section shall be construed—

''(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or

''(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

''(2) REPORTS AND FINDINGS.—None of the reports submitted under this section or research findings disseminated by the Institute shall be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

''LIMITATIONS ON USE OF COMPARATIVE EFFECTIVENESS RESEARCH BY THE SECRETARY

''SEC. 1182. The Secretary may only use evidence and findings from comparative effectiveness research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which meets the following requirements:

''(1) Stakeholders and other individuals have the opportunity to provide informed and relevant information with respect to the determination.

''(2) Stakeholders and other individuals have the opportunity to review draft proposals of the determination and submit public comments with respect to such draft proposals.

''(3) In making the determination, the Secretary considers—

''(A) all other relevant evidence, studies, and research in addition to such comparative effectiveness research; and

''(B) evidence and research that demonstrates or suggests a benefit of coverage with respect to a specific subpopulation of individuals, even if the evidence and findings from the comparative effectiveness research demonstrates or suggests that, on average, with respect to the general population the benefits of coverage do not exceed the harm.

''TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

''SEC. 1183. (a) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the 'PCORTF') under section 9511 of the Internal Revenue Code of 1986, the following:

''(1) For fiscal year 2013, an amount equal to $1 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

''(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to $2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

''(b) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

''(1) such dollar amount for the previous fiscal year, multiplied by

''(2) the percentage increase in the projected per capita amount of National Health Expenditures from the calendar year in which the previous fiscal year ends to the calendar year in which the fiscal year involved ends, as most recently published by the Secretary before the beginning of the fiscal year.''.

(b) COORDINATION WITH PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Section 1889(a) of the Social Security Act (42 U.S.C. 1395zz(a)) is amended by inserting ''and to enhance the understanding of and utilization by providers of services and suppliers of research findings disseminated by the Patient-Centered Outcomes Research Institute established under section 1181'' before the period at the end.

(c) PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND; FINANCING FOR TRUST FUND.—

(1) ESTABLISHMENT OF TRUST FUND.—

(A) IN GENERAL.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to establishment of trust funds) is amended by adding at the end the following new section:

''SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

''(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the 'Patient-Centered Outcomes Research Trust Fund' (hereafter in this section referred to as the 'PCORTF'), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

''(b) TRANSFERS TO FUND.—

''(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

''(A) For fiscal year 2010, $10,000,000.

''(B) For fiscal year 2011, $50,000,000.

''(C) For fiscal year 2012, $150,000,000.

''(D) For fiscal year 2013—

''(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

''(ii) $150,000,000.

''(E) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019—

''(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

''(ii) $150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

''(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.

''(3) AMERICAN RECOVERY AND REINVESTMENT FUNDS.—In addition to the amounts appropriated under paragraph (1) and the amounts credited under paragraph (2), of amounts appropriated for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services under the heading Agency for Healthcare Research and Quality under the heading Department of Health and Human Services under title VIII of Division A of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5), $10,000,000 shall be transferred to the Trust Fund.

''(4) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

''(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and

''(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

''(c) TRUSTEE.—The Secretary of Health and Human Services shall be a trustee of the PCORTF.

''(d) EXPENDITURES FROM FUND.—Amounts in the PCORTF are available, without further appropriation, to the Patient-Centered Outcomes Research Institute established by section 2(a) of the Patient-Centered Outcomes Research Act of 2009 for carrying out part D of title XI of the Social Security Act (as in effect on the date of enactment of the Patient-Centered Outcomes Research Act of 2009).

''(e) NET REVENUES.—For purposes of this section, the term 'net revenues' means the amount estimated by the Secretary of the Treasury based on the excess of—

''(1) the fees received in the Treasury under subchapter B of chapter 34, over

''(2) the decrease in the tax imposed by chapter 1 resulting from the fees imposed by such subchapter.

''(f) TERMINATION.—No amounts shall be available for expenditure from the PCORTF after September 30, 2019, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.''.

(B) CLERICAL AMENDMENT.—The table of sections for subchapter A of chapter 98 of such Code is amended by adding at the end the following new item:

''Sec. 9511. Patient-Centered Outcomes Research Trust Fund.''.

(2) FINANCING FOR FUND FROM FEES ON INSURED AND SELF-INSURED HEALTH PLANS.—

(A) GENERAL RULE.—Chapter 34 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subchapter:

''Subchapter B—Insured and Self-Insured Health Plans

''SEC. 4375. HEALTH INSURANCE.

''(a) IMPOSITION OF FEE.—There is hereby imposed on each specified health insurance policy for each policy year ending after September 30, 2012, a fee equal to the product of $2 ($1 in the case of policy years ending during fiscal year 2013) multiplied by the average number of lives covered under the policy.

''(b) LIABILITY FOR FEE.—The fee imposed by subsection (a) shall be paid by the issuer of the policy.

''(c) SPECIFIED HEALTH INSURANCE POLICY.—For purposes of this section:

''(1) IN GENERAL.—Except as otherwise provided in this section, the term 'specified health insurance policy' means any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States.

''(2) EXEMPTION FOR CERTAIN POLICIES.—The term 'specified health insurance policy' does not include any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c).

''(3) TREATMENT OF PREPAID HEALTH COVERAGE ARRANGEMENTS.—

''(A) IN GENERAL.—In the case of any arrangement described in subparagraph (B)—

''(i) such arrangement shall be treated as a specified health insurance policy, and

''(ii) the person referred to in such subparagraph shall be treated as the issuer.

''(B) DESCRIPTION OF ARRANGEMENTS.—An arrangement is described in this subparagraph if under such arrangement fixed payments or premiums are received as consideration for any person's agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how such coverage is provided or arranged to be provided.

''(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any policy year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such policy year shall be equal to the sum of such dollar amount for policy years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

''(1) such dollar amount for policy years ending in the previous fiscal year, multiplied by

''(2) the percentage increase in the projected per capita amount of National Health Expenditures from the calendar year in which the previous fiscal year ends to the calendar year in which the fiscal year involved ends, as most recently published by the Secretary of Health and Human Services before the beginning of the fiscal year.

''(e) TERMINATION.—This section shall not apply to policy years ending after September 30, 2019.

''SEC. 4376. SELF-INSURED HEALTH PLANS.

''(a) IMPOSITION OF FEE.—In the case of any applicable self-insured health plan for each plan year ending after September 30, 2012, there is hereby imposed a fee equal to $2 ($1 in the case of plan years ending during fiscal year 2013) multiplied by the average number of lives covered under the plan.

''(b) LIABILITY FOR FEE.—

''(1) IN GENERAL.—The fee imposed by subsection (a) shall be paid by the plan sponsor.

''(2) PLAN SPONSOR.—For purposes of paragraph (1) the term 'plan sponsor' means—

''(A) the employer in the case of a plan established or maintained by a single employer,

''(B) the employee organization in the case of a plan established or maintained by an employee organization,

''(C) in the case of—

''(i) a plan established or maintained by 2 or more employers or jointly by 1 or more employers and 1 or more employee organizations,

''(ii) a multiple employer welfare arrangement, or

''(iii) a voluntary employees' beneficiary association described in section 501(c)(9),

the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or

''(D) the cooperative or association described in subsection (c)(2)(F) in the case of a plan established or maintained by such a cooperative or association.

''(c) APPLICABLE SELF-INSURED HEALTH PLAN.—For purposes of this section, the term 'applicable self-insured health plan' means any plan for providing accident or health coverage if—

''(1) any portion of such coverage is provided other than through an insurance policy, and

''(2) such plan is established or maintained—

''(A) by one or more employers for the benefit of their employees or former employees,

''(B) by one or more employee organizations for the benefit of their members or former members,

''(C) jointly by 1 or more employers and 1 or more employee organizations for the benefit of employees or former employees,

''(D) by a voluntary employees' beneficiary association described in section 501(c)(9),

''(E) by any organization described in section 501(c)(6), or

''(F) in the case of a plan not described in the preceding subparagraphs, by a multiple

employer welfare arrangement (as defined in section 3(40) of Employee Retirement Income Security Act of 1974), a rural electric cooperative (as defined in section 3(40)(B)(iv) of such Act), or a rural telephone cooperative association (as defined in section 3(40)(B)(v) of such Act).

''(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such plan year shall be equal to the sum of such dollar amount for plan years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

''(1) such dollar amount for plan years ending in the previous fiscal year, multiplied by

''(2) the percentage increase in the projected per capita amount of National Health Expenditures from the calendar year in which the previous fiscal year ends to the calendar year in which the fiscal year involved ends, as most recently published by the Secretary of Health and Human Services before the beginning of the fiscal year.

''(e) TERMINATION.—This section shall not apply to plan years ending after September 30, 2019.

''SEC. 4377. DEFINITIONS AND SPECIAL RULES.

''(a) DEFINITIONS.—For purposes of this subchapter—

''(1) ACCIDENT AND HEALTH COVERAGE.—The term 'accident and health coverage' means any coverage which, if provided by an insurance policy, would cause such policy to be a specified health insurance policy (as defined in section 4375(c)).

''(2) INSURANCE POLICY.—The term 'insurance policy' means any policy or other instrument whereby a contract of insurance is issued, renewed, or extended.

''(3) UNITED STATES.—The term 'United States' includes any possession of the United States.

''(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

''(1) IN GENERAL.—For purposes of this subchapter—

''(A) the term 'person' includes any governmental entity, and

''(B) notwithstanding any other law or rule of law, governmental entities shall not be exempt from the fees imposed by this subchapter except as provided in paragraph (2).

''(2) TREATMENT OF EXEMPT GOVERNMENTAL PROGRAMS.—In the case of an exempt governmental program, no fee shall be imposed under section 4375 or section 4376 on any covered life under such program.

''(3) EXEMPT GOVERNMENTAL PROGRAM DEFINED.—For purposes of this subchapter, the term 'exempt governmental program' means—

''(A) any insurance program established under title XVIII of the Social Security Act,

''(B) the medical assistance program established by title XIX or XXI of the Social Security Act,

''(C) any program established by Federal law for providing medical care (other than through insurance policies) to individuals (or the spouses and dependents thereof) by reason of such individuals being—

''(i) members of the Armed Forces of the United States, or

''(ii) veterans, and

''(D) any program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in section 4(d) of the Indian Health Care Improvement Act).

''(c) TREATMENT AS TAX.—For purposes of subtitle F, the fees imposed by this subchapter shall be treated as if they were taxes.

''(d) NO COVER OVER TO POSSESSIONS.—Notwithstanding any other provision of law, no amount collected under this subchapter shall be covered over to any possession of the United States.''.

(B) CLERICAL AMENDMENTS.—

(i) Chapter 34 of such Code is amended by striking the chapter heading and inserting the following:

''CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES

''SUBCHAPTER A. POLICIES ISSUED BY FOREIGN INSURERS

''SUBCHAPTER B. INSURED AND SELF-INSURED HEALTH PLANS

''Subchapter A—Policies Issued By Foreign Insurers''.

(ii) The table of chapters for subtitle D of such Code is amended by striking the item relating to chapter 34 and inserting the following new item:

''CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES''.

SEC. 3. COORDINATION WITH FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH.

Section 804 of Division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8) is amended—

(1) in subsection (c)—

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

(B) in paragraph (2), by striking the period at the end and inserting ''; and''; and

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

''(3) provide support to the Patient-Centered Outcomes Research Institute established under section 1181(b)(1) of the Social Security Act (referred to in this section as the 'Institute').'';

(2) in subsection (d)(2)—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following new subparagraph:

''(B) INCLUSION OF CHAIRPERSON OF THE BOARD OF GOVERNORS OF THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—In the case where the Chairperson of the Board of Governors of the Patient-Centered Outcomes Research Institute established under section 1181(f) of the Social Security Act is a senior Federal officer or employee with responsibility for a health-related program, the members of the council shall include such Chairperson.''.

(3) in subsection (e)(2), by striking ''regarding its activities'' and all that follows through the period at the end and inserting ''containing—

''(A) an inventory of its activities with respect to comparative effectiveness research conducted by relevant Federal departments and agencies; and

''(B) recommendations concerning better coordination of comparative effectiveness research by such departments and agencies.'';

(4) by redesignating subsection (g) as subsection (h); and

(5) by inserting after subsection (f) the following new subsection:

''(g) COORDINATION WITH THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—The Council shall coordinate with the Institute in carrying out its duties under this section.''.

SEC. 4. GAO REPORT ON NATIONAL COVERAGE DETERMINATIONS PROCESS.

Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit a report to Congress on the process for making national coverage determinations (as defined in section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B)) under the Medicare program under title XVIII of the Social Security Act. Such report shall include a determination whether, in initiating and conducting such process, the Secretary of Health and Human Services has complied with applicable law and regulations, including requirements for consultation with appropriate outside experts, providing appropriate notice and comment opportunities to the public, and making information and data (other than proprietary data) considered in making such determinations available to the public and to nonvoting members of any advisory committees established to advise the Secretary with respect to such determinations.

Mr. CONRAD. Mr. President, today I join my good friend and colleague, Senator BAUCUS, in introducing the Patient-Centered Outcomes Research Act of 2009. This proposal builds on the legislation we introduced during the last Congress. Our legislation is the product of months of careful deliberations regarding the best way to expand the quality and quantity of evidence available to patients, physicians, and other health care decision-makers about the comparative clinical effectiveness of health care services and treatments. We have met with dozens of key stakeholders and thought leaders to discuss various aspects of this legislation. People have come to us with many constructive suggestions, many of which are reflected in the bill that we are introducing today. I am proud of the result. This legislation lays the groundwork for improving health care quality and patient outcomes, enhancing patient safety, and reducing overall health care costs in the long run.

As Chairman of the Senate Budget Committee, I am acutely aware of the long-term budget challenges facing our Nation. Health care spending is growing at an unsustainable rate. Although demographic changes associated with the retirement of the baby boom generation contribute to this spending growth, the most significant factor is growth in health care costs in excess of per capita GDP growth. According to Congressional Budget Office projections, by 2050, Medicare and Medicaid spending alone will consume 12 percent of our Nation's gross domestic product.

But excess growth in per capita health care costs is not just a challenge for Federal health spending and the Federal budget. If we continue on the current trajectory, the private sector will also be overwhelmed by rising health care costs. In fact, total health care spending is projected to grow from about 17.6 percent of GDP in 2009—which is far higher than in other industrialized countries—to more than 37 percent of GDP in 2050.

Clearly, we need to address the underlying causes of rising health care costs, not just in the Medicare and Medicaid programs, but in the overall health care system. Simply cutting Medicare and Medicaid without making other changes will do little to solve the larger problem we face. Skyrocketing health care costs are hurting families, businesses, and State and Federal budgets. In a speech before the

Business Roundtable on March 12th, President Obama emphasized this point: ''Medicare costs are consuming our Federal budget. Medicaid is overwhelming our State budgets. At the fiscal summit we held in the White House a few weeks ago, the one thing on which everyone agreed was that the greatest threat to America's fiscal health is not the investments we've made to rescue our economy. It is the skyrocketing cost of our health care system.''

Health care reform is about achieving three important goals: choice, quality, and affordability. To achieve these three goals, we must confront the fact that our health care system does not deliver care as effectively or efficiently as it should. There is widespread agreement that Americans are not getting good value for the money we are already spending on health care. According to work by the Dartmouth Atlas Project, nearly 30 percent of total spending in our health care system, or $700 billion per year, is wasteful and does nothing to improve health outcomes.

Despite our high level of health care spending, health outcomes in the United States are no better than health outcomes in the other OECD countries. Indeed, the U.S. spends twice as much as other OECD nations on health care, yet Americans have shorter average life expectancies and higher average mortality rates than residents of other OECD countries. OECD data show that the U.S. has one of the highest rates of medical errors among industrialized nations and that U.S. patients are more likely to receive duplicate tests and more likely to visit an emergency room for a condition that could have been treated in a regular office visit than most other nations in the comparison. Similarly, a 2008 Commonwealth Fund report found that the U.S. is last among 19 industrialized nations in preventable mortality, or deaths that could have been prevented if individuals had access to timely and effective care.

We can and must find ways to deliver health care more efficiently, reduce ineffective or unnecessary care, and get better health outcomes without harming patients.

One solution is to generate better information about the relative clinical effectiveness of alternative health strategies—and encourage patients and providers to use that information to make better choices about their health. Many health care services and treatments are absorbed quickly into routine medical care—yet there is little evidence that these services and treatments are any more clinically effective than existing treatments and services. Generating more comparative clinical effectiveness research is one of the keys to transforming our health care system away from a system based on volume toward a system that focuses on evidence-based medicine and improving patient outcomes.

The Federal Government currently funds some comparative effectiveness research through the Agency for Healthcare Research and Quality, AHRQ, the National Institutes of Health, NIH, and the Veterans Health Administration. For example, the Effective Health Care Program at AHRQ has been a successful initiative. But comparative effectiveness research is not the primary focus of any Federal agency—nor is this Federal funding occurring permanently on a large scale.

Provisions included in the American Recovery and Reinvestment Act, ARRA, temporarily expanded existing Federal efforts by providing $1.1 billion to AHRQ, NIH, and the Secretary of Health and Human Services, HHS, for such research through 2010. Important work is currently underway to develop recommendations for how best to utilize some of these resources. In particular, I would like to commend the work being done by the Institutes of Medicine, IOM, to convene a panel of experts that is tasked with making recommendations on how to spend the $400 million provided to the HHS Secretary through ARRA. The IOM panel has been doing extraordinary work in gathering ideas and input from a very broad group of stakeholders under a very tight timeline. I look forward to seeing the results of its work at the end of the month. It is this model of allowing for input from a broad set of stakeholders and of conducting priority-setting activities in a transparent way that we are hoping to advance in the legislation we are introducing today.

The Congressional Budget Office, CBO, the Medicare Payment Advisory Commission, MedPAC, and the IOM have all discussed the positive impact of creating a new entity charged solely with conducting research on the comparative effectiveness of health interventions, including pharmaceuticals, medical devices, medical procedures, diagnostic tools, medical services and other therapies.

In its June 2007 report to Congress, MedPAC issued a unanimous recommendation that ''Congress should charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers.''

And the Congressional Budget Office agrees. In a report, entitled, ''Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role,'' former CBO Director Peter Orszag wrote that, ''generating better information about the costs and benefits of different treatment options—through research on the comparative effectiveness of those options—could help reduce health care spending without adversely affecting health overall.''

The IOM also supports getting better information into the hands of patients and providers. As part of its report, ''Learning What Works Best: The Nation's Need for Evidence on Comparative Effectiveness in Health Care,'' the Institute concluded that, ''[a] substantially increased capacity to conduct and evaluate research on clinical effectiveness of interventions brings many potential opportunities for improvement across a wide spectrum of healthcare needs.''

This bill that Senator BAUCUS and I are introducing today represents an important step in creating a long-term vision for expanding comparative clinical effectiveness research. The bill would significantly expand the conduct of comparative clinical effectiveness research to get better information into the hands of patients and providers in the hopes of improving health outcomes and reducing unnecessary or ineffective care.

The purpose of this bill is to provide patients and physicians with objective and credible evidence about which health care treatments and services are most clinically effective for particular patient populations. The research conducted under our bill would evaluate and compare the clinical effectiveness of two or more health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, and pharmaceutical, including biologicals

Access to better evidence about what works best will help patients and health care providers make better-informed decisions about how best to treat particular diseases and conditions. Our hope is that the evidence generated by this research could lead to savings in the overall health care system over the long-term by empowering patients and doctors with information about treatments and services that may be clinically ineffective, while at the same time improving health care outcomes and quality.

Specifically, our bill creates a private, nonprofit corporation, known as the Patient-Centered Outcomes Research Institute, which would be responsible setting national research priorities and carrying out a comparative clinical effectiveness research agenda. In conducting the research, the Institute would contract with AHRQ, the VA, and other appropriate public and private entities and could use a variety of research methods, including clinical trials, observational studies and systematic reviews of existing evidence.

Many leading experts on this issue, such as MedPAC, have concerns that a large entity within the Federal government would be vulnerable to political interference that could hamper the Institute's credibility, and, therefore, limit the usefulness of its research. As a result, we chose a model outside of the Federal government, but subject to government oversight.

In order to ensure that the information developed is credible and unbiased, our bill establishes a 21-Member Board of Governors to oversee the Institute's activities. Permanent board members would include the HHS Secretary and

the Directors of AHRQ and NIH. The remaining 18 board members would be appointed by the Comptroller General of the U.S. and would include a balanced mix of patients, physicians, public and private payers, academic researchers, philanthropic organizations, quality improvement entities, and medical technology manufacturers.

To ensure further credibility, the Institute is also required to appoint expert advisory panels of patients, clinicians, researchers and other stakeholders that would assist in the development and carrying out of the research agenda; establish a methodology committee that would help create methodological standards by which all research commissioned by the Institute must be conducted; create a peer review process through which all primary research findings must be assessed; and develop protocols to help translate and disseminate the evidence in the most effective, user-friendly way.

Moreover, Senator BAUCUS and I want to ensure that the operations of the Institute are transparent and focused on the needs of patients. Therefore, we built in a strong role for public comment prior to all key decisions made by the Institute. For example, the bill requires public comment periods prior to the approval of research priorities and individual study designs. In addition, the bill calls for public forums to seek input, requires that all proceedings of the Institute be made public at least seven days in advance and be made available through annual reports, and requires that any conflicts of interest be made public and that board members recuse themselves from matters in which they have a financial or personal interest.

Because all health care users will benefit from this research, our legislation funds the Institute with contributions from both public and private payers. These contributions will include mandatory general revenues from the Federal Government, amounts from the Medicare Trust Funds equal to $2 per beneficiary annually, and amounts from a $2 fee per-covered life assessed annually on insured and self-insured health plans. Funding will ramp up over a series of years. By the 5th year, we expect the Institute's total annual funding to reach nearly $600 million per year and continue to grow thereafter.

The concept of an all-payer approach for comparative effectiveness research has been embraced by a number of health care experts. For example, on the subject of comparative effectiveness information in its June 2008 report, MedPAC stated: ''The Commission supports funding from federal and private sources as the research findings will benefit all users—patients, providers, private health plans, and federal health programs. The Commission also supports a dedicated funding mechanism to help ensure the entity's independence and stability. Dedicated broadly based financing would reduce the likelihood of outside influence and would best ensure the entity's stability . . .''

To ensure accountability for these funds and to the Institute's mission, our bill requires an annual financial audit of the Institute. In addition, the bill requires GAO to report to Congress every five years on the processes developed by the Institute and its overall effectiveness, including how the research findings are used by health care consumers and what impact the research is having on the health economy. Finally, the bill requires a review of the adequacy of the Institute's funding, which will include a review of the appropriateness and adequacy of each funding source.

Let me take a moment to address some of the criticisms that might be levied against this proposal. Some may say this Institute will impede access to care and will deny coverage for high-cost health care services. That is simply not the case. Our proposal explicitly prohibits the Institute from making coverage decisions or setting practice guidelines. It will be up to medical societies and patient groups to use the research findings as they see fit. Moreover, to the extent that high-cost health care services or new technologies are studied by the Institute and found to be clinically ineffective compared to other services and technologies, such evidence will be made public to consumers and providers so that they can make informed choices.

We have been working with colleagues on the other side of the aisle who have concerns about the impact this research could have on patient safety and access to health care treatments and services. For several months, we have been engaged in an active dialogue to address these concerns. While I am disappointed that those discussions did not result in cosponsorships for this legislation at this time, I look forward to continuing that dialogue in a constructive manner as we work to include a long-term vision for comparative effectiveness research in a comprehensive health reform bill.

In the meantime, we have made a number of meaningful changes to our legislation that address the concerns voiced by our colleagues. For example, we have placed a greater focus on aspects of personalized medicine and included new patient safeguards to ensure that when CMS uses this research it does so through a process that is transparent, allows for public comment, and takes into account the benefits to particular subpopulations.

This bill is a balanced, carefully crafted proposal that has taken into consideration the recommendations of a broad range of stakeholders and thought-leaders. We welcome further discussion and suggested improvements. But we refuse to allow this proposal to get bogged down in political maneuvering or scare tactics. Our nation needs to immediately ramp up and sustain a major comparative clinical effectiveness research initiative to improve health outcomes and reduce ineffective and inefficient care.

Senator BAUCUS and I will work jointly to push for the expeditious enactment of this bill as part of a comprehensive health reform bill. I urge all of my colleagues to join our effort and cosponsor the Patient-Centered Outcomes Research Act of 2009. There is no time to waste.

By Mr. LIEBERMAN (for himself, Mr. CASEY, Mr. BOND, Ms. STABENOW, Mr. CARDIN, Mr. SANDERS, Mr. WHITEHOUSE, and Mr. CRAPO):

S. 1214. A bill to conserve fish and aquatic communities in the United States through partnerships that foster fish habitat conservation, to improve the quality of life for the people of the United States, and for other purposes; to the Committee on Environment and Public Works.

Mr. LIEBERMAN. Mr. President, I rise to speak about the National Fish Habitat Conservation Act, which I am introducing today along with my colleagues Senators BOND, CASEY, STABENOW, CARDIN, WHITEHOUSE, and SANDERS. This legislation will significantly advance ongoing efforts to restore and protect fish habitat, improve the health of our waterways and ensure that we have robust fish populations far into the future.

Today, nearly half of our fish populations are in decline and half of our waters are impaired, which is why it is especially important that we work together to protect and restore remaining habitat. The National Fish Habitat Conservation Act will leverage federal, state and private funds to support voluntary regional conservation partnerships, which in turn will allow federal and state governments, the recreational and commercial fishing industries, the conservation community, and businesses to work together—for the first time—to effectively conserve aquatic habitats.

Our legislation authorizes $75 million annually for fish habitat projects. Based on the highly successful North American Wetlands Conservation Act model, the bill establishes a multi-stakeholder National Fish Habitat Board to recommend science-based conservation projects to the Secretary of Interior for funding. Regional partners will then work to implement those conservation projects to protect, restore and enhance fish habitats and fish populations.

The National Fish Habitat Conservation Act will go a long way toward ensuring the viability of our fish and their habitats for generations to come. I look forward to working with my colleagues to pass this important legislation and reverse the decline of our ailing waterways and fisheries.

By Mr. CASEY (for himself and Mr. SCHUMER):

S. 1215. A bill to amend the Safe Drinking Water Act to repeal a certain

exemption for hydraulic fracturing, and for other purposes; to the Committee on Environment and Public Works.

Mr. CASEY. Mr. President, I rise today to introduce the Fracturing Responsibility and Awareness of Chemicals, FRAC, Act along with my colleague, Senator SCHUMER, that protects drinking water and public health from the risks associated with an oil and gas extraction process called hydraulic fracturing. Specifically, our bill does two things. First, it repeals an exemption to the Safe Drinking Water Act that was granted to oil and gas companies four years ago. Second, it requires oil and gas companies to publicly disclose the chemicals used in hydraulic fracturing.

The regulation of hydraulic fracturing under the Safe Drinking Water Act is supported by 77 groups, including 14 groups from Pennsylvania.

The oil and gas industry uses hydraulic fracturing in 90 percent of wells. The process, which is also called ''fracking,'' involves injecting tens of thousands of gallons of water mixed with sand and chemical additives deep into the rock under extremely high pressure. The pressure breaks open the rock releasing trapped natural gas, which is then captured. Fracking often occurs near underground sources of drinking water. Unfortunately, a provision included in the 2005 Energy Policy Act exempted hydraulic fracturing from compliance with the Safe Drinking Water Act. The oil and gas industry is the only industry to have this exemption.

The Casey-Schumer legislation is extremely important to people living in Pennsylvania, especially those living in communities along a geological formation called the Marcellus Shale. The Marcellus is a geological formation covering 34 million acres extending from southern New York, through central and western Pennsylvania, into the eastern half of Ohio and across most of West Virginia. The deepest layer of the Marcellus formation—the Marcellus Shale—contains a significant amount of natural gas trapped in deep rock formations up to 9,000 feet below ground. Last year, a professor at Penn State estimated that there was 168 million cubic feet of natural gas in the Marcellus Shale. In the industry it is what is known as a ''Super Giant gas field.'' It is enough natural gas to provide for the entire country for 7 years. This vast amount of natural gas combined with a more complete knowledge of the natural fractures in the Marcellus Shale through which the gas can be easily extracted, has led to what Pennsylvanians are calling a gas rush.

As I have mentioned, fracking involves injecting water mixed with chemicals. My major concern is that the chemicals added to the water to create fracking fluids are highly toxic. We're talking about chemicals like formaldehyde, benzene, and toluene. These chemicals are injected right below underground drinking water. This is especially important to Pennsylvania because our state has the second highest number of private wells for drinking water in the nation, second only to Michigan. Three million Pennsylvanians are dependent on private wells to provide safe drinking water to their homes. So massive drilling to get to the natural gas in the Marcellus Shale is not required to comply with the Safe Drinking Water Act, but drilling is happening right next to drinking water supplies. You can see why Pennsylvanians are concerned about their future access to safe drinking water.

Now, the oil and gas industry would have you believe that there is no threat to drinking water from hydraulic fracturing. But the fact is we are already seeing cases in Pennsylvania, Colorado, Virginia, West Virginia, Alabama, Wyoming, Ohio, Arkansas, Utah, Texas, and New Mexico where residents have become ill or groundwater has become contaminated after hydraulic fracturing operations began in the area. This is not simply anecdotal evidence; scientists have found enough evidence to raise concerns as well. In a recent letter supporting our bill, 23 health professionals and scientists wrote the following:

> . . . Oil and gas operations are known to release substances into the environment that are known to be very hazardous to human health, including benzene, arsenic, mercury, hydrogen sulfide, and radioactive materials. The demonstrated health effects caused by these substances include cancers, central nervous system damage, skin and eye irritation, and lung diseases. For example, fluids used in the hydraulic fracturing process may contain toxic chemicals such as 2–butoxyethanol, formaldehyde, sodium hydroxide, glycol ethers, and naphthalene. For these reasons, we support regulation of hydraulic fracturing under the Safe Drinking Water Act and the disclosure of all chemical constituents in hydraulic fracturing fluids to public agencies, including the disclosure of constituent formulas in cases of medical need. Moreover, we support full regulation of stormwater runoff, which can pollute drinking water supplies, under the Clean Water Act.
>
> There are growing reports of individuals living near oil and gas operations who suffer illnesses that are linked to these activities, yet there has been no systemic attempt to gather the necessary data, establish appropriate monitoring, analyze health exposure or assess risk related to any of these activities. This should be done, in addition to full Health Impact Assessments to inform future planning and policy efforts.

In Dimock, Pennsylvania, we have a recent example of the risks involved with hydraulic fracturing. On New Year's Day, Norma Fiorentino's drinking water well exploded. It literally blew up. Stray methane leaked and migrated upward through the rock and into the aquifer as natural gas deposits were drilled nearby. An investigation by the Commonwealth of Pennsylvania shows that a spark created when the pump in the well house turned on may have led to the explosion. The blast cracked in half the several-thousand-pound concrete slab at the drilling pad on Ms. Fiorentino's property and tossed it aside. Fortunately, no one was hurt in the explosion. But throughout the town, several drinking water wells have exploded and nine wells have been found to contain so much natural gas that one homeowner was advised to open a window if he plans to take a bath. Tests of the well water show high amounts of aluminum and iron, which leads researchers to believe that drilling fluids are contaminating the water along with the gas. So this is a real concern. We are talking about serious implications if we don't develop the Marcellus Shale carefully and responsibly.

I would point out that Pennsylvania has a long history of developing our natural resources to power the region and the nation. In fact, Pennsylvania is home to the Drake Well near Titusville, Pennsylvania, which celebrates its 150th anniversary this year. The Drake Well was the first commercial oil well in the United States and it launched the modern petroleum industry. In addition to oil, Western Pennsylvania has long produced natural gas. Pennsylvania also mines coal which we use to provide electricity to many of our neighboring states. Pennsylvanians are proud of the contributions we have made to the growth of our nation. Contributions that were made because we developed our abundant natural resources. But we also bear the burden of some environmental legacies, most created in previous generations when we were not as concerned with responsible development. We have old natural gas wells that were not capped and leak methane into homes in Versailles, PA. We have acid mine drainage that we spend millions of dollars every year to try and remediate. These examples are the lessons from which we need to learn.

Pennsylvania will develop the natural gas in the Marcellus Shale. We are doing it right now, and we will see more drilling over the next few years. But we must develop the Marcellus Shale using the best environmental practices to protect our communities and our state. That is why I am introducing the Fracturing Responsibility and Awareness of Chemicals Act. This legislation will ensure that hydraulic fracturing does not unnecessarily jeopardize our groundwater. There are affordable alternatives that oil and gas companies can use so that they are not risking contaminating drinking water wells with potentially hazardous chemicals.

I think Norma Fiorentino from Dimock, Pennsylvania, summed it up best when she told a reporter, ''You can't buy a good well.''

So I urge all of my colleagues to support this legislation and ensure that our groundwater is protected as we responsibly develop our natural resources.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1215

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Fracturing Responsibility and Awareness of Chemicals (FRAC) Act''.

SEC. 2. REGULATION OF HYDRAULIC FRACTURING.

(a) UNDERGROUND INJECTION.—Section 1421(d) of the Safe Drinking Water Act (42 U.S.C. 300h(d)) is amended by striking paragraph (1) and inserting the following:

''(1) UNDERGROUND INJECTION.—

''(A) IN GENERAL.—The term 'underground injection' means the subsurface emplacement of fluids by well injection.

''(B) INCLUSION.—The term 'underground injection' includes the underground injection of fluids or propping agents pursuant to hydraulic fracturing operations relating to oil or gas production activities.

''(C) EXCLUSION.—The term 'underground injection' does not include the underground injection of natural gas for the purpose of storage.''.

(b) DISCLOSURE.—Section 1421(b) of the Safe Drinking Water Act (42 U.S.C. 300h(b)) is amended—

(1) in paragraph (1)(C), by inserting before the semicolon the following: '', including a requirement that any person using hydraulic fracturing disclose to the State (or to the Administrator in any case in which the Administrator has primary enforcement responsibility in a State) the chemical constituents (but not the proprietary chemical formulas) used in the fracturing process''; and

(2) by adding at the end the following:

''(4) DISCLOSURES OF CHEMICAL CONSTITUENTS.—

''(A) IN GENERAL.—The State (or the Administrator, as applicable) shall make available to the public the information contained in each disclosure of chemical constituents under paragraph (1)(C), including by posting the information on an appropriate Internet website.

''(B) IMMEDIATE DISCLOSURE IN CASE OF EMERGENCY.—

''(i) IN GENERAL.—Subject to clause (ii), the regulations promulgated pursuant to subsection (a) shall require that, in any case in which the State (or the Administrator, as applicable) or an appropriate treating physician or nurse determines that a medical emergency exists and the proprietary chemical formula or specific chemical identity of a trade-secret chemical used in hydraulic fracturing is necessary for emergency or first-aid treatment, the applicable person using hydraulic fracturing shall immediately disclose to the State (or the Administrator) or the treating physician or nurse the proprietary chemical formula or specific chemical identity of a trade-secret chemical, regardless of the existence of—

''(I) a written statement of need; or

''(II) a confidentiality agreement.

''(ii) REQUIREMENT.—A person using hydraulic fracturing that makes a disclosure required under clause (i) may require the execution of a written statement of need and a confidentiality agreement as soon as practicable after the determination by the State (or the Administrator) or the treating physician or nurse under that clause.''.

By Mr. KOHL:

S. 1219. A bill to amend subtitle A of the Antitrust Criminal Penalty Enhancement and Reform Act of 2004 to extend the operation of such subtitle for a 1-year period ending June 22, 2010; to the Committee on the Judiciary.

Mr. KOHL. Mr. President, I rise today to introduce the Antitrust Criminal Penalties Enforcement and Reform Act of 2004 Extension Act. This legislation extends a critical component of the Antitrust Criminal Penalty Enforcement and Reform Act of 2004, set to expire on June 22, which encourages participation in the Antitrust Division's leniency program. As a result, the Justice Department will be able to continue to detect, investigate and aggressively prosecute price-fixing cartels which harm consumers.

The Antitrust Division of the Department of Justice has long considered criminal cartel enforcement a top priority, and its Corporate Leniency Policy is an important tool in that enforcement. Criminal antitrust offenses are generally conspiracies among competitors to fix prices, rig bids, or allocate markets of customers. The Leniency Policy creates incentives for corporations to report their unlawful cartel conduct to the Division, by offering the possibility of immunity from criminal charges to the first-reporting corporation, as long as there is full cooperation. For more than 15 years, this policy has allowed the Division to uncover cartels affecting billions of dollars worth of commerce here in the U.S., which has led to prosecutions resulting in record fines and jail sentences.

An important part of the Division's Leniency Policy, added by the Antitrust Criminal Penalties Enforcement and Reform Act of 2004, limits the civil liability of leniency participants to the actual damages caused by that company—rather than triple the damages caused by the entire conspiracy, which is the typical in civil antitrust lawsuits. This removed a significant disincentive to participation in the leniency program—the concern that, despite immunity from criminal charges, a participating corporation might still be on the hook for treble damages in any future antitrust lawsuits.

Maintaining strong incentives to make use of the Leniency Policy provides important benefits to the victims of antitrust offenses, often consumers who paid artificially high prices. It makes it more likely that criminal antitrust violations will be reported and, as a result, consumers will be able to identify and recover their losses from paying illegally inflated prices. The policy also requires participants to cooperate with plaintiffs in any follow-on civil lawsuits, which makes it more likely that the plaintiff consumers will be able to build strong cases against all members of the conspiracy.

Since the passage of ACPERA, the Antitrust Division has uncovered a number of significant cartel cases through its leniency program, including the air cargo investigation, which so far has yielded over a billion dollars in criminal fines. In that investigation, several airlines pled guilty to conspiring to fix international air cargo rates and international passenger fuel surcharges. Not only were criminal fines levied, but one high-ranking executive pled guilty and agreed to serve eight months in prison. In fiscal year 2004, before the passage of ACPERA, criminal antitrust fines totaled $350 million. Criminal antitrust fines in fiscal year 2009 have already surpassed $960 million. Scott Hammond, the Deputy Assistant Attorney General for Criminal Enforcement in the Antitrust Division, has stated that the damages limitation has made its Corporate Leniency Program ''even more effective'' at detecting and prosecuting cartels.

ACPERA's damages limitation is set to expire later this month, so we must act quickly to extend it. Otherwise, the Justice Department will lose an important tool that it uses to investigate and prosecute criminal cartel activity. This bill extends that provision for 1 year. Over the next year, we will fully review ACPERA, and consider potential changes to make it more effective.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1219

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Antitrust Criminal Penalties Enforcement and Reform Act of 2004 Extension Act''.

SEC. 2. DELAY OF SUNSET.

Section 211(a) of the Antitrust Criminal Penalty Enhancement and Reform Act of 2004 (15 U.S.C. 1 note) is amended by striking ''5 years'' and inserting ''6 years''.

SEC. 3. EFFECTIVE DATE OF AMENDMENT.

The amendment made by section 2 shall take effect immediately before June 22, 2009.

By Mr. SPECTER (for himself and Mr. WYDEN):

S. 1220. A bill to require that certain complex diagnostic laboratory tests performed by an independent laboratory after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected shall be treated as services for which payment may be made directly to the laboratory under part B of title XVIII of the Social Security Act; to the Committee on Finance.

Mr. SPECTER. Mr. President, I have sought recognition today to introduce The Patient Access to Critical Lab Tests Act. The legislation would modernize Medicare billing rules to improve beneficiary access to important, life-saving advanced diagnostic technologies.

Mapping the human genome has enabled revolutionary advances in understanding a wide variety of diseases, and ushered in an era where treatments can be tailored to individual patients based on their DNA and specific molecular character of their disease. Complex diagnostic laboratory tests make such ''personalized medicine'' possible. By understanding the molecular nature of

disease, these new technologies increasingly allow clinicians and patients to pick individualized treatment options, rather than basing treatment choices on broad assessments of what works best for a population.

Unfortunately Medicare payment, coding and coverage practices are harming Medicare beneficiary access to specialized diagnostic tests. In particular is the Centers for Medicare and Medicaid Services, CMS, Medicare ''date of service'' regulation. Under the regulation, any test furnished within 14 days after the patient's discharge from a hospital is deemed to have been performed on the day of collection, when the patient was in or at the hospital, even though the patient may no longer be at the hospital when the test is ordered, and the test is not used to guide treatment during the patient's hospital encounter. A laboratory test that is deemed to coincide with the date on which the patient was a hospital patient becomes a service furnished by the hospital, even though the hospital may have nothing to do with the ordering, performance, or use of the test.

The combination of these rules creates a host of administrative and financial disincentives for hospitals to embrace these tests.

Hospitals are required to exercise professional responsibility over these services, but are unwilling to do so for tests that are not offered by the hospital, and which are, in fact, offered by laboratories that are otherwise unaffiliated with and unfamiliar to the hospital.

Hospitals are required to bill for the service; the laboratories may not bill Medicare directly, and instead must bill the hospital for the services they provide, which means the hospital assumes the financial risk that the service is covered and that Medicare will pay for it.

In light of these administrative and financial disincentives, hospitals are encouraging physicians to delay ordering the tests until after the 14 days; others are cancelling orders altogether. These disincentives create obstacles for physicians and their patients, and genuine barriers to access these beneficial tests.

These rules also create substantial hardship for the laboratories that are seeking to develop these tests. In order for the tests to be covered, hospitals must enter into agreements with the laboratories furnishing the tests. It is administratively overwhelming for these small laboratories to seek to enter into agreements with all potential originating hospitals, which may number in the thousands when considering sites where tissue may be stored.

The legislation that I am introducing today with Senator WYDEN would require CMS to take a small, but important step toward facilitating Medicare beneficiary access to innovative, lifesaving diagnostic tests by updating the ''date of service'' regulation. Specifically, the Patient Access to Critical Lab Tests Act would permit independent laboratories offering complex diagnostic laboratory tests to bill Medicare directly for tests performed anytime following a patient's hospital stay, without forcing the hospital into an unnecessary middleman role.

Given the promise of these new technologies, it is important that all regulatory regimes keep pace with the rapidly evolving world of science and technology, and operate to promote innovation. Out-dated regulations and calcified regulatory agencies can stifle innovation and prevent new life-saving diagnostics and therapies from ever coming to market. They can also serve as a drag on our economy.

Fixing this rule is a matter of critical importance to Medicare beneficiaries, as well as to the laboratories developing these technologies.

I encourage colleagues to join Senator WYDEN and me in cosponsoring this bill. I likewise urge Senators BAUCUS and GRASSLEY to consider this important measure as part of health care reform.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1220

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Access to Critical Lab Tests Act''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—The Congress finds as follows:

(1) Timely access to laboratory testing is essential to ensure quality of care for patients.

(2) Genetic and molecular laboratory testing are the new cornerstones of high quality, cost-effective preventive medicine.

(3) The completion of the Human Genome Project in 2003 paved the way for a more sophisticated understanding of disease causation, which has contributed to the advent of ''personalized medicine''.

(4) Personalized medicine is the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a patient's predisposition to a particular disease or condition.

(5) Personalized medicine offers the promise of smarter, more effective, and safer care as physicians and patients become equipped with better information to guide treatment decisions.

(6) Some of the most encouraging personalized medicine developments involve highly specialized laboratory tests that, using biomarkers and vast stores of historical data, provide individualized information that enable physicians and patients to develop personalized treatment plans.

(7) Several outdated Medicare regulations for laboratory billing are obstructing access to highly specialized laboratory tests and delaying patients' diagnoses and treatments. These same rules are discouraging investments in development of new tests.

(8) Realizing the promise of personalized medicine will require improved regulation that appropriately encourages development of and access to these specialized tests.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) where practical, Medicare regulations and policies should be written to promote development of and access to the highly specialized laboratory tests referred to in subsection (a)(6); and

(2) the Medicare regulation described in section 414.510 of title 42, Code of Federal Regulations, is one such regulation that should be revised to permit laboratories furnishing certain specialized tests to bill for and be paid directly by Medicare for furnishing such tests.

SEC. 3. TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS.

(a) IN GENERAL.—Notwithstanding sections 1862(a)(14) and 1866(a)(1)(H)(i) of the Social Security Act (42 U.S.C. 1395y(a)(14) and 1395cc(a)(1)(H)(i)), in the case that a laboratory performs a covered complex diagnostic laboratory test, with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital, if the test is performed after such period the Secretary of Health and Human Services shall treat such test, for purposes of providing direct payment to the laboratory under section 1833(h) or 1848 of such Act (42 U.S.C. 13951(h) or 1395w–4), as if such specimen had been collected directly by the laboratory.

(b) COVERED COMPLEX DIAGNOSTIC LABORATORY TEST DEFINED.—For purposes of this section, the term ''covered complex diagnostic laboratory test'' means an analysis—

(1) of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies, or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, or gene expression or similar method or is a cancer chemotherapy sensitivity assay or similar method, but does not include methods principally comprising routine chemistry or routine immunology;

(2) that is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3));

(3) that is developed and performed by a laboratory which is independent of the hospital in which the specimen involved was collected and not under any arrangements (as defined in section 1861(w)(1) of such Act (42 U.S.C. 1395x(w)(1)); and

(4) that is not furnished by the hospital where the specimen was collected to a patient of such hospital, directly or under arrangements (as defined in section 1861(w)(1) of such Act (42 U.S.C. 1395x(w)(1)) made by such hospital.

SEC. 4. EFFECTIVE DATE.

The provisions of section 3 shall apply to tests furnished on or after the date of the enactment of this Act.

By Mr. SPECTER (for himself and Mr. ROBERTS):

S. 1221. A bill to amend title XVIII of the Social Security Act to ensure more appropriate payment amounts for drugs and biologicals under part B of the Medicare Program by excluding customary prompt pay discounts extended to wholesalers from the manufacturer's average sales price; to the Committee on Finance.

Mr. SPECTER. Mr. President, I have sought recognition today to introduce legislation that will help ensure Medicare beneficiaries' access to cancer drugs provided by community-based cancer clinics.

Cancer takes a great toll on our families, friends, and our Nation. On average, one American dies from cancer each minute and the overall cost of cancer to the U.S. is $220 billion annually. While these statistics are daunting, the rate of cancer deaths in the U.S. has decreased since 1993. This decrease is the result of earlier detection and diagnosis, more effective and targeted cancer therapies, and greater accessibility to quality care provided by oncologists. These vital services have allowed millions of individuals to lead healthy and productive lives after successfully battling cancer.

Leading the treatment against cancer, community cancer clinics treat 84 percent of Americans with cancer. Community cancer clinics are freestanding outpatient facilities that provide comprehensive cancer care in physician's office settings located in patients' communities. These clinics are especially critical in rural areas where access to larger cancer clinics is not available.

In 2003, the Medicare Prescription Drug Improvement and Modernization Act was signed into law. This legislation contained numerous provisions that were beneficial to America's seniors and medical facilities; however, it also provided a reduction in Medicare's reimbursement for cancer treatment. The new Medicare drug reimbursement rates, based on average sales price or ASP, are artificially lowered by the inclusion of prompt payment discounts. These discounts are provided by the pharmaceutical manufacturer to the distributor and are a financing mechanism between the manufacturer and the distributor for prompt payment of invoices. As such, they are not passed on to community oncology clinics, which purchase drugs from distributors. However, pharmaceutical manufacturers are required by statute to include all discounts and rebates in the calculation of ASP, including prompt payment discounts that are not provided to community oncology clinics. The inclusion of these prompt payment discounts results in the artificially lowering of Medicare drug reimbursement rates by approximately 2 percent. Community cancer clinics are reporting that they are finding more cancer drugs reimbursed by Medicare at a rate less than their cost.

The Congressional Budget Office estimated that Medicare reimbursements to oncologists would be reduced by $4.2 billion from 2004–2013. PricewaterhouseCoopers estimated that reductions will reach $14.7 billion over that time. This increased reduction will have a debilitating effect on oncologists' ability to provide cancer treatment to Medicare beneficiaries, especially those in the community setting.

This legislation will remove manufacturer to distributor prompt payment discounts from the calculation of ASP to provide a more appropriate Medicare drug reimbursement and will help ensure Medicare beneficiaries' access to community-based cancer treatment. I encourage my colleagues to work with me to move this legislation forward promptly.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1221

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS EXTENDED TO WHOLESALERS FROM MANUFACTURER'S AVERAGE SALES PRICE FOR PAYMENTS FOR DRUGS AND BIOLOGICALS UNDER MEDICARE PART B.

(a) IN GENERAL.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended—

(1) in the first sentence, by inserting ''(other than customary prompt pay discounts extended to wholesalers)'' after ''prompt pay discounts''; and

(2) in the second sentence, by inserting ''(other than customary prompt pay discounts extended to wholesalers)'' after ''other price concessions''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs and biologicals that are furnished on or after January 1, 2010.

By Mr. MCCONNELL (for himself, Mrs. FEINSTEIN, Mr. MCCAIN, and Mr. DURBIN:)

S.J. Res. 17. A joint resolution approving the renewal of import restrictions contained in the Burmese Freedom and Democracy Act of 2003, and for other purposes; to the Committee on Finance.

Mr. MCCONNELL. Mr. President, I rise to introduce the annual renewal of the Burmese Freedom and Democracy Act of 2003. Once again, I am joined by Senators FEINSTEIN, MCCAIN and DURBIN who have been steadfast and longtime advocates for the Burmese people.

This resolution extends for another year the sanctions that are currently in place against the illegitimate Burmese regime, the State Peace and Development Council, SPDC. This bill would keep those sanctions in place unless and until the regime takes a number of clear steps towards democracy and reconciliation. This measure also includes renewal of the enhanced sanctions enacted last year as part of the Tom Lantos Block Burmese JADE Act of 2008.

As many of my colleagues know, the news from Burma has been particularly troubling of late. Nobel Peace Prize winner Daw Aung San Suu Kyi, who has been under house arrest for 13 of the last 19 years, was charged last month with permitting a misguided American to enter her home. As a result, she faces up to 5 years in prison. My colleagues in the Senate and I remain deeply concerned about the outcome of her ''trial.'' I was pleased that the Senate responded to this outrageous prosecution by unanimously passing S. Res. 160, which condemned the ''trial'' of Suu Kyi and the dubious actions taken by the SPDC against her.

The Obama administration has indicated that a new strategy on Burma is forthcoming, and I look forward to reviewing it. Whatever the content of this strategy, it appears from correspondence between my House colleagues and the State Department that the administration will continue to support sanctions against the Burmese regime, even as it considers additional means of effecting positive change in the troubled country.

Mr. President, I ask unanimous consent that the text of the joint resolution be printed in the RECORD.

There being no objection, the text of the joint resolution was ordered to be printed in the RECORD, as follows:

S.J. RES. 17

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. AMENDMENT TO BURMESE FREEDOM AND DEMOCRACY ACT OF 2003.

Section 9(b)(3) of the Burmese Freedom and Democracy Act of 2003 (Public Law 108–61; 50 U.S.C. 1701 note) is amended by striking ''six years'' and inserting ''nine years''.

SEC. 2. RENEWAL OF IMPORT RESTRICTIONS UNDER BURMESE FREEDOM AND DEMOCRACY ACT OF 2003.

(a) IN GENERAL.—Congress approves the renewal of the import restrictions contained in section 3(a)(1) and section 3A (b)(1) and (c)(1) of the Burmese Freedom and Democracy Act of 2003.

(b) RULE OF CONSTRUCTION.—This joint resolution shall be deemed to be a ''renewal resolution'' for purposes of section 9 of the Burmese Freedom and Democracy Act of 2003.

SEC. 3. EFFECTIVE DATE.

This joint resolution and the amendments made by this joint resolution shall take effect on the date of the enactment of this joint resolution or July 26, 2009, whichever occurs first.

Mrs. FEINSTEIN. Mr. President, I rise today with Senator MCCONNELL to introduce a joint resolution renewing the ban on all imports from Burma for another year.

I regret that we must take this action once again.

I had hoped that since we last took up this resolution last year, the ruling military junta, the State Peace and Development Council, SPDC, would have, at long last, heeded the voices of the people of Burma and the international community and put Burma on a path to democracy, human rights, and the rule of law.

Sadly, the regime responded to these calls in true fashion, by trying yet again to break the will of Burma's democratic opposition and stifle any movement for change.

Just last month, the military junta arrested and detained Nobel Peace Prize Laureate and Burma's democratically elected leader Aung San Suu Kyi on trumped-up charges of violating her house arrest.

Currently standing trial—behind closed doors and without due process—she faces up to 5 years in prison if convicted. This will come on top of spending the better part of the past 19 years isolated and alone under house arrest.

The regime's actions should come as no surprise. They represent yet another attempt to hold on to power and crush any opposition.

Almost 20 years ago, it annulled parliamentary election results overwhelmingly won by Aung San Suu Kyi's National League for Democracy.

Six years ago government-sponsored thugs attempted to assassinate Suu Kyi and other members of her National League for Democracy by attacking her motorcade in northern Burma.

Two years ago, the regime brutally put down pro-democracy demonstrations of the Saffron Revolution led by Buddhist monks.

And last year, we saw the regime ignore offers made by the international community and international humanitarian organizations to help Burma respond to the devastation caused by Cyclone Nargis, leading to countless deaths of innocent civilians.

In addition, they imposed a new constitution on the people of Burma, one that was negotiated behind closed doors without the input of the democratic opposition and one that will entrench the military's grip on power.

The SPDC understands all too well that the vast majority of Burmese citizens embrace Suu Kyi's call for freedom and democracy and reject the junta's oppressive rule.

That is why they are trying once again to silence her voice.

We cannot allow this brutal dictatorship to succeed.

For those of my colleagues who are disappointed with the lack of progress in bringing freedom and democracy to Burma since we first enacted this ban in 2003, I share their disappointment.

But now is not the time to turn back. Now is not the time to reward the regime for its oppressive tactics by lifting any part of our sanctions regime on Burma.

It has not made ''substantial and measurable progress'' towards:

ending violations of internationally recognized human rights;

releasing all political prisoners;

allowing freedom of speech and press;

allowing freedom of association;

permitting the peaceful exercise of religion and;

bringing to a conclusion an agreement between the SPDC and the National League for Democracy and Burma's ethnic nationalities on the restoration of a democratic government.

By renewing the import ban we express our solidarity with Aung San Suu Kyi and the democratic opposition who bravely stand up to the regime and reject their abuses.

They understand that the import ban is not directed at the people of Burma, but at the military junta that dominates economic and political activity in their country and denies them their rights.

And I remind my colleagues that this import ban renewal is good for 1 year and we will have the opportunity to revisit this issue again next year.

I am hopeful that the United Nations Security Council and the international community will follow our example and put additional pressure on the SPDC to release Aung San Suu Kyi and all political prisoners immediately and unconditionally and engage in a true dialogue on national reconciliation, one that will lead to a truly democratic constitution.

I urge my colleagues to pass this Joint Resolution as soon as possible.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 173—SUPPORTING NATIONAL MEN'S HEALTH WEEK

Mr. CRAPO submitted the following resolution; which was referred to the Committee on Health, Education, Labor, and Pensions:

S. RES. 173

Whereas despite advances in medical technology and research, men continue to live an average of more than 5 years less than women, and African-American men have the lowest life expectancy;

Whereas 9 of the 10 leading causes of death, as defined by the Centers for Disease Control and Prevention, affect men at a higher percentage than women;

Whereas between ages 45 and 54, men are 3 times more likely than women to die of heart attacks;

Whereas men die of heart disease at 1½ times the rate of women;

Whereas men die of cancer at almost 1½ times the rate of women;

Whereas testicular cancer is 1 of the most common cancers in men aged 15 to 34, and when detected early, has a 96 percent survival rate;

Whereas the number of cases of colon cancer among men will reach almost 75,590 in 2009, and almost ½ of those men will die from the disease;

Whereas the likelihood that a man will develop prostate cancer is 1 in 6;

Whereas the number of men developing prostate cancer in 2009 will reach more than 192,280, and an estimated 27,360 of them will die from the disease;

Whereas African-American men in the United States have the highest incidence in the world of prostate cancer;

Whereas significant numbers of health problems that affect men, such as prostate cancer, testicular cancer, colon cancer, and infertility, could be detected and treated if men's awareness of such problems was more pervasive;

Whereas more than ½ of the elderly widows now living in poverty were not poor before the death of their husbands, and by age 100, women outnumber men 8 to 1;

Whereas educating both the public and health care providers about the importance of early detection of male health problems will result in reducing rates of mortality for these diseases;

Whereas appropriate use of tests such as prostate specific antigen exams, blood pressure screenings, and cholesterol screenings, in conjunction with clinical examination and self-testing for problems such as testicular cancer, can result in the detection of many problems in their early stages and increase the survival rates to nearly 100 percent;

Whereas women are twice as likely as men to visit the doctor for annual examinations and preventive services;

Whereas men are less likely than women to visit their health center or physician for regular screening examinations of male-related problems for a variety of reasons, including fear, lack of health insurance, lack of information, and cost factors;

Whereas National Men's Health Week was established by Congress in 1994 and urges men and their families to engage in appropriate health behaviors, and the resulting increased awareness has improved health-related education and helped prevent illness;

Whereas the governors of more than 45 States issue proclamations annually declaring Men's Health Week in their States;

Whereas since 1994, National Men's Health Week has been celebrated each June by dozens of States, cities, localities, public health departments, health care entities, churches, and community organizations throughout the Nation that promote health awareness events focused on men and family;

Whereas the National Men's Health Week Internet website has been established at www.menshealthweek.org and features governors' proclamations and National Men's Health Week events;

Whereas men who are educated about the value that preventive health can play in prolonging their lifespan and their role as productive family members will be more likely to participate in health screenings;

Whereas men and their families are encouraged to increase their awareness of the importance of a healthy lifestyle, regular exercise, and medical checkups; and

Whereas June 15 through June 21, 2009, is National Men's Health Week, which has the purpose of heightening the awareness of preventable health problems and encouraging early detection and treatment of disease among men and boys: Now, therefore, be it

Resolved, That the Senate—

(1) supports the annual National Men's Health Week in 2009; and

(2) calls upon the people of the United States and interested groups to observe National Men's Health Week with appropriate ceremonies and activities.

SENATE RESOLUTION 174—RECOGNIZING THE REGION FROM MANHATTAN, KANSAS TO COLUMBIA, MISSOURI AS THE KANSAS CITY ANIMAL HEALTH CORRIDOR

Mr. BOND (for himself, Mr. ROBERTS, Mr. BROWNBACK, and Mrs. MCCASKILL) submitted the following resolution; which was referred to the Committee on the Agriculture, Nutrition, and Forestry:

S. RES. 174

Whereas a 34 percent of the $16,800,000,000 annual global animal health industry is based in the Kansas City region;

Whereas more than 120 companies involved in the animal health industry are located in Kansas and Missouri, including 4 of the 10 largest global animal health companies and 1 of the 5 largest animal nutrition companies;

Whereas several leading veterinary colleges and animal research centers are located in Kansas and Missouri, including the College of Veterinary Medicine and the $54,000,000 Biosecurity Research Institute of Kansas State University and the College of Veterinary Medicine, the College of Agriculture, Food and Natural Resources' Division of Animal Sciences, the $60,000,000 Life Sciences Center, the National Swine Resource and Research Center, and the Research Animal Diagnostic Laboratory of the University of Missouri;

Whereas Kansas City, Missouri, is centrally located in the United States and is