Management, the same office that governs the health insurance of Federal employees and Members of Congress.

There is a part in this bill on tort reform. It sets up State grants to test alternatives to litigation.

In my remaining minute, let's don't forget the 31 million more people who are going to come in insured and how this, over time, is going to bring down the cost of Medicare. It is not going to cut Medicare. It is going to save Medicare. It is going to do that with efficiencies such as electronic records and accountable care organizations and emphasis on primary care physicians.

To conclude, what else does the bill do? It lowers the deficit over the next 10 years by $132 billion. In the second 10-year period, it is going to lower it by up to $1.3 trillion. That is serious deficit reduction.

On that happy note, I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Let me thank Senator NELSON for his strong commitment to Medicare. I know of no Senator who fights harder for Medicare and for making prescription drugs more affordable to seniors than the Senator from Florida. He has contributed his great expertise as a former insurance commissioner to the provisions we have in this bill on cracking down on insurance company abuses, and he just went through some of them there. I thank my good friend Senator NELSON from Florida for all of his great input into this bill.

In a few minutes, the Senate will close its doors for a brief recess. When those doors reopen just after midnight, the Senate will reconvene for a historic purpose: to bring the promise of quality, affordable health care to millions of Americans. When those doors reopen, we who have the privilege of serving in this body will have the opportunity to vote for hope and opportunity and new help for working families who worry every day that their illness will cause them to go bankrupt.

Mr. President, I yield the floor.

AMENDMENTS SUBMITTED AND PROPOSED

SA 3284. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table.

SA 3285. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3286. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3287. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3288. Mr. REID submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3289. Mr. REID submitted an amendment intended to be proposed to amendment SA 3288 submitted by Mr. REID and intended to be proposed to the amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3290. Mr. REID submitted an amendment intended to be proposed by him to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3291. Mr. REID submitted an amendment intended to be proposed to amendment SA 3290 submitted by Mr. REID and intended to be proposed to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3292. Mr. REID submitted an amendment intended to be proposed by him to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3293. Mr. MCCAIN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 3284. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—HEALTHY MOTHERS AND HEALTHY BABIES

SEC. __01. SHORT TITLE.

This title may be cited as the ''Healthy Mothers and Healthy Babies Access to Care Act''.

SEC. __02. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON WOMEN'S ACCESS TO HEALTH SERVICES.—Congress finds that—

(A) the current civil justice system is eroding women's access to obstetrical and gynecological services;

(B) the American College of Obstetricians and Gynecologists (ACOG) has identified nearly half of the States as having a medical liability insurance crisis that is threatening access to high-quality obstetrical and gynecological services;

(C) because of the high cost of medical liability insurance and the risk of being sued, one in seven obstetricians and gynecologists have stopped practicing obstetrics and one in five has decreased their number of high-risk obstetrics patients; and

(D) because of the lack of availability of obstetrical services, women—

(i) must travel longer distances and cross State lines to find a doctor;

(ii) have longer waiting periods (in some cases months) for appointments;

(iii) have shorter visits with their physicians once they get appointments;

(iv) have less access to maternal-fetal medicine specialists, physicians with the most experience and training in the care of women with high-risk pregnancies; and

(v) have fewer hospitals with maternity wards where they can deliver their child, potentially endangering the lives and health of the woman and her unborn child.

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

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

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

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

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

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

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

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

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

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

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

SEC. __03. DEFINITIONS.

In this title:

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

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

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

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

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

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

(D) any other publicly or privately funded program.

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

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

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

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

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

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

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider who delivers obstetrical or gynecological services or a health care institution (only with respect to obstetrical or gynecological services) regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

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

(12) HEALTH CARE PROVIDER.—

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

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

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

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

(15) OBSTETRICAL OR GYNECOLOGICAL SERVICES.—The term ''obstetrical or gynecological services'' means services for prenatal care or labor and delivery, including the immediate postpartum period (as determined in accordance with the definition of postpartum used for purposes of title XIX of the Social Security Act (42 U.S.C. 1396 et seq.)).

(16) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider who delivers obstetrical or gynecological services or a health care institution. Punitive damages are neither economic nor noneconomic damages.

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

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

SEC. _04. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

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

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

(1) fraud;

(2) intentional concealment; or

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

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

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

SEC. _05. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing

in this title shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

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

(2) HEALTH CARE INSTITUTIONS.—

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

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

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

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

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

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

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations provided for in subsection (b), the future noneconomic damages shall be reduced first.

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

SEC. __06. MAXIMIZING PATIENT RECOVERY.

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

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

(2) CONTINGENCY FEES.—

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

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

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

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

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

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

(b) APPLICABILITY.—

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

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

(c) EXPERT WITNESSES.—

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

(A) except as required under paragraph (2), is a health care professional who—

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

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

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

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

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

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

SEC. __07. ADDITIONAL HEALTH BENEFITS.

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

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

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

SEC. __08. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

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

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

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

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

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

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

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

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

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

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

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

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

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

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

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

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

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

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

SEC. __09. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

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

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

SEC. __10. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

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

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

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

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

(b) SMALLPOX VACCINE INJURY.—

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

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

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

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

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

SEC. __11. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

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

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

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

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this title shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this title, notwithstanding section __05(a).

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

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

(2) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections for a health care provider or health care institution from liability, loss, or damages than those provided by this title;

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

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

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

SEC. __12. APPLICABILITY; EFFECTIVE DATE.

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

SA 3285. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 80, line 22, strike ''and''.

On page 80, after line 25, add the following:

''(i) adherence to or participation in reasonably designed programs of health promotion and disease prevention, if such programs exist; and''.

On page 81, line 4, insert before the period the following: '', except that group health plans and health insurance issuers offering group or individual health insurance coverage may establish premium discounts or rebates for modifying otherwise applicable copayments or deductibles in return for adherence to or participation in reasonably designed programs of health promotion or disease prevention''.

Beginning on page 84, strike line 15 and all that follows through line 3 on page 94, and insert the following:

''(j) PROGRAMS OF HEALTH PROMOTION OR DISEASE PREVENTION.—

''(1) GENERAL PROVISIONS.—

''(A) GENERAL RULE.—For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a 'wellness program') shall be a program that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.

''(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

''(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

''(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.—If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

''(A) A program that reimburses all or part of the cost for memberships in a fitness center.

''(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

''(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under an individual or group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

''(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.

''(E) A program that provides a reward to individuals for attending a periodic health education seminar.

''(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described

in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

''(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

''(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease. The plan or issuer shall evaluate the program's reasonableness at least once per year.

''(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

''(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

''(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—

''(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

''(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

''(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

''(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

''(k) EXISTING PROGRAMS.—Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to the date of enactment of this section and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.

''(l) REGULATIONS.—Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.''.

SA 3286. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 114, beginning with line 17, strike all through page 116, line 6, and insert the following:

(e) CATASTROPHIC PLAN.—A health plan not providing a bronze, silver, gold, or platinum level of coverage shall be treated as meeting the requirements of subsection (d) with respect to any plan year if the plan provides—

(1) except as provided in paragraph (1), the essential health benefits determined under subsection (b), except that the plan provides no benefits for any plan year until the individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year (except as provided for in section 2713); and

(2) coverage for at least three primary care visits.

On page 155, beginning with line 22, strike all through page 156, line 3, and insert the following:

(A) INDIVIDUALS ALLOWED TO ENROLL IN ANY PLAN.—A qualified individual may enroll in any qualified health plan.

On page 250, lines 7 through 10, strike '', except that such term shall not include a qualified health plan which is a catastrophic health plan described in section 1302(e) of such Act''.

SA 3287. Mr. GREGG submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PREVENTING THE GAMING OF THE 10 YEAR BUDGET WINDOW.

Section 402 of the Congressional Budget Act of 1974 5 (2 U.S. C. 653) is amended—

(1) in paragraph (2), by striking ''and'' after the semicolon;

(2) in paragraph (3), by striking the period and insert ''; and''; and

(3) by inserting at the end the following:

''(4) for any provisions with delayed effective dates or phase-in periods, an estimate of the costs for the year that the provision first becomes fully effective and for each of the following 9 fiscal years.''.

SA 3288. Mr. REID submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the amendment, insert the following: The provisions of this section shall be effective upon enactment.

SA 3289. Mr. REID submitted an amendment intended to be proposed to amendment SA 3289 submitted by Mr. REID and intended to be proposed to the amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

In the amendment, strike ''upon enactment'' and insert ''5 days after enactment''.

SA 3290. Mr. REID submitted an amendment intended to be proposed by him to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the language proposed to be stricken, insert the following:

This section shall become effective 4 days after enactment.

SA 3291. Mr. REID submitted an amendment intended to be proposed to amendment SA 3290 submitted by Mr. REID and intended to be proposed to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was orded to lie on the table; as follows:

In the amendment, strike ''upon enactment'' and insert ''5 days after enactment''.

SA 3292. Mr. REID submitted an amendment intended to be proposed by him to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the amendment, insert the following:

This section shall become effective 5 days after enactment.

SA 3293. Mr. MCCAIN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 1859, strike line 6 and all that follows through line 5 on page 1906, and insert the following:

Subtitle A—Patient Access to Safe and Competitive Biologics

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the ''Patient Access to Safe and Competitive Biologics Act''.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR THERAPEUTICALLY EQUIVALENT.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting ''under this subsection or subsection (k)'' after ''biologics license''; and

(2) by adding at the end the following:

''(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR THERAPEUTICALLY EQUIVALENT.—

''(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

''(2) CONTENT.—

''(A) IN GENERAL.—

''(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

''(I) the biological product is biosimilar to a reference product based upon data derived from—

''(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

''(bb) animal studies (including the assessment of toxicity); and

''(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) conducted by the applicant that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

''(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

''(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

''(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

''(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, after public notice and comment, that an element described in item (aa) or (bb) of clause (i)(I) is unnecessary in an application submitted under this subsection.

''(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

''(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

''(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

''(B) THERAPEUTIC EQUIVALENCE.—If a sponsor submits an application (or supplement to an application) under this subsection claiming that the biologics product is therapeutically equivalent to the reference product, such application (or supplement) shall include information demonstrating that the biological product meets the standards described in paragraph (4)(A).

''(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

''(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

''(i) is biosimilar to the reference product; or

''(ii) meets the standards described in paragraph (4)(A), and therefore is therapeutically equivalent to the reference product; and

''(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(4) SAFETY STANDARDS FOR DETERMINING THERAPEUTIC EQUIVALENCE.—

''(A) DETERMINATION BY THE SECRETARY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to have demonstrated therapeutic equivalence to the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

''(i) the biological product—

''(I) is biosimilar to the reference product; and

''(II) can be expected to produce the same clinical result as the reference product in any given patient; and

''(ii) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

''(B) APPLICATION OF THERAPEUTIC EQUIVALENCE ONLY WITH PRESCRIPTION.—Notwithstanding any other provision of law, no biological product determined to be therapeutically equivalent to a reference product under subparagraph (A) shall be deemed to be therapeutically appropriate with respect to an individual unless so determined by a health care professional treating such individual.

''(5) GENERAL RULES.—

''(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

''(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

''(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

''(6) EXCLUSIVITY FOR FIRST THERAPEUTICALLY EQUIVALENT BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of therapeutic equivalence for any condition of use, the Secretary shall not make a determination under paragraph (4)(A) that the second or subsequent biological product is therapeutically equivalent for any condition of use until the earlier of—

''(A) 1 year after the first commercial marketing of the first biosimilar biological product to be approved as therapeutically equivalent for that reference product;

''(B) 18 months after—

''(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved therapeutically equivalent biosimilar biological product; or

''(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved therapeutically equivalent biosimilar biological product; or

''(C)(i) 42 months after approval of the first therapeutically equivalent biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

''(ii) 18 months after approval of the first therapeutically equivalent biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

''(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

''(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—

''(i) IN GENERAL.—Except as provided in clause (ii) and (iii), approval of an application under this subsection may not be made effective by the Secretary until the date that is 10 years after the date on which the reference product was first licensed under subsection (a).

''(ii) EXTENSION OF EXCLUSIVITY.—The period of exclusivity described in clause (i) for a reference product shall be extended for an additional 2 years beyond the 10 years provided in such clause if the sponsor or manufacturer of the reference product submits a subsequent application for a change (not including a modification to the structure of the reference product) that results in a new indication for the reference product.

''(iii) SIGNIFICANT THERAPEUTIC ADVANCEMENT.—If a reference product represents a

significant therapeutic advancement (including a modification that results in a new dosage form, new dosing regimen, or new route of administration of such biological product) of a biological product that was previously licensed under subsection (a) and that has the same sponsor or manufacturer as such reference product, then the period of exclusivity for such reference product shall be the number of years equal to the sum of—

''(I) the remaining period of exclusivity under clause (i) for biological product on which the reference product representing the significant therapeutic advancement was based, plus

''(II) 2 years.

''(iv) NO EXTENSION FOR SIGNIFICANT THERAPEUTIC ADVANCEMENT.—In no case may the period of exclusivity under clause (iii) be extended.

''(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

''(C) FIRST LICENSURE.—The date on which the reference product was first licensed under subsection (a) does not include the date of approval of a supplement or of a subsequent application for a new indication, route of administration, dosage form, or strength for the previously licensed reference product.

''(8) GUIDANCE DOCUMENTS.—

''(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

''(B) PUBLIC COMMENT.—

''(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

''(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

''(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

''(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

''(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

''(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4)(A).

''(E) CERTAIN PRODUCT CLASSES.—

''(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

''(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

''(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

''(l) PATENTS.—

''(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

''(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

''(B) IN GENERAL.—

''(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information').

''(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

''(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

''(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

''(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

''(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

''(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

''(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

''(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

''(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

''(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

''(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

''(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

''(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

''(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

''(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

''(3) LIST AND DESCRIPTION OF PATENTS.—

''(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

''(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

''(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

''(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

''(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

''(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

''(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

''(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

''(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

''(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

''(4) PATENT RESOLUTION NEGOTIATIONS.—

''(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

''(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

''(5) PATENT RESOLUTION IF NO AGREEMENT.—

''(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

''(B) EXCHANGE OF PATENT LISTS.—

''(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

''(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

''(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

''(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

''(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

''(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

''(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

''(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

''(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

''(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

''(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

''(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

''(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

''(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

''(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

''(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

''(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

''(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

''(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

''(ii) not included, as applicable, on—

''(I) the list of patents described in paragraph (4); or

''(II) the lists of patents described in paragraph (5)(B).

''(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

''(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

''(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

''(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

''(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.''.

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking ''In this section, the term 'biological product' means'' and inserting the following: ''In this section:

''(1) The term 'biological product' means'';

(2) in paragraph (1), as so designated, by inserting ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,''; and

(3) by adding at the end the following:

''(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

''(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

''(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

''(3) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

''(4) The term 'therapeutically equivalent' or 'therapeutic equivalence', in reference to a biological product, means that such product has been determined to meet the standards described in subsection (k)(4).''.

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''or'' at the end;

(ii) in subparagraph (B), by adding ''or'' at the end; and

(iii) by inserting after subparagraph (B) the following:

''(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

''(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,''; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)), by striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product'';

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product''; and

(II) striking ''and'' at the end;

(ii) in subparagraph (C), by—

(I) striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product''; and

(II) striking the period and inserting '', and'';

(iii) by inserting after subparagraph (C) the following:

''(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.''; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking ''and (C)'' and inserting ''(C), and (D)''; and

(C) by adding at the end the following:

''(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

''(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

''(ii) for which an action for infringement of the patent with respect to the biological product—

''(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

''(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

''(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

''(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.''.

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: '', or section 351 of the Public Health Service Act''.

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: ''or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies''.

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by adding at the end the following:

''(n) NEW ACTIVE INGREDIENT.—

''(1) NON-THERAPEUTICALLY EQUIVALENT BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for therapeutic equivalence with the reference product, shall be considered to have a new active ingredient under this section.

''(2) THERAPEUTICALLY EQUIVALENT BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is therapeutically equivalent with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.''.

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the ''Secretary'') before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term ''biological product'' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(B)) is amended by striking ''section 351'' and inserting ''subsection (a) or (k) of section 351''.

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT.—

(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(m) PEDIATRIC STUDIES.—

''(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (l), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

''(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

''(A) the periods for such biological product referred to in subsection (k)(7)(B) are deemed to be 4 years and 6 months rather than 4 years and the date that is 6 months after the date described in subsection (k)(7)(A) rather than the date described in such subsection; and; and

''(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

''(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

''(A) the periods for such biological product referred to in subsection (k)(7)(B) are deemed to be 4 years and 6 months rather than 4 years and the date that is 6 months after the date described in subsection (k)(7)(A) rather than the date described in such subsection; and

''(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

''(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.''.

(2) STUDIES REGARDING PEDIATRIC RESEARCH.—

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS.—Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended by inserting '', biological products,'' after ''including drugs''.

(B) INSTITUTE OF MEDICINE STUDY.—Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

''(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Patient Access to Safe and Competitive Biologics Act and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

''(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

''(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.''.

(h) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar or therapeutically equivalent to, such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of—

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the period of exclusivity described in subsection (k)(7)(A) of such section 351.

RECESS UNTIL 12:01 A.M. TOMORROW

The PRESIDING OFFICER. The time of the Senator has expired.

Under the previous order, the Senate stands in recess until 12:01 a.m., Monday, December 21, 2009.

Thereupon, the Senate, at 11:31 p.m., recessed until Monday, December 21, 2009, at 12:01 a.m.