lot of issues with respect to the Finance Committee, has basically pushed the Finance Committee aside.

I do not know whether he does not trust the committee, whether he does not trust the leadership. I do not know what it is, but the Finance Committee has pretty much been made irrelevant over the past several months by the majority leader. What we have as a result of that is a procedure that is doomed to failure.

The PRESIDING OFFICER. Who yields time? The Senator from Massachusetts.

Mr. KENNEDY. I understand we have 5 minutes 40 seconds left. Is that right?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. What I would like to do is give 1½ minutes to the Senator from New York and 3 minutes to the Senator from New Jersey.

Mr. SCHUMER. I yield my remaining time. Senator GREGG corrected the time. I would be happy to yield my remaining time.

Mr. KENNEDY. I yield 4½ minutes to the Senator from New Jersey.

The PRESIDING OFFICER. The Senator from New Jersey.

Mr. CORZINE. Mr. President, I rise to speak about the unspeakable, as far as I am concerned. I picked up the paper this morning and I read House GOP leaders fight audit plan, an audit plan that passed this body 97 to 0.

There are rumors circulating out among those on the Hill that a procedural process called blue-slipping has been applied to the Senate-passed corporate responsibility act, more formally known as the Accounting Reform and Investor Protection Act, which our Nation is crying out for, in response to corporate malfeasance and the deterioration of the quality of financial reporting corporate governance in this Nation.

If we have ever seen a situation where politics is an overwhelming necessity, where the politics of a given issue is undermining the needs of the American people, investors across this country, retirees, people who are dependent on our financial system having integrity and how it responds to information presented from companies, it is demonstrated by these actions with regard to trying to stop or hold back something that is absolutely essential for making sure that our economy and our markets function properly.

In case people had not noticed, we have lost over $2.5 trillion in our financial markets this year alone with respect to what is going on in corporate governance, corporate malfeasance. Yesterday we heard a positive statement out of the Chairman of the Federal Reserve Board about the underlying fundamentals of the economy. Productivity is up; inflation is down. There is plenty of reason for why our market should be moving forward, why the marketplace should feel comfortable with itself, but what is standing in its way is the integrity of corporate responsibility, the integrity of our financial statements, the integrity of how our marketplace works. We are refusing to deal with this on a straightforward and expeditious manner.

The President has asked for it to be placed on his desk in less than 3 weeks, and now we are being stopped cold dead by the House leadership.

Mr. SCHUMER. Will my colleague yield for a question?

Mr. CORZINE. Absolutely.

Mr. SCHUMER. I could not agree more with what my colleague from New Jersey has said. We passed a 31(e) bill, which reduced taxes on corporate transactions but was supposed to fund the SEC. We could not even get an authorization to have pay parity for the SEC to hire new people. That is one of the reasons we are in the pickle we are in.

So I ask my colleague from New Jersey: Is this not the same type of thing where they say, oh, yes, we are for enforcement, but they do not put any money in to either get enforcers or the quality of enforcers that we need?

Mr. CORZINE. The reason we have had responses like we have had in the marketplace in the last 2 weeks is that people are hot on rhetoric and low, low, low with regard to results and doing anything that is proper action to deal with the problem.

Mr. SCHUMER. If the Senator will continue to yield, the best place we can have action is in the bowels of the agencies where they find the wrongdoing; capable people, Government workers, they find it, nail them, so it does not happen again. Am I wrong about that?

Mr. CORZINE. The Senator is certainly right.

The PRESIDING OFFICER. The Senator has used 3 minutes.

Mr. CORZINE. I hope we take real action soon to stop this crisis of confidence from continuing.

Mr. KENNEDY. Mr. President, how much time remains?

The PRESIDING OFFICER. Fifteen seconds.

Mr. KENNEDY. Vote for cloture and get on with debate. This is an important first step that can take us on the road to lower prices and better availability of drug coverage for people who need it in our country.

I understand under the procedure the yeas and nays are automatic; is that correct?

The PRESIDING OFFICER. That is right.

Mr. KENNEDY. I understand all time has expired.

CLOTURE MOTION

The PRESIDING OFFICER. Under the previous order, the clerk will report the motion to invoke cloture.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close the debate on the motion to proceed to Calendar No. 491; S. 812, the Greater Access to Affordable Pharmaceuticals Act of 2001:

Senators Harry Reid, Jon Corzine, Byron L. Dorgan, Ron Wyden, Maria Cantwell, Paul Sarbanes, Debbie Stabenow, Dick Durbin, Thomas Carper, Tom Daschle, Jack Reed, Daniel K. Akaka, Kent Conrad, Zell Miller, Charles Schumer, Ernest Hollings, Hillary Clinton.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call under the rule is waived.

The question is, Is it the sense of the Senate that debate on the motion to proceed to S. 812, a bill to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, shall be brought to a close? The yeas and nays are required under the rule.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. NICKLES. I announce that the Senator from North Carolina (Mr. HELMS is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The yeas and nays resulted—yeas 99, nays 0, as follows:

[Rollcall Vote No. 178 Leg.]

YEAS—99

Akaka	Dorgan	Lugar
Allard	Durbin	McCain
Allen	Edwards	McConnell
Baucus	Ensign	Mikulski
Bayh	Enzi	Miller
Bennett	Feingold	Murkowski
Biden	Feinstein	Murray
Bingaman	Fitzgerald	Nelson (FL)
Bond	Frist	Nelson (NE)
Boxer	Graham	Nickles
Breaux	Gramm	Reed
Brownback	Grassley	Reid
Bunning	Gregg	Roberts
Burns	Hagel	Rockefeller
Byrd	Harkin	Santorum
Campbell	Hatch	Sarbanes
Cantwell	Hollings	Schumer
Carnahan	Hutchinson	Sessions
Carper	Hutchison	Shelby
Chafee	Inhofe	Smith (NH)
Cleland	Inouye	Smith (OR)
Clinton	Jeffords	Snowe
Cochran	Johnson	Specter
Collins	Kennedy	Stabenow
Conrad	Kerry	Stevens
Corzine	Kohl	Thomas
Craig	Kyl	Thompson
Crapo	Landrieu	Thurmond
Daschle	Leahy	Torricelli
Dayton	Levin	Voinovich
DeWine	Lieberman	Warner
Dodd	Lincoln	Wellstone
Domenici	Lott	Wyden

NOT VOTING—1

Helms

The PRESIDING OFFICER. On this vote, the yeas are 99, the nays are 0. Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001

The PRESIDING OFFICER. Under the previous order, the motion to proceed is agreed to and the clerk will report the bill.

The assistant legislative clerk read as follows:

A bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

The Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment, as follows:

(The parts of the bill intended to be stricken are shown in boldface brackets and the parts of the bill intended to be inserted are shown in italics.)

S. 812

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Greater Access to Affordable Pharmaceuticals Act of 2001''.

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) prescription drug costs are increasing at an alarming rate and are a major worry of American families and senior citizens;

(2) enhancing competition between generic drug manufacturers and brand-name manufacturers can significantly reduce prescription drug costs for American families;

(3) the pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals, but competition must be further stimulated and strengthened;

(4) the Federal Trade Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in a manner that could restrain trade and greatly reduce competition and increase prescription drug costs for consumers;

(5) generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals;

(6) the Congressional Budget Office estimates that—

(A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between $8,000,000,000 and $10,000,000,000 each year; and

(B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of $15 to $30 on each prescription;

(7) generic pharmaceuticals are widely accepted by consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled during the last decade, from approximately 19 percent to 43 percent, according to the Congressional Budget Office;

(8) expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs;

(9) Congress should ensure that measures are taken to effectuate the amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (98 Stat. 1585) (referred to in this section as the ''Hatch-Waxman Act'') to make generic drugs more accessible, and thus reduce health care costs; and

(10) it would be in the public interest if patents on drugs for which applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) were extended only through the patent extension procedure provided under the Hatch-Waxman Act rather than through the attachment of riders to bills in Congress.

(b) PURPOSES.—The purposes of this Act are—

(1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and

(2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.

SEC. 3. FILING OF PATENT INFORMATION WITH THE FOOD AND DRUG ADMINISTRATION.

(a) FILING AFTER APPROVAL OF AN APPLICATION.—

(1) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as amended by section 9(a)(2)(B)(ii)) is amended in subsection (c) by striking paragraph (2) and inserting the following:

''(2) PATENT INFORMATION.—

''(A) IN GENERAL.—Not later than the date that is 30 days after the date of an order approving an application under subsection (b) (unless the Secretary extends the date because of extraordinary or unusual circumstances), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) with respect to any patent—

''(i)(I) that claims the drug for which the application was approved; or

''(II) that claims an approved method of using the drug; and

''(ii) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

''(B) SUBSEQUENTLY ISSUED PATENTS.—In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

''(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

''(i) the patent number;

''(ii) the expiration date of the patent;

''(iii) with respect to each claim of the patent—

''(I) whether the patent claims the drug or claims a method of using the drug; and

''(II) whether the claim covers—

''(aa) a drug substance;

''(bb) a drug formulation;

''(cc) a drug composition; or

''(dd) a method of use;

''(iv) if the patent claims a method of use, the approved use covered by the claim;

''(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

''(vi) a declaration that the applicant, as of the date of the filing, has provided complete and accurate patent information for all patents described in subparagraph (A).

''(D) PUBLICATION.—On filing of patent information required under subparagraph (A) or (B), the Secretary shall—

''(i) immediately publish the information described in clauses (i) through (iv) of subparagraph (C); and

''(ii) make the information described in clauses (v) and (vi) of subparagraph (C) available to the public on request.

''(E) CIVIL ACTION FOR CORRECTION OR DELETION OF PATENT INFORMATION.—

''(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

''(I) to correct patent information filed under subparagraph (A); or

''(II) to delete the patent information in its entirety for the reason that—

''(aa) the patent does not claim the drug for which the application was approved; or

''(bb) the patent does not claim an approved method of using the drug.

''(ii) LIMITATIONS.—Clause (i) does not authorize—

''(I) a civil action to correct patent information filed under subparagraph (B); or

''(II) an award of damages in a civil action under clause (i).

''(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

''(i) has filed an application under subsection (b)(2) or (j); or

''(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j).''.

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred from bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

(b) FILING WITH AN APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(2)—

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

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

(C) by adding at the end the following:

''(C) with respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed—

''(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and

''(ii) a statement under subparagraph (B) regarding the method of use claim.''; and

(2) in subsection (j)(2)(A), by inserting after clause (viii) the following:

''With respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed, the application shall contain a certification under clause (vii)(IV) on a claim-by-claim basis and a statement under clause (viii) regarding the method of use claim.''.

SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) in clause (iii)—

(i) by striking ''(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii),'' and inserting the following:

''(iii) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary under subsection (c)(2)(B).'';

(B) by redesignating clause (iv) as clause (v); and

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

''(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was published by the Secretary under subsection (c)(2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

''(aa) on the date of a court action declining to grant a preliminary injunction; or

''(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(AA) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(BB) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

''(CC) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

''(II) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under subclause (I).

''(III) EXPEDITED NOTIFICATION.—If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under subclause (I), the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

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

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the patent fails to 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 is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.''.

(b) OTHER APPLICATIONS.—Section 505(c)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 9(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking ''(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A),'' and inserting the following:

''(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under paragraph (2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary under paragraph (2)(B).''; and

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

''(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

''(I) on the date of a court action declining to grant a preliminary injunction; or

''(II) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(aa) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(bb) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

''(cc) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

''(ii) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under clause (i).

''(iii) EXPEDITED NOTIFICATION.—If the notice under subsection (b)(3) contains an address for the receipt of expedited notification of a civil action under clause (i), the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

(2) by inserting after paragraph (3) the following:

''(4) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the patent fails to 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 is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under subsection (b)(2).''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by subsections (a) and (b) shall be effective 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) made after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section.

(2) TRANSITION PROVISION.—In the case of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed before the date of enactment of this Act—

(A) a patent (other than a patent that claims a process for manufacturing a listed drug) for which information was submitted to the Secretary of Health and Human Services under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (as in effect on the day before the date of enactment of this Act) shall be subject to subsections (c)(3)(C) and (j)(5)(B)(iii) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section); and

(B) any other patent (including a patent for which information was submitted to the Secretary under section 505(c)(2) of that Act (as in effect on the day before the date of enactment of this Act)) shall be subject to subsections (c)(3)(D) and (j)(5)(B)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section).

SEC. 5. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG APPLICANTS.

(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 4(a)) is amended—

(1) in subparagraph (B)(v), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court (from which no appeal has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) holding that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not infringed;''; and

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

''(D) FORFEITURE OF 180-DAY PERIOD.—

''(i) DEFINITIONS.—In this subparagraph:

''(I) APPLICATION.—The term 'application' means an application for approval of a drug under this subsection containing a certification under paragraph (2)(A)(vii)(IV) with respect to a patent.

''(II) FIRST APPLICATION.—The term 'first application' means the first application to be filed for approval of the drug.

''(III) FORFEITURE EVENT.—The term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

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

''(AA) the date that is 60 days after the date on which the approval of the application for the drug is made effective under clause (iii) or (iv) of subparagraph (B) (unless the Secretary extends the date because of extraordinary or unusual circumstances); or

''(BB) if 1 or more civil actions have been brought against the applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or 1 or more civil actions have been brought by the applicant for a declaratory judgment that such a patent is invalid or not infringed, the date that is 60 days after the date of a final decision (from which no appeal

has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) in the last of those civil actions to be decided (unless the Secretary extends the date because of extraordinary or unusual circumstances).

''(bb) WITHDRAWAL OF APPLICATION.—The applicant withdraws the application.

''(cc) AMENDMENT OF CERTIFICATION.—The applicant, voluntarily or as a result of a settlement or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

''(dd) FAILURE TO OBTAIN APPROVAL.—The applicant fails to obtain tentative approval of an application within 30 months after the date on which the application is filed, unless the failure is caused by—

''(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

''(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

''(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which the applicant submitted the application, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is required under paragraph (2)(A), the applicant fails to submit, not later than the date that is 60 days after the date on which the Secretary publishes the new patent information under paragraph (7)(A)(iii) (unless the Secretary extends the date because of extraordinary or unusual circumstances)—

''(AA) a certification described in paragraph (2)(A)(vii)(IV) with respect to the patent to which the new patent information relates; or

''(BB) a statement that any method of use claim of that patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii).

''(ff) UNLAWFUL CONDUCT.—The Federal Trade Commission determines that the applicant engaged in unlawful conduct with respect to the application in violation of section 1 of the Sherman Act (15 U.S.C. 1).

''(IV) SUBSEQUENT APPLICATION.—The term 'subsequent application' means an application for approval of a drug that is filed subsequent to the filing of a first application for approval of that drug.

''(ii) FORFEITURE OF 180-DAY PERIOD.—

''(I) IN GENERAL.—Except as provided in subclause (II), if a forfeiture event occurs with respect to a first application—

''(aa) the 180-day period under subparagraph (B)(v) shall be forfeited by the first applicant; and

''(bb) any subsequent application shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), and clause (v) of subparagraph (B) shall not apply to the subsequent application.

''(II) FORFEITURE TO FIRST SUBSEQUENT APPLICANT.—If the subsequent application that is the first to be made effective under subclause (I) was the first among a number of subsequent applications to be filed—

''(aa) that first subsequent application shall be treated as the first application under this subparagraph (including subclause (I)) and as the previous application under subparagraph (B)(v); and

''(bb) any other subsequent applications shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), but clause (v) of subparagraph (B) shall apply to any such subsequent application.

''(iii) AVAILABILITY.—The 180-day period under subparagraph (B)(v) shall be available to a first applicant submitting an application for a drug with respect to any patent without regard to whether an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

''(iv) APPLICABILITY.—The 180-day period described in subparagraph (B)(v) shall apply to an application only if a civil action is brought against the applicant for infringement of a patent that is the subject of the certification.''.

(b) APPLICABILITY.—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, except that if a forfeiture event described in section 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(v) of that Act without regard to when the applicant made a certification under section 505(j)(2)(A)(vii)(IV) of that Act.

SEC. 6. FAIR TREATMENT FOR INNOVATORS.

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

(1) in subsection (b)(3)(B), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''; and

(2) in subsection (j)(2)(B)(ii), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the opinion of the applicant that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''.

(b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) (as amended by section 4(a)(1)) is amended—

(1) in clause (iii), by adding at the end the following: ''A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''; and

(2) in clause (iv), by adding at the end the following:

''(IV) INJUNCTIVE RELIEF.—A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''.

SEC. 7. BIOEQUIVALENCE.

(a) IN GENERAL.—The amendments to part 320 of title 21, Code of Federal Regulations, promulgated by the Commissioner of Food and Drugs on July 17, 1991 (57 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect as an exercise of authorities under sections 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 371).

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

(c) EFFECT OF SECTION.—This section shall not be construed to alter the authority of the Secretary of Health and Human Services to regulate biological products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Any such authority shall be exercised under that Act as in effect on the day before the date of enactment of this Act.

SEC. 8. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this Act—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000.

SEC. 9. CONFORMING AND TECHNICAL AMENDMENTS.

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

(1) in subsection (a), by striking ''(a) No person'' and inserting ''(a) IN GENERAL.—No person'';

(2) in subsection (b)—

(A) by striking ''(b)(1) Any person'' and inserting the following:

''(b) APPLICATIONS.—

''(1) REQUIREMENTS.—

''(A) IN GENERAL.—Any person'';

(B) in paragraph (1)—

(i) in the second sentence—

(I) by redesignating subparagraphs (A) through (F) as clauses (i) through (vi), respectively, and adjusting the margins appropriately;

(II) by striking ''Such persons'' and inserting the following:

''(B) INFORMATION TO BE SUBMITTED WITH APPLICATION.—A person that submits an application under subparagraph (A)''; and

(III) by striking ''application'' and inserting ''application—'';

(ii) by striking the third through fifth sentences; and

(iii) in the sixth sentence—

(I) by striking ''The Secretary'' and inserting the following:

''(C) GUIDANCE.—The Secretary''; and

(II) by striking ''clause (A)'' and inserting ''subparagraph (B)(i)''; and

(C) in paragraph (2)—

(i) by striking ''clause (A) of such paragraph'' and inserting ''paragraph (1)(B)(i)'';

(ii) in subparagraphs (A) and (B), by striking ''paragraph (1) or''; and

(iii) in subparagraph (B)—

(I) by striking ''paragraph (1)(A)'' and inserting ''paragraph (1)(B)(i)''; and

(II) by striking ''patent'' each place it appears and inserting ''claim''; and

(3) in subsection (c)—

(A) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''(A) If the applicant'' and inserting the following:

''(A) CLAUSE (i) OR (ii) CERTIFICATION.—If the applicant''; and

(II) by striking ''may'' and inserting ''shall'';

(ii) in subparagraph (B)—

(I) by striking ''(B) If the applicant'' and inserting the following:

''(B) CLAUSE (iii) CERTIFICATION.—If the applicant''; and

(II) by striking ''may'' and inserting ''shall'';

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

(iv) in subparagraph (E) (as redesignated by clause (iii)), by striking ''clause (A) of subsection (b)(1)'' each place it appears and inserting ''subsection (b)(1)(B)(i)''; and

(B) by redesignating paragraph (4) as paragraph (5); and

(4) in subsection (j)—

(A) in paragraph (2)(A)—

(i) in clause (vi), by striking ''clauses (B) through ((F)'' and inserting ''subclauses (ii) through (vi) of subsection (b)(1)'';

(ii) in clause (vii), by striking ''(b) or''; and

(iii) in clause (viii)—

(I) by striking ''(b) or''; and

(II) by striking ''patent'' each place it appears and inserting ''claim''; and

(B) in paragraph (5)—

(i) in subparagraph (B)—

(I) in clause (i)—

(aa) by striking ''(i) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (I) OR (II) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(II) in clause (ii)—

(aa) by striking ''(ii) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (III) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(III) in clause (iii), by striking ''(2)(B)(i)'' each place it appears and inserting ''(2)(B)''; and

(IV) in clause (v) (as redesignated by section 4(a)(1)(B)), by striking ''continuing'' and inserting ''containing''; and

(ii) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively.

(b) SECTION 505A.—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)—

(A) by striking ''(c)(3)(D)(ii)'' each place it appears and inserting ''(c)(3)(E)(ii)''; and

(B) 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)—

(A) by striking ''(c)(3)(D)'' each place it appears and inserting ''(c)(3)(E)''; and

(B) by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)'';

(3) in subsections (e) and (l)—

(A) by striking ''505(c)(3)(D)'' each place it appears and inserting ''505(c)(3)(E)''; and

(B) by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''; and

(4) in subsection (k), by striking ''505(j)(5)(B)(iv)'' and inserting ''505(j)(5)(B)(v)''.

(c) SECTION 527.—Section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is amended in the second sentence by striking ''505(c)(2)'' and inserting ''505(c)(1)(B)''.

The PRESIDING OFFICER. The majority leader.

Mr. DASCHLE. Mr. President, I will propound a unanimous consent request. It has been agreed to on both sides. And then I would like to put the Senate in a quorum call so we might proceed in an organized way. I think we are just about there.

I ask unanimous consent that the committee-reported amendment be considered and agreed to, and the motion to reconsider be laid upon the table; that the bill, as thus amended, be considered as original text for the purpose of further amendment; that no points of order be considered waived by virtue of this agreement.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The committee amendment was agreed to.

Mr. DASCHLE. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. REID. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Ms. STABENOW). Without objection, it is so ordered.

Mr. REID. Madam President, I ask unanimous consent the Senator from Arizona be recognized for up to 15 minutes and that I get the floor following the completion of his statement.

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

Mr. REID. The Senator from Arizona has indicated this is for debate only.

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

The Senator from Arizona is recognized for up to 15 minutes.

Mr. MCCAIN. Madam President, I thank the Senator from Nevada.

It is time to talk about the bill that is before us which, as we all know, is going to be used as a vehicle to attempt to address the very controversial issue of prescription drug benefits for Medicare.

I also thank the Senator from Massachusetts for passing this bill through his committee and reporting it to the floor.

I thank especially Senator SCHUMER who really is the person responsible for this legislation. All of us like to take credit for things in this body. The fact is, the reality is, Senator SCHUMER brought this issue, certainly the idea for this legislation, to my attention. He is the one who really worked on it. I am grateful he included me in this very important issue.

It is important to the people of my State and to all Americans. As we all know, there are large numbers of retirees who have been intelligent enough to move from New York to Arizona, and they are deeply affected by the cost of prescription drugs.

Mr. SCHUMER. Will the Senator yield for a brief comment?

Mr. MCCAIN. I am glad to yield to the Senator from New York.

Mr. SCHUMER. I thank my friend. I want to thank him. We have been in this together from the beginning—almost 2 years ago, when we realized that something had to be done. His steadfastness, his courage, and his constant efforts to refine the legislation and make it better and make sure we bring it to the floor has been a large part of why we are here. I thank the Senator for being a great colleague with whom to work. I wanted to repay the accolades and compliment of the Senator.

Mr. MCCAIN. I thank my friend from New York. Again, I reiterate that he really is the one who has been the leader in this issue and in this legislation. He is also well known for his tenacity.

Madam President, first of all, I think we also ought to understand that this issue alone—that of getting affordable drugs to all Americans—obviously, as I spoke of before, particularly seniors and those on fixed retirement incomes are the ones most dramatically affected. That is a critical issue in America today. I don't claim that this bill before us solves the problem of providing prescription drugs for all Americans, particularly seniors, but I do argue that this is a very important step in the right direction in lowering the cost of prescription drugs to all Americans.

Now, the drug companies have mounted a massive attack on this legislation. They were the major contributors in recent fundraisers on both sides of the aisle. It is not complicated. The bill is not complicated. It only has three or four provisions. Basically, what it achieves is an ability to do what the Hatch-Waxman bill was intended to do, and that is to make available generic drugs as early as possible, with respect for the rights of those who invested massive amounts of money, in many cases, in research and development and testing, and for them to have an adequate return on their investment. There is no intent here to harm the drug companies. What it is intended to do is to get drugs to the market in the generic fashion so people would only have to pay less.

Madam President, Allen Feezor, CalPERS' Assistant Executive Officer for Health Benefits, said:

> In two of the past three years, pharmaceutical costs have increased more than any other component in our CalPERS health rate.

CalPERS is the retirement plan for California employees, which are very large in number.

> In our Medicare Choice/Supplemental plans, pharmacy trend can account for over 50 percent of the increase in premium rates that we see in our retiree plans one year to the next.

The obvious result is very clear. Every year, prescription drugs become less and less affordable to all Americans but especially retirees. It should be noted. He goes on to say:

> It should be noted that in both our hospital and [prescription drug] trends, a measurable portion of the trend is due to increased utilization by our enrollees, but this cannot take away from the extraordinarily high trends in both pharmacy and hospital pricing.

The rising cost of prescription drugs is also playing a significant role in the growing financial burden companies experience as they struggle to provide employees with health care coverage. For example, General Motors, the largest provider of private sector health care coverage, spends over $4 billion a year to insure over 1.2 million workers, retirees and their dependents, $1.3 billion of which is on prescription drugs alone. Even with aggressive cost-saving mechanisms in place, GM's prescription drug costs continue to rise between 15 percent and 20 percent per year.

Given the crises in both corporate America and our Nation's health care

system, anticompetitive behavior in the marketplace is particularly onerous. That is what we are trying to get at, the anticompetitive behavior. This legislation is intended not to weaken patent laws to the detriment of the pharmaceutical industry, nor is it to impede the tremendous investments they make in the research and development of new drugs. The purpose of the underlying legislation is to close loopholes in the Hatch-Waxman act, and to ensure more timely access to generic medications. This is an important distinction which must be made clear.

However, to believe that patent laws are not being abused is to ignore the mountain of testimony from consumers, industry analysts, and the Federal Trade Commission. The Commerce Committee heard testimony regarding the extent by which pharmaceutical companies, including generic manufacturers, engage in anticompetitive activities and impede access to affordable medications. During that hearing, Chairman Muris, of the FTC, testified:

In spite of this remarkable record of success, the Hatch-Waxman amendments have also been subject to abuse. Although many drug manufacturers, including both branded companies and generics, have acted in good faith, some have attempted to ''game'' the system, securing greater profits for themselves without providing a corresponding benefit to consumers.

The intent of the Hatch-Waxman act was to address the escalating costs of prescription drugs by encouraging generic competition, while at the same time providing incentives for brand name drug companies to continue research and development into new and more advanced drugs. To a large extent, Hatch-Waxman has succeeded in striking that difficult balance between bringing new lower cost alternatives to consumers, while encouraging more investment in U.S. pharmaceutical research and development.

In the 15 years since the enactment of Hatch-Waxman, research and development has increased from $3 billion to $21 billion. However, some bad actors have manipulated the law in a manner that delays and, at times, prohibits generics from entering the marketplace.

I believe this legislation will improve the current system while preserving the intent of Hatch-Waxman. This legislation is not an attempt to jeopardize the patent rights of innovative companies, nor does it seek to provide unfair advantage to generic manufacturers. Rather, the intent of this legislation is to strike a balance between these two interests so that we can close the loopholes that allow some companies to engage in anticompetitive actions by unfairly prolonging patents or eliminating fair competition. In doing so, we offer consumers more choice in the marketplace.

It is imperative that Congress build upon the strengths of our current health care system while addressing its weaknesses. This should not be done by imposing price controls or creating a universal, Government-run health care system. Rather, a balance must be found that protects consumers with market-based, competitive solutions without allowing those protections to be manipulated at the consumers' expense, particularly senior citizens and working families without health care insurance.

Madam President, today, there are probably buses leaving places in the Northeast and in the Southwest, loaded with seniors who are going either to Mexico or Canada to purchase drugs, which will probably cost them around half of what they would at their local pharmacy. There are people today, as we speak, who are making a choice between their health and their income. That is wrong. It is wrong. It is wrong when patent drug companies game the system by doing things like bringing suits, which then delays the implementation. It is wrong when the patent drug companies actually pay generic drug companies not to produce a particular prescription drug while they continue their profits, and it is wrong to game this system.

So here we are with a bill that with proper debate and perhaps amendments, could be passed by this body and is supported by an overwhelming number of consumer organizations. Even the patent drug companies and the generic drug companies themselves will admit that we need to make reforms.

Unfortunately, this statement that I have made and those made by Senator SCHUMER may be the only debate we have on this legislation which could be passed between now and September. So what are we going to do? What we are really going to do is have a debate over the prescription drug issue, Medicare, and that will bog us down with competing proposals, all of which will require 60 votes, and none of which has the 60 votes. At the end of 2 weeks, rather than passing this bill, which we should, we are going to say, oops, we really cannot come to an agreement, and if we did have an agreement, the House bill is very different, and we would have to go to a conference, from which bills would never emerge.

I think the American people deserve better. Why do we not pass this underlying bill, or at least make a commitment to pass this underlying bill, if the competing proposals that will be before us on Medicare prescription drugs do not receive 60 votes?

What I am afraid is going to happen is that none of the three will receive 60 votes. Then we will drop the bill and move on to other issues, and I think that is wrong. I think we know that with this approach, this underlying legislation, with some changes, absent, of course, the huge campaign contributions of the drug companies, we could reach an agreement which would be fair to the prescription drug companies, fair to the generics, and fair to the American public, and, indeed, in the view of anyone, including a recent study by the Federal Trade Commission that shows that these abuses are having a direct impact on the increasing costs of prescription drugs to all Americans particularly.

I remind my colleagues that we may be doing an injustice and a disservice to Americans for this year by not addressing this particular aspect of it and having it encumbered and bogged down by competing proposals.

I believe this legislation is fairly simple. It passed through the committee of jurisdiction with half of the Republican members voting for it. I know Senator GREGG, the ranking member, has some problems with it. I think with debate, amendment, and discussion, we could resolve those concerns that we might have and move forward.

Mr. GREGG. Will the Senator yield for a question?

Mr. MCCAIN. I would be glad to yield.

Mr. GREGG. The Senator characterizes my views accurately, and I agree with the Senator that this bill should be moved independent of the drug bill. Unfortunately, the greater issue, or game, of the drug fight has been set up to lose so that nothing will happen, as the Senator from Arizona so appropriately pointed out. I do think this is important legislation. I hope we will pass it somehow.

My concerns go to the expansion of lawsuits under the new cause of action. Much of the rest of the bill—in fact the vast majority of the rest of the bill—I think is excellent. I appreciate the work of the Senator from Arizona in bringing it forward.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. MCCAIN. I ask unanimous consent for an additional 5 minutes, for debate purposes only.

Mr. REID. Under the same conditions we put forward earlier.

The PRESIDING OFFICER. There is no objection under the same conditions: When the Senator has completed, the Senator from Nevada will be recognized.

Mr. MCCAIN. I thank the Senator from Nevada.

Again, I thank the Senator from Massachusetts for getting this bill through the committee. I thank Senator GREGG from New Hampshire for his willingness to work with us, even though he has a couple of concerns that I think we could work out.

I urge my colleagues again, if the Medicare prescription drug issue is not resolved, to go back to the underlying bill, pass it, and perhaps we can give the American people at least some relief between now and next year.

This issue is not going away. Maybe after this year's elections we could try to address it in a more nonpartisan fashion.

On another issue, very briefly, in this morning's Washington Post there is an article by Mr. Andrew Grove, who is the chairman of the Intel Corporation.

I believe he is one of the most respected men in America. He makes a case that is very important. He outlines some of the changes he thinks need to be made in the area of increasing corporate responsibility. I think it is worthwhile to be included in the RECORD.

I ask unanimous consent that the article appearing in the Washington Post by Andrew S. Grove called ''Stigmatizing Business'' be printed in the RECORD.

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

STIGMATIZING BUSINESS

(By Andrew S. Grove)

I grew up in Communist Hungary. Even though I graduated from high school with excellent grades, I had no chance of being admitted to college because I was labeled a ''class alien.'' What earned me this classification was the mere fact that my father had been a businessman. It's hard to describe the feelings of an 18-year-old as he grasps the nature of a social stigma directed at him. But never did I think that, nearly 50 years later and in a different country, I would feel some of the same emotions and face a similar stigma.

Over the past few weeks, in reaction to a series of corporate scandals, the pendulum of public feeling has swung from celebrating business executives as the architects of economic growth to condemning them as a group of untrustworthy, venal individuals.

I have been with Intel since its inception 34 years ago. During that time we have become the world's largest chip manufacturer and have grown to employ 50,000 workers in the United States, whose average pay is around $70,000 a year. Thousands of our employees have bought houses and put their children through college using money from stock options. A thousand dollars invested in the company when it went public in 1971 would be worth about $1 million today, so we have made many investors rich as well.

I am proud of what our company has achieved. I should also feel energized to deal with the challenges of today since we are in one of the deepest technology recessions ever. Instead, I'm having a hard time keeping my mind on our business. I feel hunted, suspect—a ''class alien'' again.

I know I'm not alone in feeling this way. Other honest, hard-working and capable business leaders feel similarly demoralized by a political climate that has declared open season on corporate executives and has let the faults, however egregious, of a few taint the public perception of all. This just at a time when their combined energy and concentration are what's needed to reinvigorate our economy. Moreover, I wonder if the reflexive reaction of focusing all energies on punishing executives will address the problems that have emerged over the past year.

Today's situation reminds me of an equally serious attack on American business, one that required an equally serious response. In the 1980s American manufacturers in industries ranging from automobiles to semiconductors to photocopiers were threatened by a flood of high-quality Japanese goods produced at lower cost. Competing with these products exposed the inherent weakness in the quality of our own products. It was a serious threat. At first, American manufacturers responded by inspecting their products more rigorously, putting ever-increasing pressure on their quality assurance organizations. I know this firsthand because this is what we did at Intel.

Eventually, however, we and other manufacturers realized that if the products were of inherently poor quality, no amount of inspection would turn them into high-quality goods. After much struggle—hand-wringing, finger-pointing, rationalizing and attempts at damage control—we finally concluded that the entire system of designing and manufacturing goods, as well as monitoring the production process, had to be changed. Quality could only be fixed by addressing the entire cycle, from design to shipment to the customer. This rebuilding from top to bottom led to the resurgence of U.S. manufacturing.

Corporate misdeeds, like poor quality, are a result of a systemic problem, and a systemic problem requires a systemic solution. I believe the solutions that are needed all fit under the banner of ''separation of powers.''

Let's start with the position of chairman of the board of directors. I think it is universally agreed that the principal function of the board is to supervise and, if need be, replace the CEO. Yet, in most American corporations, the board chairman is the CEO. This poses a built-in conflict. Reform should start with separating these two functions. (At various times in Intel's history we have combined the functions, but no longer). Furthermore stock exchanges should require that boards of directors be predominantly made up of independent members having no financial relationship with the company. Separation of the offices of chairman and CEO, and a board with something like a two-thirds majority of independent directors, should be a condition for listing on stock exchanges.

In addition, auditors should provide only one service: auditing. Many auditing firms rely on auxiliary services to make money, but if the major stock exchanges made auditing by ''pure'' firms a condition for listing, auditing would go from being a loss leader for these companies to a profitable undertaking. Would this drive the cost of auditing up? Beyond a doubt. That's a cost of reform.

Taking the principle a step further, financial analysts should be independent of the investment banks that do business with corporations, a condition that could do business with corporations, a condition that could and should be required and monitored by the Securities and Exchange Commission.

The point is this: The chairman, board of directors, CEO, CFO, accountants and analysts could each stop a debacle from developing. A systemic approach to ensuring the separation of powers would put them in a position where they would be free and motivated to take action.

I am not against prosecuting individuals responsible for financial chicanery and other bad behavior. In fact, this must be done. But tarring and feathering CEOs and CFOs as a class will not solve the underlying problem. Restructuring and strengthening the entire system of checks and balances of the institutions that make up and monitor the U.S. capital markets would serve us far better.

Reworking design, engineering and manufacturing processes to meet the quality challenge from the Japanese in the 1980s took five to 10 years. It was motivated by tremendous losses in market share and employment. Similarly, the tremendous loss of market value from the recent scandals provides a strong motivation for reform. But let us not kid ourselves. Effective reform will take years of painstaking reconstruction.

Our society faces huge problems. Many of our citizens have no access to health care; some of our essential infrastructure is deteriorating; the war on terror and our domestic security require additional resources. Attacking these problems requires a vital economy. Shouldn't we take time to think through how we can address the very real problems in our corporations without demonizing and demoralizing the managers whose entrepreneurial energy is needed to drive our economy?

Mr. MCCAIN. I will read the last paragraph of Mr. Grove's column. He said:

Our society faces huge problems. Many of our citizens have no access to health care; some of our essential infrastructure is deteriorating; the war on terror and our domestic security require additional resources. Attacking these problems requires a vital economy. Shouldn't we take time to think through how we can address the very real problems in our corporations without demonizing and demoralizing the managers whose entrepreneurial energy is needed to drive our economy?

I might point out that a number of the proposals Mr. Grove has made are not incorporated in the Sarbanes bill, and if we have to go back and revisit this issue, which I am afraid we might, I hope everyone will pay attention to some of his proposals.

As is well known to most of us, Mr. Grove grew up in Communist Hungary, escaped at a very early age. He wrote a marvelous book about it. It is a great American success story. I think he is one of the most respected men in America. He has been at Intel since its inception 34 years ago, and it has become the world's largest chip manufacturer and grown to employ 50,000 workers in the United States, whose average pay is around $70,000 a year.

So I hope we will pay attention to Mr. Grove's recommendations, as well as his statements of principle.

I thank my colleagues for allowing me to debate the bill, and I yield back the remainder of my time.

Mr. REID. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. REID. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

AMENDMENT NO. 4299

(Purpose: To permit commercial importation of prescription drugs from Canada)

Mr. REID. Madam President, I send an amendment to the desk on behalf of Senators DORGAN, WELLSTONE, and STABENOW.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Nevada [Mr. REID], for Mr. DORGAN, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, and Mr. FEINGOLD, proposes an amendment numbered 4299.

Mr. REID. I ask unanimous consent reading of the amendment be dispensed with.

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

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. REID. Mr. President, I ask for the yeas and nays on this amendment.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second. The yeas and nays are ordered.

AMENDMENT NO. 4300 TO AMENDMENT NO. 4299

(Purpose: To provide a substitute for the amendment)

Mr. REID. I send an amendment to the desk.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Nevada [Mr. REID], for Mr. DORGAN, proposes an amendment numbered 4300 to amendment No. 4299.

Mr. REID. Madam President, I ask unanimous consent reading of the amendment be dispensed with.

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

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. REID. Madam President, we appreciate the cooperation of the managers of this bill. At this point, we are now going to be in a posture to debate drug reimportation. We would hope we could have time agreements on this on whatever the minority wishes to offer.

Prior to that, I ask unanimous consent the Senator from Maine, Ms. SNOWE, be recognized for 20 minutes to speak on the bill, or whatever she chooses to speak on.

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

Ms. SNOWE. Madam President, I rise today to begin a discussion on the prescription drug benefit and specifically the one that has been introduced by the tripartisan group including Senator GRASSLEY, Senator BREAUX, Senator JEFFORDS, Senator HATCH, and myself.

Before I proceed, I express my support for the amendment offered by Senator DORGAN regarding reimportation. I have long supported that initiative. Many of my seniors in the State of Maine have to travel across the border into Canada in order to get prescription drugs that are offered lower there than in the United States. It is a tragedy that compels seniors to be put in a situation where they have to cross the border in order to do that. I hope we can support that amendment so they can have the benefit of those lower priced prescription drugs in the United States. It is the only fair approach. It is one way of addressing the issue of controlling costs and making costs competitive so they can have the benefit of lower prices.

I am very pleased to talk about the tripartisan proposal. I regret we have not had the opportunity in the Senate Finance Committee to be able to consider competing proposals, certainly the one that has been introduced by the ranking member, Senator GRASSLEY, Senator BREAUX, Senator JEFFORDS, and Senator HATCH and myself, along with other proposals, that obviously has the support of other members of the committee.

We should do everything we can to have the opportunity to explore, to debate, to consider the various proposals. Obviously, that starts within the committee process. It is unfortunate at this point as we begin to debate the other issues in the underlying bill, which is an important piece of legislation, that we are not in a position of being able to consider a prescription drug benefit plan. That is not the way the process ought to work. If you look at what happened on the tax bill last year, no one knew what the vote would be in the committee, let alone on the floor, but we had the opportunity to address the issue within the Senate Finance Committee. It ultimately passed 14 to 6.

When it came to the floor, it had 53 votes and ultimately yielded a vote of 62 to 38. That is the way the process works. We did not write the ending first. The prologue begins in the committee.

In this case, one of the most significant social domestic issues facing this country today, prescription drug benefits, Medicare authorization, and we have not been able to have a markup in the committee of jurisdiction, the Senate Finance Committee, we are told, because it does not have 60 votes. How many bills that are marked up in the committee have 60 votes before they hit the floor of the Senate? How do we know? How do we know until we begin the process of debating, analyzing, considering various issues? That is what this process is all about.

I truly regret we have not had the chance to be able to consider this bill in the manner it deserves and in the manner it deserves for the seniors of this country who are dealing with the overwhelming burden of the high costs of prescriptions. Why are we allowing this to be politicized? Why are we allowing this to be a matter of partisanship?

We have come a long way just on the funding issue alone. I have been working on this issue in the Senate Budget Committee with then-Chairman DOMENICI, Senator WYDEN, Senator SMITH, and others, and we were able to develop a reserve fund. We started with $40 billion, which was more than then-President Clinton had proposed. We are up to $300 billion, and our tripartisan proposal is $370 billion, recognizing that as every year passes, the price goes up and up. We have come a long way in even understanding that we are going to have to spend more to provide a strong benefit to seniors, and we must start now.

Some people might just want the issue for the next election. Maybe that is what it is all about. Maybe some people want to see a headline that says: Senate fails to muster the 60 votes; the issue is put off for another year. I do not want to see that kind of headline. I do not think it is fair to the seniors in this country because I know this institution can do better, and that is why we put forward this tripartisan proposal because we did not want partisan differences, political differences, philosophical differences to impede our ability to address this most important issue to the seniors in this country.

That is why we undertook this effort more than a year ago in our tripartisan group to see what we could agree to that would provide a most substantial benefit to the seniors in this country. Seniors cannot put off their illnesses. We should not be putting off a solution, and we crossed the political divide to develop our tripartisan proposal.

We worked closely with the Congressional Budget Office to ascertain the precise cost of our proposal so we do not jeopardize the solvency of the Medicare Program for future generations. We developed a competitive, efficient model to yield the best results for seniors as well as for the Government.

I do not want partisanship to jeopardize our ability to send a bill to the President, Madam President. I want to break the logjam here and now. Seniors have heard the excuses. How can we do anything less than give this our full effort here and now, particularly for the one-third of the Medicare beneficiaries who have no coverage whatsoever?

The Medicare Program is outdated, given the fact that it does not include a prescription drug benefit first and foremost, and we need to bring Medicare into the 21st century. The best way we can do it is by adding a prescription drug benefit.

It is simply unconscionable in a country of our means and wealth that older Americans should ever have to choose between filling their cupboards and filling their prescriptions. That is not hyperbole; that is not exaggeration; that is the truth. It certainly is the truth in my State. People are forced to make those tragic choices, and we have within our means right here and now, Madam President, to make the difference so seniors are no longer forced to make that terrible choice.

That is why we have offered the plan that we have. That is why I do not want to bypass the committee, because I know that is our best opportunity to pass a prescription drug benefit when we complete the process that begins in the committee.

We should not have any political motivations or maneuvers to bypass the process. I have been told: We cannot consider a bill in the committee that does not have 60 votes. Since when has that been a precondition for any markup in the committee? Then I am told: We cannot have a bill that is not supported by the Democratic leadership. I never thought that prevented us from doing our job; that eventually we could reach results.

We are not saying our bill is written in concrete. We are saying this is a beginning. It is a basis for action. Henry Ford used to tell his Model T customers that they could have any color they wanted for a car as long as it was black. It sort of reminds me of the situation we are in today: We will consider a prescription drug bill as long as it is ours.

We are saying let's bring out the proposals in the committee, let's go through the committee process, and then let's report out a bill to the floor. The tripartisan bill has the support of 12 members of the committee as we speak—12 members of the 21. We have the support in the committee, but let's go through the committee process. Let's do what we need to do.

Refusing to have a markup in the Senate Finance Committee is hiding behind false pretenses that we should only act if we have 60 votes.

Madam President, I want to discuss the tripartisan proposal and what it is.

First and foremost, it is a plan that offers an affordable, comprehensive, and available prescription drug benefit to seniors. It maximizes the benefits for the low-income seniors, and finally, it is a fully funded, permanent part of the Medicare process. There will be no sunsets. Providing a sunset in legislation, as has been recommended by the other competing plan offered by the Senator from Florida, is really providing a false hope to seniors. How can we tell them: Oh, by the way, in 7 years your benefit will expire? I think that is doing a tremendous disservice to seniors in this country, saying we are only willing to give this benefit for 7 years, so you had better not have an illness because we are not going to be able to give you a benefit in 7 years.

Our plan is fully funded and a permanent part of Medicare. It has been scored and estimated for cost by the Congressional Budget Office. They have vetted every aspect of our proposal. It is right here in a major legislative initiative. It is right here for everybody to review and to evaluate.

The plan is universal. It is offered to every Medicare beneficiary. That was a major priority for us, and it was a major priority for the seniors in this country in all the discussions we had with seniors and AARP. They wanted a universal, at the lowest possible monthly premium, and that is exactly what our benefit provides. It is lower than any other proposal that has been offered: A monthly premium of $24.

It will be offered to seniors whether they live in urban areas or rural areas. They will have a choice of a minimum of two plans, no matter where they live in America. The plan is targeted for seniors between 135 percent and 150 percent of the poverty level. That is about $18,000 for an elderly couple. They will receive coverage for about $12 a month at 150 percent of the poverty level. Below 135 percent they will pay no premium, no deductible whatsoever.

The plan is comprehensive. They will have access to every drug, whether it is a generic drug or the most advanced innovative therapies. It also will provide relief from catastrophic costs from high annual prescription drug costs.

Most of all, the plan will save the seniors real money, anywhere from 33 percent to 98 percent in out-of-pocket expenses, with the average senior saving more than $1,600 every year, as my colleagues can see on this chart. The average spending for seniors without any drug benefit in 2005 will be $3,059 per year; more than a quarter of Medicare beneficiaries spend more than $4,000.

The average savings under our proposal for seniors above 150 percent of the poverty level will be more than 53 percent. For those below 135 percent, they will save 98 percent—98 percent—in their costs of prescription drugs. But no matter, the average savings to seniors will be at least one-half, more than $1,600.

Our plan eliminates the so-called donut for lower income seniors, the seniors hardest hit by high drug costs. There are 11.7 million Medicare beneficiaries who have incomes below 150 percent of the poverty level, and they are exempt from the $3,450 benefit limit. The enrollees between 135 percent and 150 percent of the poverty level will have a monthly premium based on a sliding scale that ranges from anywhere from zero to 24 percent.

The 10 million Medicare beneficiaries who have incomes below 135 percent of the poverty level will see, as I said, 98 percent of their prescription drug costs covered by this plan with no monthly premium. These seniors are exempt from the deductible and will pay an average coinsurance of anywhere from $1 to $2 for prescription drugs.

They also have the protection of catastrophic limits, which will be $3,700 under our legislation. That is where the catastrophic benefit limit will begin, at $3,700. And they will have full protection against all drug costs with no coinsurance.

All enrollees will have access to discounted prescription drugs after reaching the $3,450 benefit limit and before the $3,700 catastrophic benefit limit.

They will all still have access to discounted drugs between the $3,450 and the $3,700 catastrophic benefit. In fact, 80 percent—let me repeat, 80 percent—of the enrollees will never be affected by the benefit limit of $3,450.

As you can see from this chart, I want to repeat, it has the lowest premium of any of the comprehensive proposals that have been introduced, at $24. Ninety-nine percent of Medicare beneficiaries, according to CBO, will be participating under this program—99 percent. Let me repeat, 99 percent.

The coinsurance paid for the top 50 drugs is $21. I want to compare that to the proposal offered by the Senator from Florida, because under the nonpreferred drug plan, of the top 50 drugs, we provide a lower coinsurance on all but one. And for the top 50 drugs in the preferred drug list, we provide a lower coinsurance than the proposal offered by Senator GRAHAM of Florida on all but 11 of the 50 drugs on the top 50 list.

So we are not only more substantial when it comes to providing the coinsurance on all of these preferred and nonpreferred drugs—as you see listed on the chart are the preferred drugs. For all but 11 out of the 50 drugs, we are lower in our copays than the proposal offered by Senator GRAHAM of Florida. And for the nonpreferred drug list, we are lower for all but 1 out of the 50 drugs. In other words, for 49 out of the 50 we are lower. We provide a lower copay for these prescription drugs, not to mention the fact that we provide a lower monthly premium of $24 a month for those who are 150 percent above the poverty level. For those that are below 135 percent of the poverty level, they pay zero. And more importantly, our proposal is not sunsetted.

CBO estimated, as I said, that 99 percent of seniors will have coverage under this proposal—99 percent of seniors. I think it is important for everybody to understand that if we are going to offer a prescription drug benefit, and if we are serious about making sure it is part of the Medicare Program, then, clearly, it is important that we make sure that it never expires, that we do not resort to budget gimmicks or artificial sunset requirements that provide a false hope to seniors.

Seniors deserve better than a false hope of a drug benefit that expires after 7 years with no guarantee of further coverage. I think that would be regretable if we decided to take that approach.

That is why we initiated this effort more than a year ago, to provide a benefit that was generous, that would help the low incomes first and foremost, that was universal, that was affordable, that did not jeopardize the future financial stability of the Medicare Program—because, obviously, that has to be the foremost concern to all of us as well as to seniors—and that we had the maximum benefits possible for seniors against high annual drug costs.

So I hope we will have the opportunity to have an honest, thorough debate on a prescription drug benefit that can be included as a permanent part of the Medicare Program.

Seniors are struggling under the burden of high prescription drug costs. We cannot allow election year politics to overwhelm any chances, any possibilities of getting a Medicare drug benefit through the Senate this year. We must allow a full debate to occur on this issue both in the committee and on the floor.

The Finance Committee should be a part of this process. Each of us has a stake—individually and collectively—about the kind of process we are willing to embrace in the Senate.

It does make a difference as to whether or not we are going to choose to bypass the committees repeatedly and bring up significant legislation on the floor without having the benefit of the committee process and for those Members who serve on those respective committees to be part of that process.

So each of us has a responsibility to that process, and, most critically, when it comes to such an important issue to millions of Americans: Those who are struggling under the weight of

high prescription drug costs and those who can expect to face the same problem in the future.

I think each of us here knows that without a markup in the committee we are creating a predetermined train wreck. We are heading for a train wreck because we are creating a process designed for failure. It is designed for politics. It is not designed for creating a solution to a serious problem.

I think if we continue to resort to these ill-advised procedures and political maneuvers and charades, and if we continue to allow this political choreographing which sort of superficially addresses the issue but does not really because we do not really want to create a consensus and a compromise because we want the issue for this year's elections, then we have failed and this Senate has abrogated its responsibility to do what is right.

That is what it is all about. It is whether or not we choose to do what is right. I think we all know what is right. Those of us in our tripartisan group—I am not saying that our proposal, as I said earlier, is written in stone. It is not a finite product, but it is a serious product. It is one that has evolved for more than a year. It is one that has been evaluated by the Congressional Budget Office. And it is the only proposal that has been introduced that has bipartisan, tripartisan support, and the only one that has been scored by the Congressional Budget Office.

It is the only one that has the lowest monthly premium. And it is the one that is not sunsetted. It is a permanent part of Medicare.

Getting back to this chart, seniors pay less for the top 50 prescriptions under the tripartisan plan versus the Graham-Kennedy-Miller proposal. They pay less. So they pay less on their monthly premium, and they pay less in their copays for the top 50 prescriptions, either on the preferred drug list or on the nonpreferred drug list.

Those are the facts.

I just hope that we will have the opportunity to consider this legislation and other competing proposals—such as the one offered by the Senator from Florida, Senator GRAHAM—in committee; utilizing the committee process to amend, to debate and to vote on a final measure. My proposal, as it stands, has the votes in the committee.

But let us go through the committee process. We would be more than happy to evaluate other issues and other amendments of the members of the committee.

I just do not understand why we can't have a markup in the Senate Finance Committee. We are here to do our job. That is our responsibility. That is why we have the committee process. I want to be able to legislate the best solution to the problem. We have come up with a proposal. Others have other proposals. But let us have a competition of ideas and debate in the committee that allows for the best hope for getting a bill through on the floor of the Senate that will yield the 60 votes, that will go to conference, and the differences worked out with the House.

As others have said, let us get a bill to the President for his signature this year. I don't want another year to go by. That is what I have been hearing every year. I have been hearing it every year now. Four years ago, they said next year. Next year turns into 2 years, 4 years, 6 years. How long do we think seniors can wait for this prescription drug benefit? How long? How long is it going to take? Why is it that we have to have these political machinations? Our group—Senator GRASSLEY, Senator BREAUX, Senator JEFFORDS, Senator HATCH—has worked long and hard for more than a year. Why can't we have a markup in the committee on this issue?

I would like to have a reasonable answer to that question. But I don't think I am going to get a reasonable answer. There is nothing to justify precluding us from doing our jobs in the committee. There is nothing acceptable by what is happening here.

I am here to legislate. I don't expect everybody to agree with my thoughts or my ideas or my proposals. But I do expect that we will honor the process by which we have the ability to do our job. Otherwise, we have all failed.

I don't care if it is a day before the election. I don't care. The time is now. To be frank with all of you, I think that we should reach the limits of our frustration with this process. Why do we continue to say it is acceptable? The same machinations existed with the health care proposal back in 1994. It is exactly the process it took. It bypassed the committee process and came to the floor. Guess what. Nothing happened.

Here we are in the year 2002—2002. We don't have a bill. The same is going to happen with prescription drugs. People will say next year: We can't do it.

We are getting paid to do our jobs now—not next year. We were elected to do our job now. Senator GRASSLEY has worked long and hard.

Senator GRASSLEY, the ranking member of the Senate Finance Committee, has gone the extra mile to reach out to both sides, to the chairman, to other members of the committee, and to others here on the Senate floor across the aisle, and as he did in this tripartisan proposal. Senator BREAUX and Senator JEFFORDS have also worked with us. We have been working together because we know this is the only way we can accomplish this most important issue for the seniors of this country.

I hope we will do the right thing. Let's begin this process in the Finance Committee so that we can consider the proposals on the floor which will ultimately yield the best results, not only in terms of policy but for the seniors of this country.

I yield the floor.

The PRESIDING OFFICER (Mr. REED of Rhode Island). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I intend to speak for a very few moments, and then hopefully we will be on the amendment of the Senator from North Carolina.

First of all, I thank my good friend, the Senator from Maine, for her very eloquent and passionate speech and statement in favor of the strong prescription drug program. It was eloquent, indeed. There were parts of it that I agree with very much. There were some parts to which I take exception. But I welcome the opportunity to have the kind of discussion and debate that she eagerly awaits here in the Senate.

I agree with her that it is long overdue. I agree with her that the time is now. I agree certainly with her that we are going to have to find common ground. I hope very much that we can.

I respect those who have gone forward and supported the tripartisan proposal.

Let me offer a few quick facts. Virtually none of the senior groups are supporting the tripartisan program. That doesn't have to be the bottom-line test. But they believe it doesn't provide the kind of protections that are in the Graham-Miller legislation—I think that they believe this for a very good reason. The tripartisan proposal has an assets test that will exclude many of the neediest of our senior citizens. The assets test says that if you have assets worth more than $1,500, or a car worth more than $400, or personal property worth more than $4,000, you are not eligible. That would affect a great many of the people in my State.

I think it is also demeaning to seniors to have to go in and try to give an assessment of what these personal items really are. I think we will have a chance to debate that.

One of the very important aspects of the Graham bill is that it doesn't have that test.

Second, there has been a good deal of talk about the estimated premium of $24. That is just an estimate because this program is turned over to the insurance companies. There is virtually no guarantee that the premium is going to remain $24. It may be $34 or $44.

I find that senior citizens in my State want certainty, they want predictability, they want to know exactly what that premium is going to be now. That is something that we will have to debate.

Third, as the Congressional Budget Office indicated, it will mean that 3.5 million seniors who are covered by their employer will be dropped for a less adequate program because there is no reimbursement for the employers.

That is not a finding that I make. It is a finding that the Congressional Budget Office makes.

Finally, I want to make this point. The issue of prescription drugs has been before the Finance Committee for 5 years. For 4 of the last 5 years, the Finance Committee has been under Republican control, and we have had Republican leaders on the committee.

This is the first chance we have had to debate it.

I listened to the Senator talk about wanting an answer to why we are not having a markup. I question why we didn't have one over the last 4 years. Now, under a Democratic leader, we are going to debate and hopefully take action on the floor.

I don't think people in my State are wondering about the committee process and how we are going to give adequate time for the committees to work. They want the Senate to act. That is the commitment of our leader. That is what they want.

I look forward to having the opportunity to act.

As the leader has pointed out, we want to try to deal with some of the issues of accessibility and also cost containment. In that cost containment debate, we have had strong bipartisan support in our committee—now 16 to 5. We had five Republicans who worked very closely on this issue.

We are going to find that there will be substantial savings for seniors as a result. We are going to hopefully have the opportunity to consider other amendments on this that are going to help deal with the problems of the cost of prescription drugs. Then we will have an opportunity to debate the other provisions.

But, as always, the Senator from Maine is eloquent, she is passionate, and she is knowledgeable about these issues.

I am very hopeful that before the end of this debate we will be on the same side in terms of supporting a program that will be worthy of the people of Maine as well as Massachusetts.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, it is appropriate to address again the issue of why this bill should have been vetted—not this bill we are hearing about, the big bills that are coming at us, the drug bills for drug benefits under Medicare—why they should have been vetted by the Finance Committee.

The Senator from Massachusetts represents that it didn't happen the last 5 years. There was no bill reported out of the committee. So why should the committee have to take it up this year? Why not just write it in the office of the majority leader, which is what has happened here? We haven't seen the bill. It is ironic. We have had all the representations as to what the Democratic bill is. We haven't even seen the bill. It hasn't been scored. It doesn't exist, as far as we know. Yet there are people out here puffing its strengths.

The reason you have to take this to committee is that if you don't take it to committee, you guarantee, almost, that you will not pass a bill. You are certainly not going to pass a bill that was drafted in some back office around here. If the bill does not go through the Finance Committee, it requires 60 votes to pass this body. It is subject to a point of order under the Budget Act.

It appears that the reason Senator GRASSLEY, being ranking member on the Finance Committee, Senator BREAUX, Senator SNOWE, being members of the Finance Committee, and Senator HATCH is supportive of this bill and is a member of the committee—it appears within the Finance Committee there is a working majority to pass a bill out, specifically the tripartite bill. Senator JEFFORDS is a member of the committee who is on this bill. There is a working majority to pass the bill out of the committee right now. If that happens, when the bill comes to the floor, it only needs 51 votes to pass and you actually get a drug benefit for senior citizens.

The way this process has been set up by the Democratic leadership is to create a hurdle that makes it virtually impossible to get a bill off the floor of the Senate. That is the difference. That is why you need to go through committee. The difference is that simple.

If you want to pass a bill, you go through the committee so you only need 51 votes to pass it. If you don't want to pass a bill, don't take it through the committee, because then you create a hurdle of 60 votes, and it makes it virtually impossible to pass the bill.

This is a process which has been set up to fail, as has been mentioned by innumerable speakers. It has been set up to fail. It has been set up to create a political issue as we go into the August recess before the November elections.

That is unfortunate. It is cynical. The Senator from Maine has, in terms of considerable outrage, expressed her frustration with that type of process. She has worked conscientiously with the Senators from Iowa and Louisiana, and other Senators in this body, to develop what is a consensus piece of legislation which will give seniors who are in dire need of it a very significant benefit in the area of drugs, for purchasing the drugs they need to live a decent life. It is a bill which is fairly expensive. We are talking, I believe, about $400 billion. That is a lot of money. Maybe it is $350 billion over 10 years.

Whatever it is, it is a very expensive bill. We are talking about taking a large amount of money from working Americans out of their paycheck through taxes and using it to support a seniors drug benefit, a very reasonable approach. Because it is such a large amount of money, it is outside the budget which we presently have in place. We have a $300 billion number which we put in place as a Congress last year to try to address the drug issue to help seniors. The plan, bipartisanly reached, tripartisanly reached, exceeds that number, as does every other plan being proposed, except for the Hagel-Ensign plan which is below that number.

All the other plans, with the exception of Hagel-Ensign, are subject to a point of order and, thus, subject to 60 votes. And it is extremely unlikely, considering the nature of the Senate, that you will get 60 votes for a final package. There are three different competing packages on our side, and there is this phantom package on the other side being written in an office, or a cloakroom, or a closet somewhere, and which we will see someday.

In any event, we know it has not been adequately vetted and we know the number is very high, over $600 billion minimum, maybe as high as $1 trillion if it is honestly scored.

That is why you have to go through committee. The committee has the expertise on it. That is important. More importantly than that, the committee gives the imprimatur of budgetary action, and if a bill is reported out of the committee, it meets the budgetary guidelines; it is not subject to a point of order.

So the misrepresentation that if it didn't happen the last 4 years that the committee reported out a bill on this issue, why should the committee have to report now, is a bit of a red herring. The issue isn't that you didn't do it 4 years ago. The issue is, do you want to pass a drug benefit package today or do you want a political issue? If you want a political issue, don't run it through the committee, bring it out on the floor and guarantee it fails because it can't get 60 votes. If you want a drug benefit package, put it through committee, and the committee comes out with a package, which would probably be the package outlined by Senator SNOWE, and it gets 51 votes at least. I suspect it will get more than 51—in the midfifties, probably.

Then you have a package with which you can turn to your senior citizens and say: This will be a significant benefit to you as you deal with the issue of prescription drugs. That is the difference. That is why you need committee action on this bill. As long as there is no committee action, I suspect you are guaranteeing failure.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, we will move on from here, but the fact is, as the Senator stated correctly, if it were less than $300 billion, then it would need 51 votes. But the Senator from Maine's proposal is $370 billion. So they are going to need 60 votes, too. Do we understand? I don't understand what the Senator from New Hampshire was talking about. They are going to need 60 votes for their proposal because they are going to violate the point of order.

When we are talking about the fact that the seniors are going to spend, over 10 years, $1.8 trillion. With $300 billion you are going to do very little to offset the kinds of challenges they are facing.

Finally, I have listened to our Republican leader, to my good friend from New Hampshire about following the committees and how important it is to follow the procedures. I am so thankful that we have a leader who is bringing this to the floor of the Senate at last.

Now we hear this is circumventing procedure.

In May of 2000, Republicans brought S. 2557 to the floor, an energy bill sponsored by Senator LOTT, without committee approval; that was the big energy bill. In March 2000, Republicans brought legislation to the floor to eliminate the earnings test for individuals without committee approval. I voted for that. I am glad they did it. In June of 1999, Republicans brought the Social Security lockbox to the floor without committee approval. In July 1996, Republicans brought the Taxpayer Bill of Rights.

It seems they were prepared to bring a lot of other things, but they didn't bring a prescription drug bill to the floor. This leader has said this is the priority and that is why we are having this debate today.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, the amendment we are now considering, a first- and second-degree amendment, I have offered for myself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Ms. SNOWE. It is a bipartisan amendment. It is a very important amendment—one that addresses a part of that which we are here to consider on the floor of the Senate on the issue of prescription drugs.

Let me describe what the problems are. One, we don't have a prescription drug benefit in the Medicare Program, and we need to change that. We need to add a prescription drug benefit to the Medicare Program. Why do we need to do that? Because when Medicare was created, many of the lifesaving miracle drugs that exist now that allow senior citizens to live a longer and healthier life did not exist. So Medicare was basically an opportunity to provide health insurance coverage for doctors and hospitals but no prescription drug coverage. That was back in the 1960s. Things have changed.

Were we to write a Medicare Program today, we would clearly include prescription drug coverage in that Medicare Program. I mentioned senior citizens especially because that is who benefits from the Medicare Program. They represent about 12 percent of the population of our country, and they consume one-third of all prescription drugs. It is not unusual at all to talk to a senior citizen who has a series of health issues, as they have reached the later stages of their lives, and they have to take 4, 5, 10, and in some cases 12 different prescription medicines every day in order to deal with their health issues.

The problem is, when senior citizens reach that time of their lives where they have retired and have a lower income, they have less ability to be able to afford those prescription drugs. With the cost and spending increasing substantially, senior citizens are finding all too often that the prescription drugs they need to take are simply out of reach.

Let me describe some of the consequences that result. I talked yesterday about the woman who came up to me—and all of us have had this experience—she grabbed me by the elbow and said: Senator DORGAN, can you help me?

I said: What is wrong?

She said: Well, I have very serious health problems and my doctor prescribed prescription drugs that I must take, but they are too expensive. I don't have the money to be able to afford them.

Her eyes welled up with tears and her chin began to quiver and she began to cry.

She said: Can you help me, please?

This happens all across the country every day. Let me just read some letters. This is from a North Dakotan who wrote me some while ago, about 2 months ago:

> DEAR SENATOR DORGAN: I just returned from a drug store, where I happened to witness a very pathetic situation that brought tears to my eyes. Standing in front of me at the counter was an elderly gentleman about 80 years of age. He handed 2 prescriptions to the pharmacist. He said, ''Before you fill these, can you tell me what the price is?'' The pharmacist checked the price through her computer and told the elderly man, ''The first prescription is $94.76. The next prescription is $49.88. Do you want me to fill them for you?'' The old man looked around and was deep in thought and said, ''No, I guess not. I haven't bought Christmas presents for my wife and grandchildren. I will just put up with the pain.'' Using his cane, he walked away.
>
> ''God bless America,'' she writes. ''I just thought,'' she said, ''you and your Senate colleagues who have reservations about the need for lower priced prescription drugs ought to understand that this is going on in our country.''

A North Dakotan wrote to me and said:

> I am 86 years old, so I cannot work.

Her first thought, of course, would be to work.

> I am 86 years old, so I cannot work. I am writing in regard to the medication I take. I get $303 in Social Security every month. I have never worked out of my home. I pay $400 a month for my medication. I have had heart surgery and have osteoporosis of the bones. The medicines are very high priced. We need help. We are using all of our savings. I am 86 years old, so I cannot work.

Another woman from my State says:

> I am a person with scleroderma, diagnosed at the Mayo 24 years ago. While this disease attacks different parts of my body, it's mainly my lungs. I have been on oxygen for 2 years now. A new medication is out named Tracleer. One pill a day is $3,600 a year. I called Medicare to see if there was an insurance I can buy for medications. I was told I could not do that. I am a farm wife, 74 years old, who drove a tractor until 2 years ago when I lost my husband and then my lungs got worse.

She goes on at some great length.

I recall a snowy North Dakota day in January, in a small van going to Canada with some senior citizens from my State. Among the people who traveled to a little one-room drugstore in Emerson, Canada, that snowy day was Silvia Miller, a 70-year-old Medicare beneficiary from Fargo, ND, with no prescription drug coverage. She has diabetes, heart problems, and emphysema. She takes 10 to 12 medications every day. In 1999, she spent more than $4,900 for her medications. Well, Silvia Miller, like a lot of others, struggles to try to make do and deal with very serious health problems and tries to catch an increased price every year—increased costs of prescription drugs. Of course, she cannot catch that. It is moving out of sight.

Last year, there was a 17- to 18-percent cost increase for prescription drugs. The year before that, it was about 16 percent. The year behalf that, it was about 17 percent. So year after year after year, there are relentless increases in the cost of prescription drugs. This trend continues. What can we do about it?

Well, the point we make with this amendment is this: We support fully putting a prescription drug benefit in the Medicare Program. That ought to be done. I hope it will be done. But if that is all we do—if we do nothing to try to dampen down prices, put some downward pressure on prescription drug prices, we will have done nothing but hook up a hose to the Federal trough and we will suck it dry.

The American taxpayer beware. If we don't do something to try to put some downward pressure on prescription drug prices, we cannot afford putting a prescription drug benefit in the Medicare Program. We must do both, in my judgment. Let's put the benefit in the Medicare Program, make it optional, make it good, and at the same time let's do some things that put downward pressure on prescription drug prices.

I mentioned that I went to Canada with a group of North Dakota senior citizens. More recently, the Alliance For Retired Americans arranged 16 bus trips to Canada between May and June of this year to highlight the enormous price differences that exist for the identical prescription drugs between the United States and Canada. Participants in those 16 trips saved $506,000, or $1,340 per person.

I think it is important that we talk about policy in theory in the U.S. Senate, but let me do something a bit more than that, if I can.

I ask unanimous consent to show some prescription drug bottles that describe the real problem.

The PRESIDING OFFICER. Is there objection? Without objection, it is so ordered.

Mr. DORGAN. Mr. President, if I might go through a few of these, it will be useful for people to understand what senior citizens are discovering with respect to pricing.

This prescription drug is Celebrex, quite a remarkable drug for pain. It is sold both in the United States and Canada bottles that are essentially identical. The U.S. consumer is charged

$2.22 per tablet. The Canadian consumer is charged 79 cents per tablet. Same drug, same bottle, made by the same company; the difference is the American consumer is charged dramatically more for the same prescription drug.

Mr. President, Paxil is a prescription drug used to treat depression. As you can see, these two pill bottles are identical. The cost is $2.22 per tablet to the U.S. consumer; for the Canadians, for the same drug, it is 97 cents. Again, it is $2.22 for the American purchaser and 97 cents for the Canadian purchaser.

One might ask, as you go through this—and I have a couple more examples—why the difference in pricing? Well, that is a good question. We have had hearings on this and it is not that there is a difference in the tablets in the bottles.

This is Zocor. A famous football coach talks about Zocor on television every day. He says he takes this prescription drug and recommends it to others who need it. Zocor is sold in the United States in this bottle. It is $3.33 cents per tablet in the United States, and it is $1.12 per tablet in Canada.

Finally, this is a prescription drug called Prevacid. As one can see, this prescription drug, like the others, is marketed in an identical bottle in the U.S. and Canada. This is used for ulcers. It has a label that is of a slightly different color, but the bottle is identical—same pill, same bottle, made by the same company. In the United States, a purchaser pays $3.58 per tablet; in Canada, it is $1.26 per tablet. I have more.

Mr. WELLSTONE. Will the Senator yield for a question?

Mr. DORGAN. I will be happy to yield.

Mr. WELLSTONE. What was the last drug?

Mr. DORGAN. Prevacid. It is used for ulcers.

Mr. WELLSTONE. May I add to the Senator's list two drugs? So much of this is personal. I am sure he hears from people in North Dakota what I hear from people in Minnesota, that this drives them crazy.

Permax is a drug to manage Parkinson's disease. The same bottle in the United States is $398.24, and the Canadian price is $189. I mention this because I ran into a teacher a couple months ago in my hometown who, when I met him—I have not seen him for a while—I said: How are you doing? We shook hands. I know Parkinson's. Both my parents had it. I know it in the palm of my hand. I felt the shake. I said: Are you taking Sinemet?

He said: Yes, but there is a better drug.

I said: Are you taking the other one?

He said: I cannot afford it.

This is by way of an example.

Did the Senator from North Dakota mention tamoxifen? It is a breast cancer drug. The United States price, same bottle, is $287; Canadian price, $24. I wanted to add two more examples to what my colleague mentioned.

Mr. DORGAN. Tamoxifen is a good example because it is priced at 10 times the Canadian price for those in this country who need it to deal with breast cancer. It is a good example.

This is a chart that shows other drugs, which I have not listed. It shows the substantial changes in prices between the United States and Canada.

Let me make a couple additional points.

I do not come here suggesting that the pharmaceutical manufacturing industry or the manufacturers themselves are bad. I do not suggest they are bad companies. In many cases, they do good work. They produce lifesaving miracle drugs. I might say, they could from time to time give more credit to the American taxpayer for some of that because a substantial amount of research also goes on through the National Institutes of Health that is federally funded, the benefits of which then are used by the pharmaceutical manufacturers.

It is not my intention to tarnish those manufacturers as somehow unworthy companies. It is my point to say that the pricing strategy employed by those manufacturers is wrong and it penalizes the American consumer.

They say: We must have this kind of pricing practice and pricing strategy by which the American consumer pays the highest prices by far because that is the way we get the money to do research and development.

It is interesting that a report I read says they do slightly more research and development in Europe than they do in the United States: 37 percent in Europe; 36 percent in the United States. And still in virtually every country in Europe, they charge a much lower price for the identical prescription drug they sell in the United States.

It is not the case that this is all about research and development. The legislation we have introduced, the Prescription Drug Price Parity for Americans Act, would allow U.S. consumers to benefit from the international price competition for prescription medicines.

We have changed this approach from the previous legislation that was enacted by the Congress because we make this apply only to the country of Canada. We would like licensed and registered pharmacists and distributors to be able to reimport into this country prescription drugs that are approved by the FDA. We are limiting that to Canada only. We will allow in this legislation pharmacists and distributors to access FDA-approved drugs from Canada and bring them into this country and pass the savings along to the American consumer.

This bill would become effective immediately. We have, as I said, passed this legislation before. It has not been implemented by two administrations because some have raised the question that this would pose risks for the consumer. However, we have included provisions in this legislation on page 9 addressing suspension of importation which will minimize those risks.

While I talk about that for a moment, let me describe why I think those risks are very minimal. Of course, we now have risks with respect to the shipment of prescription drugs across borders. We ship a substantial amount of United States manufactured drugs to Canada. In fact, the Congressional Research Service has a report quoting an information officer from Canada who says that most of the pharmaceuticals marketed and distributed in Canada originate from U.S. manufacturers.

The question we should ask, it seems to me, as policymakers, is, Why should an American citizen have to go to Canada to get a fair price on a prescription drug made in the United States? It is a rhetorical question but I suspect one without an answer in this Chamber.

In any event, a substantial amount of the prescription drugs sold in Canada are prescription drugs originating in the United States, and there is now a law on the books that says the United States consumer, through their pharmacists or through their licensed distributors, may not access those drugs even if they are less costly in Canada. In my judgment, that makes no sense at all.

Included in the legislation we have introduced is a provision that would allow the Secretary of Health and Human Services to suspend reimportation. Let me read the language we are including in the second-degree amendment:

> 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 the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section or poses an additional risk to the public health 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).

David Kessler, former head of the FDA, had this to say in a letter to us:

> The Senate bill which allows only the importation of FDA-approved drugs, manufactured in approved FDA facilities, for which the chain of custody has been maintained, addresses my fundamental concerns.

This is a larger description of his letter:

> Let me address your specific questions. I believe U.S. licensed pharmacists and wholesalers who know how drugs need to be stored and handled and would be importing them under the strict oversight of the FDA are well positioned to safely import quality products rather than having American consumers do this on their own.

The Congressional Research Service report I referred to a few moments ago is a report that I had asked they complete in which they should evaluate the chain of custody in Canada so we would understand whether there is a chain of custody issue.

If we manufacture a prescription drug, for example, in the United States and send it to end up on the shelf of a drugstore in Winnipeg, Canada, is there a chain of custody problem that would allow someone to say: You cannot have a pharmacist go to Winnipeg and buy that drug because that is inherently unsafe?

The answer is no, that is just sheer nonsense that there is any kind of a problem with that.

The CRS report says both countries have similar requirements and processes for reviewing and approving pharmaceuticals, including compliance with good manufacturing practices. We have similar rules for requiring labeling. The Canadian Federal Government inspects drug manufacturing facilities. Pharmacists and drug wholesalers have to be licensed. There is no chain of custody question.

I understand one thing about this. If I were a pharmaceutical manufacturer, I would want to kill this legislation. Why? Because the pharmaceutical industry confronts price controls in some other countries, and they do not like them. Those price controls allow them to charge their costs and add a profit to it, and that is the price they are able to exact.

There are no price controls in this country. So the pharmaceutical manufacturers make the point that, if you can reimport prescription drugs from somewhere else such as Canada, you are reimporting price controls from Canada.

We have price controls in this country really. It is just that the prescription drug manufacturers control the price, and they control the price by charging the U.S. consumer the highest prices in the world. Medicine after medicine, we find the U.S. consumers paying the highest prices in the world.

Lifesaving prescription drugs save no lives if you cannot afford to purchase them. Show me something else in the daily lives of the American people, or especially of senior citizens, that they need—that they don't have a choice on—that is increasing at 16, 17, 18 percent a year. Can anyone come up with anything that relates to those kinds of relentless increases? I do not think anyone can.

I want us to continue an aggressive search for miracle drugs and lifesaving medicines. That is why many of us in this Chamber have agreed to double the amount of funding at the National Institutes of Health. This is the fifth and final year to do that. We have gone from $12 billion to $24 billion. That was bipartisan. We did it. I want the drug manufacturers as well to also engage in robust research and development. I support research and development tax credits for that purpose, from which they benefit. But I do not want the pharmaceutical manufacturers to say to the American people: We have a scheme by which we will impose upon you the highest prices of any group of people in the world for our prescription drugs. We will have multitiered price policies, and you, American citizens, shall pay the highest. We want you to pay 10 times the cost for tamoxifen that our friends in Winnipeg, Canada, are charged. We want you to pay substantially higher prices for Zocor, Lipitor, Premarin, and Celebrex. It is simply not fair.

The point of this amendment is not to try to force anyone to go to Canada to buy prescription drugs. It is to try to force a repricing of prescription drugs in this country, for if our registered pharmacists and licensed distributors can access an FDA-approved drug in Canada and bring it back and pass the savings along, it will certainly force a repricing of prescription drugs in this country. That is my goal. That is our goal.

So what we have today is an amendment that will allow the reimportation, under very strict circumstances, of FDA approved prescription drugs from Canada to the United States only by licensed distributors and licensed pharmacists, and that will put downward pressure on prescription drug prices.

What we also have in this Chamber, I think, are those who want to kill this because the pharmaceutical industry does not like it. I understand that. If I were the pharmaceutical industry, I would not like it either. They have the best deal in the world in the United States, but it is unfair to American consumers. It is unfair to those in this country who need prescription drugs, who need lifesaving drugs, who need these miracle drugs, and cannot afford them.

So even while we put a prescription drug benefit in the Medicare plan, which I fully support, we must pass the underlying generic amendment, which also has the effect of putting downward pressure on prices.

We must pass this amendment, the reimportation amendment, which gives very careful consideration to the safety issues that others have raised, and we should not fear, and we should not shrink from, the pharmaceutical manufacturers' attacks that somehow this is bad public policy.

It is good public policy. They just do not like it. It is good public policy for the American consumer, and it is safe for the American consumer as well. My hope is that my colleagues will support this amendment and I strongly urge them to do so.

The PRESIDING OFFICER. The Senator from Nevada.

Mr. REID. Mr. President, during the fine presentation of the Senator from North Dakota, which is standard for the Senator from North Dakota, I have been speaking with the managers of the bill. The other side would accept his amendment by voice vote. I have not had a chance to speak to the Senator from North Dakota, but it is my understanding that he does want a recorded vote.

Mr. DORGAN. That is correct.

Mr. REID. May I ask the manager of the bill and Senator COCHRAN, who is heavily involved in this, if we could set a time—we would draw something up on paper—for a vote on this amendment at 2:30? I do not, frankly, know if all the time would be taken up on this amendment. This would give the Senator from Mississippi time, if he were so inclined, to talk about his amendment. Part of the deal would be that the next amendment in order would be the amendment of the Senator from Mississippi, which will, of course, occur if this passes, and it obviously is going to.

Mr. GREGG. As long as the position of the Senator from Mississippi is protected as being the next amendment offered, I certainly have no objection, but it is the call of the Senator from Mississippi.

Mr. COCHRAN. Mr. President, if the Senator will yield, I am happy to recommend that to our side of the aisle. The only Senators I know of who want to be heard on this amendment I will offer after the amendment of Senator from North Dakota are Senator BREAUX and Senator ROBERTS, both of whom have expressed an interest in this amendment. I would like the opportunity to see, though, if there are others who want to speak and make sure we can accommodate everybody. But I personally do not have any objection to a 2:30 vote.

Mr. REID. I say to my friend from Mississippi, I am sure his amendment will take a little bit of time because he has people who want to speak on it; the majority and others want to speak on it. We will not set a time for dealing with his amendment.

Mr. COCHRAN. Good.

Mr. REID. If it gets out of hand, we can always move to table, but I am sure the Senator from Mississippi, being one of the most experienced legislators we have, understands the rules. We will try to be fair and move this along as quickly as possible.

Mr. COCHRAN. Mr. President, I appreciate the assistance of the distinguished Senator from Nevada. We will be glad to try to work with him to accommodate that suggestion.

Mr. REID. What we will do is have the staffs prepare something on paper, but generally we all understand what it would be; there would be a vote on the Dorgan amendment at 2:30.

Mr. GREGG. With no intervening action?

Mr. REID. No intervening action. The person next to be recognized to offer an amendment would be the Senator from Mississippi.

Mr. GREGG. With the time equally divided.

Mr. WELLSTONE. Mr. President, if I could say to the Senator from Nevada, and I will relinquish the floor in a second, one of the things we need to do on our side—I know Senator STABENOW wants to speak on this. There are other Senators who also want to speak.

Mr. REID. That is why I set the time. We have until 2:30, and even though

there is a conference, people can step out of that and speak. So we will prepare something, and we should have it in the next few minutes.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. WELLSTONE. Before there is any unanimous consent agreement propounded, I do want to make sure I state to my colleague from North Dakota we have quite a few Senators who have worked on this for some time and we want to make sure they do have a chance to come down.

I thank my colleague from North Dakota and my colleague from Michigan, and all the other Senators on both sides of the aisle, who support this legislation. I think this has been like about 5 years of work, as I think back to when some of us first started this journey.

One of the things I want to do right away is deal with one of the arguments that are made against this legislation. It is an argument by the pharmaceutical companies that, look, we have to charge American citizens a lot more because we need that money for the research. Senator STABENOW was there, Senator GRAHAM was there, as well as Senator MILLER.

One of the arguments we hear over and over again from the pharmaceutical companies, the drug companies, is they need to make this excessive amount of money, they need to have the very high priced drugs because this goes to research for the miracle drugs that help everyone.

When the President was in Minneapolis in my State last week, he adopted the pharmaceutical or the drug lobby's position and said that the high prices everyone sees are necessary to sustain the research and development.

One of the arguments made against this reimportation bill is, if you begin to do that and people start getting discounts and we cannot charge as much, we cannot put the money into the research. Families USA came out with a report they called ''Profiting From Pain.'' They looked at the drug company's recent submissions before the Securities and Exchange Commission about their activities in 2001. They looked at the nine publicly traded companies that market the top 50 drugs to seniors. I will go over their key findings.

The first finding is these large pharmaceutical companies spent $45.4 billion on marketing and advertising and administration—this is from their own SEC report—and $19 billion for research and development—2½ times more for marketing, advertising, and administration as for research and development.

The second finding for profits over the last 10 years, profits last year as percentage of revenue, was 18.5 percent, 5.5 times the median profit for the Fortune 500 companies.

The third key finding is these companies lavish huge compensation packages and even larger stock options—does this sound familiar to anyone—to the top drug executives. Mr. C.A. Heimbold, the former chairman at Bristol-Myers, had the following compensation package, not including unexercised stock options: Ready? $74.9 million; John R. Stafford, chairman of Wyeth, $44.5 million. The five highest paid executives received over $183 million last year.

Looking at the unexercised stock options, Mr. Raymond Gilmartin, president and CEO of Merck, $93.3 million; Mr. C.A. Heimbold, $76.1 million; two Pfizer executives, $60.2 million and 56.5 million.

I make the plea in the Senate because pharmaceutical companies do not want this bill. By the way, I said to my colleague from Michigan, who has worked so hard on this, one of the reasons I love this legislation, this helps all of our citizens, all our families. Pharmaceutical companies and wholesalers can meet every strict FDA safety rule, reimport back the prescription drugs and pass on the savings. That is what this is about.

The drug industry should stop scaring citizens in our country, seniors and others, with the false claim that if there is a discount and people are charged a reasonable price, this will prevent research in medicine. I thank Families USA for their excellent study. I make the point which they made today, in light of the huge industry profits, enormous executive compensation and big marketing budgets, these claims that we need to rip people off with the obsessive, obscene profits in order to do the research, are irresponsible and wrong.

The next point, by way of context of this amendment, it seems to me the drug companies in this country are making Viagra-like profits—you get the meaning of what I am saying—on the backs of American consumers, on the backs of Minnesota consumers. The thought that these companies, acting as a cartel, can make Viagra-like profits based on the misery and illness and sickness of people is obscene.

We are going to do something about it and we are going to make sure people in Minnesota and people around the country get a discount and they get the same fair price that people in Canada get so people can afford these prescriptions that are so important.

What does our amendment do? It allows for the reimportation of the drugs from Canada. Believe me, many citizens from Michigan and Minnesota and North Dakota know all too well what the differences are. People can save as much as 40 percent, if not more, for their prescription drugs. The amendment of Senator DORGAN, myself, Senator STABENOW, and others would allow pharmacists, drug wholesalers, and individuals to reimport safe and effective FDA-approved prescription drugs from Canada. These drugs, developed in the United States, are available in Canada for a fraction of the price of what we get charged. This would help not only senior citizens but other Minnesotans and other Americans as well.

Some examples to add to what my colleague from North Dakota mentioned: Coumadin, blood thinner, same bottle, $20.99 in the United States; Canadian price is $6.23. Zocor, a cholesterol drug, is $116.69 in the United States and $53.51 in Canada—same bottle, same prescription. Permax, for Parkinson's disease, which so important to people with that neurological disease, is $398.24 in the United States, $189 in Canada. Tamoxifen, a breast cancer drug, is $287 in the United States, $24.78 in Canada.

When I am traveling around Minnesota, people are asking me, more than anything else, can't we get a discount? Isn't there something to do to make the drugs affordable? A lot of Minnesotans ask why we can't have the same price as our neighbors to the north. This is the best of free trade and fair trade. Let our pharmacists and wholesalers meeting FDA guidelines reimport these drugs back and pass on the savings to the citizens we represent.

We have a provision for a suspension. If there is a problem with the drug, the Secretary can stop the batch of drugs coming into the United States until the investigation is completed.

Now we made it stronger, saying if there is any risk to public health, any kind of risk at all to people in this country who deals with public health where we have to worry about a batch of drugs that should not be in here, that violates safety standard, then the Secretary can stop the importation immediately. It is important to protect the health of people. We do that. This language assures that bad drugs are not going to reach patients in the United States and the Secretary at that point in time can suspend those drugs.

What we cannot do, and what I want every Senator to be aware of, we cannot let the pharmaceutical industry gut this amendment. We cannot say that the Secretary of Health and Human Services, be it Democrat or Republican, can set out conditions and certify those conditions have to be met before we have the reimportation. If that is the case, we will allow any Secretary of Health and Human Services in any administration to kill this.

Our citizens are tired of being ripped off. They are tired of the pharmaceutical companies running the show. Our people want a discount. We move forward with this. If, God forbid, there is any tampering with any drugs or any violation of public safety, then the Secretary of State can immediately suspend. But we do not want to have any kind of provision or any kind of amendment that passes that creates a huge loophole that enables the pharmaceutical industry to do all their behind the scenes lobbying and kill this legislation so that, in fact, the Secretary of Health and Human Services never ends

up implementing it. That is not what the people in Minnesota are asking. That is not what people in the country are asking.

Mr. REID. Mr. President, will my friend yield?

Mr. WELLSTONE. Yes.

Mr. REID. Mr. President, I ask unanimous consent that the time until 2:30 today be for debate on the pending amendments, with the time equally divided and controlled between Senators DORGAN and GREGG or their designees; that no intervening amendment be in order prior to the disposition of amendment No. 4300; that a vote on or in relation to amendment No. 4300 occur at 2:30 this afternoon, without further intervening action or debate; provided further, upon disposition of that amendment, Senator COCHRAN be recognized to offer an amendment on the issue of drug reimportation.

The PRESIDING OFFICER (Mrs. CARNAHAN). Is there objection?

Without objection, it is so ordered.

The PRESIDING OFFICER. Under the previous order, the Senator from Minnesota is recognized.

Mr. WELLSTONE. Madam President, I will take 1 more minute. Other Senators want to speak. Senator STABENOW has been a leader on this legislation for a long time and has been coordinating the effort of all Democrats.

Let me just conclude this way: I know Senators do not want to be seen as opposing an amendment that would enable all of our seniors and all of our citizens to be able to get a reasonable price for prescription drugs. My fear is that we will have an amendment out here with fine-sounding language which will create a huge loophole and will basically kill this amendment by giving any Secretary of Health and Human Services the ability to stop this legislation before it is ever implemented. That is unacceptable. That is unacceptable. We cannot let the pharmaceutical industry kill this bill and kill this amendment.

I believe that people in Minnesota, people in Michigan, and people around the country look at this as simple. I have said it before. I will conclude it this way. I think this is a test case of whether we have a system of democracy for the few or a democracy for the many. If it is a democracy for the many, we will support this provision. If is democracy for a few of the pharmaceutical companies, the devil is in the details. They will be able to create a huge loophole, which will mean this will never be implemented and they will be able to kill it.

I urge all colleagues to support this Dorgan, Wellstone, Stabenow, et al, amendment and to resist any amendment to essentially gut this amendment and stop this piece of legislation from being implemented.

I yield the floor.

APPOINTMENT OF CONFEREES—H.R. 3763

The PRESIDING OFFICER. Under the authority of the order of July 15, the Chair appoints the following conferees on the part of the Senate on H.R. 3763.

The Presiding Officer appointed Mr. SARBANES, Mr. DODD, Mr. JOHNSON, Mr. REED of Rhode Island, Mr. LEAHY, Mr. GRAMM of Texas, Mr. SHELBY, Mr. BENNETT, and Mr. ENZI conferees on the part of the Senate.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Continued

The PRESIDING OFFICER. Who yields time?

The Senator from Michigan.

Mrs. STABENOW. I thank the Chair, I yield myself up to 15 minutes under the agreement.

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

Ms. STABENOW. Madam President, this is a very important second-degree amendment that not only will help our seniors be able to lower the prices they pay for prescription drugs, as my colleagues have said. I thank the Senator from Minnesota for his ongoing leadership on this issue and, of course, the Senator from North Dakota for his sponsorship and ongoing leadership and advocacy, as well as my other colleagues who are cosponsoring this amendment.

This not only affects our seniors, this affects everyone. It affects the president of Michigan State University, who called me about his health clinics and his college of medicine looking for ways to be able to lower prices so that he does not have to deal with possibly laying off more staff, which he had to do this year as a result of the dramatic increases in the health care costs at the university.

It addresses the big three automakers, small businesses, families, and everyone who is paying exorbitant prices for prescription drugs.

I want to start by quoting our President, President Bush, when he was a candidate for President. He indicated that he thought this idea was a good idea. He said:

> Allowing the new bill that was passed in the Congress made sense to allow for, you know, drugs that were sold overseas to come back and other countries to come back into the United States.

That was what then-candidate George W. Bush and now President Bush said makes sense. It does make sense. It made sense before. The problem before was that there was an amendment added which basically killed our ability to be able to do this. We know that same amendment which is supported by the pharmaceutical industry will be offered later. There will be an attempt to kill it again.

But we are hopeful that our colleagues will join with us in what is a very reasonable proposal that addresses any legitimate issues regarding safety and health and allow us to open the border to Canada and be able to provide the kind of competition we need to lower prices.

I think it is important also to reiterate that at a September 5, 2001, hearing before the Senate Commerce Committee's Subcommittee on Consumer Affairs, William Hubbard, FDA Senior Associate Commissioner, testified:

> I think as a potential patient, were I to be ill and purchase a drug from Canada, I would have a relatively high degree of confidence in Canadian drugs.

We know the Canadian system is similar to ours as it relates to the regulatory and safety system.

We feel very confident that this modest proposal of simply opening the border to Canada—and we know that Canada right now exchanges goods and services with us every single day. We have the largest port of entry in Detroit, MI, which I am proud to represent, with over $1 billion in goods going across. We trade every day with them.

We believe this proposal will allow one thing to be traded which is desperately needed by our citizens and is not now allowed to go back and forth across that port of entry. It makes sense. This is a reasonable, modest proposal.

Instead of opening all of our borders, some would argue that this does not go far enough; that we should open to Mexico, Europe, or other places around the world. But we are taking a modest step to begin to show that this kind of approach can work.

We want to simply start with Canada with a very modest approach that will allow us to be able to share with our neighbors to the north the ability to bring back to our citizens American-made prescription drugs which are sold in Canada.

I think this is an issue of fairness as well because we are talking about prescription drugs on which we helped to underwrite research. As I have said so many times, $23.5 billion this year alone was given by the taxpayers of this country. And I support that strongly. I support having that be a higher number. I think basic research into new potential treatments is absolutely critical and is a good investment. But we are making those investments. We are then giving that information to the drug companies, that pick up the information and then proceed to do their own research and development.

We allow tax writeoffs for that research and development, tax credits, and tax reductions. We subsidize them further. We allow up to 20-year patents so they can recover their costs because we know it costs a lot to research and develop new drugs. So we let them be able to recover those costs without competition for their name brand. So we highly subsidize—highly subsidize—this area; the most profitable industry in the world, highly subsidized by American taxpayers.