game winning streak in this season's playoffs;

Whereas Pat Burns, head coach of the New Jersey Devils, has enjoyed the kind of success that has eluded so many other great coaches, winning his first Stanley Cup title in his first season as head coach of the Devils;

Whereas Byron Scott, head coach of the New Jersey Nets, has guided the Nets to the most wins in franchise history, and has led them to the NBA Finals in 2 of his 3 seasons as head coach;

Whereas Martin Brodeur, regarded by many as the premier playoff goaltender in hockey history, recorded 3 shutouts in the Finals, giving him 7 shutouts during this season's playoffs and 20 during his illustrious postseason career;

Whereas the outstanding playmaking abilities of Jason Kidd, widely regarded as the best point guard in the NBA, has been key to the success of the Nets during the past 2 seasons;

Whereas the outstanding play of Ken Daneyko, Martin Brodeur, Scott Stevens, Sergei Brylin, and Scott Neidermayer has been a vital part of each of the 3 Stanley Cup Championships enjoyed by the New Jersey Devils organization;

Whereas Jason Kidd has superb teammates in Brandon Armstrong, Jason Collins, Lucious Harris, Richard Jefferson, Anthony Johnson, Kerry Kittles, Donny Marshall, Kenyon Martin, Dikembe Mutombo, Rodney Rogers, Brian Scalabrine, Tamar Slay, and Aaron Williams, allowing the team to win its second consecutive NBA Eastern Conference championship; and

Whereas the name of each Devils player will be inscribed on the Stanley Cup, including Tommy Albelin, Jiri Bicek, Martin Brodeur, Sergei Brylin, Ken Daneyko, Patrik Elias, Jeff Friesen, Brian Gionta, Scott Gomez, Jamie Langenbrunner, John Madden, Grant Marshall, Jim McKenzie, Scott Niedermayer, Joe Nieuwendyk, Jay Pandolfo, Brian Rafalski, Pascal Rheaume, Mike Rupp, Corey Schwab, Richard Schmelik, Scott Stevens, Turner Stevenson, Oleg Tverdovsky, and Colin White: Now, therefore, be it

Resolved, That the Senate congratulates—

(1) the New Jersey Devils for their determination, perseverance, and excellence in winning the National Hockey League's 2003 Stanley Cup; and

(2) the New Jersey Nets for their success during the 2002-2003 NBA season.

SENATE RESOLUTION 177—TO DIRECT THE SENATE COMMISSION ON ART TO SELECT AN APPROPRIATE SCENE COMMEMORATING THE GREAT COMPROMISE OF OUR FOREFATHERS ESTABLISHING A BICAMERAL CONGRESS WITH EQUAL STATE REPRESENTATION IN THE UNITED STATES SENATE, TO BE PLACED IN THE LUNETTE SPACE IN THE SENATE RECEPTION ROOM IMMEDIATELY ABOVE THE ENTRANCE INTO THE SENATE CHAMBER LOBBY, AND TO AUTHORIZE THE COMMITTEE ON RULES AND ADMINISTRATION TO OBTAIN TECHNICAL ADVICE AND ASSISTANCE IN CARRYING OUT ITS DUTIES

Mr. DODD submitted the following resolution, which was referred to the Committee on Rules and Administration:

S. RES. 177

Resolved, That (a) a Member of the Senate or any other person may not remove a work of art, historical object, or an exhibit from the Senate wing of the Capitol or any Senate office building for personal use.

(b) For purposes of this resolution, the term ''work of art, historical object, or an exhibit'' means an item, including furniture, identified on the list (and any supplement to the list) required by section 4 of Senate Resolution 382, 90th Congress, as enacted into law by section 901(a) of Public Law 100–696 (2 U.S.C. 2104).

(c) For purposes of this resolution, the Senate Commission on Art shall update the list required by section 4 of Senate Resolution 382, 90th Congress (2 U.S.C. 2104) every 6 months after the date of adoption of this resolution and shall provide a copy of the updated list to the Committee on Rules and Administration.

AMENDMENTS SUBMITTED & PROPOSED

SA 936. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table.

SA 937. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 938. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 939. Mr. DASCHLE (for himself, Mr. NELSON of Nebraska, Ms. MIKULSKI, and Mr. JOHNSON) proposed an amendment to the bill S. 1, supra.

SA 940. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 941. Mr. WYDEN (for himself, Mrs. MURRAY, and Mr. SMITH) submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 942. Ms. CANTWELL submitted an amendment intended to be proposed by her to the bill S. 1, supra; which was ordered to lie on the table.

SA 943. Ms. CANTWELL submitted an amendment intended to be proposed by her to the bill S. 1, supra; which was ordered to lie on the table.

SA 944. Mr. ENZI (for Ms. CANTWELL) proposed an amendment to amendment SA 932 proposed by Mr. ENZI (for himself, Mr. REED, and Mr. PRYOR) to the bill S. 1, supra.

SA 945. Mr. GREGG (for himself, Mr. SCHUMER, Mr. MCCAIN, Mr. KENNEDY, Mr. ROBERTS, Mr. EDWARDS, Ms. COLLINS, Mr. LEAHY, Mr. JOHNSON, Mr. FEINGOLD, Mr. HARKIN, Mr. KOHL, Mr. SMITH, Ms. STABENOW, Mr. MILLER, and Mr. COLEMAN) proposed an amendment to the bill S. 1, supra.

SA 946. Mr. DORGAN (for himself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEAHY, Mrs. BOXER, Mr. PRYOR, Mr. FEINGOLD, and Ms. COLLINS) proposed an amendment to the bill S. 1, supra.

SA 947. Mr. FRIST (for Mr. COCHRAN (for himself, Mr. FRIST, Mr. BREAUX, and Mr. SANTORUM)) proposed an amendment to amendment SA 946 proposed by Mr. DORGAN (for himself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEAHY, Mrs. BOXER, Mr. PRYOR, Mr. FEINGOLD, and Ms. COLLINS) to the bill S. 1, supra.

SA 948. Mr. GRAHAM, of South Carolina submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 949. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 950. Mr. PRYOR submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 936. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table, as follows:

At the end of subtitle C of title II, add the following:

SEC. ____. EXTENSION OF DEMONSTRATION FOR ESRD MANAGED CARE.

The Secretary shall extend without interruption, through December 31, 2007, the approval of the demonstration project, Contract No. H1021, under the authority of section 2355(b)(1)(B)(iv) of the Deficit Reduction Act of 1984, as amended by section 13567 of the Omnibus Reconciliation Act of 1993. Such approval shall be subject to the terms and conditions in effect for the 2002 project year with respect to eligible participants and covered benefits. The Secretary shall set the monthly capitation rate for enrollees on the basis of the reasonable medical and direct administrative costs of providing those benefits to such participants.

SA 937. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table, as follows:

At the end of subtitle B of title IV, add the following:

SEC. ____. PROHIBITION OF INCIDENTAL FEES AND REQUIRED PURCHASE OF NONCOVERED ITEMS OR SERVICES UNDER MEDICARE.

(a) IN GENERAL.—Section 1842 (42 U.S.C. 1395u) is amended by adding at the end the following new subsection:

''(u) PROHIBITION OF INCIDENTAL FEES OR REQUIRING PURCHASE OF NONCOVERED ITEMS OR SERVICES.—

''(1) IN GENERAL.—A physician, practitioner (as described in section 1842(b)(18)(C)), or other individual may not—

''(A) charge a membership fee or any other incidental fee to a medicare beneficiary (as defined in section 1802(b)(5)(A)); or

''(B) require a medicare beneficiary (as so defined) to purchase a noncovered item or service,

as a prerequisite for the provision of a covered item or service to the beneficiary under this title.

''(2) CONSTRUCTION.—Nothing in this subsection shall be construed to apply the prohibition under paragraph (1) to a physician, practitioner, or other individual described in such subsection who does not accept any funds under this title.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to membership fees and other charges made, or purchases of items and services required, on or after the date of enactment of this Act.

SA 938. Mr. NELSON of Florida submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle B of title IV, add the following:

SEC. ____. GAO STUDY AND REPORT ON THE PROPAGATION OF CONCIERGE CARE.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on concierge care (as defined in paragraph (2)) to determine the extent to which such care—

(A) is used by medicare beneficiaries (as defined in section 1802(b)(5)(A) of the Social Security Act (42 U.S.C. 1395a(b)(5)(A))); and

(B) has impacted upon the access of medicare beneficiaries (as so defined) to items and services for which reimbursement is provided under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) CONCIERGE CARE.—In this section, the term ''concierge care'' means an arrangement under which, as a prerequisite for the provision of a health care item or service to an individual, a physician, practitioner (as described in section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C))), or other individual—

(A) charges a membership fee or another incidental fee to an individual desiring to receive the health care item or service from such physician, practitioner, or other individual; or

(B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

(b) REPORT.—Not later than the date that is 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a)(1) together with such recommendations for legislative or administrative action as the Comptroller General determines to be appropriate.

SA 939. Mr. DASCHLE (for himself, Mr. NELSON of Nebraska, Ms. MIKULSKI, and Mr. JOHNSON) proposed an amendment to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; as follows:

On page 103, strike lines 10 though 13 and insert the following:

''(B) the lesser of—

''(i) the amount by which the monthly plan premium approved by the Administrator for the plan exceeds the amount of the monthly national average premium; or

''(ii) in the case of an eligible beneficiary who is enrolled in a Medicare Prescription Drug plan that provides standard prescription drug coverage or an actuarially equivalent prescription drug coverage and does not provide additional prescription drug coverage pursuant to section 1860D–6(a)(2), an amount equal to 10 percent of the amount of the monthly national average premium.

On page 77, strike lines 10 through 22 and insert the following:

''(A) IN GENERAL.—In the case of an eligible beneficiary receiving access to qualified prescription drug coverage through enrollment with an entity with a contract under paragraph (1)(B), the monthly beneficiary obligation of such beneficiary for such enrollment shall be an amount equal to the lesser of—

''(i) the applicable percent (for the area in which the beneficiary resides, as determined under section 1860D–17(c)) of the monthly national average premium (as computed under section 1860D–15) for the year as adjusted using the geographic adjuster under subparagraph (B); or

''(ii) 110 percent of an amount equal to the applicable percent (as determined under section 1860D–17(c) before any adjustment under paragraph (2) of such section) of the monthly national average premium (as computed under section 1860D–15 before any adjustment under subsection (b) of such section) for the year.

SA 940. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

On page 200, between lines 13 and 14, insert the following:

SEC. ____. ACCESS TO DISCOUNTED PRESCRIPTION DRUGS.

(a) IN GENERAL.—From amounts made available under subsection (c), the Secretary of Health and Human Services shall award grants to covered entities described in section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) to enable such entities to pay the start-up costs associated with the establishment of pharmacies to provide covered drugs under such section 340B.

(b) APPLICATION.—To be eligible to receive a grant under subsection (a), a covered entity shall prepare and submit to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.

(c) FUNDING.—There shall be made available from the Prescription Drug Account established under section 1860DD-25 of the Social Security Act, $300,000,000 to carry out this section. Amounts made available under this subsection shall remain available until expended.

SA 941. Mr. WYDEN (for himself, Mrs. MURRAY, and Mr. SMITH) submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title IV, add the following:

SEC. ____. MEDPAC STUDY ON MEDICARE PAYMENTS AND EFFICIENCIES IN THE HEALTH CARE SYSTEM.

Not later than 18 months after the date of enactment of this Act, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall provide Congress with recommendations to recognize and reward, within payment methodologies for physicians and hospitals established under the medicare program under title XVIII of the Social Security Act, efficiencies, and the lower utilization of services created by the practice of medicine in historically efficient and low-cost areas. Measures of efficiency recognized in accordance with the preceding sentence shall include—

(1) shorter hospital stays than the national average;

(2) fewer physician visits than the national average;

(3) fewer laboratory tests than the national average;

(4) a greater utilization of hospice services than the national average; and

(5) the efficacy of disease management and preventive health services.

SA 942. Ms. CANTWELL submitted an amendment intended to be proposed by her to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

On page 204, after line 22, insert the following:

SEC. 133. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

(a) MEDICARE.—Subpart 3 of part D of title XVIII of the Social Security Act (as added by section 101) is amended by adding at the end the following new section:

''PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS

''SEC. 1860D–27. Notwithstanding any other provision of law, an eligible entity offering a Medicare Prescription Drug plan under this part or a MedicareAdvantage organization offering a MedicareAdvantage plan under part C shall not enter into a contract with any pharmacy benefit manager (in this section referred to as a 'PBM') to manage the prescription drug coverage provided under such plan, or to control the costs of such coverage, unless the PBM satisfies the following requirements:

''(1) The PBM is not owned by a pharmaceutical manufacturing company.

''(2) The PBM agrees to pass along any cost savings negotiated with a pharmacy to the Medicare Prescription Drug plan or the MedicareAdvantage plan.

''(3) The PBM agrees to make public on an annual basis the percent of manufacturer's rebates received by the PBM that is passed back to the Medicare Prescription Drug plan or the MedicareAdvantage plan on a drug-by-drug basis.

''(4) The PBM agrees to provide, at least annually, the Medicare Prescription Drug plan or the MedicareAdvantage plan with all financial and utilization information requested by the plan relating to the provision of benefits to eligible beneficiaries through the PBM and all financial and utilization information relating to services provided to the plan. A PBM providing information under this paragraph may designate that information as confidential. Information designated as confidential by a PBM and provided to a plan under this paragraph may not be disclosed to any person without the consent of the PBM.

''(5) The PBM agrees to provide, at least annually, the Medicare Prescription Drug plan or the MedicareAdvantage plan with all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler, including formulary management and drug-switch programs, educational support, claims processing and

pharmacy network fees that are charged from retail pharmacies and data sales fees.

''(6) The PBM agrees to disclose the retail cost of a prescription drug upon request by a consumer.''.

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

''SEC. 714. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

''The provisions of section 1860D–27 of the Social Security Act shall apply to a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, in the same manner as such provisions apply to an eligible entity offering a Medicare Prescription Drug plan under part D of title XVIII of the Social Security Act or to a MedicareAdvantage organization offering a MedicareAdvantage plan under part C of title XVIII of that Act.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following:

''Sec. 714. Pharmacy benefit managers transparency requirements.''.

(3) EFFECTIVE DATES.—The amendments made by this subsection shall apply with respect to plan years beginning on or after the date of enactment of this Act.

(c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE GROUP MARKET.—

(1) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following:

''SEC. 2707. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

''The provisions of section 1860D–27 of the Social Security Act shall apply to a group health plan and a health insurance issuer providing health insurance coverage in connection with a group health plan, in the same manner as such provisions apply to an eligible entity offering a Medicare Prescription Drug plan under part D of title XVIII of the Social Security Act or to a MedicareAdvantage organization offering a MedicareAdvantage plan under part C of title XVIII of that Act.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to group health plans and health insurance issuers in connection with group health plans for plan years beginning on or after the date of enactment of this Act.

(d) AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE INDIVIDUAL MARKET.—

(1) IN GENERAL.—The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-51 et seq.) is amended—

(A) by redesignating such subpart as subpart 2; and

(B) by adding at the end the following:

''SEC. 2753. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

''The provisions of section 1860D–27 of the Social Security Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to an eligible entity offering a Medicare Prescription Drug plan under part D of title XVIII of the Social Security Act or to a MedicareAdvantage organization offering a MedicareAdvantage plan under part C of title XVIII of that Act.''.

(2) EFFECTIVE DATE.—The amendment made by subsection (c)(1)(B) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the date of enactment of this Act.

(e) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by inserting after section 9812 the following:

''SEC. 9813. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

''The provisions of section 1860D–27 of the Social Security Act shall apply to a group health plan in the same manner as they apply to an eligible entity offering a Medicare Prescription Drug plan under part D of title XVIII of the Social Security Act or to a MedicareAdvantage organization offering a MedicareAdvantage plan under part C of title XVIII of that Act.''.

(2) CLERICAL AMENDMENT.—The table of contents for chapter 100 of such Code is amended by inserting after the item relating to section 9812 the following

''Sec. 9813. Required coverage of young adults.''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after the date of enactment of this Act.

SA 943. Ms. CANTWELL submitted an amendment intended to be proposed by her to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

On page 516, after line 22, add the following:

SEC. ___. INCENTIVE PAYMENT IN MEDICARE HEALTH PROFESSIONAL SHORTAGE AREAS DEMONSTRATION PROJECT.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

''INCENTIVE PAYMENTS IN MEDICARE HEALTH PROFESSIONAL SHORTAGE AREAS DEMONSTRATION PROJECT

''SEC. 1897. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary shall establish a demonstration project under which—

''(A) pursuant to paragraph (3), the Secretary designates areas in a State selected under paragraph (5) as medicare health professional shortage areas; and

''(B) an incentive payment is provided under part B to primary care physicians for each physician's service (as defined in section 1861(q)) that is furnished in a medicare health professional shortage area to an individual enrolled under such part.

''(2) PRIMARY CARE PHYSICIAN DEFINED.—For purposes of this section, the term 'primary care physician' has the meaning given such term for purposes of designating health professional shortage areas under section 332(a) of the Public Health Service Act (42 U.S.C. 254e(a)).

''(3) DESIGNATION OF AREAS.—The Secretary shall designate an area in a State selected under paragraph (5) as a medicare health professional shortage area if the Secretary determines, using the methodology established under subsection (b)(1)(B), that individuals enrolled under part B and residing in the area have inadequate access to primary care physicians.

''(4) TERMS AND CONDITIONS.—

''(A) INCENTIVE PAYMENT IN ADDITION TO PAYMENT OTHERWISE MADE.—

''(i) IN GENERAL.—Subject to clause (ii), the incentive payment made under the demonstration project for a physician's service shall be in addition to the amount otherwise made for the service under part B.

''(ii) NO PAYMENTS UNDER THE INCENTIVE PAYMENT PROGRAM IN A DEMONSTRATION STATE DURING OPERATION OF THE DEMONSTRATION PROGRAM.—Subject to subparagraph (D), notwithstanding section 1833(m), during the operation of the demonstration project in a State selected under paragraph (5), the Secretary may not make any incentive payment to any physician under such section for any service furnished in any part of such State, regardless of—

''(I) whether the physician is eligible for bonus payments under the demonstration program; and

''(II) where the service was furnished in the State.

''(B) AMOUNT OF INCENTIVE PAYMENT.—The amount of the incentive payment for a physician's service furnished under the demonstration project shall be an amount equal to 40 percent of the payment amount for the service under part B.

''(C) NO EFFECT ON AMOUNT OF COINSURANCE AN INDIVIDUAL IS REQUIRED TO PAY.—The amount of any coinsurance that an individual enrolled under part B is responsible for paying with respect to a physicians' service furnished to the individual shall be determined as if this section had not been enacted.

''(D) NO EFFECT ON PAYMENTS TO CRITICAL ACCESS HOSPITALS.—The amount of payment for outpatient critical access services of a critical access hospital under section 1834(g) shall be determined as if this section had not been enacted.

''(5) DEMONSTRATION SITES.—The Secretary shall conduct the demonstration project in 5 States selected by the Secretary as demonstration sites.

''(6) AUTOMATION OF INCENTIVE PAYMENTS.—

''(A) IN GENERAL.—Under the demonstration project, incentive payments under paragraph (1)(B) to a primary care physician shall be made automatically to the physician rather than the physician being responsible for determining when a payment is required to be made under that paragraph.

''(B) INCENTIVE PAYMENT BASED ON ZIP CODES.—In order to comply with subparagraph (A), the Secretary shall establish procedures in which the amount of payment otherwise made for a physician's service is automatically increased by the amount of the incentive payment under the demonstration project if the service was furnished in any zip code that is entirely or partially in a designated medicare health professional shortage area in a State selected under paragraph (5).

''(7) DURATION.—The demonstration project shall be conducted for a 3-year period. The period for establishing the methodology under subsection (b) shall not be counted for purposes determining such 3-year period.

''(b) ESTABLISHMENT OF METHODOLOGY FOR ASSISTING SECRETARY IN DESIGNATING MEDICARE HEALTH PROFESSIONAL SHORTAGE AREAS.—

''(1) IN GENERAL.—The Secretary shall select 1 or more Federal rural health research centers within the Health Resources Services Administration to establish a methodology to assist the Secretary in designating areas within the States selected under subsection (a)(5) as medicare health professional shortage areas pursuant to subsection (a)(3).

''(2) RULES FOR ESTABLISHING METHODOLOGY.—

''(A) IN GENERAL.—The methodology established under paragraph (1) shall address—

''(i) how to measure the percentage of the total population in an area that consists of individuals enrolled under part B; and

''(ii) the appropriate ratio of such individuals to primary care physicians in an area in order to ensure that such individuals have adequate access to services furnished by such physicians.

''(B) METHODOLOGY MAY BE SIMILAR TO METHODOLOGIES USED UNDER THE PUBLIC HEALTH SERVICE ACT.—The methodology established under paragraph (1) may be similar to methodologies utilized by the Secretary for designating areas, and population groups within areas, as health professional shortage areas under section 332(a) of the Public Health Service Act (42 U.S.C. 254e(a)).

''(C) CONSULTATION.—The Federal rural health research centers selected under paragraph (1) shall consult with the State and local medical societies of the States selected under subsection (a)(5) in establishing the methodology under paragraph (1).

''(c) NO EFFECT ON DESIGNATION AS A HEALTH PROFESSIONAL SHORTAGE AREA.—Except as provided in subsection (a)(4)(A)(ii), the designation of an area as a medicare health professional shortage area under subsection (a)(3) shall have no effect on the designation of such area as a health professional shortage area under section 332(a) of the Public Health Service Act (42 U.S.C. 254e(a)).

''(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XI and this title as may be necessary for the purpose of carrying out the demonstration project.

''(e) REPORT.—

''(1) IN GENERAL.—Not later than 6 months after the completion of the demonstration project, the Secretary shall submit to Congress a report on such project.

''(2) CONTENTS.—The report submitted under paragraph (1) shall contain—

''(A) an evaluation of whether the demonstration project has had the effect of stabilizing, maintaining, or increasing access of individuals enrolled under part B to physicians' services furnished by primary care physicians, including whether the amount of the incentive payment is adequate to stabilize, maintain, or increase such access and if not, then what amount will;

''(B) a comparison of the effectiveness of the demonstration project in stabilizing, maintaining, or increasing such access with the effectiveness of other Federal, State, and local programs, such as the incentive program under section 1833(m), that are designed to stabilize, maintain, or increase such access;

''(C) recommendations for such legislation and administrative actions as the Secretary considers appropriate; and

''(D) any other items that the Secretary considers appropriate.

''(f) FUNDING.—

''(1) INCENTIVE PAYMENTS.—The Secretary shall use funds in the Federal Supplementary Medical Insurance Trust Fund under section 1841 to make the incentive payments under this section.

''(2) ESTABLISHMENT OF METHODOLOGY.—

''(A) IN GENERAL.—There is authorized to be appropriated $6,000,000 to establish the methodology under subsection (b)(1).

''(B) AVAILABILITY.—Any amounts appropriated pursuant to subparagraph (A) shall remain available until expended.''.

SA 944. Mr. ENZI (for Ms. CANTWELL) proposed an amendment to amendment SA 932 proposed by Mr. ENZI (for himself, Mr. REED, and Mr. PRYOR) to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; as follows:

On page 2 of amendment SA#932 between lines 18 and 19 strike ''.'' and insert the following: ''with the auditor of the Administrator's choice.''

SA 945. Mr. GREGG (for himself, Mr. SCHUMER, Mr. MCCAIN, Mr. KENNEDY, Mr. ROBERTS, Mr. EDWARDS, Ms. COLLINS, Mr. LEAHY, Mr. JOHNSON, Mr. FEINGOLD, Mr. HARKIN, Mr. KOHL, Mr. SMITH, Ms. STABENOW, Mr. MILLER, and Mr. COLEMAN) proposed an amendment to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; as follows:

At the end, add the following:

TITLE ____—ACCESS TO AFFORDABLE PHARMACEUTICALS

SEC. ____01. SHORT TITLE.

This title may be cited as the ''Greater Access to Affordable Pharmaceuticals Act''.

SEC. ____02. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2), by striking subparagraph (B) and inserting the following:

''(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

''(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

''(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

''(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

''(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

''(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

''(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

''(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking ''under the following'' and inserting ''by applying the following to each certification made under paragraph (2)(A)(vii)''; and

(ii) in clause (iii)—

(I) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted.''; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

''(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(aa) the date on which the court enters judgment reflecting the decision; or

''(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(bb) by striking subclause (II) and inserting the following:

''(II) if before the expiration of such period the district court decides that the patent has been infringed—

''(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

''(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(cc) in subclause (III), by striking ''on the date of such court decision.'' and inserting ''as provided in subclause (I); or''; and

(dd) by inserting after subclause (III) the following:

''(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).'';

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

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

''(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under paragraph (2)(B) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

''(aa) the drug for which the application was approved; or

''(bb) an approved method of using the drug.

''(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

''(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under subparagraph (i) or a counterclaim under subparagraph (ii).''.

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b), by striking paragraph (3) and inserting the following:

''(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

''(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

''(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

''(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

''(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

''(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

''(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

''(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(2) in subsection (c)(3)—

(A) in the first sentence, by striking ''under the following'' and inserting ''by applying the following to each certification made under subsection (b)(2)(A)(iv)'';

(B) in subparagraph (C)—

(i) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted.'';

(ii) in the second sentence—

(I) by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(II) by striking clause (i) and inserting the following:

''(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(I) the date on which the court enters judgment reflecting the decision; or

''(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(III) by striking clause (ii) and inserting the following:

''(ii) if before the expiration of such period the district court decides that the patent has been infringed—

''(I) if the judgment of the district court is appealed, the approval shall be made effective on—

''(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(IV) in clause (iii), by striking ''on the date of such court decision.'' and inserting ''as provided in clause (i); or''; and

(V) by inserting after clause (iii), the following:

''(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).''; and

(iii) in the third sentence, by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(C) by redesignating subparagraph (D) as subparagraph (E); and

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

''(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under subsection (b)(3) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

''(aa) the drug for which the application was approved; or

''(bb) an approved method of using the drug.

''(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

''(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).''.

(c) INFRINGEMENT ACTIONS.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(5) The filing of an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and the failure of the owner of the patent to bring an action for infringement of a patent that is the subject of the certification before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of that section is received, shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.''.

(d) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amendments made by subsections (a), (b), and (c) apply to any proceeding under section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is pending on or after the date of enactment of this Act regardless of the date on which the proceeding was commenced or is commenced.

(2) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—The amendments made by subsections (a)(1) and (b)(1) apply with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section or in an amendment or supplement to an application filed under subsection (b)(2) or (j) of that section.

(3) EFFECTIVE DATE OF APPROVAL.—The amendments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i) apply with respect to any patent information submitted under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act.

SEC. ____03. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section ____02) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

''(iv) 180-DAY EXCLUSIVITY PERIOD.—

''(I) DEFINITIONS.—In this paragraph:

''(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

''(bb) FIRST APPLICANT.—The term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) for the drug.

''(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

''(dd) TENTATIVE APPROVAL.—

''(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

''(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

''(II) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.''; and

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

''(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

''(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

''(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

''(aa) the earlier of the date that is—

''(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

''(BB) 30 months after the date of submission of the application of the first applicant; or

''(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

''(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

''(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

''(CC) The patent expires.

''(DD) The patent is withdrawn by the holder of the application approved under subsection (b).

''(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

''(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

''(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

''(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

''(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

''(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

''(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

''(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

''(II) no applicant shall be eligible for a 180-day exclusivity period.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(D)(i)(V) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(iv) of that Act without regard to when the first certification under section 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was made.

(3) DECISION OF A COURT WHEN THE 180-DAY EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect to an application filed before, on, or after the date of enactment of this Act for a listed drug for which a certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act and for which neither of the events described in subclause (I) or (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on the day before the date of enactment of this Act) has occurred on or before the date of enactment of this Act, the term ''decision of a court'' as used in clause (iv) of section 505(j)(5)(B) of that Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

SEC. ____04. BIOAVAILABILITY AND BIOEQUIVALENCE.

(a) IN GENERAL.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

(1) by striking subparagraph (A) and inserting the following:

''(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

''(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.''; and

(2) by adding at the end the following:

''(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.''.

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter

the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. ___05. REMEDIES FOR INFRINGEMENT.

Section 287 of title 35, United States Code, is amended by adding at the end the following:

''(d) CONSIDERATION.—In making a determination with respect to remedy brought for infringement of a patent that claims a drug or a method or using a drug, the court shall consider whether information on the patent was filed as required under 21 U.S.C. 355 (b) or (c), and, if such information was required to be filed but was not, the court may refuse to award treble damages under section 284.''.

SEC. ___06. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

SA 946. Mr. DORGAN (for himself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEAHY, Mrs. BOXER, Mr. PRYOR, Mr. FEINGOLD, and Ms. COLLINS) proposed an amendment to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; as follows:

At the end, add the following:

TITLE ____—IMPORTATION OF PRESCRIPTION DRUGS

SEC. ___01. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

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

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

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

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

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

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

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

''(5) WHOLESALER.—

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

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

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

''(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a

prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(l) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

''(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) EFFECTIVENESS OF SECTION.—

''(1) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

''(2) PROCEDURE.—The Secretary shall not submit a certification under paragraph (1) unless, after a hearing on the record under sections 556 and 557 of title 5, United States Code, the Secretary—

''(A)(i) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

''(ii) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

''(iii) identifies specifically the causes of the increased risk; and

''(iv)(I) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

''(II) if the Secretary determines that any measures described in subclause (I) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

''(B) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

''(C)(i) compares in specific terms the detriment identified under subparagraph (A) with the benefits identified under subparagraph (B); and

''(ii) determines that the benefits do not outweigh the detriment.

''(o) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

SA 947. Mr. FRIST (for Mr. COCHRAN (for himself, Mr. FRIST, Mr. BREAUX, and Mr. SANTORUM)) proposed an amendment to amend SA 946 proposed by Mr. DORGAN (for himself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEAHY, Mrs. BOXER, Mr. PRYOR, Mr. FEINGOLD, and Ms. COLLINS) to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; as follows:

At the appropriate place, insert the following:

''( ) CONDITIONS.—this section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

''(A) pose no additional risk to the public's health and safety, and

''(B) result in a significant reduction in the cost of covered products to the American consumer.''.

SA 948. Mr. GRAHAM of South Carolina submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in title II, insert the following:

Subtitle ____—National Bipartisan Commission on Medicare Reform

SEC. ____01. MEDICAREADVANTAGE GOAL; ESTABLISHMENT OF COMMISSION.

(a) ENROLLMENT GOAL.—It is the goal of this title that, not later than January 1, 2010, at least 15 percent of individuals entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act and enrolled under part B of such title should be enrolled in a MedicareAdvantage plan, as determined by the Center for Medicare Choices.

(b) FAILURE TO ACHIEVE GOAL.—If the goal described in subsection (a) is not met by January 1, 2012, as determined by the Center for Medicare Choices, there shall be established a commission as described in section 2.

SEC. ___02 NATIONAL BIPARTISAN COMMISSION ON MEDICARE REFORM.

(a) ESTABLISHMENT.—Upon a determination under section ___01(b) that the enrollment goal has not been met, there shall be established a commission to be known as the National Bipartisan Commission on Medicare Reform (in this section referred to as the ''Commission'').

(b) DUTIES OF THE COMMISSION.—The Commission shall—

(1) review and analyze the long-term financial condition of the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(2) identify problems that threaten the financial integrity of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under sections 1817 and 1841 of such Act (42 U.S.C. 1395i and 1395t), including—

(A) the financial impact on the medicare program of the significant increase in the number of medicare eligible individuals; and

(B) the ability of the Federal Government to sustain the program into the future;

(3) analyze potential solutions to the problems identified under paragraph (2) that will ensure both the financial integrity of the medicare program and the provision of appropriate benefits under such program, including methods used by other nations to respond to comparable demographic patterns in eligibility for health care benefits for elderly and disabled individuals and trends in employment-related health care for retirees;

(4) make recommendations to restore the solvency of the Federal Hospital Insurance Trust Fund and the financial integrity of the Federal Supplementary Medical Insurance Trust Fund;

(5) make recommendations for establishing the appropriate financial structure of the medicare program as a whole;

(6) make recommendations for establishing the appropriate balance of benefits covered under, and beneficiary contributions to, the medicare program;

(7) make recommendations for the time periods during which the recommendations described in paragraphs (4), (5) and (6) should be implemented;

(8) make recommendations on the impact of chronic disease and disability trends on future costs and quality of services under the current benefit, financing, and delivery system structure of the medicare program;

(9) make recommendations regarding a comprehensive approach to preserve the medicare program, including ways to increase the effectiveness of the MedicareAdvantage program and to increase MedicareAdvantage enrollment rates; and

(10) review and analyze such other matters as the Commission determines appropriate.

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members, of whom—

(A) four shall be appointed by the President;

(B) six shall be appointed by the Majority Leader of the Senate, in consultation with the Minority Leader of the Senate, of whom not more than 4 shall be of the same political party;

(C) six shall be appointed by the Speaker of the House of Representatives, in consultation with the Minority Leader of the House of Representatives, of whom not more than 4 shall be of the same political party; and

(D) one, who shall serve as Chairperson of the Commission, shall be appointed jointly by the President, Majority Leader of the Senate, and the Speaker of the House of Representatives.

(2) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than April 1, 2012.

(3) TERMS OF APPOINTMENT.—The term of any member appointed under paragraph (1) shall be for the life of the Commission.

(4) MEETINGS.—The Commission shall meet at the call of the Chairperson or a majority of its members.

(5) QUORUM.—A quorum for purposes of conducting the business of the Commission shall consist of 8 members of the Commission, except that 4 members may conduct a hearing under subsection (e).

(6) VACANCIES.—A vacancy in the membership of the Commission shall be filled, not later than 30 days after the Commission is given notice of the vacancy, in the same manner in which the original appointment was made. Such a vacancy shall not affect the power of the remaining members to carry out the duties of the Commission.

(7) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

(8) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(d) STAFF AND SUPPORT SERVICES.—

(1) EXECUTIVE DIRECTOR.—

(A) APPOINTMENT.—The Chairperson shall appoint an executive director of the Commission.

(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule under title 5, United States Code.

(2) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) PHYSICAL FACILITIES.—The Administrator of the General Services Administration shall locate suitable office space for the operation of the Commission. The facilities shall serve as the headquarters of the Commission and shall include all necessary equipment and incidentals required for the proper functioning of the Commission.

(e) POWERS OF COMMISSION.—

(1) HEARINGS AND OTHER ACTIVITIES.—The Commission may hold such hearings and undertake such other activities as the Commission determines to be necessary to carry out its duties under this section.

(2) STUDIES BY GAO.—Upon the request of the Commission, the Comptroller General shall conduct such studies or investigations as the Commission determines to be necessary to carry out its duties under this section.

(3) COST ESTIMATES BY CONGRESSIONAL BUDGET OFFICE AND OFFICE OF THE CHIEF ACTUARY OF THE CENTERS FOR MEDICARE & MEDICAID.—

(A) IN GENERAL.—The Director of the Congressional Budget Office or the Chief Actuary of the Center for Medicare & Medicaid Services, or both, shall provide to the Commission, upon the request of the Commission, such cost estimates as the Commission determines to be necessary to carry out its duties under this section.

(B) REIMBURSEMENTS.—The Commission shall reimburse the Director of the Congressional Budget Office for expenses relating to the employment in the office of the Director of such additional staff as may be necessary for the Director to comply with requests by the Commission under subparagraph (A).

(4) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Commission, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the Commission to assist the Commission in carrying out its duties under this section. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(5) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties under this section.

(6) USE OF MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(7) OBTAINING INFORMATION.—The Commission may secure directly from any Federal agency information necessary to enable it to carry out its duties under this section, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairperson of the Commission, the head of each such agency shall furnish such information to the Commission.

(8) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(9) PRINTING.—For purposes of costs relating to printing and binding, including the cost of personnel detailed from the Government Printing Office, the Commission shall be deemed to be a committee of Congress.

(f) REPORT.—Not later than October 1, 2012, the Commission shall submit to the President and Congress a report and an implementation bill that shall contain a detailed statement of only those recommendations, findings, and conclusions of the Commission that receive the approval of at least 11 members of the Commission.

(g) TERMINATION.—The Commission shall terminate on the date that is 30 days after the date on which the report and implementation bill is submitted under subsection (f).

SEC. ___03 CONGRESSIONAL CONSIDERATION OF REFORM PROPOSALS.

(a) DEFINITIONS.—In this section:

(1) IMPLEMENTATION BILL.—The term ''implementation bill'' means only a bill that is introduced as provided under subsection (b), and contains the proposed legislation included in the report submitted to Congress under section ___02(f), without modification.

(2) CALENDAR DAY.—The term ''calendar day'' means a calendar day other than 1 on which either House is not in session because of an adjournment of more than 3 days to a date certain.

(b) INTRODUCTION; REFERRAL; AND REPORT OR DISCHARGE.—

(1) INTRODUCTION.—On the first calendar day on which both Houses are in session immediately following the date on which the report is submitted to Congress under section ___02(f), a single implementation bill shall be introduced (by request)—

(A) in the Senate by the Majority Leader of the Senate, for himself and the Minority Leader of the Senate, or by Members of the Senate designated by the Majority Leader and Minority Leader of the Senate; and

(B) in the House of Representatives by the Speaker of the House of Representatives, for himself and the Minority Leader of the House of Representatives, or by Members of the House of Representatives designated by the Speaker and Minority Leader of the House of Representatives.

(2) REFERRAL.—The implementation bills introduced under paragraph (1) shall be referred to any appropriate committee of jurisdiction in the Senate and any appropriate committee of jurisdiction in the House of Representatives. A committee to which an implementation bill is referred under this paragraph may report such bill to the respective House without amendment.

(3) REPORT OR DISCHARGE.—If a committee to which an implementation bill is referred has not reported such bill by the end of the 15th calendar day after the date of the introduction of such bill, such committee shall be immediately discharged from further consideration of such bill, and upon being reported or discharged from the committee, such bill shall be placed on the appropriate calendar.

(c) FLOOR CONSIDERATION.—

(1) IN GENERAL.—When the committee to which an implementation bill is referred has reported, or has been discharged under subsection (b)(3), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for any Member of the respective House to move to proceed to the consideration of the implementation bill, and all points of order against the implementation bill (and against consideration of the implementation bill) are waived. The motion is highly privileged in the House of Representatives and is privileged in the Senate and is not debatable. The motion is not subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the implementation bill is agreed to, the implementation bill shall remain the unfinished business of the respective House until disposed of.

(2) AMENDMENTS.—An implementation bill may not be amended in the Senate or the House of Representatives.

(3) DEBATE.—Debate on the implementation bill, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 20 hours, which shall be divided equally between those favoring and those opposing the resolution. A motion further to limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the implementation bill is not in order. A motion to reconsider the vote by which the implementation bill is agreed to or disagreed to is not in order.

(4) VOTE ON FINAL PASSAGE.—Immediately following the conclusion of the debate on an implementation bill, and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the appropriate House, the vote on final passage of the implementation bill shall occur.

(5) RULINGS OF THE CHAIR ON PROCEDURE.—Appeals from the decisions of the Chair relating to the application of the rules of the Senate or the House of Representatives, as the case may be, to the procedure relating to an implementation bill shall be decided without debate.

(d) COORDINATION WITH ACTION BY OTHER HOUSE.—If, before the passage by 1 House of an implementation bill of that House, that House receives from the other House an implementation bill, then the following procedures shall apply:

(1) NONREFERRAL.—The implementation bill of the other House shall not be referred to a committee.

(2) VOTE ON BILL OF OTHER HOUSE.—With respect to an implementation bill of the House receiving the implementation bill—

(A) the procedure in that House shall be the same as if no implementation bill had been received from the other House; but

(B) the vote on final passage shall be on the implementation bill of the other House.

(e) RULES OF SENATE AND HOUSE OF REPRESENTATIVES.—This section is enacted by Congress—

(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of an implementation bill described in subsection (a), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(2) with full recognition of the constitutional right of either House to change the rules (so far as relating to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

SEC. ___04. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this subtitle for each of fiscal years 2012 through 2013.

SA 949. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle B of title IV, add the following:

SEC. ___. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 13951(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography''.

(b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

SA 950. Mr. PRYOR submitted an amendment intended to be proposed by him to the bill S. 1, to amend title XVIII of the Social Security Act to make improvements in the medicare program, to provide prescription drug coverage under the medicare program, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. EQUAL ACCESS TO COMPETITIVE GLOBAL PRESCRIPTION MEDICINE PRICES FOR AMERICAN PURCHASERS.

(a) DEFINITION OF COVERED PRODUCT.—In this section, the term ''covered product'' has the meaning given the term in section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384).

(b) PROHIBITION.—It shall be unlawful for the manufacturer of a covered product or any other person that sells a covered product to refuse to sell to any wholesaler or retailer (or other purchaser representing a group of wholesalers or retailers) of covered products in the United States on terms (including such terms as prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers, and any other term that effectively reduces the cost to the manufacturer of supplying the drug) that are not substantially the same as the most favorable (to the purchaser) terms on which the person has sold or has agreed to sell the covered product to any purchaser in Canada.

(c) ENFORCEMENT.—The Secretary of Health and Human Services, or any wholesaler or retailer in the United States aggrieved by a violation of subsection (b), may bring a civil action in United States district court against a person that violates subsection (b) for an order—

(1) enjoining the violation; and

(2) awarding damages in the amount that is equal to 3 times the amount of the value of the difference between—

(A) the terms on which the person sold a covered product to the wholesaler or retailer; and

(B) the terms on which the person sold the covered product to a person in Canada.

(d) EFFECTIVENESS OF SECTION.—This section takes effect on the date that is 2 years after the date of enactment of this Act, except that this section shall not be in effect during any period after that date in which there is in effect a final regulation promulgated by the Secretary of Health and Human Services permitting the importation or reimportation of prescription drugs under section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384).

NOTICES OF HEARINGS/MEETINGS

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. CRAIG. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled before the Subcommittee on Public Lands and Forests.

The hearing that was originally scheduled for June 19, 2003 has been postponed and will now be held on Wednesday, June 25 at 2:30 p.m. in Room SD–366 of the Dirksen Senate Office Building.

The purpose of this oversight hearing is to gain an understanding of the grazing programs of the Bureau of Land Management and the United States Forest Service. The Subcommittee will receive testimony on grazing permit renewal, BLM's potential changes to grazing regulations, range monitoring, drought and other grazing issues. This hearing will also provide the basis for other grazing hearings that we may want to undertake at the subcommittee level as the year goes on.